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eAF DES Change Summary

Summary of DES changes applied to v.1.20.0.0

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Purpose

The aim of this document is to summarise the changes applied to the Data Exchange Standard covering all forms for version 1.20.0.0 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 is split into three sections, one for each of the forms affected by the DES changes:

- MAA Human
- Renewal
- Variation

To enable cross reference to the release notes for 1.20.0.0, this document will reference the corresponding Change Request reference number associated with the DES change.

ADDENDUM: 6th June 2016.

This document has been updated, and includes two new changes to the DES for the Variation form: EAF-2156 and EAF-2090 (*See pages 10-12*).

MAA-Human

There was only one change applied to the human form, and required only a minimal change to the maa_human.xsd file.

Schema File Affected: maa_human.xsd

Change Request Reference: EAF-1932

Summary of Human change (EAF-1932):

To allow multiple pharmacovigilance records to be captured.

Original Human xsd Schema definition:

```

525 | </xs:element name="contact-clinical-procedures" />
527 | <xs:element name="contact-after-procedures" />
528 | <xs:element name="contact-pharmaco-vigilances">
529 |   <xs:complexType>
530 |     <xs:sequence>
531 |       <xs:element name="contact-pharmaco-vigilance" type="rdm:contact-details-type" maxOccurs="unbounded"/>
532 |       <xs:element name="details-pharmaco-vigilance" type="rdm:pharmaco-vigilance"/>
533 |     </xs:sequence>
534 |   </xs:complexType>
535 | </xs:element>
536 | <xs:element name="contact-scientific-advice" />

```

Updated/Amended Human xsd Schema Definition:

```

527 | <xs:element name="contact-pharmaco-vigilances">
528 |   <xs:complexType>
529 |     <xs:sequence>
530 |       <xs:element name="contact-pharmaco-vigilance" type="rdm:contact-details-type" maxOccurs="unbounded"/>
531 |       <xs:element name="details-pharmaco-vigilance" type="rdm:pharmaco-vigilance" maxOccurs="unbounded"/>
532 |     </xs:sequence>
533 |   </xs:complexType>
534 | </xs:element>

```

In this instance the addition of a `maxOccurs="unbounded"` has been added to the `details-pharmaco-vigilance` entry.



Renewal

There were two changes applied to the renewal form.

Schema File Affected: renewal_human_vet.xsd

Change Request Reference: EAF-1844 and EAF-1894

Summary of change (EAF-1844):

Add a repeating section for invented name and will have a link to member state.

Extract from Renewal DES:

This is the extract of the change applied to the Renewal DES for this change request.

E21-12	Invented Name	maa:invented-names	
		maa:invented-name	Medicinal Product Group>invented name
		maa:invented/maa:member-states/rdm:member-state	

Original Renewal xsd Schema definition:

Note: The original entry is at line 41.

```

19 <xs:element name="concerned" maxOccurs="unbounded">
20 <xs:complexType>
21 <xs:sequence>
22 <xs:element name="member-state" type="rdm:string50"/>
23 </xs:sequence>
24 </xs:complexType>
25 </xs:element>
26 <xs:element name="currently-marketed" type="rdm:yes-no"/>
27 <xs:element name="currently-marketed-in" minOccurs="0" maxOccurs="unbounded">
28 <xs:complexType>
29 <xs:sequence>
30 <xs:element name="member-state" type="rdm:string50"/>
31 </xs:sequence>
32 </xs:complexType>
33 </xs:element>
34 <xs:element name="attach-annex" type="rdm:yes-no" minOccurs="0" maxOccurs="1">
35 <xs:annotation>
36 <xs:documentation>
37 attach-annex element added to cater for emea00026998. currently-marketed-in minOccurs attribute updated for same issue.
38 </xs:documentation>
39 </xs:annotation>
40 </xs:element>
41 <xs:element name="invented-name" type="rdm:string250"/>
42 <xs:element name="medicinal-products" type="rdm:medicinal-product-renewals" maxOccurs="unbounded"/>
43 <xs:element name="ma-holder" type="rdm:contact-details-type" maxOccurs="unbounded"/>
    
```

