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Information Technology  
EMA/477434/2020

## eAF Release Notes v1.26.0.0

The scope of release v1.26.0.0 covers the following fixes and features:

1. SD-508617 [Vet Variation] eAF variation update to align with VMP-reg requirements
2. SD-574425 [Vet Variation] eAF VMP-Reg release v1.26.0.0 update of the variation form section 'Extended data exclusivity/market protection'
3. SD-587688 [Vet Variation] eAF VMP-Reg release v1.26.0.0 variation form - alternative timetable tick box and field
4. SD-573178 [Vet Variation and Vet MAA] eAF VMP-Reg release v1.26.0.0 display the sms ID in the pdf
5. SD-403904 [Vet MAA] eAF MAA update to align with VMP-Reg requirements
6. SD-574469 [Vet MAA] eAF MAA form VMP-Reg new change in section 1.5
7. SD-587679 [Vet MAA] eAF VMP-Reg release v1.26.0.0 UAT comment - MAA Vet form
8. SD-573186 [Vet MAA] VMP-Reg release v1.26.0.0 - Target species list update in eAF and eAF webservice
9. SD-562925 [Human MAA, Human Variation, Renewal] Mandatory OMS in eAF (for EU authorisation)
10. SD-603297 [Vet MAA] eAF VMP-Reg release v1.26.0.0 reintroduce free text address fields (2.4.1 proof of payment and 2.5.4 studies)
11. SD-589669 [Vet MAA] eAF VMP-Reg release v1.26.0.0 UAT feedback - MAA Vet form
12. SD-598408 [Vet MAA] eAF VMP-Reg release v1.26.0.0 webservice update 2.1.4 withdrawal period and update of 1.3.3 Hybrid application
13. SD-609927 [Vet MAA] eAF VMP-Reg release v1.26.0.0 – update of section 1.2

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| 14. SD-603296  | [Vet Variation] eAF VMP-Reg release v1.26.0.0 - update of the label name for the UPD product identifier   |
| 15. SD-610514  | [Vet Variation, Human Variation] eAF release v1.26.0.0 optional harmonisation/parallel variation section with new tooltip                                     |
| 16. SD-628828  | [Vet MAA] Error in sections 4.2   |
| 17. SD-631524  | [Vet MAA] Empty fields in 2.4.4 after the form is re-opened   |
| 18. SD-616348  | [Vet MAA] Correction to section 1.2   |
| 19. SD-627433  | [Human MAA, Renewal] Wrong picklist values displayed for Member States in some fields   |
| 20. SD-519223  | [Human Variation] Variation eAF - form validation rule missing  |
| 21. SD-626262  | [Vet MAA, Human MAA, Vet Variation, Human Variation, Renewal] - validation rule for mandatory addresses in the eAFs   |
| 22. SD-642359  | [Vet Variation, Human Variation] - validation rule for mandatory addresses in the variation eAFs  |
| 23. SD-645775  | [Vet MAA] - eAF Veterinary MAA form - User feedback - corrections to business rules needed  |
| 24. SD-634403  | [Vet Variation] – UPD Product Identifier field  |
| 25. SD-589125  | [Vet Variation] - VMP-Reg related improvements/corrections  |
| 26. SD-665048  | [Human Variation, Vet Variation] – Validation rule for mandatory use of OMS in the ‘proposed’ section of the form   |
| 27. SD-647719  | [Human Variation] - Business rule error correction in section 4b of the human variation form  |
| 28. ADO 133942 | [Human Variation, Vet Variation, Renewal] - [eAF] Add Non-Current terms for Variations and Renewals (Human and Vet) for "Pharmaceutical Form" list <b>New</b> |

Additional details can also be found in the release notes accessed here: [eAF esubmission website](#).

#### 1. **SD-508617 [Vet Variation] eAF variation update to align with VMP-reg requirements**

In Vet Variation form the following are implemented:

##### **Deliver 2 Variation forms.**

- The Variation-Human form will have checkbox “Human” on Section 1: selected, read-only (the Veterinary checkbox will be hidden)
- The Variation-Veterinary form will have checkbox “Veterinary” on Section 1: selected, read-only (the Human checkbox will be hidden)

##### **Cover page:**

Update cover page to reflect the new form version 1

**Section 1:**

Add “/SRP” at the check box “National Authorisation in MRP/DCP”

Delete the selection of procedure type e.g. Type IAIN, Type IA, IB etc

Update “changes of concern(s)” list to reflect the update (check boxes should always be visible)

- Quality
- Indication
- Safety
- Non-food producing target species
- Other

Name and address of MA holder: The address must be retrieved from OMS:

- the user cannot manually enter “Company name”, “address”, “City”, “State”, “County”, “postcode”, “Country”. These fields will become visible when the user selects an organisation from OMS.
- the user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

Name and address of contact person: The address must be retrieved from OMS:

- the user cannot manually enter “Company name”, “address”, “City”, “State”, “County”, “postcode”, “Country”. Also, these fields will become visible when the user selects an organisation from OMS.
- the user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

**Section 2:**

- Add the “UPD Permanent Identifier for the concerned national product(s):” and the “UPD Product Identifier (only relevant for MRP and CP):”
- Pharmaceutical form column reduced in size so the 2 UPD fields can fit
- A ‘?’ button to be added next to UPD fields that will show the footnote, related to these 2 new UPD fields

**Section 3:**

- A link to a new Veterinary Variation Classification list is established. Only variations related to VRA are displayed and selectable.
- Procedure type section has been removed

- New extended attribute 'Timetable' with possible values R or S or E (one possible value each time) will be displayed as text field (not as a check box). The "timetable" information is part of "Application Submission Type" attribute.
- Variation classifications with timetable "VNRA", are filtered out from the response.
- Implementation Date and Note have to be deleted
- Article 5 tick box has been deleted
- Update the text into "Precise scope and background for change, and justification for a z) classification, grouping, worksharing (as applicable) (Include a description and background of all the proposed changes. In case of a z) scope, grouping and worksharing a justification should be provided in a separate paragraph.)."
- PRESENT/PROPOSED: For the present the user will be able to enter manually the address field and OMS is optional.
- In the Proposed address fields, the address must be retrieved from OMS:
  - the user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". These fields will become visible when the user selects an organisation from OMS.
  - the user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.

