April 2022

Information Technology
EMA/708694/2021

eAF Release Notes

This document lists and briefly describes the new features and fixed issues included in the release of the electronic application form: *Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment, June 2021, Version 1.*

The most recent release appears first.

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Version 1.26.0.0 (Release Date: 26/04/2022)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment, June 2021, Version 1.*	This release note is for the BUGFIX version of 1.26.0.0 release (go-live 26/04/2022).

Issues fixed for this version

Id	Description	Comments
SD-626262	eAF (human and VET) - validation rule for mandatory addresses in the eAFs	Validation rule for mandatory use of OMS has been accidentally removed and is returned. Specifically, when the free text address fields were removed when mandatory use of OMS was implemented (VMP-Reg requirement for all procedure types), the validation rule was accidentally removed. The fields are now shown however, they are read only and cannot be manually edited. The address when selected from OMS will be shown in these fields. The following sections with address fields are modified as described above: • section 2.4.1 • section 2.4.2 • section 2.4.3 • section 2.4.4 • Section 2.5.1a) (2 points) • Section 2.5.1b) • section 2.5.1.1 • section 2.5.1.2 • section 2.5.2 (2 points) • section 2.5.3 (2 points) • Declaration and signature – Applicant • On behalf of the applicant at declaration and signature
SD-645775	User feedback - corrections to business rules needed	The following are implemented: • In Section 4.3 the tick boxes for "Multiple applications submitted Simultaneously", "or Subsequently", to the initial application/MA for: the selection can now be unticked if an unintentional selection has been made to

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

Known issues

Id	Description	Workaround/Comment

Version 1.26.0.0 (Release Date: 31/03/2022)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment, June 2021, Version 1.*	This release note is for the BUGFIX version of 1.26.0.0 release (go-live 31/03/2022). Form date: 16/03/2022.

Issues fixed for this version

Id	Description	Comments
SD-616348	Correction to section 1.2	The following errors were fixed: In section 1.2 Application for a variation requiring assessment; when the check box "Qualitative change in declared active substance not defined as a new active substance" is ticked, there should be 6 radio buttons (options). Two of the options are merged together. Additionally, the typo in the last option ('extraction').
SD-628828	Error in section 4.2	The following error is fixed: In section 4.2: when 'Refused' is selected the suspended/revoked box is ticked automatically each time when the document is re-opened.
SD-631524	Empty fields in 2.4.4 after the form is re-opened	The following error is fixed: In 2.4.4 when you add RMS and CMS using 'Add selected' feature the fields are filled in properly, however, when you save and reopen the form the fields are empty.

Known issues

Id	Description	Workaround/Comment
SD-626262	Validation rule for mandatory use of OMS has been accidentally removed. Please note that use of OMS to select MAH and for example MAH contact person are mandatory fields.	Please always ensure you fill in all sections of the form where relevant, even if there is no validation error when MAH is left empty, the company details still must be provided.

Id	Description	Workaround/Comment
	Number of corrections/changes have been introduced to the Veterinary MAA form, these changes/corrections will be introduced in future versions.	

Version 1.26.0.0 (UAT feedback/known issues fix version, Release Date: 20/01/2022, for use from 28th January 2022)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment, June 2021, Version 1.*	This release note is for the 1.26.0.0 release, for the veterinary MAA eAF.

Issues fixed for this version

Id	Description	Comments
SD-603297	eAF VMP-Reg release v1.26.0.0 Veterinary MAA form - Reintroduce free text address fields in the (2.4.1 proof of payment and 2.5.4 studies)	Free text address fields are reintroduced in section 2.4.1. Proof of Payment section (only). Meaning that when 'no' is selected and an address needs to be provided (for all procedure types), then it is possible to enter the address for Proof of payment using free text fields, copy address from above address fields or add address using OMS search. The same reintroduction of free text address fields is done in section 2.5.4 for the addition of Contract companies used for clinical trial(s) for studies.

