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## eAF Release Notes

This document lists and briefly describes the new features and fixed issues included in the release of the electronic application form: *Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, November 2017, Revision 8.*

The most recent release appears first.

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## Version 1.23.1.2 (Release Date: 03/2019)

### Version content

| Functionality / use case   | Comments   |
|--|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, November 2017, Revision 8.</i> | This release note is for the 1.23.1.2 hotfix, for the eAF forms. |

### Issues fixed for this version

| Id | Description | Comments                             |
|----|-------------|--------------------------------------|
| -  | -           | No issues addressed in this release. |

### Known issues

| Id        | Description   | Workaround/Comment  |
|-----------|---|---|
| SD-35463  | Adobe Reader displaying forms as not being locked down and with red fields.   | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398  | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|           | When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology.   | Always 'trust' the form prior to importing xml from previous forms.   |
| SD-249735 | The label in section 2.5.4 is incorrect:<br>'Contract companies used for all clinical trial(s) (including bioavailability or bioequivalence trials) included in the application or used for the validation of blood product manufacturing processes.' | The label in section 2.5.4 should read:<br>'Contract companies used for clinical trial(s) on bioavailability or bioequivalence.'  |

| Id        | Description   | Workaround/Comment  |
|-----------|---|---|
| SD-261865 | Incorrect tooltips in section 2.5. Manufacturers under each instance where additional admin address can be provided. The tooltip incorrectly reads 'Select this option if the site is in the EEA, then review/complete sub-section' | Ignore the incorrect tooltip.<br>The correct tooltip should read;<br>Yes: Select this option if you have a separate admin address<br>No: Select this option if you do not have separate admin and manufacturers addresses |

## Version 1.23.1.1 (Release Date: /01/2019)

### Version content

| Functionality / use case   | Comments  |
|--|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, November 2017, Revision 8.</i> | This release note is for the 1.23.1.1 release, for the eAF forms. |

### Issues fixed for this version

| Id       | Description  | Comments  |
|----------|--|---|
| EAF-2786 | section 4.2 - "Procedure number for MRP/DCP (if applicable)" caused validation errors however it says "if applicable". | This refers to MAA Vet form – section 1.3 .<br>The field "Procedure Number For MRP/DCP" is no longer mandatory in any of the duplicated instances.  |
| EAF-2985 | Section 2.4.1: Button is missing in original section but available in the added section                                | Now in the MAA Vet form – section 2.4 ,<br>the buttons (Add Selected, Remove All) of Member States will be visible only if the user has clicked one of the following:<br>MRP - Section 1.1.2<br>DCP - Section 1.1.3 |



| Id       | Description   | Comments  |
|----------|---|---|
| EAF-2987 | Section 2.4.4 Added Section have Member States as new Field in Vet Form               | Now in the MAA Vet form – section 2.4 , Member States will be visible only if the user has clicked one of the following:<br>MRP - Section 1.1.2<br>DCP - Section 1.1.3<br>National - Section 1.1.4  |
| EAF-2988 | Section 2.5.3 Both Fields are Optional by language but made mandatory in Vet Form     | In MAA Vet form – section 2.5.3 under subsection “Is an active substance master file..”, the fields “Name of the Manufacturer if different from Above” and “EU ASMF reference Number if Available” are no longer mandatory.   |
| EAF-2990 | "+" Button not working correctly in Section 1.3.2 and more                            | In MAA Vet form – in sections 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4<br>The [+] button next to Member States to add instances is now working properly. Please mind that in order for the button to be visible, the user must click first in section 1.1.2 or 1.1.3 |
| EAF-3052 | For a Radio Button Validation Error message is incorrect in Human and Vet Form        | Filling the whole form except the field "Do you have a separate admin and manufacturer address?" in section 2.5.2, the validation error message has been changed from: "Site is in/outside the EEA" to: "Do you have a separate admin and manufacturer address?"          |
| EAF-3053 | In Section 1.3.4, Only Unit Field is mandatory when clicked on (+) in Veterinary Form | In MAA Vet form – section 1.3,<br>Now when adding additional strength blocks the fields: Strength(s), Units, Marketing authorisation holder, Marketing authorisation number, Date of authorisation are Mandatory.   |
| EAF-2989 | Section 2.6.3 link "Annex 5.13" is not clickable                                      | In MAA Vet form – section 2.6.3<br>The Annex 5.13 is now clickable and leads to section 5, annex 5.13   |
| EAF-3010 | errors in MAA eAF   | For MAA Human form, in section 2.1.2 , now when clicking the button to add additional active substance field, the fields "Base/active moiety of the active substance(s)(if different from above)" are not mandatory.<br>Please note that:                                 |

| Id       | Description                                     | Comments   |
|----------|---|--|
|          |   | <p>The 2nd observation " It appears that Claim for "New active substances" or "Known active substances" is mandatory even if it should only have been for Art. 8(3) and Art. 10.a" , is covered in EAF-3061 .</p> <p>Fixes for section 2.6 have been provided in EAF-3035 in version 1.23.1.0</p>                                  |
| EAF-3036 | eAF: Field for reasons of refused MAA too small | For MAA Vet form – section 4.2 'Refused' , the 'Reason of refusal' field now supports up to 100 characters.  |
| EAF-3060 | issue EAF-2995 was not fixed in the correct way | <p>In MAA Vet form - section 1.3 is always visible. The rule for mandatory is the below:</p> <p>section 1.3 is mandatory only when in section 1.2 the option 'No' is selected.</p> <p>section 1.3 is not mandatory by default (cases of section 1.2 option 'Yes' is selected, or section 1.2 neither 'Yes','No' is selected.).</p> |

### ***Known issues***

| Id       | Description   | Workaround/Comment  |
|----------|---|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields.   | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398 | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|          | When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |

## Version 1.23.1.0 (Release Date: 28/09/2018)

### Version content

| Functionality / use case   | Comments  |
|--|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, November 2017, Revision 8.</i> | This release 1.23.1.0 is for high priority bug fixes. (No change requests are included) |

### Issues fixed for this version

| Id        | Description  | Comments  |
|-----------|--|---|
| EAF-2785  | Section 2.5.3 - copy contact button details not copied to second section instead replacing first part.                 | In the MAA Human & MAA Vet forms – In sections 2.5.2 and 2.5.3; when pressing the button “copy contact details from 2.5.1.a” – if there are multiple sections\addresses present they shall all now be correctly copied into the respective sections.                      |
| EAF-2786  | Section 4.2 - “Procedure number for MRP/DCP (if applicable)” caused validation errors however it says “if applicable”. | In the MAA Human & MAA Vet forms – In sections 4.2; when the user selects the checkbox “Withdrawn (by applicant before authorisation)” The “Procedure number for MRP/DCP” has now been corrected to be an optional field rather than a mandatory field.                   |
| EAF-2995  | Section 1.2: Validation Error of Section 1.3 remains same even if Radio button is changed from “No” to “Yes”.          | In the MAA Vet form – In sections 1.2; when the user toggles between “Yes” and “No” Radio buttons, then selects the “Yes”; Section 1.3 has been fixed so it is no longer mandatory.   |
| EAF-3003  | XML Import Bug   | This change is a minor change to the XML import process for correctly importing country codes – there is no visible change in the form.   |
| SD-183493 | UAT_eAF_1.23_Base/active Moiety mandatory  | In the MAA Human & MAA Vet forms – In sections 2.6.1; If the active substance is a base without any salt or hydrate, there is no need to provide the base/active moiety again i.e. The base/active moiety fields (including the strength & unit fields) are now optional. |

| Id        | Description   | Comments   |
|-----------|---|--|
| SD-184890 | UAT_eAF_1.23_ 2.5.3 section MAA_H - ASMF EU number validation error | In the MAA Human form – In sections 2.5.3; when the user selects “Yes” for “Is a Active Substance Master File to be used for the active substance(s)” The field “EU ASMF reference number if available” has been fixed so it is no longer mandatory. |

***Known issues***

| Id       | Description   | Workaround/Comment  |
|----------|---|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields.   | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398 | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|          | When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |

## Version 1.23.0.0 (Release Date: 13/07/2018)

### Version content

| Functionality / use case   | Comments  |
|--|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, November 2017, Revision 8.</i> | This release note is for the 1.23.0.0 release, for the eAF forms. |

### Issues fixed for this version

| Id        | Description  | Comments  |
|-----------|--|---|
| SD-145156 | NTA changes for All 4 eAF forms.   | All changes described in the NTA form specification have been implemented. Please refer to the user guide and Release Notes summary for detailed changes. |
| SD-159756 | Add Switzerland (CH) to drop-down list under 2.5.1 b.  | Switzerland (CH) has been added in the Countries dropdown under section 2.5.1.b.  |
| SD-182135 | In All OMS address sections - "Org-modified date" field is required only in xml and should not be visible in pdf.                        | This issue has now been resolved now by hide the field in the pdf.  |
| SD-156002 | In All Address section - format of the email address is not recognized and invalid if the name of the company is more than 9 characters. | Email address can be entered more than 9 characters of company name.  |
| SD-184876 | In section 1.4 – "Note 2" is missing in the pdf.   | In section 1.4 – "Note 2" has been added.   |
| SD-186883 | Remove\Hide OMS entry related fields from eAFs where no OMS data exists  | In section 2.4.1 - payment section and 2.5.4 section - OMS address search is hidden, only manual entry is allowed in this section.                        |
| SD-182135 | In all OMS address sections - "Org-modified date" field is required only in xml and should not be visible in pdf.                        | In all OMS address sections – "Org-modified date" has been added to schema and this field is not visible in the pdf.                                      |
| EAF-2943  | In section 2.6.1, one of dropdown of "Quantity/Unit" Highlights as yellow without any validation error in error section "validation      | In section 2.6.1 – the validation error has been fixed for Quantity/Units fields.   |

| Id       | Description  | Comments  |
|----------|--|---|
|          | error".  |   |
| EAF-2984 | In section 2.5.1 a - Space is missing between label "Manufacturing facility Telephone" and text box.           | In section 2.5.1.a – "Manufacturing facility Telephone" layout issue has been resolved. |
| EAF-2979 | In section 1.2 – when 'No' is selected remaining fields in the section should be hidden after reopen the form. | In section 1.2 - Incorrect behaviour of Yes/No radio button has now been resolved.      |

### ***Known issues***

| Id        | Description   | Workaround/Comment  |
|-----------|---|---|
| SD-183493 | Base/active Moiety – Quantity/units fields should be optional.  | For the Base/active Moiety field the associated Quantity/unit is mandatory when an entry is provided in this section, however currently the form validation returns an error when the Base/active Moiety is <u>not</u> provided,. Users are advised to ignore this error.           |
| SD-35463  | Adobe Reader displaying forms as not being locked down and with red fields.   | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398  | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|           | When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |

## Version 1.22.0.1 (Release Date: 16/02/2018)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.22.0.1 release, for the eAF forms. |