#### **Section 4c:**

- Section 4c should be always visible
- Update the label of the text "Consideration of this application is also requested under the following article in directive 2001/83/EC or regulation (EC) No 726/2004:" into "Consideration of this application is also requested under the following article of Regulation (EU) 2019/6:"
- Update section by removing the old radio buttons and replace with updated (mutually exclusive) radio buttons.
- There will not be business rule related with the new radio buttons.
  - Article 40(1) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 1 year for each additional target species, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (a) or (b) of Article 39(1)).
  - Article 40(2) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 4 years, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (d) of Article 39(1)).
  - Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out.

- Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection).

**Annexed documents section:**

- Update the label of the text from “The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:” into “The following amended product information proposals are provided in the relevant sections of the variation application dossier, where applicable:”
- Update the label of the check box “Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation” into “Conditions of the Marketing Authorisation”

**Declaration of the applicant section:**

- Update the label of the text and label of check boxes
- Delete the check box “Where applicable, all conditions as set for the variation(s) concerned are fulfilled”
- Delete “Next production run/next printing”
- Update the label of the “Date” into “Proposed implementation date”
- Add two new separate sections under the existing section of declaration of the applicant. These 2 new sections should be displayed only if the user selects MRP or National authorisation. If only EU authorisation is selected these 2 new sections will not be displayed.
- Parallel variations section:
  - If no is selected then nothing will be displayed (below the radio buttons)
  - If yes is selected, then the fields below the radio buttons will be displayed in a frame and that will be repeatable. The list of Country field will be the EEA list including Northern Ireland.
- Harmonisation section:
  - If the user selects yes to the questions 1) and/or 2) he has to fill in the following fields that will be appeared in a repeatable frame:
    - Procedure(s) reference number:
    - Specify the section(s) of SPC/PIL/labelling:
  - If the user selects no to the questions 1) and/or 2) the fields below the radio buttons will not be appeared.

**Main Signatory section:**

- Update the label of the existing check box from “For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the MAs concerned.” into “For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4 in Part IA/ Application Form for each of the MAs concerned.”

**Across the form:**

Update the footnotes

**2. SD-574425 [Vet variation] eAF VMP-Reg release v1.26.0.0 update of the variation form section 'Extended data exclusivity/market protection**

In the Vet Variation form the following are implemented:

**Section Extended data exclusivity/market protection:**

- Add 3 new options with radio button selection (mutually exclusive) and the option which is already there needs to be modified slightly to replace the text 'four' with number '4'
- The new options to be added are;  
Article 40(1) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 1 year for each additional target species, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (a) or (b) of Article 39(1)).

Article 40(2) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 4 years, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (d) of Article 39(1)).

Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out.

Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection).

### **3. SD-587688 [Vet Variation] eAF VMP-Reg release v1.26.0.0 variation form - alternative timetable tick box and field**

In Vet Variation form the following are implemented:

The existing Timetable value should be displayed as text with value: "Default timetable: X" where X is the value of the timetable returned by RMS e.g. R.

A text with label "Alternative timetable agreed in advance:" should be displayed below "Default timetable" with 3 possible values "R", "E" and "S" displayed as radio buttons.

The radio button with the timetable value returned from RMS will be selected as default e.g. "R".

The new text "Alternative timetable agreed in advance:" will have a tooltip "Please select an alternative timetable if one has been agreed in advance of submission."

When the user selects an alternative value of the radio buttons e.g. "E" or "S" (different from the one returned from RMS list), a new mandatory check box will be displayed below with text "Please tick to confirm that the correspondence confirming the alternative timetable is included in the submission." When the user selects the default radio button value e.g. "R" this check box becomes hidden.

### **4. SD-573178 [Vet MAA and Vet Variation] eAF VMP-Reg release v1.26.0.0 display the sms ID in the pdf**

In Vet Variation form the following are implemented:

In section 2, there is a field for SMS ID which is hidden. This field has been made visible.

In Vet MAA form the following are implemented:

There is a field for SMS ID which is hidden. This field should be visible.

The SMS ID is currently available in the xml in the form, this change is to display that sms id in the form pdf in the corresponding field.

This change applies to the following sections:

- Section MRL
- Section 2.1.2
- Section 2.2.1
- Section 2.5.3
- Section 2.6.1 (4 instances, active substance, for salts and hydrates only, excipients and active substances and excipients under overages)
- Section 2.6.2

## 5. SD-403904 [Vet MAA] eAF MAA update to align with VMP-Reg requirements

In Vet MAA the following are implemented:

### **Cover page:**

Update the cover page to reflect the new form version 1

### **Declaration section:**

The Declaration section has been removed as the first section of the form

### **Section 1.1.1:**

- Update the label of 1.1.1 section
- Only one article can be selected
- The following have been deleted:
  - Radio button "Generic of a centrally authorised veterinary medicinal product" (Article 3(3))"
  - CVMP Rapporteur
  - CVMP Co-rapporteur
- Update the business rule:



When the radio button « Mandatory scope» (Article 42(2)) is selected, the following radio buttons are shown:

- Article 42(2)(a)(i) of Regulation (EU) 2019/6 - Biotech VMP developed by recombinant DNA technology
  - Article 42(2)(a)(ii) of Regulation (EU) 2019/6 - Biotech VMP developed by controlled expression of genes coding
  - Article 42(2)(a)(iii) of Regulation (EU) 2019/6 - Biotech VMP developed by hybridoma and monoclonal antibody methods
  - Article 42(2)(b) of Regulation (EU) 2019/6 - Performance enhancers
  - Article 42(2)(c) of Regulation (EU) 2019/6 - New active substance which has not been authorised as a VMP within the Union at the date of the submission of the application
  - Article 42(2)(d) of Regulation (EU) 2019/6 - Biological VMP which contains or consists of engineered allogeneic tissues or cells
  - Article 42(2)(e) of Regulation (EU) 2019/6 - Novel therapy VMP
- When the radio button « Optional scope » (Article 42(4)) is selected, the following radio buttons are shown:
    - Article 42(4) of Regulation (EU) 2019/6 - VMP other than those listed under Article 42(2) of Regulation (EU) 2019/6, for which no other marketing authorisation has been granted within the Union
  - Also, the field “Date of acceptance/confirmation by CVMP” will be at dd-mm-yyyy format
  - “EMA product number” field should be renamed to “EMA procedure number”

#### **Section 1.1.2:**

- Update the label of 1.1.2 section
- Update the label of the radio button “Repeat use 1st wave (Please also complete section 4.2)”
- Update the format of “Date of authorization” to dd-mm-yyyy.
- Delete the following fields:
  - Proposed/Agreed common renewal date
  - If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate,
  - please specify

#### **Section 1.1.3:**

- Update the label of 1.1.3 section
- Delete the following fields:
  - If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify
  - Proposed Common Renewal Date

#### **Section 1.1.4:**

- Update the “Application number” label into “If available, application number “
- Delete the field “If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify”

#### **Section 1.2:**

- Update the label of section 1.2
- When the “Yes” radio button is selected the following new free text, non mandatory fields should be displayed:
  - UPD Product Identifier (only relevant for MRP and CP)
  - UPD Permanent Identifier for the concerned national product(s)  
Variation Procedure number (mandatory for MRP)
- Update the label of the radio button “modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the clinical/safety characteristics are not significantly different
- Update the label of the “Note”
- Update the label of the text “For an existing marketing authorisation in the European Union/ Member State where the application is made”

#### **Section 1.3:**

- Update the label of the section 1.3
- Update the label of the “Note”

#### **Section 1.3.1:**

- Update the label of the section 1.3.1
- Update the label of the “\*”

#### **Section 1.3.2:**

- Update the label of the section 1.3.2
- Update the label of the “Notes”
- Update the label of the “Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA: “
- Update the format of “Date of authorisation” field into dd-mm-yyyy.
- Update the text “Note 2: Should be considered the “same” as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are “licencees”)” into “Note 2: Should be

considered the “same” as the one identified above (i.e. belonging to the same mother company or group of companies or which are “licensees”)

- Update the Note under the text “Veterinary medicinal product which is or has been authorised in accordance with Union provision in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies”

#### **Section 1.3.3:**

- Update the label of the section 1.3.3
- The new articles will be radio buttons in order to select only one
- Update the Note under the section 1.3.3
- Update the Note under “Reference Medical product:”
- Update the label of “Veterinary medicinal product which is or has been authorised in accordance with Union provision in force for not less than 6/8/10 years in the EEA”
- Update the format of “Date of authorisation” field into dd-mm-yyyy.
- Add the following new check boxes at the section “Difference(s) compared to this reference medicinal product”
  - change(s) in the raw material(s) (compared to the reference biological veterinary medicinal product)
  - change(s) in the manufacturing process(es) (compared to the reference biological veterinary medicinal product)
  - other
- Update the label of “Veterinary medicinal product which is or has been authorised in accordance with Union provision in force used for the demonstration of bioequivalence (if applicable) and/or in other studies.” and under this section add a new check box “Third country” (under Member State (EEA) and update the label of “Member State of source”.

#### **Section 1.3.4:**

- Remove section “1.3.4 Article 13(4) Similar biological application”
- Update the section to reflect Article 20 - Combination veterinary medicinal products

#### **Section 1.3.5:**

- Update the section number from 1.3.5 to 1.3.7, the text and note accordingly.

#### **Section 1.3.6:**

- Remove section “1.3.6 Article 13b - Fixed combination”
- Update the section to reflect Article 22 – Bibliographic application

**Section 1.3.7:**

- Remove section “1.3.7 Article 13c - Informed consent application”
- Update the section to reflect Article 23 – Applications for limited markets
- add a date new field in dd-mm-yyyy format.

**Section 1.3.8:**

- Remove section “1.3.8 Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted”
- Update the section to reflect Exceptional Circumstances
- add a date new field in dd-mm-yyyy format.

**Section 1.4:**

- The text “Application for a Maximum Residue Limit has been made to the EMA” has to be updated and above that add the following new text:
  - Biological substance considered as not requiring an MRL evaluation as per Commission Regulation (EU) No 2018/782:  
Entry in the list of biological substances considered as not requiring an MRL evaluation. This should be a free text field with no validation.
- The label of substance should be updated into “Pharmacologically active substance
- Update the footnote “All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.”

**Section 1.5:**

- Update the label into “1.5 consideration of this application is also requested under the following PROVISION of Regulation (EU) 2019/6 “

**Section 1.5.1:**

- Update the section number from 1.5.1 to 1.5.2, the text and the note
- Update the format of the “Date of acceptance by CVM” field into dd-mm-yyyy.