Id	Description	Comments
SD-589669	eAF VMP-Reg release v1.26.0.0 UAT feedback - MAA Vet form	The following issues are solved: • When MRP/DCP is selected in section 1.1, the RMS/CMS autofill from 'add selected' has been fixed in sections 2.4.2, 2.4.3 and 2.4.4. • Section 1.3 heading has been changed to capital letters • Section 1.4 MRL, the tick boxes for biological substances have red frames • In 1.4 MRL When 'Not applicable' is selected in 'Application for a Maximum Residue Limit or for an inclusion in the list of biological substances considered as not requiring an MRL evaluation has been made to the EMA' the sub-selection is no longer displayed. The sub-selection is only available if Yes is selected. • Business Rules in section 1.4 MRL have been updated; Pharmacologically active substance, Biological substance and Application for Maximum Residue Limit/inclusion on the list are all optional fields, but one of the 3 should be selected.
SD-598408	eAF VMP-Reg release v1.26.0.0 webservices call update for 2.1.4 withdrawal period and update of eAF section 1.3.3 Hybrid application	• Section 1.3.3 Hybrid applications, the top-level radio button selection of detailed changes has been deleted • Section 2.1.4 the correctly filtered list of Target species is now displayed. Target species with extended attributes: Edible tissue 'And' Edible and MRL tissue are displayed.
SD-609927	eAF VMP-Reg release v1.26.0.0 – update of section 1.2	Section 1.2 the text "(complete section 1.3. and 1.4.)" has been deleted

Version 1.26.0.0 (Release Date: 1/12/2021, for use from 28th January 2022)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Application form for marketing authorisation for veterinary medicinal products according to Regulation EU 2019/6 and for specific variations requiring assessment, June 2021, Version 1.*	This release note is for the 1.26.0.0 release, for the veterinary MAA eAF.

Issues fixed for this version

Id	Description	Comments

SD-403904	eAF vet MAA form is updated based on VMP-Reg	In the MAA vet form:
		
		Cover page:
		Update the cover page to reflect the new form version 1
		
		Declaration section:
		The Declaration section has been removed as the first section of the form
		
		Section 1.1.1:
		• Update the label of 1.1.1 section
		• Only one article can be selected
		• The following is deleted:
		  ○ Radio button "Generic of a centrally authorised veterinary medicinal product" (Article 3(3))"
		  ○ CVMP Rapporteur
		  ○ CVMP Co-rapporteur
		• Update the business rule:
		When the radio button « Mandatory scope» (Article 42(2)) is selected, the following radio buttons are shown:
		  ○ Article 42(2)(a)(i) of Regulation (EU) 2019/6 - Biotech VMP developed by recombinant DNA technology
		  ○ Article 42(2)(a)(ii) of Regulation (EU) 2019/6 - Biotech VMP developed by controlled expression of genes coding
		  ○ Article 42(2)(a)(iii) of Regulation (EU) 2019/6 - Biotech VMP developed by hybridoma and monoclonal antibody methods
		  ○ Article 42(2)(b) of Regulation (EU) 2019/6 - Performance enhancers
		  ○ Article 42(2)(c) of Regulation (EU) 2019/6 - New active substance which has not been authorised as a VMP within the Union at the date of the submission of the application
		  ○ Article 42(2)(d) of Regulation (EU) 2019/6 - Biological VMP which contains or consists of engineered allogeneic tissues or cells
		  ○ Article 42(2)(e) of Regulation (EU) 2019/6 - Novel therapy VMP
		
		• When the radio button « Optional scope » (Article 42(4)) is selected, the following radio buttons are shown:
		  ○ Article 42(4) of Regulation (EU) 2019/6 - VMP other than those listed under Article 42(2) of Regulation (EU) 2019/6, for which no other marketing authorisation has been granted within the Union
		• Also, the field "Date of acceptance/confirmation by CVMP" will be at dd-mm-yyyy format
		• "EMA product number" field should be renamed to "EMA procedure number"
		
		Section 1.1.2:

Id	Description	Comments

		• Update the label of 1.1.2 section
		• Update the label of the radio button "Repeat use 1st wave (Please also complete section 4.2)"
		• Update the format of "Date of authorisation" to dd-mm-yyyy.
		• Delete the following fields:
		  ○ Proposed/Agreed common renewal date
		  ○ If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate,
		  ○ please specify
		
		Section 1.1.3:
		• Update the label of 1.1.3 section
		• Delete the following fields:
		  ○ If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify
		  ○ Proposed Common Renewal Date
		
		Section 1.1.4:
		• Update the "Application number" label into "If available, application number "
		• Delete the field "If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify"
		
		Section 1.2:
		• Update the label of section 1.2
		• When the "Yes" radio button is selected the following new free text, non-mandatory fields should be displayed:
		  ○ UPD Product Identifier (only relevant for MRP and CP)
		  ○ UPD Permanent Identifier for the concerned national product(s)
		  Variation Procedure number (mandatory for MRP)
		• Update the label of the radio button "modification of the vector used to produce the antigen or the source material, including a new master cell bank from a different source, where the clinical/safety characteristics are not significantly different
		• Update the label of the "Note"
		• Update the label of the text "For an existing marketing authorisation in the European Union/ Member State where the application is made"
		
		Section 1.3:
		• Update the label of the section 1.3
		• Update the label of the "Note"
		
		Section 1.3.1:

Id	Description	Comments

		• Update the label of the section 1.3.1
		• Update the label of the "*"
		
		Section 1.3.2:
		• Update the label of the section 1.3.2
		• Update the label of the "Notes"
		• Update the label of the "Veterinary medicinal product which is or has been authorised in accordance with Union provisions in force for not less than 6/8/10 years in the EEA: "
		• Update the format of "Date of authorisation" field into dd-mm-yyyy.
		• Update the text "Note 2: Should be considered the "same" as the one identified above, as per the Commission Communication (98/C 299/03) (i.e. belonging to the same mother company or group of companies or which are "licencees")" into "Note 2: Should be considered the "same" as the one identified above (i.e. belonging to the same mother company or group of companies or which are "licensees")"
		• Update the Note under the text "Veterinary medicinal product which is or has been authorised in accordance with Union provision in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies"
		
		Section 1.3.3:
		• Update the label of the section 1.3.3
		• The new articles will be radio buttons in order to select only one
		• Update the Note under the section 1.3.3
		• Update the Note under "Reference Medical product:"
		• Update the label of "Veterinary medicinal product which is or has been authorised in accordance with Union provision in force for not less than 6/8/10 years in the EEA"
		• Update the format of "Date of authorisation" field into dd-mm-yyyy.
		• Add the following new check boxes at the section "Difference(s) compared to this reference medicinal product"
		  ○ change(s) in the raw material(s) (compared to the reference biological veterinary medicinal product)
		  ○ change(s) in the manufacturing process(es) (compared to the reference biological veterinary medicinal product)
		  ○ other
		• Update the label of "Veterinary medicinal product which is or has been authorised in accordance with Union provision in force used for the demonstration of bioequivalence (if applicable) and/or in other studies." and under this section add a new check box "Third country" (under Member State (EEA) and update the label of "Member State of source".
		
		Section 1.3.4:
		• Remove section "1.3.4 Article 13(4) Similar biological application"
		• Update the section to reflect Article 20 - Combination veterinary medicinal products

Id	Description	Comments
		Section 1.3.5: • Update the section number from 1.3.5 to 1.3.7, the text and note accordingly. **Section 1.3.6:** • Remove section "1.3.6 Article 13b - Fixed combination" • Update the section to reflect Article 22 – Bibliographic application **Section 1.3.7:** • Remove section "1.3.7 Article 13c - Informed consent application" • Update the section to reflect Article 23 – Applications for limited markets • add a date new field in dd-mm-yyyy format. **Section 1.3.8:** • Remove section "1.3.8 Immunological Veterinary Medicinal Product for which the results of certain trials are not being submitted" • Update the section to reflect Exceptional Circumstances • add a date new field in dd-mm-yyyy format. **Section 1.4:** • The text "Application for a Maximum Residue Limit has been made to the EMA" has to be updated and above that add the following new text: ○ Biological substance considered as not requiring an MRL evaluation as per Commission Regulation (EU) No 2018/782: Entry in the list of biological substances considered as not requiring an MRL evaluation. This should be a free text field with no validation. • The label of substance should be updated into "Pharmacologically active substance • Update the footnote "All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given." **Section 1.5:** • Update the label into "1.5 consideration of this application is also requested under the following PROVISION of Regulation (EU) 2019/6 " **Section 1.5.1:** • Update the section number from 1.5.1 to 1.5.2, the text and the note • Update the format of the "Date of acceptance by CVM" field into dd-mm-yyyy.

Id	Description	Comments
		Section 1.5.2: • Update the section number from 1.5.2 to 1.5.3 and the text. **1.5.4 section:** • This new option 1.5.4 should be added as the 4th tick box option to the list, this addition will mean that the existing entry for 1.5.4 is renumbered to 1.5.5, Vaccine antigen master file becomes 1.5.6 and Vaccine platform technology master file becomes 1.5.7 • The text for the new 1.5.4 is; 1.5.4 Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out)) **Sections 1.5.3 – 1.5.7:** • These sections have to be added **Section 2.1:** • Update the label of this section **Section 2.1.1:** • Update the label of the text (incl. the label of the check box). • proposed name in section 2.1.1 that was populated by Declaration section and is disabled for manual entry should be editable and mandatory. • The note "value populated .." in this field indicating this should be deleted. **Section 2.1.2:** • Update the label of "For applications submitted in accordance with Article 12(3) of Directive 2001/82/EC" • Update the Note under "Claim for new active substance(s)" radio button • Add Note "** New/known active substance in relation to structure and properties, including significant differences in terms of safety or efficacy compared to an already authorised veterinary medicinal product in the Union. Please provide evidence and justification to support the claim of new active substance status in annex 5.22" • The text "(The value of the active substances field has been populated from "Declaration" section.)" should be removed. • The user should be able to search the active substance as currently is doing at the declaration form. • Add Button "Populate data in section 2.6.1" above "Substance type". When this button is clicked, it will

Id	Description	Comments
		populate the Substance data from section 2.1.2 to section 2.6.1 **Section 2.1.3:** • Add "ATC vet Code flag" label at the check box **Section 2.1.5:** • New section to be added **Section 2.2.1:** • The text "(The values of the following fields have been populated from "Declaration" section.)" should be removed. • The user should be able to search the pharmaceutical form, strength and unit as currently is doing at the declaration form. • Add button "Populate data in section 2.6.1" at the end of section 2.2.1. When this button is clicked, it will populate the data of the pharmaceutical form, strength inserted in section 2.2.1 to section. 2.6.1 **Section 2.2.3:** • Update the label of section 2.2.3 • Update the label of "Administration Device" field • Update the label of the check box **Section 2.3:** • The existing sections 2.3.1, 2.3.2, 2.3.3, 2.3.4 and 2.3.5 have to be deleted and replaced. **Section 2.4.1:** • Update the label of the section 2.4.1 • Update the format of "Date of expiry" field into dd-mm-yyyy. • Update the label of the check box "Attach copy of the "Qualification of SME Status" • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is missing. Also, the user should be able to find the address using "Loc ID/Org ID" or "Organization name/Country" or previously selected address. • Remove "Copy contact details from Declaration Section" button **Section 2.4.2:** • Update the label related to section 2.4.2 • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is missing. Also,

Id	Description	Comments
		the user should be able to find the address using "Loc ID/Org ID" or "Organization name/Country" or previously selected address. • Remove "Copy contact details from Declaration Section" button **Section 2.4.3:** • Update the label related to section 2.4.3 • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is missing. Also, the user should be able to find the address using "Loc ID/Org ID" or "Organization name/Country" or previously selected address. • Remove "Copy contact details from Declaration Section" button **Section 2.4.4:** • Update the label of the check box "Detailed description of the pharmacovigilance system • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is messing. Also, the user should be able to find the address using " Loc ID/Org ID " or "Organization name/Country" or previously selected address. • Add the following new fields: (Pharmacovigilance System) Master file • PSMF reference number: ((PSMF) reference number/identifier as assigned by the QPPV shall be specified) • PSMF location: Address from OMS **Section 2.5.1:** • Update the label of 2.5.1.a and 2.5.1b • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is missing. Also, the user should be able to find the address using " Loc ID/Org ID " or "Organization name/Country" or previously selected address. **Section 2.5.1.1:** • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is messing. Also, the user should be able to find the address using "Loc ID/Org ID " or "Organization name/Country" or previously selected address.

Id	Description	Comments
		Section 2.5.1.2: • Update the label of the section 2.5.1.2 • Update the label of the check box "Attach copy of manufacturing authorisation(s) or proof of GMP compliance" • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is messing. Also, the user should be able to find the address using "Loc ID/Org ID " or "Organization name/Country" or previously selected address. **Section 2.5.2:** • Update the label of the check box "Attach document equivalent of manufacturing authorisation in accordance with Article 12(m) of Directive 2001/82/EC" • Update the label of the radio button "Has the site been inspected for GMP Compliance by an EEA authority or by an authority of countries where Mutual Recognition Agreements (MRA) (except USA/USA excluded) or other European Union arrangements apply within the terms of the agreement" • Update the label of the radio button "Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)" • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is messing. Also, the user should be able to find the address using "Loc ID/Org ID" or "Organization name/Country" or previously selected address. **Section 2.5.3:** • Remove "Copy contact details from Declaration Section" button • Update the label of the text "Has the site been inspected for GMP compliance by an EEA authority or by an authority of countries where MRA or other European Union arrangements apply within the terms of agreement" • Update the label of the check box "Attach latest GMP certificate in (Annex 5.9) • Update the label of the text "Has the site been inspected for GMP compliance by any other authority (including those of countries where MRA or other European Union arrangements apply but not within their respective territory)" • Update the format of "date of last update" into dd-mm-yyyy • Add a new check box "attach, if applicable, the confirmation in writing from the CEP holder to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines and HealthCare. (Annex 5.11)" under "date of last update" field

Id	Description	Comments
		• Update the label of the text "Is an Active Substance Master File (European Drug Master File) to be used for the active substance(s) reference/original?" • Update the label of the text "National ASMF reference number (when applicable and only if EU ASMF reference number is not available)" • Update the format of the dates "date of submission" and "date of last update" into dd-mm-yyyy • Update the label of the check box "Attach letter of access for european Union/Member State authorities where the application is made (see • "Guideline on Active Substance Master File" • Delete the check box "Attach copy of written confirmation from the manufacturer of the active substance to inform the applicant in case of modification of the manufacturing process or specifications according to Annex 1 of Directive 2001/82/EC" • Update the label of the text "Is an EMA certificate for a Vaccine Antigen Master File (VAMF) issued or submitted in accordance with Directive 2001/82/EC (Annex I), being used for this MAA" • Update the format of the dates "date of submission (if pending)" and "date of approval or last update (if approved)" into dd-mm-yyyy • At the end of this section add the segment "Is an EMA certificate for a Vaccine Platform Technology Master File (PTMF) issued or submitted in accordance with Regulation (EU) 2019/6 (Annex II), being used for this MAA". • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is missing. Also, the user should be able to find the address using " Loc ID/Org ID " or "Organization name/Country" or previously selected address. **Section 2.5.4:** • Update the label of the section • Cannot manually enter Company name, address, City, State, County, postcode, Country. These fields will be visible when the user selects an organisation from OMS. Add "find organisation" when this is messing. Also, the user should be able to find the address using " Loc ID/Org ID " or "Organization name/Country" or previously selected address. **Section 2.6.1:** • The text "(The values of the pharmaceutical form, strength and active substances fields have been populated from "Declaration" section.)" has to be updated into "The values of the pharmaceutical form and strength fields have been populated from "2.2.1" section and active substances field have been populated from "2.1.2" section.) • Use the existing free text field above the "Name of active substance" to reflect the actual name of the active substance and use a tooltip at this free text field to indicate this functionality

Id	Description	Comments
		Section 3: • Update the format of the two Dates fields into dd-mm-yyyy. **Section 4.1:** • Update the label of 4.1 section • Update the label of "Are there any differences which have therapeutic implications between this application and the applications/authorisations for the same product in other Member States (for national applications, Article 21 or 22 of Directive 2001/82/EC shall apply)?" **Section 4.2:** • Delete the "Note: refer to Commission Communications 98/C229/03" • Update all the dates to be in dd-mm-yyyy format **Section 4.3:** • Update all the dates to be in dd-mm-yyyy format **Section 4.4:** • The following date fields should be in dd-mm-yyyy format: "date of authorisation", "date of submission", "date of refusal"," date of withdrawal", "date of suspension/revocation" **Declaration and Signature:** • New section to be added under 4.4 section **Section 5:** • Update the following sections: 5.5, 5.6, 5.11, 5.15, 5.16, 5.17, 5.20-5.24
SD-574469	eAF VMP-Reg release v1.26.0.0 MAA form - new change in section 1.5	**Section 1.5:** • add new 1.5.4 section. This new option 1.5.4 should be added as the 4th tick box option to the list, this addition will mean that the existing entry for 1.5.4 is renumbered to 1.5.5, Vaccine antigen master file becomes 1.5.6 and Vaccine platform technology master file becomes 1.5.7 • The text for the new 1.5.4 is; 1.5.4 Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a marketing authorisation or for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out))

Id	Description	Comments
SD-573186	eAF VMP-Reg release v1.26.0.0 - Target species list update in eAF and eAF webservices	The list 100000108853 Target Species which is called at the sections 2.1.3, 2.1.4 and 2.2.2 has to be filtered in order to add the following parameters: Values with Extended attribute 'IT application: eAF' should be displayed. Note: when in section 1.1.2 MRP is selected and SRP (subsequent recognition procedure) is selected, then in the Target species list needs to display the values from the target species list that have been marked as IT application: eAF and IT application: UPD
SD-573178	eAF VMP-Reg release v1.26.0.0 display the sms ID in the pdf	The SMS ID is currently available in the xml in the form, this change is to display that sms id in the form pdf in the corresponding field. This change applies to the following sections: • Section MRL • Section 2.1.2 • Section 2.2.1 • Section 2.5.3 • Section 2.6.1 (4 instances, active substance, for salts and hydrates only, excipients and active substances and excipients under overages) • Section 2.6.2
SD-587679	eAF VMP-Reg release v1.26.0.0 UAT comment - MAA Vet form	At declaration and Signature section, a missing section for Applicant is included above of the section "On behalf of the applicant".
		•
		•

Known issues

Id	Description	Workaround/Comment

Additional information

None

Version 1.25.0.0 (Release Date: 10/2021)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	This release note is for the 1.25.0.0 release, of the eAF MAA form.

Issues fixed for this version

Id	Description	Comments
SD-179089	Addition of new section for Proposed storage condition after dilution or reconstitution	Addition of a new repeatable section 2.2.3.7 Proposed storage condition after reconstitution or dilution
SD-121617	Ability to indicate the Ph.Eur. Certificate of suitability for multiple active substances.	In section 2.5.3 a + button has been added to give ability to add multiple instances of Ph. Eur. Certificate of suitability has been issued

Id	Description	Comments
		for the active substance(s)

Known issues

Id	Description	Workaround/Comment

Version 1.24.0.1 (Release Date: 12/2020)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	This release note is for the 1.24.0.1 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-450512	eAF - Brexit related change request - to be implemented in the eAFs	In all 4 forms, some country drop down lists will have dynamic values,

Id	Description	Comments
		depending on the Authorisation Selection in Section 1.

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 1.24.0.0 (Release Date: 09/2020)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	This release note is for the 1.24.0.0 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-404120	eAF - Bug in 2.5.1 when second instance is created then Annex 5.9 is not automatically ticked	Bug is fixed and checkbox is ticked as expected
SD-375785	eAF No Longer Validating Version	All forms check all digits of the form version.