Updated/Amended Renewal xsd Schema Definition:

```

41 <xs:element name="InventedNames" maxOccurs="unbounded" minOccurs="1">
42 <xs:complexType>
43 <xs:sequence>
44 <xs:element name="invented-name" type="rdm:string250"/>
45 <xs:element name="memberStates" minOccurs="0" maxOccurs="unbounded">
46 <xs:complexType>
47 <xs:sequence>
48 <xs:element name="member-state" type="rdm:string50"/>
49 </xs:sequence>
50 </xs:complexType>
51 </xs:element>
52 </xs:sequence>
53 </xs:complexType>
54 </xs:element>
    
```



Summary of Renewal change (EAF-1894):

Amend the functionality to allow for multiple MA Contact addresses.

Extract from Renewal DES:

This is the extract of the change applied to the Renewal DES for this change request.

E21-15	Name and address of Contact	maa:maContact/maa:role/rdm:personal-title	Application>Role>Party>Person> Personal Title
		maa:maContact/maa:role/rdm:given-name	Role>Party>Person> given name
		maa:maContact/maa:role/rdm:family-name	Role>Party>Person> family name
		maa:maContact/maa:member-states/rdm:member-state	
		maa:maContact/maa:contact-details/rdm:companyName	Role>Party>Person> Company name
		maa:maContact/maa:contact-details/rdm:address	Role>Party>Contact Details > Address
		maa:maContact/maa:contact-details/rdm:city	Role>Party>Contact Details > City
		maa:maContact/maa:contact-details/rdm:post-code	Role>Party>Contact Details > Post Code
		maa:maContact/maa:contact-details/rdm:country	Role>Party>Contact Details > Address > Country CTL
		maa:maContact/maa:contact-details/rdm:phone	Role>Party>Contact Details > Electronic contact>electronic contact
		maa:maContact/maa:contact-details/rdm:fax	Role>Party>Contact Details > Electronic contact>electronic contact
		maa:maContact/maa:contact-details/rdm:email	Role>Party>Contact Details > Electronic contact>electronic contact

Original Renewal xsd Schema definition:

The original schema entry has been highlighted in blue.

```

11 <xs:element name="application-information">
12 <xs:complexType>
13 <xs:sequence>
14 <xs:element name="human" type="rdm:yes-no"/>
15 <xs:element name="veterinary" type="rdm:yes-no"/>
16 <xs:element name="authorisation" type="rdm:radiobutton"/>
17 <xs:element name="procedure-number" type="rdm:string50"/>
18 <xs:element name="reference-member-state" type="rdm:string50"/>
19 <xs:element name="concerned" maxOccurs="unbounded"/>
26 <xs:element name="currently-marketed" type="rdm:yes-no"/>
27 <xs:element name="currently-marketed-in" minOccurs="0" maxOccurs="unbounded"/>
34 <xs:element name="attach-annex" type="rdm:yes-no" minOccurs="0" maxOccurs="1"/>
41 <xs:element name="invented-name" type="rdm:string250"/>
42 <xs:element name="medicinal-products" type="rdm:medicinal-product-renewals" maxOccurs="unbounded"/>
43 <xs:element name="ma-holder" type="rdm:contact-details-type" maxOccurs="unbounded"/>
44 <xs:element name="contact" type="rdm:contact-details-type"/>
45 <xs:element name="applicants-ref" type="rdm:string50"/>
46 <!-- Has this date anything to do with Concerned Member State? -->
47 <xs:element name="rms-auth-date" type="xs:date"/>
48 <xs:element name="rms-exp-date" type="xs:date"/>
49 <xs:element name="cms-dates" maxOccurs="unbounded"/>
58 <xs:element name="cms-renewal-date" type="xs:date"/>
59 </xs:sequence>
60 </xs:complexType>
61 </xs:element>
    
```



Updated/Amended Renewal xsd Schema Definition:

The update to the schema has been highlighted in grey.

```

11 <xs:element name="application-information">
12 <xs:complexType>
13 <xs:sequence>
14 <xs:element name="human" type="rdm:yes-no"/>
15 <xs:element name="veterinary" type="rdm:yes-no"/>
16 <xs:element name="authorisation" type="rdm:radiobutton"/>
17 <xs:element name="procedure-number" type="rdm:string50"/>
18 <xs:element name="reference-member-state" type="rdm:string50"/>
19 <xs:element name="concerned" maxOccurs="unbounded"/>
26 <xs:element name="currently-marketed" type="rdm:yes-no"/>
27 <xs:element name="currently-marketed-in" minOccurs="0" maxOccurs="unbounded"/>
34 <xs:element name="attach-annex" type="rdm:yes-no" minOccurs="0" maxOccurs="1"/>
41 <xs:element name="invented-name" type="rdm:string250"/>
42 <xs:element name="medicinal-products" type="rdm:medicinal-product-renewals" maxOccurs="unbounded"/>
43 <xs:element name="ma-holder" type="rdm:contact-details-type" maxOccurs="unbounded"/>
44 <xs:element name="maContact" maxOccurs="unbounded">
45 <xs:complexType>
46 <xs:sequence>
47 <xs:element name="member-states" type="rdm:member-states"/>
48 <xs:element name="role" type="rdm:role"/>
49 <xs:element name="contact-details" type="rdm:contact-details-type"/>
50 </xs:sequence>
51 </xs:complexType>
52 </xs:element>
53 <xs:element name="applicants-ref" type="rdm:string50"/>
54 <!-- Has this date anything to do with Concerned Memeber State? -->
55 <xs:element name="rms-auth-date" type="xs:date"/>
56 <xs:element name="rms-exp-date" type="xs:date"/>
57 <xs:element name="cms-dates" maxOccurs="unbounded"/>
66 <xs:element name="cms-renewal-date" type="xs:date"/>
67 </xs:sequence>
68 </xs:complexType>
69 </xs:element>

```

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Variation

There were two changes applied to the renewal form.

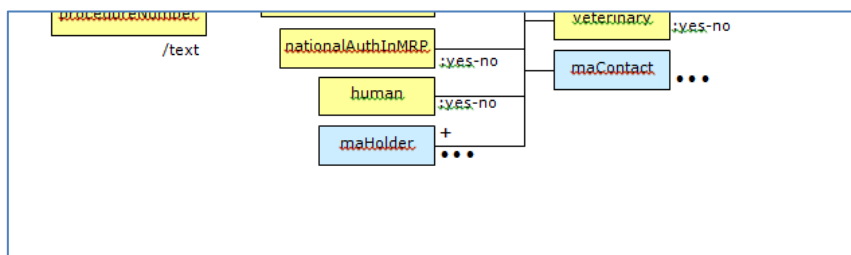
Schema File Affected: variation.xsd

Change Request Reference: EAF-1828, EAF-1931, EAF-2090, EAF-2156

Summary of Variation change (EAF-1828):

Include a + and – button to allow additional MA Holders.

Extract from Variation DES:



Original Variation xsd Schema definition:

The original line has been highlighted in grey.

```

49 <xs:element name="targetSpecies" type="rdm:yes-no"/>
50 <xs:element name="other" type="rdm:yes-no"/>
51 <xs:element name="maHolder">
52   <xs:complexType>
53     <xs:sequence>
54       <xs:element name="role" type="rdm:role" minOccurs="1"/>
55       <xs:element name="contact-details" type="rdm:contact-details-type"/>
56     </xs:sequence>
57   </xs:complexType>
58 </xs:element>
59 <xs:element name="maContact" maxOccurs="unbounded">
68 <xs:element name="inventedName" type="rdm:string250"/>
69 </xs:sequence>
70 </xs:complexType>
71 </xs:element>

```

Updated/Amended Variation xsd Schema Definition:

The update to the schema has been highlighted in blue.

```

51 <xs:element name="maHolder" maxOccurs="unbounded">
52   <xs:complexType>
53     <xs:sequence>
54       <xs:element name="role" type="rdm:role" minOccurs="1"/>
55       <xs:element name="contact-details" type="rdm:contact-details-type"/>
56     </xs:sequence>
57   </xs:complexType>
58 </xs:element>