### Issues fixed for this version

| Id       | Description   | Comments  |
|----------|---|---|
| EAF-2812 | Section 2.4.1 – proof of payment - LogID/OrgID missing in the within the pdf once saved and reopen.                                   | In section 2.4.1 – Proof of payment - LogID/OrgID is visible after saved and reopen.  |
| EAF-2811 | Section 2.6 – “Clone” button - After export the XML from the 1.22v eAF the EUTCT code is missing in substance and excipient sections. | In section 2.6 – when “Clone” button is clicked - EUTCT code is available in substance and excipient sections after export the XML. |
| EAF-2810 | Empty Tag <rdm:org-modifiedDate> in eAF MAA should be removed.  | Empty Tag <rdm:org-modifiedDate> in eAF MAA has been removed from schema.   |
| EAF-2809 | Missing timestamp in loc-modifiedDate when copy contact button is clicked in Declaration section, section 2.4 and 2.5.                | In sections Declaration, 2.4 and 2.5 – when copy contact button is clicked – loc-modifiedDate timestamp is available.               |

### Known issues

| Id       | Description  | Workaround/Comment  |
|----------|--|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |

| Id       | Description   | Workaround/Comment  |
|----------|---|---|
| SD-47398 | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF. |
|          | <u>When importing xml from v1.20.0.5 or previous version to latest version (1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology.</u> | <u>Always 'trust' the form prior to importing xml from previous forms.</u>  |



## Version 1.22.0.0 (Release Date: 15/12/2017)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.22.0.0 release, for the eAF forms. |

### Issues fixed for this version

| Id        | Description   | Comments  |
|-----------|---|---|
| SD-65517  | eAF-OMS integration   | All Address sections <ul style="list-style-type: none"><li>Address fields has been amended to in line with OMS data.</li><li>OMS data can be searched now to fill address fields via search button. <a href="#">For all address fields users can now choose to either enter an OMS organisation thus auto populating address fields or they can choose to enter the address details manually.</a> <del>If data is not found in OMS, then manual entry is allowed to fill the address.</del></li></ul> |
| SD-124981 | XSD - error - Section 1.1.3 - "Proposed common renewal date" field type should be String and not date | Section 1.1.3 - "Proposed common renewal date" field type has been changed to String in xsd.  |
| SD-105001 | Section 4.1.1 - 'not applicable' radio button should be removed from the form                         | Section 4.1.1 - 'not applicable' radio button has been removed.   |
| SD-106023 | Redesign the MRL section 1.4 – "Application for a MRL has been made to the EMA"                       | In section 1.4 – <ul style="list-style-type: none"><li>"Yes" and "Not applicable" has been amended from radio boxes into check boxes.</li><li>When "Yes" is selected - <b>Substance, Date of Submission, Species and Remarks</b> is displayed below.</li><li>When "Not Applicable" is selected then <b>Substance, Species</b></li></ul>   |

| Id        | Description   | Comments  |
|-----------|---|---|
|           |   | and <b>Remarks</b> is displayed and <b>Date of submission</b> is hidden.  |
| SD-124640 | NTA changes should be implemented.  | <ul style="list-style-type: none"> <li>• Section 1.1.4 "If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birth-date, please specify" text field has been implemented.</li> <li>• Section 1.5.4 "Article 77 (5) of Directive 2001/82/EC and Article 49 (3) of Regulation (EC) No 726/2004 (other requirements for the PSUR submission cycle)". The new Check box has been implemented.</li> <li>• Section 4.1 – Label has been amended as .“FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12 (N) OF DIRECTIVE 2001/82/EC.</li> <li>• Section 4.3 "Multiple applications submitted simultaneously or subsequently to the initial application/MA for". The new radio buttons has been implemented.</li> <li>• Section 5.24 "Justification for requesting deviation from the 'standard' PSUR cycle as stated in legislation". The new annex 5.24 check box has been implemented.</li> </ul> |
| SD-121233 | Validation issue in Section 1.4.2   | In section 1.4.2 – "units" field validation issue has been resolved.  |
| SD-116128 | Pagination issue in section 1.3.3   | In section 1.3.3 – pagination issue has been resolved.  |
| EAF-2761  | Section 2.2.3.1 - Package size - numbers are not appearing in order   | In section 2.2.3.1 - package size (label) field - numbers had been removed when more rows added.  |
| EAF-2762  | Section 1.3.2 - "Medicinal product authorised in the Union/Member State where the application is made or European" – "Date of authorisation" field should not appear when + button is clicked in subsequent rows. | In Section 1.3.2 - "Medicinal product authorised in the Union/Member State where the application is made or European" – "Date of authorisation" field is not visible when subsequent rows added.  |
| EAF-2764  | The 'Update Lists' Button's tooltip needs to be updated as it incorrectly displays the 'Import XML' tooltip   | Validation section – "Update lists" button - tooltip has been amended as "Click to update/reload the control lists".  |
| EAF-2767  | Section 2.6.1 – tooltip should be amended in units field to in line   | In Section 2.6.1 – "Units" field tooltip has been amended has "Click  |

| Id       | Description  | Comments  |
|----------|--|---|
|          | "Pharmaceutical form" - Units field  | the arrow button to select unit of measurement for the Pharmaceutical form".  |
| EAF-2769 | Section 2.5.3 - Manufacturers active substance - free text field - tool tip should be amended.   | In Section 2.5.3 - Manufacturers active substance - free text field - tool tip has been amended as "Click to enter information on active substance related to this manufacturer." |
| EAF-2773 | Section 2.4.1 - Proof of payment - When export and import in the new version, the field proof of payment does not permit select different tax for different countries. Member states field is hidden which is wrong. | Section 2.4.1 - Proof of payment - When export and import in the new version, the field proof of payment allows to select different tax for different countries.                  |
| EAF-2781 | Section 1.1.2/1.1.3 - Proposed/Agreed common renewal date should be optional field.  | In section 1.1.2/1.1.3 - Proposed/Agreed common renewal date field is optional now.   |

### Known issues

| Id       | Description   | Workaround/Comment  |
|----------|---|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields  | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398 | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|          | <a href="#"><u>When importing xml from v1.20.0.5 or previous version to latest version (1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology.</u></a> | <a href="#"><u>Always 'trust' the form prior to importing xml from previous forms.</u></a>  |

## Version 1.21.0.1 (Release Date: 12/07/2017)

### Version content

| Functionality / use case  | Comments   |
|---|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.21.0.1 hotfix release, for the eAF forms. |

### Issues fixed for this version

| Id        | Description  | Comments   |
|-----------|--|--|
| SD-110175 | In section 1.4 – “substance” field data is removed after save and reopen | In section 1.4 – “substance” field data remains after save and reopen. |

### Known issues

| Id       | Description   | Workaround/Comment  |
|----------|---|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields  | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398 | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|          | When importing xml from v1.20.0.3 or previous version to latest version (1.21.0.1/1.20.0.5/1.20.0.4) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |

| Id        | Description  | Workaround/Comment  |
|-----------|--|---|
| SD-105001 | Radio button 'not applicable' in section 4.1.1 should be removed. This option is not allowed for NP, MRP/DCP applications. | Please note that 'Not applicable' is not a valid option for NP, MRP and DCP applications in section 4.1.1. This option will be removed in a future release. |

## Version 1.21.0.0 (Release Date: 20/06/2017)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.21.0.0 release, for the eAF forms. |

### Issues fixed for this version

| Id       | Description   | Comments  |
|----------|---|---|
| SD-79626 | Section 2.2.3.6/2.2.3.5 – option “NA” should be added to the dropdown list.   | In Section 2.2.3.6/2.2.3.5 – option “NA” has been added to the dropdown list.   |
| SD-70029 | Section 1.3.3 – validation error  | Section 1.3.3 – This section is not mandatory now and no validation error appears.  |
| SD-45930 | Section 2.6.1 - Add clone button in Qualitative and quantitative composition – active substance and excipients table.                                       | In section 2.6.1 - Qualitative and quantitative composition – clone button is added in active substance and excipients tables (two clone buttons - inner and outer section of the table). |
| SD-45834 | Section 1 - Numeric value text should be added in strength field.   | In Declaration section – “For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002” text has been added in strength field.                    |
| SD-27733 | Section 1.5.2 - Accelerated Review - the form requires to add the date that the request was accepted by the CHMP  | In section 1.5.2 - Accelerated Review – the free text field has been added.   |
| SD-27731 | Section 1.2, 1.3.2, 1.3.3, 1.3.4 and 1.3.7 – “unit field” should be added.  | In section 1.2, 1.3.2, 1.3.3, 1.3.4 and 1.3.7 – “Unit field” has been added next to “strength” field.   |
| SD-27730 | This usability improvement applies to 1.3.2, 1.3.3, 1.3.4. In the second and third boxes, add a button at the top that says 'Copy data from above section'. | In sections 1.3.2, 1.3.3, 1.3.4 – “Copy data from above section” button has been added in second and third boxes to copy data from first box.   |

| Id       | Description   | Comments  |
|----------|---|---|
| SD-45907 | Section 1.4 – MRL status – It is only possible to select the active substances entered under declaration and signature above        | In section 1.4 – “search” option has been added to search for active substance in this section.                       |
| SD-27717 | 1.4 – MRL status: in case “all food producing species” is the concerned animal species, more “other provisions” might be applicable | In section 1.4 – “+” and “-” buttons has been added to add more than one “other provisions”.                          |
| SD-27782 | 1.4 MRL Status: In the case of a product for use in non-food producing animal, this section no need to be filled                    | In section 1.4 – Check box has been added to display the section only for food producing species.                     |
| SD-99501 | Section 2.5.3 – “Manufacturer of the active substance and site of manufacturer” delete button (-) is not working                    | In Section 2.5.3 – delete button (-) in “Manufacturer of the active substance and site of manufacturer” is fixed now. |
| EAF-2402 | Section 1.2, 1.3.2, 1.3.3, 1.3.4 and 1.3.7 – “Date of authorisation” field is overlapped after form is locked.                      | In Section 1.2, 1.3.2, 1.3.3, 1.3.4 and 1.3.7 – “Date of authorisation” field overlapped issue is fixed now.          |

### ***Known issues***

| Id        | Description   | Workaround/Comment  |
|-----------|---|---|
| SD-35463  | Adobe Reader displaying forms as not being locked down and with red fields  | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398  | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.  | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|           | When importing xml from v1.20.0.3 or previous version to latest version (1.21.0.0/1.20.0.5/1.20.0.4) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |
| SD-105001 | Radio button 'not applicable' in section 4.1.1 should be removed. This option is not allowed for NP, MRP/DCP applications.  | Please note that 'Not applicable' is not a valid option for NP, MRP and DCP applications in section 4.1.1. This option will be removed in a future release.   |

## Version 1.20.0.4 (Release Date: 07/02/2017)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.20..0.0 (previously known as 1.21) technical release, for the eAF forms. |

