



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Information Technology  
EMA/396650/2016

## eAF DES Change Summary

Summary of DES changes applied to v.1.22.0.1



## Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all forms for version 1.22.0.1 of the Electronic Application Form.

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

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

The document has one section which explains about one schema defect in below forms:

- MAA Human
- MAA Vet
- Renewal

To enabled cross reference to the release notes for 1.22.0.1, this document will reference the corresponding defect reference number associated with the DES change.

## Defects

1. EAF-2810



**Summary of defect (EAF-2810):**

org-modifiedDate node is removed in the common Dictionary schema. The sections affected in the pdf forms are listed below.

**Human Form / Veterinary form**

Section 2.5.1.a Admin & Manufacturer  
 Section 2.5.2 Admin & Manufacturer  
 Section 2.5.3 Admin & Manufacturer

**Renewal Form**

Section 2 – Batch Control Testing Admin & Manufacturer  
 Section 2 – Medicinal Product Admin & Manufacturer  
 Section 2 – Active Substance Section 2 – Batch Release  
 Section 2 – Batch Release Admin & Manufacturer  
 Section 2 – For blood Products Admin & Manufacturer

**Original eaf\_Dictionary xsd Schema definition:**

```

<xs:complexType name="admin-office">
  <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="org-modifiedDate" type="xs:date"/>
    <xs:element name="log-modifiedDate" type="xs:date"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30"/>
    <xs:element name="email" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>
<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="org-modifiedDate" type="xs:date"/>
    <xs:element name="log-modifiedDate" type="xs:date"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30"/>
    <xs:element name="email" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>
  
```



## Updated/Amended eaf\_Dictionary xsd schema definition:

```

<xs:complexType name="admin-office">
  <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="language" type="rdm:string30"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30"/>
    <xs:element name="email" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>
<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="language" type="rdm:string30"/>
    <xs:element name="phone" type="rdm:string50"/>
    <xs:element name="fax" type="rdm:string30"/>
    <xs:element name="email" type="rdm:string100"/>
  </xs:sequence>
</xs:complexType>

```

The org-modifiedDate node is removed :

```
<xs:element name="org-modifiedDate" type="xs:date"/>
```