**Section 1.5.2:**

- Update the section number from 1.5.2 to 1.5.3 and the text.

**1.5.4 section:**

- This new option 1.5.4 should be added as the 4th tick box option to the list, this addition will mean that the existing entry for 1.5.4 is renumbered to 1.5.5, Vaccine antigen master file becomes 1.5.6 and Vaccine platform technology master file becomes 1.5.7
- The text for the new 1.5.4 is;  
1.5.4 Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out))

#### **Sections 1.5.3 – 1.5.7:**

- These sections have to be added

#### **Section 2.1:**

- Update the label of this section

#### **Section 2.1.1:**

- Update the label of the text (incl. the label of the check box).
- proposed name in section 2.1.1 that was populated by Declaration section and is disabled for manual entry should be editable and mandatory.
- The note “value populated ..” in this field indicating this should be deleted.

#### **Section 2.1.2:**

- Update the label of “For applications submitted in accordance with Article 12(3) of Directive 2001/82/EC”
- Update the Note under “Claim for new active substance(s)” radio button
- Add Note “\*\* New/known active substance in relation to structure and properties, including significant differences in terms of safety or efficacy compared to an already authorised veterinary medicinal product in the Union. Please provide evidence and justification to support the claim of new active substance status in annex 5.22”
- The text “(The value of the active substances field has been populated from "Declaration" section.)” should be removed.
- The user should be able to search the active substance as currently is doing at the declaration form.
- Add Button “Populate data in section 2.6.1” above “Substance type”. When this button is clicked, it will populate the Substance data from section 2.1.2 to section 2.6.1

#### **Section 2.1.3:**

- Add “ATC vet Code flag” label at the check box

#### **Section 2.1.5:**

- New section to be added

#### **Section 2.2.1:**

- The text “(The values of the following fields have been populated from "Declaration" section.)” should be removed.
- The user should be able to search the pharmaceutical form, strength and unit as currently is doing at the declaration form.
- Add button “Populate data in section 2.6.1” at the end of section 2.2.1. When this button is clicked, it will populate the data of the pharmaceutical form, strength inserted in section 2.2.1 to section. 2.6.1

#### **Section 2.2.3:**

- Update the label of section 2.2.3
- Update the label of “Administration Device” field
- Update the label of the check box

#### **Section 2.3:**

- The existing sections 2.3.1, 2.3.2, 2.3.3, 2.3.4 and 2.3.5 have to be deleted and replaced.

#### **Section 2.4.1:**

- Update the label of the section 2.4.1
- Update the format of “Date of expiry” field into dd-mm-yyyy.
- Update the label of the check box “Attach copy of the “Qualification of SME Status”
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organization name/Country” or previously selected address.
- Remove “Copy contact details from Declaration Section” button

#### **Section 2.4.2:**

- Update the label related to section 2.4.2

- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organization name/Country” or previously selected address.
- Remove “Copy contact details from Declaration Section” button

#### **Section 2.4.3:**

- Update the label related to section 2.4.3
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organization name/Country” or previously selected address.
- Remove “Copy contact details from Declaration Section” button

#### **Section 2.4.4:**

- Update the label of the check box “Detailed description of the pharmacovigilance system
  - Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID ” or “Organisation name/Country” or previously selected address.
  - Add the following new fields:  
(Pharmacovigilance System) Master file
- 
- PSMF reference number: ((PSMF) reference number/identifier as assigned by the QPPV shall be specified)
  - PSMF location:  
Address from OMS

#### **Section 2.5.1:**

- Update the label of 2.5.1.a and 2.5.1b

- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

#### **Section 2.5.1.1:**

- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

#### **Section 2.5.1.2:**

- Update the label of the section 2.5.1.2
- Update the label of the check box “Attach copy of manufacturing authorisation(s) or proof of GMP compliance”
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organization name/Country” or previously selected address.

#### **Section 2.5.2:**

- Update the label of the check box “Attach document equivalent of manufacturing authorisation in accordance with Article 12(m) of Directive 2001/82/EC”
- Update the label of the radio button “Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where Mutual Recognition Agreements (MRA) (except USA/USA excluded) or other European Union arrangements apply within the terms of the agreement”
- Update the label of the radio button “Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)”
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

#### **Section 2.5.3:**

- Remove “Copy contact details from Declaration Section” button
- Update the label of the text “Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement”



- Update the label of the check box “Attach latest GMP certificate in (Annex 5.9)
- Update the label of the text “Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)”
- Update the format of “date of last update” into dd-mm-yyyy
- Add a new check box “attach, if applicable, the confirmation in writing from the CEP holder to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines and HealthCare. (Annex 5.11)” under “date of last update” field
- Update the label of the text “Is an Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?”
- Update the label of the text “National ASMF reference number (when applicable and only if EU ASMF reference number is not available)”
- Update the format of the dates “date of submission” and “date of last update” into dd-mm-yyyy
- Update the label of the check box “Attach letter of access for european Union/Member State authorities where the application is made (see
- "Guideline on Active Substance Master File"
- Delete the check box “Attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC”
- Update the label of the text “Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/82/EC (Annex I), being used for this MAA”
- Update the format of the dates “date of submission (if pending)” and “date of approval or last update (if approved)” into dd-mm-yyyy
- At the end of this section add the segment “Is an EMA certificate for a Vaccine Platform Technology Master File (PTMF) issued or submitted in accordance with Regulation (EU) 2019/6 (Annex II), being used for this MAA”.
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID ” or “Organization name/Country” or previously selected address.