### Issues fixed for this version

| Id       | Description   | Comments  |
|----------|---|---|
| SD-53863 | When MRP/DCP selected in Section 1 – ‘Add selected’ button doesn't work in Section 2.4.2, 2.4.3   | Section 2.4.2 and 2.4.3 – ‘Add selected’ button is now working when MRP/DCP selected in section 1.  |
| SD-68395 | Additional "copy contact details from 2.4.2" button should be added in Section 2.4.3 in MAA   | Section 2.4.3 – new “copy contact details from 2.4.2” button has been added.  |
| SD-60492 | Section 1.2.2: '-' button always removes the first Pharmaceutical form entry no matter which button is clicked  | In section 1.2.2 – Pharmaceutical field – fixed the issue in remove button to delete corresponding row.   |
| SD-60221 | Section 2.6 - It is not possible to select more than two Overages.  | In section 2.6 – the issue has been resolved to select more than two overages.  |
| SD-45939 | Title, first name and surname are not in line with company and address fields   | In Sections – Declaration, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.5.1.a, 2.5.1.b, 2.5.2 and 2.5.3<br>Title, first name and surname are aligned with company and address fields now.                             |
| SD-45957 | In Section 2.4.1 – “Copy contact details from declaration section” button should copy details from “person authorised” rather than “Applicant part” of Declaration section. | In Section 2.4.1 – the issue has been fixed in “Copy contact details from declaration section” button now copy details from “on behalf of the applicant” rather than “Applicant part” of Declaration section. |



| Id       | Description   | Comments   |
|----------|---|--|
| SD-45923 | Section 2.4.2 – “copy contact details from 2.4.1 section” tool tip is incorrect   | Section 2.4.1 – “copy contact details from 2.4.1 section” tool tip is changed to “Click to auto-complete the contact details in section 2.4.2 with those already added in section 2.4.1”.                                |
| SD-45880 | Declaration section – Active substance – If 2 <sup>nd</sup> active substance is searched however selected button is not pressed, but ‘Populate date in sections 2.1.2, 2.2.1 and 2.6.1 is pressed an empty row is created in 2.6.1 for the 2 <sup>nd</sup> active substance. The ‘Ok’ button does not clear the row if the 2 <sup>nd</sup> active substance isn’t selected. | Declaration section – Active substance – Ok button clears the 2 <sup>nd</sup> active substance if it is not selected with value. When ‘Populate’ button is pressed after ‘Ok’ the empty row in section 2.6.1 is deleted. |
| SD-45856 | Section 2.2.2: “click find to use the list of standard terms” - ‘find’ should be replaced by ‘search’   | Section 2.2.2: “click find to use the list of standard terms” - ‘find’ has been replaced by ‘search’.  |
| SD-45862 | Address Fields in the form, Address Line 2, It may be clearer if the comment were beneath the caption instead of beneath the field.   | All address Fields in the form, Address Line 2, the comment is beneath the caption now.  |
| SD-45884 | Address Fields in the form – ‘European Union’ should not displayed in the dropdown list as this is not a country.   | All Address Fields in the form – ‘European Union’ is removed from the drop down list.  |
| SD-45935 | Section 2.4.1 - Proof of Payment - Tooltip for this section missing, wording unclear.   | Section 2.4.1 - Proof of Payment - Tooltip for ‘No’ is amended as “If exemptions from fees have been given or an invoice is expected from the NCA, please select No”   |
| SD-45916 | Section 1.1.2 and 1.1.3 – CMS - Each time we want to delete a country from the concerned member states list we receive the pop-up “do you want to delete...” where we have to click yes or no. This is time consuming. Remove pop up message.   | Section 1.1.2 and 1.1.3 – for Concerned Member States (CMS) – pop up message in delete button has been removed.  |
| SD-45911 | Section 2.6 - Active Substances are cropped for overages section.   | Section 2.6 - Active Substances field width is increased in overages section to display long active substance names.   |
| SD-45890 | When parts of section 2.4.1 are duplicated for multiple MS and “no” is selected for the first MS then the checkbox for Annex 5.1 will not be activated in section 5 even if “yes” is selected for fees for any other MS in section 2.4.1.   | In Section 2.4.1 – proof of payment - when “no” is selected in first instances and “yes” is selected in multiple instances then Annex 5.1 is selected in Annex 5 section.  |

| Id       | Description   | Comments   |
|----------|---|--|
| SD-45917 | Section 2.5.3 – annex 5.11 check box is not visible when Ph.Eur. certificate of suitability is selected.  | Section 2.5.3 – annex 5.11 check box is visible when Ph.Eur. certificate is selected “yes” or “no” and ASMF is selected as “yes”   |
| SD-45898 | Section 2.6 - Qualitative and quantitative composition – Quantity/Unit field - When “quantity sufficient” term is selected then quantity and unit fields should be optional | Section 2.6 - Qualitative and quantitative composition – Quantity/Unit field - When “quantity sufficient” term is selected then quantity and unit fields are optional now.   |
| SD-58464 | “Add All” and “Add selected” buttons should be reviewed in all relevant sections.   | <p>“Add selected” button removed in section 1.1.2 &amp; 1.1.3 – Concerned Member States (CMS)</p> <p>“Add All” button removed in the following sections</p> <ul style="list-style-type: none"> <li>• section 2.3.1, 2.3.2, 2.3.3, 2.3.4</li> <li>• section 2.4.1, 2.4.1 – proof of payment, 2.4.2, 2.4.3, 2.4.4</li> </ul> |
| SD-58708 | Copy contact details buttons in all sections needs to review and fix the issue which are not copying all instances  | <p>In Section 2 - Copy contact details buttons are now copy's all instances and don't delete the data which is already filled in. For more than one instance it is possible to select which contact details to be copied.</p> <p>Section 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.5.2, 2.5.3</p>                                      |
| SD-73800 | Section 2.6.1 When a second strength is added and ‘copy data’ button is used, only first instance on the active substance is copied. Not all data.                          | In Section 2.6.1 – ‘Copy data’ button is working for more than one instance.   |
| EAF-2231 | Section 2.5.3 - For CEP, the field “Name of the manufacturer if different from the above” is mandatory, but should be optional.   | Section 2.5.3 - For CEP, the field “Name of the manufacturer if different from the above” is optional now.   |
| SD-68660 | After locking the form, some text in section 2.5.3 gets dislocated (Annex 5.8 and 5.11)   | Once the form is locked - In Section 2.5.3 – dislocation of Annex 5.8 and 5.11 is fixed now.   |
| SD-45864 | Tick box for annex 5.19 should not be mandatory in section 2.5.3  | In Section 2.5.3 – annex 5.19 is optional now.   |
| SD-73810 | section 2.2.3.1 - 2nd pack type added, it is not possible to select “N/A” in the closure and administration device in the second instance                                   | In Section 2.2.3.1 – “N/A” is available in the drop down list to select in more than one instance now.   |

## ***Known issues***

| <b>Id</b> | <b>Description</b>   | <b>Workaround/Comment</b>   |
|-----------|--|---|
| SD-35463  | Adobe Reader displaying forms as not being locked down and with red fields   | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| SD-47398  | To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.   | To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.   |
|           | When importing xml from v1.20.0.3 or previous version to v.1.20.0.4 additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms.   |

## Version 1.20.0.3 (Release Date: 18/10/2016)

### Version content

| Functionality / use case  | Comments   |
|---|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.20.0.3 hotfix, for the eAF forms. |

### Issues fixed for this version

| Id       | Description  | Comments   |
|----------|--|--|
| SD-27802 | In section 2.5.4 the country menu drop down doesn't allow to select outside EU   | In Section 2.5.4 the country dropdown list now allows to select the country from outside EU also.                        |
| SD-27807 | In section 2.5.3 – Is a Active Substance Master File to be used for the active substance(s), applicant part version number field - the tooltip says that 100 characters can be added but in fact it is only 30 | In Section 2.5.3 – “Applicant part number field” now allows 100 characters.  |
| SD-52718 | More than nine Overages in section 2.6.1 cause hidden overflow and generate multiple empty pages   | In Section 2.6.1 - Now we can add more than 9 Overages and it won't hidden overflow and/or generate multiple empty pages |

### Known issues

Since it is a hot fix the known issues identified in 1.20.0.1 still remain and therefore not repeated here, so please refer to Version 1.20.0.1 (Release Date: 30/06/2016), see below. In addition there is one more defect identified and mentioned here.

| Id       | Description  | Workaround/Comment  |
|----------|--|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |

## Version 1.20.0.2 (Release Date: 19/08/2016)

### Version content

| Functionality / use case  | Comments   |
|---|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note is for the 1.20.0.2 hotfix, for the eAF forms. |

### Issues fixed for this version

| id                               | Description   | Comments  |
|----------------------------------|---|---|
| SD-35460<br>SD-35466<br>SD-36435 | Sections 2.2.3.2/3/4, 2.6.1: Decimal separators and commas: The only change should have been not to allow a comma   | In Section 2.3.2.2/3/4 and 2.6.1 all numeric fields have been reverted to text fields, and a message explaining to use full stop as decimal separator has been added.         |
| SD-40214/<br>SD-40467            | In section 2.5.3, the field National ASMF reference number: (when applicable and only if EU ASMF reference number is not available) contains a limit of 30 characters | In Section2.5.3, the EU ASMF Reference and the National ASMF Reference have been extended to allow 100 characters, up from 30.  |
| SD-37721                         | Section 1.3 stays hidden after saving/closing form and is visible again if I click "No" - "Yes" again in 1.2  | Section 1.3 is now correctly displayed when section 1.2 "Yes" is selected and when the form is opened after a save.   |
| SD-35465                         | Section 2.6.3 - even if "NO" radio button is selected, after saving/closing/opening the Annex 5.21 is selected  | Section 5.21 now correctly displayed a check box when section 2.6.3 is yes and proof of payment checked when the form is opened after a save, otherwise it remains unchecked. |
| SD-35464                         | Sections 2.5.2 and 2.5.3 - manufacturer(s) boxes overflow and stay hidden if more than 4 boxes are added  | Section 2.5.2/2.5.3 – manufacturer(s) boxes are now able to add more than 4 boxes which is not hidden and flows to next page.   |

### Known issues

Since it is a hot fix the known issues identified in 1.20.0.1 still remain and therefore not repeated here, so please refer to Version 1.20.0.1 (Release Date: 30/06/2016), see below. In addition a defect has been identified and mentioned here.

| Id       | Description   | Workaround/Comment                            |
|----------|---|---|
| EAF-2211 | Copy contact details 2.5.1.a button functionality not working when we add multiple manufacturer(s) in section 2.5.2 and 2.5.3 | Pending review for inclusion in next release. |

## Version 1.20.0.1 (Release Date: 30/06/2016)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note contains the original release made on the 15/04/2016 and also the post UAT fixes that were applied for the release on the 14/06/2016. |

### Issues fixed for this version

| id | Description  | Comments  |
|----|--|---|
|    | In Section 2.4.1, the proof of payment not expanding sections yes or no correctly. | In Section 2.4.1, the proof of payment sections for yes and no are now correctly displayed when the form is reopened. |
|    | In Section 2.6.1 the numeric fields do not allow more than 2 decimal places.       | In Section 2.6.1, all numeric fields now support up to eight decimal places.  |
|    | In proof of payment section the "add all" button was not required.                 | In section 2.4.1 the "add all" button has been removed since it was no longer required.                               |

