



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Information Technology
EMA/396650/2016

eAF DES Change Summary

Summary of DES changes applied to v.1.26.0.0 and v.1.26.0.1



Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering variation, human and renewal forms for version 1.26.0.0 and ~~vet form~~ for 1.26.0.1 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.

eAF DES Change Summary

Version 1.26.0.0

Maa-human XSD

1) From: (Version Changed)

```
<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="1.25.0.0">
```

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="1.26.0.0">
```

2) From: (Format Issue)

```
<xs:documentation>text choice(â€œyesâ€ | â€œnoâ€ | â€œnullâ€)</xs:documentation>
```

To:

```
<xs:documentation>text choice(“yes” | “no” | “null”)</xs:documentation>
```

Variation XSD

1) From (Element added)

```
<xs:element name="presentProposedAddress" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<xs:element name="present" minOccurs="0">
<xs:complexType>
<xs:sequence>
<xs:element name="contact-details" type="rdm:contact-details-type"/>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="proposed" minOccurs="0">
<xs:complexType>
<xs:sequence>
<xs:element name="contact-details" type="rdm:contact-details-type"/>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
```

To:

```
<xs:element name="presentProposedAddress" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<xs:element name="present" minOccurs="0">
<xs:complexType>
<xs:sequence>
<xs:element name="contact-details" type="rdm:contact-details-type"/>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="proposed" minOccurs="0">
<xs:complexType>
```

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```
<xs:sequence>
<xs:element name="contact-details" type="rdm:contact-details-type"/>
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="proposedAddressIsSelected" type="rdm:yes-no"/>
```

Renewal XSD

1) From (Version Changed)

```
<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="1.23.1.0">
```

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="1.26.0.0">
```

Version 1.26.0.1

Maa Vet XSD

1) From (Version Changed)

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

2) From: (Elements Removed)

```
<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>
```

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```
</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="bioequivalence" type="rdm:yes-no"/>
<xs:element name="raw-materials" type="rdm:yes-no"/>
<xs:element name="manufacturing-process" type="rdm:yes-no"/>
<xs:element name="other" type="rdm:yes-no"/>
</xs:sequence>
</xs:complexType>
</xs:element>
<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>
```

To:

```
<xs:element name="section1-3-3">
<xs:complexType>
<xs:sequence>
<xs:element name="article19-1" 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="bioequivalence" type="rdm:yes-no"/>
<xs:element name="raw-materials" type="rdm:yes-no"/>
<xs:element name="manufacturing-process" type="rdm:yes-no"/>
<xs:element name="other" type="rdm:yes-no"/>
</xs:sequence>
```

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```
</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>
```

3) From: (Removed Elements)

```
<xs:element name="max_residue_EMA_NA" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<xs:element name="max_residue_NA" 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="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>
</xs:element>
```

To :

```
<xs:element name="max_residue_EMA_NA" maxOccurs="unbounded">
<xs:complexType>
<xs:sequence>
<xs:element name="max_residue_NA" type="rdm:yes-no"/>
</xs:sequence>
</xs:complexType>
</xs:element>
```

Version 1.26.0.0 and 1.26.01

Eaf dictionary XSD

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1) From (Format issue)

```
<xs:attribute name="type">
<xs:annotation>
<xs:documentation>text choice(â€œCEPâ€ | â€œASMFâ€ | â€œVAMFâ€ |
â€œPMFâ€)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

To:

```
<xs:attribute name="type">
<xs:annotation>
<xs:documentation>text choice(“CEP” | “ASMF” | “VAMF” | “PMF”)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

2) From (Format issue)

```
<xs:annotation>
<xs:documentation>Text choice (â€œyesâ€ | â€œnoâ€)</xs:documentation>
</xs:annotation>
```

To :

```
<xs:annotation>
<xs:documentation>Text choice (“yes” | “no”)</xs:documentation>
</xs:annotation>
```

3) From: (Format Issue)

```
<xs:attribute name="leg_type" type="xs:string">
<xs:annotation>
<xs:documentation>Text choice (â€œdirectiveâ€ | â€œregulationâ€ |
â€œnationalâ€)</xs:documentation>
</xs:annotation>
</xs:attribute>
<xs:attribute name="leg_applies" type="xs:string">
<xs:annotation>
<xs:documentation>Text choice (â€œyesâ€ | â€œnoâ€)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

To:

```
<xs:attribute name="leg_type" type="xs:string">
<xs:annotation>
<xs:documentation>Text choice (“directive” | “regulation” |
“national”)</xs:documentation>
</xs:annotation>
</xs:attribute>
<xs:attribute name="leg_applies" type="xs:string">
<xs:annotation>
<xs:documentation>Text choice (“yes” | “no”)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

4) From: (Format Issue)

```
<xs:attribute name="type">
<xs:annotation>
<xs:documentation>text choice(â€œCEPâ€ | â€œASMFâ€ | â€œVAMFâ€ |
â€œPMFâ€)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

To:

```
<xs:attribute name="type">
<xs:annotation>
```

eAF DES Change Summary

```
<xs:documentation>text choice("CEP" | "ASMF" | "VAMF" | "PMF")</xs:documentation>
</xs:annotation>
</xs:attribute>
```

5) From: (Format Issue)

```
<xs:attribute name="type">
<xs:annotation>
<xs:documentation>text choice(â€œCEPâ€ | â€œASMFâ€ | â€œVAMFâ€ |
â€œPMFâ€)</xs:documentation>
</xs:annotation>
</xs:attribute>
```

To:

```
<xs:attribute name="type">
<xs:annotation>
<xs:documentation>text choice("CEP" | "ASMF" | "VAMF" | "PMF")</xs:documentation>
</xs:annotation>
</xs:attribute>
```

6) From: (Format Issue)

```
<xs:attribute name="waiver_type" type="xs:string">
<xs:annotation>
xs:documentation>Text choice(â€œproduct specificâ€ | â€œclassâ€) </xs:documentation>
</xs:annotation>
</xs:attribute>
```

To :

```
<xs:attribute name="waiver_type" type="xs:string">
<xs:annotation>
<xs:documentation>Text choice("product specific" | "class") </xs:documentation>
</xs:annotation>
</xs:attribute>
```