#### **Section 2.5.4:**

- Update the label of the section
- Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add “find organisation” when this is missing. Also, the user should be able to find the address using “Loc ID/Org ID ” or “Organization name/Country” or previously selected address.

**Section 2.6.1:**

- The text “(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)” has to be updated into “The values of the pharmaceutical form and strength fields have been populated from “2.2.1” section and active substances field have been populated from "2.1.2" section.)
- Use the existing free text field above the “Name of active substance” to reflect the actual name of the active substance and use a tooltip at this free text field to indicate this functionality

**Section 3:**

- Update the format of the two Dates fields into dd-mm-yyyy.

**Section 4.1:**

- Update the label of 4.1 section
- Update the label of “Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 21 or 22 of Directive 2001/82/EC shall apply)?”

**Section 4.2:**

- Delete the “Note: refer to Commission Communications 98/C229/03”
- Update all the dates to be in dd-mm-yyyy format

**Section 4.3:**

- Update all the dates to be in dd-mm-yyyy format

**Section 4.4:**

- The following date fields should be in dd-mm-yyyy format:  
“date of authorization”, “date of submission”, “date of refusal”, “date of withdrawal”, “date of suspension/revocation”

**Declaration and Signature:**

- New section to be added under 4.4 section

**Section 5:**

- Update the following sections: 5.5, 5.6, 5.11, 5.15, 5.16, 5.17, 5.20-5.24

#### **6. SD-574469 [Vet MAA] eAF VMP-Reg release v1.26.0.0 MAA form - new change in section 1.5**

- In the Vet MAA form the following are implemented:

##### **Section 1.5:**

- add new 1.5.4 section. This new option 1.5.4 should be added as the 4th tick box option to the list, this addition will mean that the existing entry for 1.5.4 is renumbered to 1.5.5, Vaccine antigen master file becomes 1.5.6 and Vaccine platform technology master file becomes 1.5.7
- The text for the new 1.5.4 is;  
1.5.4 Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out))

#### **7. SD-587679 [Vet MAA] eAF VMP-Reg release v1.26.0.0 UAT comment - MAA Vet form**

In Vet MAA form the following are implemented:

At declaration and Signature section, a missing section for Applicant is included above of the section “On behalf of the applicant”.

#### **8. SD-573186 [Vet MAA] VMP-Reg release v1.26.0.0 - Target species list update in eAF and eAF webservices**

In the Vet MAA form the following are implemented:

The list 100000108853 Target Species which is called at the sections 2.1.3, 2.1.4 and 2.2.2 has to be filtered in order to add the following parameters:

Read the updated list and display only the values which have Extended attribute: IT application: eAF.

There is only one exception to this rule; when in section 1.1.2 MRP is selected and the subselection SRP (subsequent recognition procedure) is selected, then in the Target species list we need to display the values from the target species list that have been marked as IT application: eAF and IT application: UPD

## 9. SD-562925 [Human MAA, Human Variation, Renewal] Mandatory OMS in eAF (for EU authorisation)

In the **Human MAA form** the following are implemented:

The use of OMS is mandatory for all centralised procedure applications. This means that free text address fields are removed when 1.1.1 is selected in the MAA human form. Specifically, Remove the free text fields for address i.e. make OMS use mandatory for all address fields. More specifically:

- the user cannot manually enter “Company name”, “address”, “City”, “State”, “County”, “postcode”, “Country”. Also, these fields will become visible when the user selects an organisation from OMS.
- Add “find organisation” button when this is missing.
- The user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

The above requirement applies to the following sections of MAA Human form when the applicant has selected 1.1.1 Centralised procedure in the form:

- Declaration and signature section (2 sub sections; the MAH and the MAH contact person)
- 2.2.4.2 Manufacturer of the device
- 2.2.4.4 Notified body
- 2.2.5.2 Notified body
- 2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State
- 2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the European Union/each Member State
- 2.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each Member State
- 2.4.4 Summary of the applicant pharmacovigilance system (2 sub sections; the QPPV and PhV system master file)
- 2.4.5 Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)

- 2.5.1a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC ( as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision): (2 sub sections; admin address and the manufacturing address)
- 2.5.1 b Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)
- 2.5.1.1 Contact person in the EEA for product defects and recalls
- 2.5.1.2 Batch control Testing arrangements
- 2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture: (2 sub sections; admin address and the manufacturing address)
- 2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture (3 sub sections; admin address, the manufacturing address and ASMF holder)
- OMS is not mandatory in Proof of payment for billing 2.4.1 and in 2.5.4 Add study (OMS search has been made available and is recommended for use) The OMS search for 2.5.4 has been added also when a non-CP is selected in section 1.1 i.e. 1.1.2, 1.1.3 or 1.1.4. The use of OMS is not mandatory.

In the **Human Variation form** the following are implemented:

The use of OMS becomes mandatory when the applicant has selected EU authorisation. If both, EU authorisation and MRP/DCP and/or National has been selected, the OMS search is mandatory. If only MRP/DCP and/or National has been selected, the optional use of OMS continues to apply.

The free text address fields have been removed to mandate the use of OMS for human domain for CAPs.

Specifically, Remove the free text fields for address i.e. make OMS use mandatory for all address fields. More specifically:

- the user cannot manually enter “Company name”, “address”, “City”, “State”, “County”, “postcode”, “Country”. Also, these fields will become visible when the user selects an organisation from OMS.
- Add “find organisation” button when this is missing.
- The user should be able to find the address using “Loc ID/Org ID” or “Organisation name/Country” or previously selected address.

The above applies to the following sections of Variation Human domain form when the applicant has selected EU authorisation in the form:

- Section 1: Name and address of the MA Holder, Name and address of contact person

- Section 3: Present and Proposed; Use of OMS in 'present' is optional and the free text address fields remain available. In 'proposed' the use of OMS is mandatory (free text fields have been removed)
- Section 4d: Manufacturer of the device, Notified Body, Companion diagnostic
- OMS is not mandatory in Proof of payment for billing (OMS search is available and recommended for use), free text address fields remain available.

In **Renewal form for Human** the following are implemented:

The use of OMS is mandatory when the applicant has selected EU authorisation. Free text address fields are not available when the applicant has selected EU authorisation.

Specifically, remove the free text fields for address i.e. make OMS use mandatory for all address fields. More specifically:

- the user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". Also, these fields will become visible when the user selects an organisation from OMS.
- Add "find organisation" button when this is missing.
- The user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.

The above applies to the following sections of Renewal Human domain form when the applicant has selected EU authorisation in the form:

- Section 1: Name and address of MA holder, Name and address of contact person
- Section 2:
  - Do you have a separate admin and manufacturer address? (Yes option – 2 sub sections),
  - For blood products and vaccines: Do you have a separate admin and manufacturer address? (Yes option – 2 sub sections),
  - Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where batch control/testing takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above: Do you have a separate admin and manufacturer address? (Yes option – 2 sub sections),
  - Manufacturer(s) of the medicinal product and site(s) of manufacture (including diluent and solvent manufacturing sites) Do you have a separate admin and manufacturer address? (Yes option – 2 sub sections),
  - Manufacturer(s) of the active substance(s): Do you have a separate admin and manufacturer address? (Yes option – 2 sub sections)
- The section on ASMF holder should be aligned to reflect the design and the fields in the MAA form i.e. rename the field Name and contact details of the ASMF holder to 'Name of ASMF holder' and add OMS search for the company name and address of the ASMF

holder. The OMS search has been added. The OMS search for this section should be added also for those cases when a non-CP is selected in section 1 i.e. MRP/DCP or NP.

- The use of OMS is not be mandatory for non-CAPs. OMS is not mandatory in Proof of payment for billing (OMS search is available and recommended for use), free text address fields remain available.

#### **10. SD-603297 [Vet MAA] eAF VMP-Reg release v1.26.0.0 reintroduce free text address fields in the Veterinary MAA form (2.4.1 proof of payment and 2.5.4 studies) to align with Human CAP implementation**

In **Vet MAA** the following are implemented:

- Free text address fields have been reintroduced in the section 2.4.1. Proof of Payment section (only). Meaning that when 'no' is selected and an address needs to be provided (for all procedure types) then it is possible to enter the address for Proof of payment using free text fields, copy address from above address fields or add address using OMS search.
- The same reintroduction of free text address fields is done is done in section 2.5.4 for the addition of Contract companies used for clinical trial(s) for studies.

#### **11. SD-589669 [Vet MAA] eAF VMP-Reg release v1.26.0.0 UAT feedback - MAA Vet form**

In **Vet MAA** the following issues are solved:

- When MRP/DCP is selected in section 1.1, the RMS/CMS autofill from 'add selected' has been fixed in sections 2.4.2, 2.4.3 and 2.4.4.
- Section 1.3 heading has been changed to capital letters
- Section 1.4 MRL, the tick boxes for biological substances have red frames
- When 'Not applicable' is selected in 'Application for a Maximum Residue Limit or for an inclusion in the list of biological substances considered as not requiring an MRL evaluation has been made to the EMA' the sub-selection is no longer displayed. The sub-selection is only available if Yes is selected
- Business Rules in section 1.4 MRL have been updated; Pharmacologically active substance, Biological substance and Application for Maximum Residue Limit/inclusion on the list are all optional fields, but one of the 3 should be selected.

**12. SD-598408 [Vet MAA] eAF VMP-Reg release v1.26.0.0 webservice call update for 2.1.4 withdrawal period and update of eAF section 1.3.3 Hybrid application**

In **Vet MAA** the following are implemented:

- Section 1.3.3 Hybrid applications, the top level radio button selection of detailed change has been deleted
- Section 2.1.4 the correctly filtered list of Target species is now displayed. Target species with extended attributes: Edible tissue 'And' Edible and MRL tissue are displayed

**13. SD-609927 [Vet MAA] eAF VMP-Reg release v1.26.0.0 – Update of section 1.2**

In **Vet MAA** the following is implemented:

Section 1.2 the text “(complete section 1.3. and 1.4.)” has been deleted

**14. SD-603296 [Vet Variation] eAF VMP-Reg release v1.26.0.0 - update of the label name for the UPD product identifier**

In **Vet Variation** the following is implemented:

In section 2, the label for UPD product information has been updated to read; "UPD Product Identifier<sup>6</sup> (only relevant for MRP, DCP, SRP and CP)" instead of the current UPD Product Identifier<sup>6</sup> (only relevant for MRP and CP).

**15. SD-610514 [Vet Variation, Human Variation] eAF VMP-Reg release v1.26.0.0 optional harmonisation/parallel variation section with new tooltip**

In **Human Variation** the following is implemented:

- The “Yes/No” radio buttons of “Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products” and “Information on harmonisation of product information for MRP/DCP/purely nationally authorised products” are now optional.
- A new tooltip providing additional information is displayed when the user hovers over the section header “Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products”



In **Vet Variation** the following is implemented:

- The “Yes/No” radio buttons of “Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products” and “Information on harmonisation of product information for MRP/DCP/purely nationally authorised products” are now optional.

#### **16. SD-628828 [Vet MAA] Error in section 4.2**

In **Vet MAA** the following error is fixed:

- In section 4.2: In section 4.2: when ‘Refused’ is selected the suspended/revoked box is ticked automatically each time when the document is re-opened.

#### **17. SD-631524 [Vet MAA] Empty fields in 2.4.4 after the form is re-opened**

In **Vet MAA** the following error is fixed:

- In 2.4.4 when you add RMS and CMS using ‘Add selected’ feature the fields are filled in properly, however, when you save and reopen the form the fields are empty.

#### **18. SD-616348 [Vet MAA] Correction to section 1.2**

In **Vet MAA** the following errors are fixed:

- In section 1.2 Application for a variation requiring assessment; when the check box “Qualitative change in declared active substance not defined as a new active substance” is ticked, there should be 6 radio buttons (options). Two of the options are merged together.
- Additionally, the typo in the last option ('extraction').

#### **19. SD-627433 [Human MAA, Renewal] Wrong picklist values displayed for Member States in some fields**

In **Human MAA** and the **Renewal** the following is implemented:

- When adding previously selected Reference Member State and Concerned Member States using the "Add selected" feature, there was an error of populating the countries (in sections 2.4.1, 2.4.4 and 2.4.5 of Human MAA) that was fixed.
- In some cases, a pop-up error message ("Same member state should not be repeated, Please select a different member state") was displayed in the form that is now fixed.

## **20. SD-519223 [Human Variation] Variation eAF - form validation rule missing**

In **Human Variation** form the following are implemented:

A missing validation rule has been added to the human variation form

- When Type IA or Type IAIN is selected in section 1, fields implementation date and implementation note appear in section 3. A validation rule has been added to make these mandatory in the following way;
- If Type IA or Type IAIN is selected, the implementation date should be mandatory, if no date has been selected, the implementation note field is mandatory

## **21. SD-626262 [Vet MAA, Human MAA, Vet Variation, Human Variation, Renewal] - Validation rule for mandatory addresses in the eAFs**

Validation rule for mandatory use of OMS has been accidentally removed and is returned.

Specifically, when the free text address fields were removed when mandatory use of OMS was implemented for CAP only submissions/for VMP-Reg, the validation rule was accidentally removed. The fields are now shown however, they are read only and cannot be manually edited. The address when selected from OMS will be shown in these fields.

Specifically, the following sections with address fields are modified as described above:

### **MAA Veterinary:**

- section 2.4.1
- section 2.4.2
- section 2.4.3
- section 2.4.4
- Section 2.5.1a) (2 points)

- Section 2.5.1b)
- section 2.5.1.1
- section 2.5.1.2
- section 2.5.2 (2 points)
- section 2.5.3 (2 points)
- Declaration and signature – Applicant
- On behalf of the applicant at declaration and signature

### **MAA Human**

The above requirement applies to the following sections of MAA Human form taking into account that the applicant has selected 1.1.1 A Centralised Procedure in the form:

- Declaration and signature section (2 points in this section, the MAH and the MAH contact person)
- 2.2.4.2 Manufacturer of the device
- 2.2.4.4 Notified body
- 2.2.5.4 Notified body contact details
- 2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State
- 2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the European Union/each Member State
- 2.4.3 Person/company authorised for communication between the marketing authorisation holder and the competent authorities after authorisation if different from 2.4.2 in European Union/each Member State
- 2.4.4 Summary of the applicant pharmacovigilance system (2 points in this section; the QPPV and PhV system master file)
- 2.4.5 Scientific service of the MAH in the EEA as referred to in Article 98 of Directive 2001/83/EC (for DCP, MRP and national applications, the contact person in the country where the application is made)
- 2.5.1a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC ( as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision): (2 points in this section; admin address and the manufacturing address)

- 2.5.1 b Official batch release for Blood products and Vaccines Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)
- 2.5.1.1 Contact person in the EEA for product defects and recalls
- 2.5.1.2 Batch control Testing arrangements
- 2.5.2 Manufacturer(s) of the medicinal product and site(s) of manufacture: (2 points in this section; admin address and the manufacturing address → mandatory if yes is selected)
- 2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture (3 points in this section; admin address, the manufacturing address and ASMF holder)

#### **Variation form for Veterinary**

- Section 1: Name and address of MA holder
- Section 1: Name and address of contact person
- Section 3: Proposed

#### **Variation form for Human**

The above requirement applies to the following sections of Variation Human domain form taking into account that the applicant has selected EU authorisation in the form:

- Section 1: Name and address of the MA Holder, Name and address of contact person
- Section 3: Proposed.
- Section 4d: Manufacturer of the device, Notified Body, Companion diagnostic

#### **Renewal form for Human**

The above requirement applies to the following sections of Renewal Human domain form taking into account that the applicant has selected EU authorisation in the form:

- Section 1: Name and address of MA holder, Name and address of contact person
- Section 2:
  - Do you have a separate admin and manufacturer address? (Yes option – 2 points),

- For blood products and vaccines: Do you have a separate admin and manufacturer address? (Yes option – 2 points),
- Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where batch control/testing takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above: Do you have a separate admin and manufacturer address? (Yes option – 2 points),
- Manufacturer(s) of the medicinal product and site(s) of manufacture (including diluent and solvent manufacturing sites) Do you have a separate admin and manufacturer address? (Yes option – 2 points),
- Manufacturer(s) of the active substance(s) : Do you have a separate admin and manufacturer address? (Yes option – 2 points)
- ASMF holder.