```

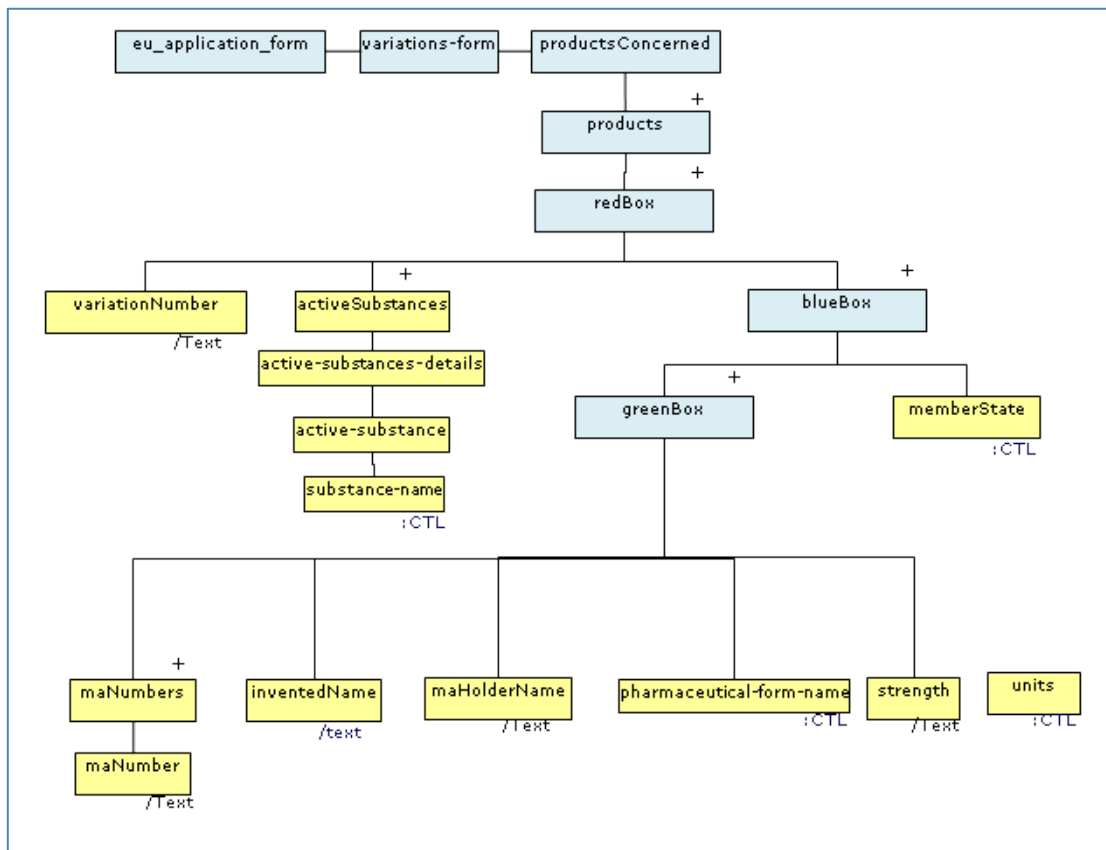


Summary of Variation change (EAF-1931):

The replacement of the existing Section 2 with a new structure to be used when the NP, CP, MRP or DCP options are chosen. The underlying schema will be modified to include this additional node of data.

Extract from Variation DES:

This is the extract of the change applied to the Variation DES for this change request.



