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: eAF esubmission website.

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
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:
  o 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
  o 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.