### Known issues

| Id           | Description   | Workaround/Comment  |
|--------------|---|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |



| Id       | Description  | Workaround/Comment   |
|----------|--|--|
|          | application from progressing through the application workflow).□   |  |
|          | There is a known issue opening eAF forms using reader, when non-traditional or special characters are used (this has been observed when copying from a Word document into the eAF form). These characters might cause reader to request the installation of the Chinese character set pack, when the form is reopened. This issue is not observed in Adobe Acrobat which will open the file without issue. | Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat. |
| EAF-1893 | Section 2.6.1: it does not make sense to autopopulate "min" when using range operator  | For consideration in a future release.   |
| EAF-1920 | Member States already selected in section 1.1 occur in the drop-down lists in section 2.4.1 and 2.4.2  | For consideration in a future release.   |
| EAF-2013 | Section 2.5.3 - Annex 5.11   | For consideration in a future release.   |
| EAF-2113 | To add information regarding the procedure number and to list the MS in the above mentioned sections.  | For consideration in a future release.   |
| EAF-2119 | Declaration Section, You should be able to populate the First name and Surname under "Applicant" directly below as Person authorised for communication on behalf of the Applicant.   | For consideration in a future release.   |
| EAF-2135 | Section 1.4 MRL Status, It is only possible to select the active substances entered under declaration and signature above.   | For consideration in a future release.   |
| EAF-2136 | Section 2.4.1, The billing address is no longer listed when "Yes" for fees paid was selected.  | For consideration in a future release.   |
| EAF-2144 | Section 1, CMS, when using the add all button, RMS is still selected.  | For consideration in a future release.   |
| EAF-2172 | Sections: 1.1.2, 2.4.1, 2.4.2, 2.4.3, We cannot select EEA member states in one time. Add an "Add All" button.   | For consideration in a future release.   |
| EAF-2173 | To have the "N/A" in all drop down lists for all eAFs, to can be selected for special cases (purposes / special cases can be defined in  | For consideration in a future release.   |

| Id       | Description   | Workaround/Comment                     |
|----------|---|--|
|          | the CL as advised in Q32 of Q&A on eAF).  |  |
| EAF-2160 | Section 1, It would be good when pressing - on a MS, that it deleted it from all subsequent MS lists throughout the form.       | For consideration in a future release. |
| EAF-2161 | Section 1, Date of First Authorisation shows is MS's which are not CMSs   | For consideration in a future release. |
| EAF-1968 | No Suggestions Provided on typing units next to Quantity in all Forms   | For consideration in a future release. |
| EAF-1962 | Ok Button does not verify the active substance selected or not..<br>Clear Button does not clear the data                        | For consideration in a future release. |
| EAF-1967 | Copy function not behaving as expected  | For consideration in a future release. |
| EAF-2186 | Active Substances are cropped for overages of Human, VET & Renewal forms  | For consideration in a future release. |
| EAF-2002 | Tool Tips not in sinc with the change made by Jira issue 1673   | For consideration in a future release. |
| EAF-2162 | Section 3, Summary table of variation, after signing the application for the variation summary table is not displayed properly. | For consideration in a future release. |
| EAF-1729 | Import of form with signatures locks new form   | For consideration in a future release. |

### ***Additional information***

**NOTE:** On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23<sup>rd</sup> October 2015 the new ID will be used for all new changes raised against eAF forms.

**NOTE:** To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

**NOTE:** From the beginning of January 2016 the eAF forms became mandatory, and the word version of the forms is no longer accepted.

## Version 1.20.0.0 (Release Date: 14/06/2016)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release note contains the original release made on the 15/04/2016 and also the post UAT fixes that were applied for the release on the 14/06/2016. |

### Issues fixed for this version

| id       | Description  | Comments   |
|----------|--|--|
| EAF-1752 | The list of MS could be executed by the form if 'all' is selected. Depending from the case, the deletion of a few MS not involved will be quicker than to add MS by MS. New button - select all button to populate all member states field and option to clear them too. | In section 2.3.1, 2.3.2, 2.3.3 and 2.3.4 new buttons (Add All, Remove All) have been added to each section and will add the elements of the drop down list. If the checkboxes for each of these sections is unticked, the concerned member states are removed automatically. |
| EAF-1845 | General usability: Data filled in from the applicants should be coloured darker than the filed names so it will be easier to review.   | In all forms, the colour for the locked grey is now darker, and the caption for each field is now made bold to ensure a distinction.   |
| EAF-1924 | 2.5.1.a, 2.5.2, 2.5.3 Manufacturers. Telefax is a mandatory field however neither of other section is needed to fill   | In Section 2.5.1a, 2.5.2 and 2.5.3 the telex field has been made non-mandatory.  |
| EAF-1928 | Name and address of the applicant "Address 2" (= confusing) – could it be changed to "City"  | An additional sub-line has been added below Address Line 2 which reads "(Name of: city, town, village, etc)"   |
| EAF-1944 | 2.2.2 Route of administration<br>Option that more than one target species can be chosen for one pharmaceutical form.   | In Section 2.2.2 a +/- button set have been added to allow for multiple target species.  |

| id       | Description  | Comments   |
|----------|--|--|
| EAF-1896 | in DE we use "," for decimal separator (e.g. quantity) in "EN" we have "." for that. We suggest to restrict all numeric input fields to allow only "." as decimal separator.   | In Sections 2.2.3.2/3/4 the duration fields are now numeric, and in section 2.6.1 the Low and High Strength numerator and the 2.6.1 Substance Overage fields are also numeric. |
| EAF-1933 | Problem short: XML contains data which is not visible in the form. Why a problem: data from re-used forms or closed sections will be submitted to NCAs/EMA via XML-import. The XML does not know that a section is closed (not visible) Causes: data quality problems<br>Solution: delete all "non-visible" data from the XML.   | In all sections, the form removes data from nodes that have been closed after having had data input.   |
| EAF-2037 | No restrictions on adding same MS as seen in Renewal and Variation forms. Users will be able to add same member states.  | In Section 2.3.1, 2.3.2, 2.3.3, 2.3.4, the add All button's now correctly assign the member state, and now prevents duplicates from being selected.                            |
| EAF-2042 | Forms not very well formatted as a result of 1845 fix  | In all sections, the caption space has been increased to allow for bold text to be displayed when the form is locked.  |
| EAF-2043 | Overage and excipient quantity fields still accept " ,"  | In Section 2.6 the overage fields are now decimal fields and will only accept numeric values, and only allow a . as decimal field separator.                                   |
| EAF-2044 | <p>1) Fill in all the details in the declaration section and save the form.<br/>2) Close the form and reopen</p> <p>Here expected to see the details saved. However the data is lost.</p> <p>1) Fill in all the details in the declaration section and save the form.<br/>2) Export the data to xml<br/>3) open a new form and import saved data in step 2</p> <p>Here expected to see the declaration form filled in but the declaration section is empty</p> | In the declaration and signature section, the data is now exported to the XML correctly and can be imported correctly again.   |

| id       | Description  | Comments   |
|----------|--|--|
| EAF-2058 | In Section 1.2, if you select "No", section 1.3 is displayed. However section 1.3 is needed in both cases. | In Section 1.2, the Yes option will now display section 1.3.   |
| EAF-2079 | In correct page numbering which starts in section 2.6 only.  | In all sections, the page number now appears across all pages .  |
| EAF-2097 | 2.6.1, 2.1.2, 2.2.1 - Active Substances are cropped  | In Section 2.6.1, 2.1.2 and 2.2.1, the active substance fields now expand to show the whole active substance name.   |
| EAF-2159 | The add all buttons in subsequent sections should only add the RMS and CMS from section 1.                 | In all sections where appropriate, an "add selected" button will be visible when MRP/DCP is selected. The new button now adds the RMS and CMS identified in section 1. Note: the RMS will be added to the bottom of the member state list, after all selected CMS have been added. |
| EAF-2182 | Update the appearance of all buttons (excluding drop down lists) to have rounded corners with no borders.  | In all sections, the look and feel of the buttons in the form has been upgraded to give them soft rounded corners. Drop down lists and selectors have been left with a square.   |
| EAF-2183 | All Sections, Footnote links are ineffective and need to be improved.                                      | In all sections, the footnote "i" button has been replaced with a "?" and now the footnote text appears within the context of the section it is in. The footnotes are still included at the bottom of the document for consistency.  |

### ***Known issues***

| Id           | Description  | Workaround/Comment  |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |
|              | There is a known issue opening eAF forms using reader, when non-traditional or special characters are used (this has been observed   | Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat.  |

| Id       | Description   | Workaround/Comment                     |
|----------|---|--|
|          | when copying from a Word document into the eAF form). These characters might cause reader to request the installation of the Chinese character set pack, when the form is reopened. This issue is not observed in Adobe Acrobat which will open the file without issue. |  |
| EAF-1893 | Section 2.6.1: it does not make sense to autopopulate "min" when using range operator   | For consideration in a future release. |
| EAF-1920 | Member States already selected in section 1.1 occur in the drop-down lists in section 2.4.1 and 2.4.2   | For consideration in a future release. |
| EAF-2013 | Section 2.5.3 - Annex 5.11  | For consideration in a future release. |
| EAF-2113 | To add information regarding the procedure number and to list the MS in the above mentioned sections.   | For consideration in a future release. |
| EAF-2119 | Declaration Section, You should be able to populate the First name and Surname under "Applicant" directly below as Person authorised for communication on behalf of the Applicant.  | For consideration in a future release. |
| EAF-2135 | Section 1.4 MRL Status, It is only possible to select the active substances entered under declaration and signature above.  | For consideration in a future release. |
| EAF-2136 | Section 2.4.1, The billing address is no longer listed when "Yes" for fees paid was selected.   | For consideration in a future release. |
| EAF-2144 | Section 1, CMS, when using the add all button, RMS is still selected.   | For consideration in a future release. |
| EAF-2172 | Sections: 1.1.2, 2.4.1, 2.4.2, 2.4.3, We cannot select EEA member states in one time. Add an "Add All" button.  | For consideration in a future release. |
| EAF-2173 | To have the "N/A" in all drop down lists for all eAFs, to can be selected for special cases (purposes / special cases can be defined in the CL as advised in Q32 of Q&A on eAF).  | For consideration in a future release. |
| EAF-2160 | Section 1, It would be good when pressing - on a MS, that it deleted it from all subsequent MS lists throughout the form.   | For consideration in a future release. |

| Id       | Description   | Workaround/Comment                     |
|----------|---|--|
| EAF-2161 | Section 1, Date of First Authorisation shows is MS's which are not CMSs   | For consideration in a future release. |
| EAF-1968 | No Suggestions Provided on typing units next to Quantity in all Forms   | For consideration in a future release. |
| EAF-1962 | Ok Button does not verify the active substance selected or not..<br>Clear Button does not clear the data                        | For consideration in a future release. |
| EAF-1967 | Copy function not behaving as expected  | For consideration in a future release. |
| EAF-2186 | Active Substances are cropped for overages of Human, VET & Renewal forms  | For consideration in a future release. |
| EAF-2002 | Tool Tips not in sinc with the change made by Jira issue 1673   | For consideration in a future release. |
| EAF-2162 | Section 3, Summary table of variation, after signing the application for the variation summary table is not displayed properly. | For consideration in a future release. |
| EAF-1729 | Import of form with signatures locks new form   | For consideration in a future release. |

### ***Additional information***

**NOTE:** On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23<sup>rd</sup> October 2015 the new ID will be used for all new changes raised against eAF forms.

**NOTE:** To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

**NOTE:** From the beginning of January 2016 the eAF forms became mandatory, and the word version of the forms is no longer accepted.





## Version 1.19.0.2 (Release Date: 23/02/2016)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This hotfix release addresses a critical issue. |

### Issues fixed for this version

| id       | Description   | Comments  |
|----------|---|---|
| EAF-2050 | The cover page for the Veterinary form does not show the full and complete eAF version number, it only shows 1.19. Please can it show the full version? | The cover page now correctly reflects the eAF version number, and now shows 1.19.0.2. |

### Known issues

| Id           | Description  | Workaround/Comment  |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

### ***Additional information***

**NOTE:** On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23<sup>rd</sup> October 2015 the new ID will be used for all new changes raised against eAF forms.

**NOTE:** To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

**NOTE:** From the beginning of January 2016 the eAF forms became mandatory, and the word version of the forms is no longer accepted.

## Version 1.19.0.1 (Release Date: 30/11/2015)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This hotfix release addresses a critical issue. |

### Issues fixed for this version

| id            | Description  | Comments   |
|---------------|--|--|
| EAF-1977/1986 | The current 2.1.2 section no longer permits the user to add active substances. This prevents the addition of ad-hoc active substances to be added from the excipients lists. This requires the active substances panel to now allow manual adding of substances. | In Section 2.1.2, the active substances panel now allows for additional substances to be selected. |

### Known issues

| Id           | Description  | Workaround/Comment  |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

### ***Additional information***

**NOTE:** On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23<sup>rd</sup> October 2015 the new ID will be used for all new changes raised against eAF forms.

**NOTE:** To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

## Version 1.19.0.0 (Release Date: 03/11/2015)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various change requests and defects as outlined below. |

### Issues fixed for this version

| id           | Description   | Comments   |
|--------------|---|--|
| emea00038570 | <ul style="list-style-type: none"> <li>Section "Person authorised for communication*", on behalf of the Applicant" the tooltip for populating details from previous section is incorrectly referring to sections 2.4.1 and 2:</li> <li>The free text field for description of the active substance in section 2.6.1 incorrectly refers to "excipients"</li> </ul> | In Section 2.4.1 and 2.4.2 and 2.6.1, the tooltips have been updated.  |
| emea00038531 | section 2.2.3.2 - 4 tooltips shows that only 30 chars. are possible. It is possible to copy-paste more. Boxes overflow.   | In Section 2.2.3.2, 2.2.3.3 and 2.2.3.4 - characters limit has been increased to 255 characters and now expands.   |
| emea00038511 | ATC code field is too short to select from the search result list.  | The ATC code field search results field length has been increased.   |
| emea00038850 | Annexes 5.9 and 5.6 won't select in 2.5.1.2 and 2.5.3 in any other than the FIRST box.  | In Section 2.5.1, 2.5.2 and 2.5.3, the Annex 5.6 and 5.9 will automatically be checked when the annex 5.6 and 5.9 check boxes are ticked.  |
| emea00038704 | Section 2.3.5: Annexes 5.10 and 5.11 won't get selected in Annex section if ticked in any other than FIRST box  | In Section 2.5.3 - 5.10 and 5.11 when checkboxes are ticked then in Section 5 - Annexed Documents - 5.10 and 5.11 the corresponding checkboxes are selected automatically.   |
| emea00038629 | 2.6.1 - When the whole substance box is multiplied then the overages box show only the first one. When there's rows, the overages show correctly.   | In Section 2.6.1 - When the whole substance/excipients box is multiplied, the overages box now shows for only the first one. The overages will show all multiple active substance and excipients that have been selected |

| id           | Description   | Comments  |
|--------------|---|---|
| emea00026582 | 2.4 marketing authorisation holder : CMDv has received advice (attachment) from the European Commission that there can only be one (1) MAH for one VMP as a result of a single procedure. Therefore it is misleading to allow for multiple entries which currently is the case.   | In Section 1, when centralised procedure is selected, Section 2,4,1 centralised procedure will be selected. If other procedures are selected in Section 1.1 then in Section 2,4,1 the corresponding: National, MRP or DCP will be selected. |
| emea00036811 | The strength is not controlled vocabulary. It is currently just free text field.  | In Section 2.1.2 and 2.6.1, the strength field has been split into two fields: a free text field and a unit dropdown field.   |
| emea00022291 | 2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture: information form DECLARATION AND SIGNATURE section should be copied via "update" button like in section 2.2  | In Section 2.5.3, a New button has been implemented "copy contact details from declaration section" and it will appear in the manufacturer section and not in admin address section.  |
| emea00037324 | When populating fields with Member State information it is possible to assign the same Member State several times within one section. This does not make sense. Consider to include a rule which impedes this.<br><br>Auto populate values from section 1   | In Sections: 1.1.2, 1.1.3, 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 3.1, an error message is displayed if the same member state is entered twice in CMS.   |
| emea00036815 | Section 4.1 – when centralised procedure is selected this section is not mandatory. Hide this field.  | In Section 4.1 – The title will be visible and content of this section will be hidden when in Section 1, the centralised procedure is selected.   |
| emea00038328 | 2.4.1 - Billing address - new populate button to copy address from above address details  | In Section 2.4.1 - billing address – there is a new populate button to copy address from above address details  |
| emea00038341 | 2.4.2 – would it be possible to have 2 different populate buttons, one as it is 'copy contact details from 2.4.1' and one 'copy contact details from declaration section'. In my particular test case it was always the different section where I wanted to copy from. This would also help to align how the address is given, in both declaration section and 2.4.2 the address was given differently even it was the same address | In Section 2.4.2 and 2.4.3 – A new populate button has been added to copy contact details from declaration section  |
| emea00038342 | 2.4.4 – button called, copy address details from 2.4.2 and also for the PhV system MF field, could have a copy from 2.4.2   | In Section 2.4.4 – A new populate button "copy address details from 2.4.2 " has been added.   |
| emea00037438 | Add warning note to confirm deletion of repeated section  | All delete buttons will now pop up with a message: "Do you want to delete this repeatable section". If the user selects "yes" the section/row is deleted, otherwise no action is taken.   |

| id                      | Description   | Comments   |
|-------------------------|---|--|
| emea00038395            | For every hyperlink to a footnote there should be a hyperlink back to the originating location  | In the footnotes section, all footnotes now contain a hyperlink back to the original location.   |
| emea00035779            | Admin and/or manufacturing address to be shown only if 'YES' is selected  | In Section 2.5. - All Manufacturer addresses are hidden at first, and it will be visible when the user selects "yes" to the question: "do you have admin address and manufacturer address".  |
| emea00035630            | section 2.5.3 group until brief description with plus and minus buttons   | In Section 2.5.3 – The full section has been changed to support a repeatable "brief description".  |
| emea00039143            | When applicant fills in 2 pharmaceutical forms, a tablet with one active substance, and granules with two active substances, the function Populate data doesn't work properly for section 2.1.2 as it carries across only 2 substances.   | In the Declaration page, when the "Populate data in Sections 2.1.2, 2.2.1 and 2.4.1 button is clicked it now populates the Section 2.1.2 "Name of Active Substances" list. In Section 2.1.2 the find, add and remove buttons have been removed.  |
| emea00037338            | user option to start or skip validation   | The performance of the form has been greatly improved by focusing on validation of only user entered fields.   |
| emea00039143            | Section 2.1.2 doesn't populate correctly when there's 2 pharmaceutical forms and 3 (and more) substances.   | In the Declaration and Signature section, all active substances now update the relevant sections. Section 2.1.2 is now populates with a unique list of active ingredient, sorted alphabetically. In Section 2.2.1, the products and active ingredient reflect those input in the Declaration section.  |
| emea00039329 / EAF-1907 | <p>In the Vet form the following tooltip are named incorrectly.</p> <p><b>DECLARATION AND SIGNATURE</b><br/> The tooltip between "Product (invented) name" and "Pharmaceutical Form" reads "Add additional medicinal product", but an additional pharmaceutical form appears when clicked.<br/> The tooltip between "Pharmaceutical Form" and "Strength" reads "Add additional medicinal product", but an additional strength appears when clicked.</p> <p><b>SECTION 1.3, sub numbering 1.3.2 – Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/10 years in the EEA:</b><br/> The tooltip besides "Strengths" reads "Click to add additional pharmaceutical form", but an additional strength appears when clicked.</p> <p><b>SECTION 1.3, sub numbering 1.3.2 – Veterinary medicinal product which is or has been authorised in accordance with Union</b></p> | <p>In the Declaration Section, The tooltip between "Product (invented) name" and "Pharmaceutical Form" has been changed. "+": Add additional pharmaceutical form and "-": Remove this pharmaceutical form, if required (One minimum). Additionally, The tooltip between "Pharmaceutical Form" and "Strength" has been changed. "+": Add additional presentation and "-": Remove this presentation, if required (One minimum).</p> <p>In Section 1.3, the +/- button tooltips beside the bioavailability studies reference number field have been modified "+": Add additional bioavailability stud(ies) reference number(s). and "-": Remove bioavailability stud(ies) reference number(s) (One minimum). Additionally, The tooltip besides "Strengths" has been changed: "+": Click to add additional strength and "-": Click to remove this strength, if required (One minimum).</p> <p>In Section 2.2, The tooltip before section "2.2.3.2 Proposed shelf life" has been changed. "+": Add additional proposed shelf life and "-": Remove proposed shelf life (One minimum).</p> <p>In Section 2.4, The tooltip besides "Member State(s)" has been changed. "+": Add additional proposed shelf life and "-": Remove</p> |

| id | Description  | Comments  |
|----|--|---|
|    | <p>provision in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies<br/>The tooltip besides "Bioavailability study(ies) reference number(s)" reads "Add additional reference veterinary medicinal product", but an additional bioavailability stud(ies) reference number(s) appears when clicked.</p> <p>SECTION 2.2, sub numbering 2.2.3 Container, closure and administration device(s) ...<br/>The tooltip before section "2.2.3.2 Proposed shelf life" reads "Add additional package size", but an additional section "2.2.3.2 Proposed shelf life" appears when clicked.</p> <p>SECTION 2.4, sub numbering 2.4.1<br/>The tooltip besides "Member State(s)" reads "Add additional proposed MAH/legally responsible person", but an additional member state appears when clicked.</p> <p>SECTION 2.4, sub numbering 2.4.1<br/>The tooltip in the section "Proof of payment" reads "Click to add additional company name(s)", but an additional section for proof of payment appears when clicked.</p> <p>SECTION 2.6, QUALITATIVE AND QUANTITATIVE COMPOSITION, sub numbering 2.6.1<br/>It seems that the tooltip under the statement "List the active substance(s) separately from the excipient(s) that reads "Add excipient details. Click again to add a second, or more excipient(s)" should be amended to "Add active substance details. Click again to add a second, or more active substance(s)."<br/>In the section of the excipients under "Quantity/Unit" the tooltip where the strength operator has to be selected should be amended from "Click the arrow button to select the strength operator of the active substance" to: "Click the arrow button to select the strength operator of the excipient."</p> <p>SECTION 2.6, QUALITATIVE AND QUANTITATIVE COMPOSITION, sub numbering 2.6.2<br/>When not ticking "None" and specifying data below the tooltip</p> | <p>proposed shelf life (One minimum). Additionally, The tooltip in the section "Proof of payment" has been changed: "+" : Add additional member state and "-" : Remove member state.</p> <p>In Section 2.6, the tooltip under the statement "List the active substance(s) separately from the excipient(s)" has been changed. "+" : Add active substance details. Click again to add a second or more active substance(s) and "-" : Remove active substance details. Additionally, In the section of the excipients under "Quantity/Unit" the tooltip where the strength operator has to be selected, the tooltip has been changed to be: Click the arrow button to select the strength operator of the excipient. If 'Range' is selected, fill in both 'From:' and 'To:' values.</p> <p>In Section 2.6.2, the + / - button tooltips have been updated to: "+" : Add additional active substance/excipient/reagent of animal and/or human origin and "-" : Remove active substance/excipient/reagent of animal and/or human origin (One minimum).</p> |



| id                      | Description  | Comments   |
|-------------------------|--|--|
|                         | reads "Add additional active substance of animal and/or human origin" and should be amended to "Add additional active substance/excipient/reagent of animal and/or human origin".  |  |
| emea00039360 / EAF-1913 | The field "Units" (following "strength") offers a picklist but single symbol can be entered manually that is not checked against the CV  | In Section 2, the unit's field no longer allows users to type characters into the field.                                       |
| emea00039362 / EAF-1914 | In Section 2 or 3, the field "Units" should be mandatory since "strength" is mandatory, too  | In Section 2, the unit's field is now mandatory, and is highlighted when the validation button is pressed.                     |
| emea00039448 / EAF-1936 | the text. Do you have admin address and manufacturer address? Yes No. The text should be reverse.  | In Section 2.5.1, the wording of the question has been changed to read: Do you have a separate admin and manufacturer address? |
| emea00039457 / EAF-1941 | If 1.3.2 is ticked and the following section "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" is not applicable and therefore not filled in, the following validation errors occurs: "Union Status must select the status". This should not be mandatory. | In section 1.3.2 has had the mandatory requirement for the Union Status and Member State(EEA) checkboxes has been removed.     |
| emea00039466 / EAF-1949 | 2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture<br><br>If more than one active substance is described in the application, than the section regarding QP/GMP/CEP information should also be duplicated automatically. Please see screenshot below:  | In section 2.5.3. the additional information is now duplicated when the + button is pressed.                                   |
| emea00039468 / EAF-1951 | eAF version from June 2014, paper version June 2015 ( <a href="http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm">http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm</a> )  | The cover sheet on all four eAF forms have been updated to be consistent with the current versions of the eAF paper forms.     |
| emea00039500 / EAF-1960 | The page numbers are missing on section 2.6 when the format of the page changes from portrait to landscape. For the renewal form, it is on section 3.  | In Section 2.6 the page number is now displayed on the page.   |

### Known issues

| Id           | Description  | Workaround/Comment  |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs |

| Id | Description   | Workaround/Comment  |
|----|---|---|
|    | an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

***Additional information***

**NOTE:** On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23<sup>rd</sup> October 2015 the new ID will be used for all new changes raised against eAF forms.

**NOTE:** To aid clarification of which version of the form is being used, the eAF Version Number (1.19) is now displayed on the cover sheet for this electronic form.

## Version 1.18.0.0 (Release Date: 07/07/2015)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various change requests and defects as outlined below. |

### Issues fixed for this version

| id           | Description   | Comments   |
|--------------|---|--|
| emea00037513 | Section 2.2.3 - The sub numbering "2.2.3.1" is missing  | In Section 2.5.3 - the sub numbering "2.2.3.1" has been added.   |
| emea00037336 | Populate button should be added in sections 2.4.3 and 2.4.1   | In Section 2.4.2 and 2.4.3 - "Copy contact details from 2.4.1 section" button has been implemented.  |
| emea00037111 | In Section 2.2.3 - Container, Closure and Administrative list returning same data set for dropdown where different dataset is required.                                     | In Section 2.2.3 - Individual data set is now returned in Container, Closure and Administrative device dropdown list.  |
| emea00037329 | In Section 2.5.2 - "Enter EudraGMP Manufacturing Authorisation reference" field gives validation error appears after close and reopen the form                              | Resolved the validation error in 2.5.2 section which appears after close and reopen the form.  |
| emea00037349 | Several addresses need to be entered multiple times. Would it be possible that the first address in the Declaration section can be used to be populated at the next section | In Declaration section – "Copy contact details from previous section" button has been implemented.<br>In 2.4.1 section - Copy contact details from declaration section" button has been implemented. |
| emea00034829 | In Section 1.3 - not possible to show the connection between the product strength and authorisation number.   | In Section 1.3.2, 1.3.3, and 1.3.4 - strength, ma holder, ma numbers date of authorisation has been implemented in a tabular format to relate between product strength and authorisation number.     |

| id           | Description   | Comments   |
|--------------|---|--|
| emea00037448 | Section 2.5.2 and 2.5.3 - it is not possible to include different company names in this section when there are different company names in the administration office (DMF holder) and the manufacturing address. It should be possible to add different company names. And it should be able to repeat manufacturer address (one admin address with many manufacturer address) | In section 2.5.2 and 2.5.3 – Company name has been added to admin and manufacturer address. Manufacturer address has been implemented with +/- buttons to repeat section.  |
| emea00037581 | 2.5.1.2, 2.5.2 and 2.5.3 - Guidance on how to complete the section should be added.   | In Section 2.5.1.2, 2.5.2, 2.5.3 – the below note has been added. "note: please see the 'Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): <a href="http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf">http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf</a> " |
| emea00037471 | In Section 2.6.1 - Add free text field to add description of active substances.   | In Section 2.6.1 - new free text field has been added to provide description of active substance field with repeatable +/- buttons.  |
| emea00037330 | In Section 2.5 – add "populate button " to repeat the same addresses in this section.   | "Populate contact details in 2.5.2 and 2.5.3" button has been added in 2.5.1 section.  |
| emea00037986 | Admin and Manufacturer address tooltip needs to be amended.   | All Admin and Manufacturer address in the form has been updated with corresponding tooltips.   |
| emea00037456 | Copy button for section 2.6.1 for repeatable active substances and excipients should be added.  | In Section 2.6.1 – when active substances and excipients section repeated for different strengths then "copy data" button will appear to click.  |
| emea00037319 | In Declaration section - It is not clear why the field 'Active Substance(s)' is provided as a grey shaded field when it is not possible to insert text directly in that field. It was only possible to add information on an Active Substance by clicking on - add active substance.  | In Declaration section – grey active substance field is hidden and it will appear when active substance searched and added into the field.   |
| emea00037517 | Section 2.4.1 - tooltip needs to be updated for payment section   | In Section 2.4.1 – Tooltips has been amended in the payment section.   |

| id           | Description  | Comments  |
|--------------|--|---|
| emea00037346 | Auto populate from Declaration section as separate fields for each of the substances in Section 2.1.2  | 2.1.2 Section is now auto populated data form declaration section by clicking "populate" button in declaration section.   |
| emea00037775 | Section 2.4.1 –payment section - it is only possible to select either "yes" or "no" for the Proof of payment.<br>We often have a situation when we submit the application for several countries and some require the payment in advance and some do not. | In Section 2.4.1 – proof pf payment section – now it is possible to select both "yes" and "no" option by repeating the section.   |
| emea00037437 | In Section 1.1 - did not reject RMS also included as CMS. If a country is chosen as a Reference Member State it should not be possible to select same member state as a Concerned Member State.  | In Section 1.1 - term "None" has be added in the concerned member states dropdown field, and if CMS is selected same as RMS then error message will pop up as below.<br>"CMS should not be same as RMS. If there is no CMS is involved then please select 'None' from the list ", |
| emea00037875 | In Section 2.6.1 – Excipient/overage field is blank and cannot be populated  | Resolved the defect in section 2.6.1 where excipient/overage field not displaying data.   |
| emea00034828 | Section 1.4 -Label change - "pharmacologically active substance" to "substance"  | In Section 1.4 - "pharmacologically active substance" label has been changed into "substance"   |
| emea00038417 | Section 2.1.3 - ATC Group field characters is limited  | In Section 2.1.3 – ATC group field characters has been increased to 100.  |
| emea00038337 | Section 2.2.1 not all strengths have been populated from Declaration section, only first 2 are visible in the 2.2.1  | Resolved the defect in "Section 2.2.1 – strength field" – where all values were not populated from declaration section.   |
| emea00038327 | Active substance in 2.1.2 and 2.5.3 - note should be added to mention that it is populating from declaration section   | Resolved the defect in "Section 2.1.2 and 2.5.3 – active substance field" – note "The value of the active substances field has been populated from Declaration section" has been added.   |

### ***Known issues***

| Id           | Description   | Workaround/Comment   |
|--------------|---|--|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being |

| Id | Description  | Workaround/Comment                           |
|----|--|--|
|    | saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | used, as it is a best practice failure only. |

***Additional information***

None

## Version 1.17.0.0 (Release Date: 23/03/2015)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various change requests and defects as outlined below. |

### Issues fixed for this version

| id           | Description  | Comments   |
|--------------|--|--|
| emea00036835 | eAF takes long time to open pdf even after the form is locked.   | Resolved this defect – Now eAF takes lesser time to open pdf after it is locked.   |
| emea00036022 | Section 2.5.3 – Cannot remove manufacturing site after export and import into another form.                              | Resolved defect in 2.5.3 section – “manufacturing site” section is working fine after export and import.   |
| emea00035944 | When previous version of xml imported into latest version of eAF, there is error message says you are using old version. | Resolved this defect - When previous version of xml imported into latest version of eAF, there will be no error message box.   |
| emea00035914 | Section 2.5.2 - remove button not working in contact details   | Resolved defect in 2.4.2 and 2.4.3 sections – “Remove button” works fine now.  |
| emea00035913 | Section 2.4.2 and 2.4.3 - remove button not working in contact details   | Resolved defect in 2.4.2 and 2.4.3 sections – “Remove button” works fine now.  |
| emea00035908 | section 2.2.1 - superscript format is not working after populated data from Declaration Section                          | As superscript format is not copied across the other sections in pdf due to limited functionality in pdf, the below tooltip has been updated in the strength fields<br>"Insert details regarding strength in the free text field. (Please enter strengths in separate fields if the composition is different for different strengths. And please insert superscripts and subscripts as symbols to maintain formatting)." |

| id           | Description   | Comments   |
|--------------|---|--|
| emea00035819 | Section 2.2.3 - It is not possible to add additional rows in Section 2.2.3 for 'proposed storage conditions'  | Section 2.2.3 – Resolved issue to add additional rows for “proposed storage conditions”.   |
| emea00035818 | Populate data' button in 'Declaration' section which leaves section 2.2.1 unpopulated   | Declaration Section – resolved issue in populate button which leaves section 2.2.1 unpopulated.  |
| emea00035643 | Section 2.6 – free text field should be changed into 1 millilitre or 1 litre or 1 drop (no valid selection), all solid forms will be 1 piece, all powders can be 1 gram or kilogram, a gas may have litre or kilogram.            | Section 2.6 free text field has been changed into 3 fields<br>1. Free text field to enter only numbers.<br>2. Dropdown field to select Units of Measurement.<br>3. Dropdown field to select Pharmaceutical form. |
| emea00035620 | Section 1.4.2: Article 10(1) generic application – Strength field needs to be repeatable.   | Section 1.4.2 – “Strength” field is now repeatable with +/- buttons.   |
| emea00035619 | In Declaration section - add multiple strengths for same active substance.  | Declaration Section – “Strength” field is now repeatable with +/- buttons.   |
| emea00035618 | All of the drop down/selectable fields in eAF from EUTCT should allow Provisional terms.  | Provisional terms of drop down/selectable fields in eAF from EUTCT are available now.  |
| emea00035605 | Section 4.1 - yes/no check box has no option to be left blank.  | Section 4.1 - “not applicable” option has been implemented.  |
| emea00035196 | Section 2.6.1 - quantity/unit section in excipients - validation error.   | Section 2.6.1 - quantity/unit section in excipients table has been implemented same as active substance table.   |
| emea00035075 | The overlap (i.e. the same substance being used in both Human and Vet products) is likely to occur mostly with excipients but it should not be exclusive to them. Please consider also using the same implementation for actives. | In Active substance and Excipient fields - both Human and VET substances will be available.  |
| emea00034825 | Section 2.6.1 – Excipients - it seems still not be possible to divide the composition into tablet core, coating 1, coating 2 or capsule content and capsule composition.  | In Section 2.6.1 – Excipients - free text field has been added in to specify coating.  |
| emea00034822 | Address fields are different format in different sections   | Declaration section - address field section has been changed to common format.<br>Section 2.4.4 – Pharmacovigilance system master file - address field section has been changed to common format.                |