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Original variation xsd Schema definition:

The original schema definition, at line 72.

```
72 <xs:element name="productsConcerned">
73   <xs:complexType>
74     <xs:sequence>
75       <xs:element name="tempProducts" maxOccurs="unbounded">
76         <xs:complexType>
77           <xs:sequence>
78             <xs:element name="medicinal-product" type="rdm:medicinal-product"/>
79             <xs:element name="maHolderName" type="rdm:string100"/>
80             <xs:element name="maNumbers" maxOccurs="unbounded">
81               <xs:complexType>
82                 <xs:sequence>
83                   <xs:element name="maNumber" type="rdm:string30"/>
84                 </xs:sequence>
85               </xs:complexType>
86             </xs:element>
87             <xs:element name="mrpVariationNumbers" maxOccurs="unbounded">
88               <xs:complexType>
89                 <xs:sequence>
90                   <xs:element name="mrpVariationNumber" type="rdm:string30"/>
91                   <xs:element name="member-states" maxOccurs="unbounded">
92                     <xs:complexType>
93                       <xs:sequence>
94                         <xs:element name="member-state" type="rdm:member-states"/>
95                         <xs:element name="maHolder" maxOccurs="unbounded">
96                           <xs:complexType>
97                             <xs:sequence>
98                               <xs:element name="maHolderName" type="rdm:string100"/>
99                               <xs:element name="maNumbers" maxOccurs="unbounded">
100                                 <xs:complexType>
101                                   <xs:sequence>
102                                     <xs:element name="maNumber" type="rdm:string30"/>
103                                   </xs:sequence>
104                                 </xs:complexType>
105                               </xs:element>
106                             </xs:sequence>
107                           </xs:complexType>
108                         </xs:element>
109                       </xs:sequence>
110                     </xs:complexType>
111                   </xs:element>
112                 </xs:sequence>
113               </xs:complexType>
114             </xs:element>
115           </xs:sequence>
116         </xs:complexType>
117       </xs:element>
118     </xs:sequence>
119   </xs:complexType>
120 </xs:element>
```

Rest of this page left intentionally blank



Updated/Amended Variation xsd Schema Definition:

```

72 <xs:element name="productsConcerned">
73 <xs:complexType>
74 <xs:sequence>
75 <xs:element name="products" maxOccurs="unbounded">
76 <xs:complexType>
77 <xs:sequence>
78 <xs:element name="redbox" maxOccurs="unbounded">
79 <xs:complexType>
80 <xs:sequence>
81 <xs:element name="variationNumber" type="rdm:string250"/>
82 <xs:element name="activeSubstances" minOccurs="0">
83 <xs:complexType>
84 <xs:sequence>
85 <xs:element name="active-substances-details" minOccurs="1" maxOccurs="unbounded">
86 <xs:complexType>
87 <xs:sequence>
88 <xs:element name="active-substance-detail" type="xs:string"/>
89 <xs:element name="active-substance" type="rdm:ingredient" minOccurs="1" maxOccurs="unbounded"/>
90 </xs:sequence>
91 </xs:complexType>
92 </xs:element>
93 </xs:sequence>
94 </xs:complexType>
95 </xs:element>
96 <xs:element name="blueBox" maxOccurs="unbounded">
97 <xs:complexType>
98 <xs:sequence>
99 <xs:element name="memberState"/>
100 <xs:element name="greenBox" maxOccurs="unbounded">
101 <xs:complexType>
102 <xs:sequence>
103 <xs:element name="maNumbers" maxOccurs="unbounded">
104 <xs:complexType>
105 <xs:sequence>
106 <xs:element name="maNumber" type="rdm:string30"/>
107 </xs:sequence>
108 </xs:complexType>
109 </xs:element>
110 <xs:element name="inventedName" type="rdm:string250"/>
111 <xs:element name="maHolderName" type="rdm:string100"/>
112 <xs:element name="pharmaceutical-form-name" type="rdm:control-term"/>
113 <xs:element name="strength" type="xs:string"/>
114 <xs:element name="units" type="rdm:control-term"/>
115 </xs:sequence>
116 </xs:complexType>
117 </xs:element>
118 </xs:sequence>
119 </xs:complexType>
120 </xs:element>
121 </xs:sequence>
122 </xs:complexType>
123 </xs:element>
124 </xs:sequence>
125 </xs:complexType>
126 </xs:element>
127 </xs:sequence>
128 </xs:complexType>
129 </xs:element>
    
```

Additional Variation Schema change:

The procedure number has been increased from 30 to 250 characters in length.

```

19 <xs:element name="procedureNumbers" maxOccurs="unbounded">
20 <xs:complexType>
21 <xs:sequence>
22 <xs:element name="procedureNumber" type="rdm:string250"/>
23 </xs:sequence>
24 </xs:complexType>
25 </xs:element>
    
```

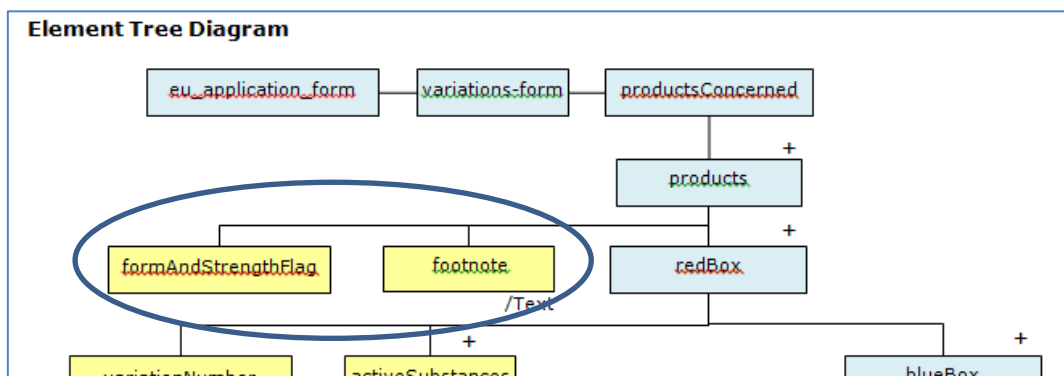


Summary of Variation change (EAF-2090):

The Section 2 structure doesn't work for vaccine applications and a specific allowance needs to be made to allow vaccine applications.

Implement a tick box where the applicant can indicate that the application is for vaccine and in those cases a free text field would appear where they can provide the strength information. Ideally again, if this box is ticked and the free text field appears the 'strength' and 'unit' fields in the table are not mandatory, but can be used if they wish to do so.

Extract from Variation DES:



Two new nodes under the products level called: formAndStrengthFlag and footnote.

Original Variation xsd Schema definition:

This is the original schema before the change.

```

73 <xs:element name="productsConcerned">
74 <xs:complexType>
75 <xs:sequence>
76 <xs:element name="products" maxOccurs="unbounded">
77 <xs:complexType>
78 <xs:sequence>
79 <xs:element name="formAndStrengthFlag" type="rdm:yes-no" maxOccurs="1"/>
80 <xs:element name="footnote" type="xs:string" maxOccurs="1"/>
81 <xs:element name="redbox" maxOccurs="unbounded">
82 <xs:complexType>
83 <xs:sequence>
84 <xs:element name="variationNumber" type="rdm:string250"/>
85 <xs:element name="activeSubstances" minOccurs="0">
86 <xs:complexType>

```



Updated/Amended Variation xsd Schema Definition:

The update to the schema has been highlighted in blue.

```

72 | <xs:element name="productsConcerned">
73 |   <xs:complexType>
74 |     <xs:sequence>
75 |       <xs:element name="products" maxOccurs="unbounded">
76 |         <xs:complexType>
77 |           <xs:sequence>
78 |             <xs:element name="formAndStrengthFlag" type="rdm:yes-no" maxOccurs="1"/>
79 |             <xs:element name="footnote" type="xs:string" maxOccurs="1"/>
80 |             <xs:element name="redbox" maxOccurs="unbounded">
81 |               <xs:complexType>
82 |                 <xs:sequence>
83 |                   <xs:element name="variationNumber" type="rdm:string250"/>
84 |                   <xs:element name="activeSubstances" minOccurs="0">
85 |                     <xs:complexType>

```

The new nodes, beneath the products parent are:

```

<xs:element name="formAndStrengthFlag" type="rdm:yes-no" maxOccurs="1"/>
<xs:element name="footnote" type="xs:string" maxOccurs="1"/>

```

Summary of Variation change (EAF-2156):

In section 1 "name and address of the applicant/MA Holder" it should be possible to assign member states to the respective MAH.

Extract from Variation DES:

