

December 2023

Information Technology EMA/477434/2020

eAF Release Notes v1.26.0.1

The scope of release v1.26.0.1 covers the following fixes and features:

1. US 133043 [Vet MAA] - [eAF] Veterinary MAA form - label and text changes to align with VMP-Reg requirements

Additional details can also be found in the release notes accessed here: <u>eAF esubmission website</u>.

- 1. US133043 [Vet MAA] Veterinary MAA form label and text changes to align with VMP-Reg requirements In Vet MAA form the following are implemented:
- The header of the form is updated to add a parenthesis into "EU"
- The table of content is updated based on the headers change
- At section 1.1 the header is updated
- At section 1.2
 - o The same footnote at UPD Product Identifier and UPD Permanent Identifier fields is added as footnote 3

- o at the check boxes below the field "Variation Procedure number (mandatory for MRP)" the numbers at the front of the sentences are added
- o footnote at the "active substance" is added as footnote 4
- At section 1.3 the header is updated
- At section 1.3.3: the text "Marketing authorisation granted by:" and "Marketing authorisation(s) granted by:" are added at two points
- At section 1.3.8 the header is updated
- At section 1.4:
 - The tick box of the header is added after 1.4 paragraph numbering
 - o Modify the number of footnote to number 5 and update its text
 - o The text "The active substance and all excipients should be addressed." Is added
 - The text above the check boxes yes/Not applicable is updated
- At section 1.5 the header is updated
- At section 1.5.6 the note is updated (adding a comma)
- At Section 1.5.7 the note is updated (adding a comma)
- At section 2.1.3 the header is updated
- At section 2.1.4 Withdrawal period (Only for food-producing species) the paragraph number and the header are updated
- At section 2.2.1: the label of "Strength" field is updated
- At section 2.2.3.1 the header and the note are updated
- At section 2.2.3 the text of the check box at the end of this section is updated
- At section 2.3 the header is updated and the business rule is modified so that the option "administration exclusively by veterinarians" not to appear anymore for CAPs
- At section 2.4.1: The list of Member states when "National procedure including mutual recognition/decentralised procedure" is selected is updated so that UK(NI) not to be included
- At section 2.4.4 the list of Member states is updated so that UK(NI) not to be included and the number of the footnote is updated to 6
- At section 2.5.1a the header is updated
- At section 2.5.2 the number of the footnote is updated to 7
- At section 2.5.3 the text change at the check box: "attach copy of the letter of access for Union/Member State .." to add a parenthesis at "EU"
- At section 2.6.1 the header is updated
- At section 4 the header is updated
- At section 4.1 the header is updated
- At section 4.2 for "authorized" the text of "authorization number" is changed
- At section 4.2 for "submitted" the text of the check box is changed
- At section 4.2 for "Withdrawn (by applicant after authorisation)" the text of the check box is changed
- At section 4.3 the header and the text below this are updated
- At section 5.15c the text is updated
- At section 5.17 the text is updated
- At section 5.21 the text is updated
- Section NOTES: this section is deleted and is also removed from table of contents. Also the question marks related to these notes are removed from the form.