| id           | Description  | Comments   |
|--------------|--|--|
| emea00034738 | Specific list of manufacturing functions list to be displayed as a drop-down lists in Manufacturers section.   | <p>2.5.1.2 - new dropdown list field has been implemented in "Brief description of control tests carried out by the laboratory(ies) concerned".</p> <p>2.5.2 - new dropdown list field has been implemented in "Brief description of functions performed".</p> <p>2.5.3 - new dropdown list field has been implemented in "Brief description of manufacturing steps performed by manufacturing site".</p> <ul style="list-style-type: none"> <li>• When Centralised procedure selected in Section 1 – Only drop down field will be visible &amp; mandatory, free text field will not be visible.</li> <li>• When other procedures selected in Section 1– both free text field and drop down field will be visible and either one is mandatory</li> </ul> |
| emea00033431 | Section 2.5.1.2 - populate button to populate data from 2.5.1  | In Section 2.5.2 – New populate button has been implemented to populate data from 2.5.1.2.   |
| emea00033424 | Section 2.4.2: would it be possible to have the option to populate the data from section 2.4.1   | In Section 2.4.2 – New populate button has been implemented to populate data from 2.4.1.   |
| emea00033201 | Section 2.2 - Container, material and closure needs to be repeatable.  | Section 2.2 - Container, material and closure fields are now grouped and repeatable with +/- buttons.  |
| emea00032941 | In Section 2.2.3 - User should be able to select N/A from Container, Closure and Administration Device drop down lists.  | In Section 2.2.3 – N/A option has been implemented in the drop down list for Container, Closure and Administration Device.   |
| emea00030754 | Section 1.4.3: Article 10(3) hybrid application – Strength field needs to be repeatable.   | Section 1.4.3 – "Strength" field is now repeatable with +/- buttons  |
| emea00027128 | Section 1.4 (last topic) - The last issue for MRLs ("An application has been made to EMA") should be optional only, i.e. there should be a choice between "Not applicable" and the box that needs to be completed if it is applicable. | In Section 1.4 – "Application for a Maximum Residue Limit has been made to the EMA" - radio buttons "yes" and "not applicable" has been included. When Yes selected the rest of the subsection will become visible and mandatory.  |
| emea00027113 | Repeated fields are not removed in a user friendly manner.   | 1.4.2, 1.4.3 1.4.4 and 1.6.1 sections have been amended with +/- buttons in relevant fields.   |

| id           | Description   | Comments  |
|--------------|---|---|
| emea00022342 | 2.5.1.1 - Should there be a company field for this section as well in case the organisation is different from MAH.  | In Section 2.5.1.1 – “Company name” field has been added.   |
| emea00037524 | In Proposed shelf life - dropdown list - N/A should be added.   | In Section 2.2.3 – proposed shelf life – “N/A” has been added to standard time unit’s dropdown list.  |
| emea00037531 | ATC code search field tooltip needs to be updated.  | In Section 2 – “ATC code” field tool tip has been updated.  |
| emea00037334 | Section 2.6 Qualitative and quantitative first row tool tip.  | In Section 2.6 – Qualitative and quantitative – quantity free text field tooltip has been updated.  |
| emea00035561 | eAF takes longer time to load and open.   | The performance issue has been resolved which was slow to load and open eAFs. “Update list” button has been added in the validation section to reload the EUTCT list if needed. |
| emea00037528 | In Human and VET - section 1.1 - proposed common renewal date field should allow both text and date in this field, And tool tip needs to be updated.  | In Section 1.1 – “The proposed common renewal date” field now allows to enter text or date.   |
| emea00037480 | Section 1.4 (MRL) - This section is not leveraging the potential of an eAF as the information on available MRLs could be selected from a selection list. Specifically entering the OJ date of publication adds unnecessary admin burden, note this is not even in the paper form. | In Section 1.4 (MRL) – “OJ date of publication” field has been removed.   |

### Known issues

| Id           | Description   | Workaround/Comment  |
|--------------|---|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow). □ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

***Additional information***

None

## Version 1.16.0.1 (Release Date: 02/10/2014)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various change requests and defects as outlined below. |

### Issues fixed for this version

| id           | Description  | Comments  |
|--------------|--|---|
| emea00035755 | In 1.16.0.0 forms - there is a space at the beginning of the version number in the XML which is causing an error message while export. | Resolved this issue in version number – space has been removed. |

### Known issues

| Id           | Description   | Workaround/Comment  |
|--------------|---|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow). □ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

### Additional information

None

## Version 1.16.0.0 (Release Date: 26/09/2014)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various change requests and defects as outlined below. |

### Issues fixed for this version

| id           | Description   | Comment  |
|--------------|---|--|
| emea00022216 | Request for a drop down field with standard time units list. e.g days, weeks, months etc.   | In Section 2.2.3 –in “Proposed shelf life section” drop down field with standard units list has been implemented.            |
| emea00022346 | There may be multiple companies, addresses and duties for the same study, so may wish to have the Name of Company etc. repeating within the same study.   | In Section 2.5.4 – “Add study” button has been added and company details are grouped and repeatable with +/- buttons inside. |
| emea00026537 | Make annexes mandatory for completed sections.  | In Section 3.2 – “Annex 5.14” check box becomes mandatory when yes is selected.  |
| emea00026543 | Relationship between fields - As a Vet product might have various target species with several routes of administration, it would be very useful to establish a relationship between those fields, i.e., when indicating the "route of administration", the applicable target species should be assigned to the "Admin route". | In Section 2.2 – “Target species” field has been added in route of administration group.                                     |
| emea00026544 | In section 2.1.3 The relationship between fields is not correct. The same applies to ACT VET code, some vet products have different ATC vet codes for different species, a relationship between these data should be established.   | Sections 2.1.3 and 2.1.4 has been grouped together with repeatable +/- buttons   |
| emea00026712 | Some companies are located in Cities, Towns or Villages. City could be changed to City/Town/VillageCity/Town/Village.   | “Address” field has been changed to “Address1” and “City” field has been changed to “Address2”                               |

| id           | Description  | Comment   |
|--------------|--|---|
| emea00031790 | A free text field has been requested for section 2.5.1.a of the MAAA-H & MAA-V to enable users to specify which packaging a manufacturer is responsible for. A free text field already exists in 2.5.2 and could be used for this purpose.   | In Section 2.5.1.a – free text field has been implemented.  |
| emea00033037 | The field 2.1.3 Pharmacotherapeutic group. The ATC code is selected from a dropdown list from EUTCT rather than free text field. This could be an issue as in many cases the ATC code has not been decided/allocated at the time of the application and the applicant will only propose higher levels. The field could be broken up to select some parts of the ATC code from a list and allow free text for the rest.     | In Section 2.1.3 – ATC code is searchable field via EUTCT list.   |
| emea00033494 | Add possible data-entry fields for administration and manufacturing location (as done in 2.5.3)  | In Section 2.5.1.a, and 2.5.2 - Address fields are changed to Manufacturer address and Admin address. <ul style="list-style-type: none"> <li>• “Do you have admin address and manufacturer address? Yes, No” has been added.</li> <li>• If ‘yes’ selected Manufacturer and Admin address are visible If ‘no’ selected one address details are visible.</li> </ul> |
| emea00034923 | Following problem with the eAF for Variations:<br>In the section “Proof of payment” it is not possible to provide the different billing addresses for the MAs in the different countries in this section.<br>Would it be possible to duplicate the section also for the address?<br>So there would be the possibility to provide the Member states A and B for the MA holder X and the Member state C for the MA holder Y? | Resolved issue in Section 2.4.1 – Proof of payment section – “Billing address” has been repeatable with +/- buttons   |
| emea00035076 | Request to include more than one contact person in sections 2.4.2 & 2.4.3 of the MAA-H.  | In Section 2.4.2 and 2.4.3 – “Contact details” are repeatable with +/- buttons  |
| emea00035564 | In Section 2.5.3 Admin/Manufacturer address fields should be in line with other address fields such as Address1 and Address 2  | In Section 2.5.3 – Admin/Manufacturer Address field changed to Admin/Manufacturer Address 1 and Address 2.  |

## ***Known issues***

| <b>id</b>    | <b>Description</b>   | <b>Workaround/Comment</b>   |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

## ***Additional information***

None

## Version 1.15.0.0 (Release Date: 22/04/2014)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various defects and change requests as outlined below. |

### Issues fixed for this version

| id           | Comment   |
|--------------|---|
| emea00022316 | In Section 2.2 – “Strength” and “Active substance” fields have been grouped with repeatable + and – buttons.  |
| emea00022347 | In Section 2.6.1 – “Strength”, “Active substance” and “Excipients” are grouped together with repeatable + and – buttons to link with each other   |
| emea00031054 | In section 2.6.1 – the terms “less than or equal to” or “more than or equal to” are suggested to use for “Quantity sufficient”.   |
| emea00033340 | In section 2.3.2 - Radio buttons are changed to check boxes.  |
| emea00033428 | Resolved issue in section 2.6.1 “strength” field - special characters such as super and subscript has been implemented which allows manual formatting.  |
| emea00033489 | In section 1.4.3 Hybrid application – under “Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product”, “Member states” field has been added with repeatable + and - buttons, and this field appears only if MRP/DCP procedure selected in Section 1.1. |
| emea00033490 | In Declaration and Signature section – “Strength” and “Active substance” fields have been grouped with repeatable + and – buttons.  |
| emea00033491 | In section 2.3.2 - “member states” field has been added separately for “subject to medical prescription” and “not subject to medical prescription” check boxes.   |
| emea00033492 | Sections 2.3.3, 2.3.4 and 2.3.5 are visible when both check boxes selected in 2.3.2 section.  |