A new tooltip is added in the **Human** Variation form when EU authorisation only, or EU authorisation and any combination with MRP/DCP or NP is selected; the new tool tip should be shown when the user is hovering over the 'Summary of product characteristics, Labelling or Product Information tick boxes in the Annexed documents section. The text should read;

The link to the document is here: [https://www.ema.europa.eu/en/documents/template-form/checklist-submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if\\_en.pdf](https://www.ema.europa.eu/en/documents/template-form/checklist-submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if_en.pdf)

Please ensure Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable) is included to your submission (if applicable). Missing checklist is considered validation issue.

Please be reminded that in accordance with Union data protection requirements, no personal data should be included in the annotated PIs. This applies to the English version submitted at the time of opinion, the draft translation versions of the PI in all the languages submitted at D+5 as well as the final translations submitted at D+25. Please submit annotated PIs in an anonymised format (i.e. names of the reviewers removed from the track-changes). If you do not wish to do so, please ensure that the individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant. EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder.

## 22. SD-642359 [Vet Variation, Human Variation] - validation rule for mandatory addresses in the eAFs

In the Vet Variation and Human Variation form the following are implemented:

- When EU authorisation only, or EU authorisation and any combination with MRP/DCP or NP is selected; then the address search from OMS in 'Proposed' should be triggered.
- A new validation rule is triggered if no organisation has been selected in the 'proposed' field using OMS and user clicks validate. A new checkbox is visible in proposed Org search area and must be ticked to get rid of the validation rule. The text of the check box should say “I declare this change does not affect organisations or the organisation concerned is being deleted”

- The new check box should only be visible if no organisation is selected in proposed and applicant clicks validate.
- if the applicant adds an organisation in the proposed Org search area after they have ticked the box, then the tick box should go away.
- if the applicant unticks the box but does not add an organisation from OMS then the validation error should come back.
- The validation rule at the end of the form when triggered should say 'At least one organisation should be selected from OMS or a declaration by application must be made that the change does not affect organisations or the organisation concerned is being deleted.'
- The validation rule should not be triggered if they have selected organisation at proposed Org search area. The validation rule is triggered only if no organisation has been selected in that section.

### **23. SD-645775 [Vet MAA] - eAF Veterinary MAA form - User feedback - corrections to business rules needed**

In **Vet MAA** form the following are implemented:

- In Section 4.3 the tick boxes for “Multiple applications submitted Simultaneously”, “or Subsequently”, to the initial application/MA for: the selection can now be unticked if an unintentional selection has been made to avoid the need for the user to restart a whole new application form to remove the selection.
- When the user has selected “1.1.1 A Centralised Procedure” in 1.1 and selects 'Yes' in 1.2 then the fields for 'Mandatory scope' or 'Optional scope' are hidden. Additionally, there should be a tooltip shown when the user is hovering over the sub-selections for Mandatory Scope and Optional scope options which says 'Do not select eligibility basis when the application is for a variation requiring assessment that is classified as a change of active substance(s), strength, pharmaceutical form, route or administration or food-producing target species'.
- In the Declaration and Signature section, in the 2nd Note: the following should be deleted '- see information on fee payments in the Notice to Applicants, Volume 6A, Chapter 7.'
- In section 2.1.2 Active substance(s) a label change should be performed and specifically an asterix " " after the word 'hydrate' in the Full name of the active substance(s) including salt or hydrate, if applicable. Should be added. This asterix refers to the 1st note.
- In section 1.1 the label for 1.1.2 now also displays SRP in the name; 1.1.2 A MUTUAL RECOGNITION PROCEDURE or A SUBSEQUENT RECOGNITION PROCEDURE (according to Article 52 or Article 53 of Regulation (EU) 2019/6)

### **24. SD-634403 [Vet Variation] – UPD Product Identifier field**

In **Vet Variation** form the following is implemented:

In Section 2, the UPD Product Identifier field is not shown any more.

25. **SD-589125 [Vet Variation]** - VMP-Reg related improvements/corrections

**Veterinary** Variation form, when MRP has been selected in section 1;

- In section for parallel variations; when Yes is selected, the value 'European union' has been removed.
- In the proof of payment section, when 'yes' is selected, then values 'European Union' and 'EMA' have been removed.
- When 'add all' option is used to add previously used member states, an empty entry in the end of the list has been removed.
- When 'grouping' is selected in section 1, but only one variation is selected in section 3 and the form is validated, when you are on top of that validation error and click jump to selected, it does jump to the label of the selected bug

26. **SD-665048 [Human Variation, Vet Variation]** – eAF variation forms - validation rule for mandatory use of OMS in the 'proposed' section of the form

In **Vet Variation** and **Human Variation** form the following is implemented:

The tickbox "I declare this change does not affect organisations or the organisation is being deleted" should be displayed by default even if the form hasn't been validated.

27. **SD-647719 [Human Variation]** - Business rule error correction in section 4b of the human variation form

In **Human Variation** form the following are implemented:

This change affects section 4b.

With regards to the overall business rule, when paediatric has been selected in section 1, at least one of the five options below needs to be selected from section 4b:

- Radio button: "Article 8 of Paediatric Regulation applies to this variation application since."
- Radio button: "Article 8 of the paediatric regulation does not apply to this application, since."
- Radio button: "This application relates to a new indication for a paediatric use marketing authorisation (PUMA)."
- Tick box: "This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation"
- Tick box: "This application relates to paediatric studies included in a paediatric investigation plan"

**28. ADO 133942 [Human Variation, Vet Variation, Renewal] - [eAF] Add Non-Current terms for Variations and Renewals (Human and Vet) for "Pharmaceutical Form" list **New****

In Renewal and Human and Veterinary Variation form the following is implemented:

The user is able to select also non-current terms from the "Pharmaceutical form" drop-down list.