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 1.23.1.3 (Release Date: 09/2019)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	This release note is for the 1.23.1.3 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
EAF-3201	Copy details from section 2.4.1 is not working as expected	updated the copy functionality so as to make the copy in respect of the instance it belongs to.
EAF-3200	Tooltip value limit is 50 characters however more than 50 characters can be entered	removed the max chars description from tooltip
EAF-3199	Field is still mandatory even after adding a value for target Species in section 2.1.4	Code enhancement so as to make the particular fields mandatory / no-mandatory.
EAF-3197	Data not copied appropriately to 2.2.1 from declaration section	Code enhancements for appropriate data-copy. Pharma forms in section 2.2.1 are now disabled as expected.
SD-267318	Incorrect tooltips in section 2.5 of initial MAAs (H&V) and section 2 of renewal form	Tooltip now has been changed to: -For 'yes' - select this option if you have separate admin and manufacturer admin address -For 'no' - select this option if the admin and manufacturer addresses are the same
SD-249735	New eAF NTA changes	On Vet form section 2.5.4, the descriptive title is as follows: "Contract companies used for clinical trial(s) on bioavailability or bioequivalence."
SD-172754	BREXIT - Remove 'United Kingdom' from the drop down "country list"	BREXIT event will not affect eAF forms. in the sections that have hardcoded values (Human and Vet forms section 2.5.1 b) , the hardcode values have been removed and a proper web service has been used.(getEEACountries has been removed and getEuAndFreeTradeCountries have been used instead)

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

Id	Description	Workaround/Comment
		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 1.23.1.2 (Release Date: 03/2019)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	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.

Version 1.23.1.1 (Release Date: 01/2019)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	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	This refers to MAA Vet form – section 1.3 .

Id	Description	Comments
	validation errors however it says “if applicable”.	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 , the buttons (Add Selected, Remove All) of Member States will be visible only if the user has clicked one of the following: MRP - Section 1.1.2 DCP - Section 1.1.3
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: MRP - Section 1.1.2 DCP - Section 1.1.3 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 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 From	In MAA Vet form – section 1.3, Now when adding additional strength blocks the fields: Strength(s), Units, Marketing authorisation holder, Marketing authorisation number, Date of authorisation are Mandatory.

Id	Description	Comments
EAF-2989	Section 2.6.3 link "Annex 5.13" is not clickable	In MAA Vet form – section 2.6.3 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. Please note that: 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 . Fixes for section 2.6 have been provided in EAF-3035 in version 1.23.1.0
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	In MAA Vet form - section 1.3 is always visible. The rule for mandatory is the below: section 1.3 is mandatory only when in section 1.2 the option 'No' is selected. 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.).

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.
	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: *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.*	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: *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.*	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 not 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: *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.*	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.
	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.	Always ‘trust’ the form prior to importing xml from previous forms.

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

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	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 • Address fields has been amended to in line with OMS data. • OMS data can be searched now to fill address fields via search button. 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..
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 – • "Yes" and "Not applicable" has been amended from radio boxes into check boxes. • When "Yes" is selected - **Substance**, **Date of Submission**, **Species** and **Remarks** is displayed below. • When "Not Applicable" is selected then **Substance**, **Species** and **Remarks** is displayed and **Date of submission** is

Id	Description	Comments
		hidden.
SD-124640	NTA changes should be implemented.	• 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. • 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. • 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. • Section 4.3 "Multiple applications submitted simultaneously or subsequently to the initial application/MA for". The new radio buttons has been implemented. • 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.
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.
	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.	Always 'trust' the form prior to importing xml from previous forms.

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

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	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: *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.*	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: *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.*	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 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 2nd 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 2nd active substance. The 'Ok' button does not clear the row if the 2nd active substance isn't selected.	Declaration section – Active substance – Ok button clears the 2nd 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.	"Add selected" button removed in section 1.1.2 & 1.1.3 – Concerned Member States (CMS) "Add All" button removed in the following sections • section 2.3.1, 2.3.2, 2.3.3, 2.3.4 • section 2.4.1, 2.4.1 – proof of payment, 2.4.2, 2.4.3, 2.4.4
SD-58708	Copy contact details buttons in all sections needs to review and fix the issue which are not copying all instances	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. Section 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.5.2, 2.5.3
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

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 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: *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.*	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: *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.*	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 SD-35466 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/ 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: *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.*	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	Delcaration 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.. 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 23rd 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: *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.*	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 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 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 fileds 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	1) Fill in all the details in the declaration section and save the form. 2) Close the form and reopen Here expected to see the details saved. However the data is lost. 1) Fill in all the details in the declaration section and save the form. 2) Export the data to xml 3) open a new form and import saved data in step 2 Here expected to see the declaration form filled in but the declaration section is empty	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	Delcaration 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.. 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 23rd 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: *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.*	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 23rd 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: *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.*	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 23rd 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: *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.*	This release fixes various change requests and defects as outlined below.

Issues fixed for this version

id	Description	Comments
emea00038570	• 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: • The free text field for description of the active substance in section 2.6.1 incorrectly refers to "excipients"	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'd 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. 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	In the Vet form the following tooktip are named incorrectly. DECLARATION AND SIGNATURE The tooltip between "Product (invented) name" and "Pharmaceutical Form" reads "Add additional medicinal product", but an additional pharmaceutical form appears when clicked. The tooltip between "Pharmaceutical Form" and "Strength" reads "Add additional medicinal product", but an additional strength appears when clicked. 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: The tooltip besides "Strengths" reads "Click to add additional pharmaceutical form", but an additional strength appears when clicked. SECTION 1.3, sub numbering 1.3.2 – Veterinary medicinal product which is or has been authorised in accordance with Union	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). 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). 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). In Section 2.4, The tooltip besides "Member State(s)" has been changed. "+":Add additional proposed shelf life and "-": Remove

id	Description	Comments
	provision in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies 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. SECTION 2.2, sub numbering 2.2.3 Container, closure and administration device(s) … 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. SECTION 2.4, sub numbering 2.4.1 The tooltip besides "Member State(s)" reads "Add additional proposed MAH/legally responsible person", but an additional member state appears when clicked. SECTION 2.4, sub numbering 2.4.1 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. SECTION 2.6, QUALITATIVE AND QUANTITATIVE COMPOSITION, sub numbering 2.6.1 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)." 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." SECTION 2.6, QUALITATIVE AND QUANTITATIVE COMPOSITION, sub numbering 2.6.2 When not ticking "None" and specifying data below the tooltip	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. 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. 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).

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 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 (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)	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 23rd 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: *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.*	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. 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): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf"
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. 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. "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: *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.*	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 "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 1. Free text field to enter only numbers. 2. Dropdown field to select Units of Measurement. 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. 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.	2.5.1.2 - new dropdown list field has been implemented in "Brief description of control tests carried out by the laboratory(ies) concerned". 2.5.2 - new dropdown list field has been implemented in "Brief description of functions performed". 2.5.3 - new dropdown list field has been implemented in "Brief description of manufacturing steps performed by manufacturing site". • When Centralised procedure selected in Section 1 – Only drop down field will be visible & mandatory, free text field will not be visible. • When other procedures selected in Section 1– both free text field and drop down field will be visible and either one is mandatory
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: *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.*	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: *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.*	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. • "Do you have admin address and manufacturer address? Yes, No" has been added. • If 'yes' selected Manufacturer and Admin address are visible If 'no' selected one address details are visible.
emea00034923	Following problem with the eAF for Variations: 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. Would it be possible to duplicate the section also for the address? 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

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 1.15.0.0 (Release Date: 22/04/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	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: *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.*	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: *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.*	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

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 1.13.2 (Release Date: 27/01/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *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.*	This release implements changes in the 7.3 version of the NTA word document. 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: *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.*	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. • The active substance fields now searches only Veterinary substance list. • The excipient field searches both Human and Veterinary substance list.
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: *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.*	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: • All fields which appear below the 'Authorised' checkbox when it is selected are now mandatory.
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: *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.*	This release addresses the locking of the form fields after the form has been signed and a mutually exclusive issue. 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: *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.*	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) The selection boxes only address active substance. This suggests that there is no need to include any MRL statement about excipients. Yet footnote 3 (accessible via the 'Information' button) at the bottom of the section states: *Excipients not included in any of the Annexes of Council Regulation (EEC) No 2377/90 should also be listed and an appropriate justification given.*	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: *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.*	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: *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.*	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