| id           | Comment  |
|--------------|--|
| emea00033499 | In Section 2.4.2 to 2.4.4 – a “Member states” field has been added with repeatable + and – buttons.  |
| emea00033723 | Resolved defect in section 2.2.3 – “Material” field now displays full text.  |
| emea00033724 | Maximum length of Package size” field under “Section 2.2.3” has been increased from 50 to unlimited characters.  |
| emea00033726 | Resolved issue in section 2.5.2 –if ‘Site outside EEA’ is selected, “If yes” text was missing in, “please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)”.  |
| emea00033727 | In section 2.5.3 - “Provide copy in Annex 5.10” appears only if yes is selected.   |
| emea00033728 | Resolved issue in Section 1.4 MRL Status– “Animal Species” field width increased to display full text.   |
| emea00033729 | Resolved issue in Section 1.4 under Application for a maximum Residue Limit has been made to the EMA – “Species” field width increased to display full text.   |
| emea00033795 | In section 1.4.2 generic application – under “Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product”, a “Member states” field has been added with repeatable + and - buttons, and this field appears only if MRP/DCP procedure selected in Section 1.1. |
| emea00033796 | In Sections 2.3.3, 2.3.4 and 2.3.5 - “member states” field has been added separately for all check boxes.  |
| emea00033797 | In section 2.3.2 – free text field has been added and grouped the member states field with repeatable + and – buttons.   |
| emea00033985 | Resolved issue in section 2.4.1 – “Billing address (when relevant)” is optional now and it is invisible when “yes” is selected under “Proof of payment”.   |
| emea00034011 | Maximum length of “(Invented) Name” field under “Section 2” has been increased from 250 to unlimited characters.   |
| emea00034399 | Resolved issue in section 1.4 – “Pharmacovigilance active substance” field under “Application for MRL has been made to the EMA” is optional now.   |
| emea00034400 | Resolved issue in 2.5.3 section - “Name of the manufacturer if different from above” field is optional now.  |
| emea00034405 | Resolved issue in version control - which was not working in 1.14.1 version.   |
| emea00034687 | Resolved the issue in annex 5.1 - which was checked even it hasn’t been checked in Declaration or 2.4.1 section.   |
| emea00034688 | Annex 5.8 tick box in 2.5.2 section has been removed from repeatable section and appears only at end of the section.   |
| emea00034689 | In Section 2.3.1 – tool tip has been amended.  |

| id           | Comment  |
|--------------|--|
| emea00034677 | Resolved the issue in email format - which was not able to enter .info and .asia   |
| emea00034701 | Telephone number field characters have been increased to 50 from 30.               |
| emea00034702 | In Section 3.1 – reference field characters limit has been increased to unlimited. |

### ***Known issues***

| id           | Description  | Workaround/Comment  |
|--------------|--|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).□ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

### ***Additional information***

None

## Version 1.14.1.0 (Release Date: 22/04/2014)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various defects as outlined below. |

### Issues fixed for this version

| id           | Comment  |
|--------------|--|
| emea00033925 | Resolved an issue in section 1.3.2 – data not visible after a save, close and a reopen.                            |
| emea00033977 | Resolved an issue in section 5.1 – tick box not selected after a save, close and a reopen.                         |
| emea00034281 | Resolved an issue in section 5.9 and 5.10 – tick box not selected after a save, close and a reopen.                |
| emea00034010 | Resolved an issue in section 2.6.1 –composition free text field data not visible after a save, close and a reopen. |

### Known issues

| id           | Description   | Workaround/Comment  |
|--------------|---|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow). □ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

### Additional information

None

## Version 1.14.1 (Release Date: 06/02/2014)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release fixes various defects as outlined below. |

### Issues fixed for this version

| id           | Comment  |
|--------------|--|
| emea00031799 | All forms, when opened, check the availability of the webservices, if webservices not available then the form gives an error message.                          |
| emea00033684 | In section 2.6.1 - free text field has been added.   |
| emea00033675 | In section 2.1.2 and 2.5.3 active substance fields - the search button has been removed in order to select the active substance from previously selected list. |
| emea00032940 | The section 2.5.1.2 is now optional.   |
| emea00033221 | In section 2.4.1 (Have all relevant fees been prepaid to competent authorities) - billing address is optional if 'No' selected.                                |
| emea00033425 | Resolved the defect in section 2.5.4- the "city" field gives a validation error if left blank.   |
| emea00026829 | Resolved the defect in Validation section – when user selects the error message and clicks the button "Jump to selected" it stays on the validation page.      |
| emea00031800 | Resolved the defect that the document often shows Directive 2001/83/EC (Human one) instead of the vet directive (2001/82/EC).                                  |
| emea00027134 | Resolved issue in section 2.2.1 – This section is now read only where the data populates by clicking the "Declaration Section.                                 |

## ***Known issues***

| <b>id</b>    | <b>Description</b>  | <b>Workaround/Comment</b>   |
|--------------|---|---|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow). □ | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

## ***Additional information***

None

## Version 1.13.2 (Release Date: 27/01/2014)

### Version content

| Functionality / use case  | Comments   |
|---|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, January 2014, Revision 7.3.</i> | This release implements changes in the 7.3 version of the NTA word document.<br>Additionally this release fixes various other defects as outlined below. |

### Issues fixed for this version

| id           | Comment  |
|--------------|--|
| emea00033114 | The latest revision of the MAA Vet Word form, revision 7.3, has been implemented in the eAF.   |
| emea00032904 | The size of the Active Substance fields have been increased in the form to display long names  |
| emea00032894 | In Section 2.1.1 – Resolved the defect which was not auto populating the Proposed invented name which has already been entered in 'Declaration and Signature' section. |
| emea00027129 | In Section 2.2.3 - Proposed shelf life section is now repeatable.  |
| emea00027275 | Container, Material, Closure and Administrative device fields are added in Section 2.2.3.  |
| emea00031798 | In Section 2.4.1 and 2.4.3 – City and Postcode fields are added to the address sections.   |
| emea00031987 | In section 2.4.2 – "Switzerland" has been added in the country list.   |
| emea00031538 | The drop down list for the selection of units of measure in section 2.6.1 now allows all available units to be selected.   |
| emea00032896 | In Section 2.6.2 - Active Substance Name field has been changed to searchable field.   |

### Known issues

| id           | Description   | Workaround/Comment   |
|--------------|---|--|
| emea00029681 | The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web | User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be |

| id | Description   | Workaround/Comment   |
|----|---|--|
|    | viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow). □ | enabled. This issue does not prevent any forms from being used, as it is a best practice failure only. |

***Additional information***

None

## Version 1.10.1 (Release Date: 02/09/2013)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This release implements changes introduced in the substance list in EUTCT. This release fixes other defect as well (see below). |

### Issues fixed for this version

| id           | Comment   |
|--------------|---|
| emea00032078 | This release implements changes introduced in the EUTCT substance list. The substance list now contains two separate lists; one for Human substances and one for Veterinary substances. <ul style="list-style-type: none"><li>• The active substance fields now searches only Veterinary substance list.</li><li>• The excipient field searches both Human and Veterinary substance list.</li></ul> |
| emea00026316 | Version control has been implemented - when the MAA-V eAF is opened via a computer that is connected to the internet, an automated version check is performed to inform the user if a more recent version of the eAF is available for download. If the most recent version is not being used a warning window appears informing the user that a more recent version should be used.                 |

### Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
|    |             |                    |

### Additional information

None



## Version 1.6.0 (Release Date: 31/10/2012)

### Version content

| Functionality / use case  | Comments                            |
|---|-------------------------------------|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This release fixes various defects. |

### Issues fixed for this version

| id           | Comment   |
|--------------|---|
| emea00026796 | The label for the 'Active Substance(s)' fields in section 1.4 has been updated to 'Pharmacological active substance(s)'.  |
| emea00027228 | The drop down list for the selection of units of measure in section 2.6.1 now allows all available units to be selected.  |
| emea00027693 | The substance and route of administration search fields no longer accept a carriage return as input. Instead, if the 'Enter' key is pressed while one of these fields has focus, the search will be executed. |
| emea00027362 | In section 4.2 – Implemented business rule: <ul style="list-style-type: none"><li>All fields which appear below the 'Authorised' checkbox when it is selected are now mandatory.</li></ul>                    |
| emea00027363 | In section 4.3 – The checkbox for annex 5.16 has been added to the repeating group, allowing it to be checked for each medicine.  |
| emea00027397 | In section 1.4, the 'Active Substance(s)' fields which previously allowed free text to be added have been converted to structured fields, requiring a substance search to be performed.                       |

### Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
|    |             |                    |

### Additional information

None

## Version 1.5.3 (Release Date: 31/08/2012)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This release addresses the locking of the form fields after the form has been signed and a mutually exclusive issue.<br>In the following tables, more details can be found for this and other change requests that have been implemented in this release. |

### Issues fixed for this version

| id           | Comment  |
|--------------|--|
| emea00026911 | eAFs are now "locked" from further editing after completion. It is still possible to extract the form data as XML. |
| emea00026527 | In section 1.5 - Entries are no longer mutually exclusive.   |

### Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
|    |             |                    |

### Additional information

None

## Version 1.4.3 (Release Date: 16/07/2012)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This release addresses the product section redesign which includes the replacement of the free text fields that were used for the description of the product, with structured fields and controlled term lists. In the following tables, more details can be found for this and other change requests that have been implemented in this release. |

### Issues fixed for this version

| id           | Comment  |
|--------------|--|
| emea00026303 | Product redesign to be implemented across all sections. Replacement of free text fields with controlled term lists wherever possible and restructuring of the sections and data model to be RDM compliant. |

### Known issues

| id           | Description  | Workaround/Comment   |
|--------------|--|--|
| emea00026796 | Vet eAF - Page 5/6 – 1.4 MRL Status (Only for food-producing species)<br>The selection boxes only address active substance. This suggests that there is no need to include any MRL statement about excipients.<br>Yet footnote 3 (accessible via the 'Information' button) at the bottom of the section states:<br><i>Excipients not included in any of the Annexes of Council Regulation (EEC) No 2377/90 should also be listed and an appropriate justification given.</i> | For the vast majority of applications this will not be an issue; those few that might have issues can still submit the word version. |

### Additional information

None

## Version 1.2.11 (Release Date: 18/06/2012)

### Version content

| Functionality / use case  | Comments   |
|---|--|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This release addresses two critical issues identified in the pilot phase. More details can be found in the section directly below. |

### Issues fixed for this version

| id           | Comment   |
|--------------|---|
| emea00026440 | In sections 2.5.1.2 and 2.5.2 "Country" drop down lists now use the Worldwide list of countries instead of the European list of countries.  |
| emea00026296 | "Find" functionality e.g. for "Route of administration" has been redesigned to avoid a data loss defect that would impact XML export users. |

### Known issues

| id           | Description   | Workaround/Comment                                      |
|--------------|---|---|
| emea00026406 | Section 1.4 - Target tissue per active substance. It should be possible to list the MRLs of one active substance for each species in the eAF (if the application concerns more than one species). The eAF should be amended to provide for this option. | This section is being redesigned to improve data entry. |

### Additional information

None

## Version 1.2.9 (Release Date: 02/05/2012)

### Version content

| Functionality / use case  | Comments  |
|---|---|
| Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Veterinary Use - Volume 6B. Presentation and content of the dossier-Part 1. Summary of the dossier Part 1A. Application form, October 2008, Revision 7.2.</i> | This implementation is the first version of the document as an electronic form. |

### Issues fixed for this version

| id  | Comment   |
|-----|---|
| n/a | This implementation is the first version of the document as an electronic form. |

### Known issues

| id   | Description | Workaround/Comment |
|------|-------------|--------------------|
| none |             |                    |

### Additional information

None