



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 October 2021 **Updated**

Information Technology
EMA/477434/2020

eAF Release Notes v1.25.0.0

The scope of release v1.25.0.0 covers the following fixes and features:

1. **SD-403901** [Human MAA and Variation] Changes as per Medical Device Regulation Art 2(1) of Regulation (EU) 2017/745
2. **SD-491930** [Renewal and Variation] Improvement of Proof of payment section in the eAF
3. **SD-179089** [MAA human and MAA vet form] Addition of new section 2.2.3.7 Proposed storage condition after dilution or reconstitution
4. **SD-121617** [MMA Human and MAA vet] Ability to indicate the Ph.Eur. Certificate of suitability for multiple active substances
5. **SD-511614** [Renewal] Correction of a business rule in section 3. Qualitative and Quantitative composition
6. **BUG FIX** Variation and Renewal forms – proof of payment ‘not relevant’ tick box becoming unticked when form is saved/signed
7. **BUG FIX** MAA forms (Human and Veterinary) – 2.5.1.a admin address cannot be selected from OMS
8. **BUG FIX** MAA form (Veterinary) – 2.4.3 LocID/OrgID of the selected address are not visible after the form is saved and reopened
9. **BUG FIX** Renewal form (Human and Veterinary) – Proof of Payment section billing address fields visible when ‘yes’ when xml is imported

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

1. **SD-403901** [Human MAA and Variation] Changes as per Medical Device Regulation Art 2(1) of Regulation (EU) 2017/745

In **Human MAA** form the following are implemented to align with the updated NtA form revision 15, September 2021 to reflect the changes implemented as a result of the Medical Device Regulation:

- Update of section 2.2.4 Medical Devices and its subsections (2.2.4.1, 2.2.4.2, 2.2.4.3 and 2.2.4.4) to reflect the changes from the Medical Devices regulation
- Addition of new section 2.2.5 Companion Diagnostics to reflect the changes from the Medical Devices regulation
- Title fields in the form are now optional

In **Variation** form **Human domain** the following are implemented to align with the updated NtA form revision September 2021 to reflect the changes implemented as a result of the Medical Device Regulation:

- New 'Changes concerns' tick box has been added to indicate 'Medical Device'. This new tick box is always visible and when selected, a new section 4.d is shown to include details on Medical Devices and Companion Diagnostics
- Addition of new section on Medical Devices (4.d) to reflect the changes from the Medical Devices regulation
- Addition of new section on Companion Diagnostics (4.d) to reflect the changes from the Medical Devices regulation
- Title fields in the form are now optional
- When Type of Application is 'Type II' a new value is available for selection in Changes concerns section: "Variation to changes related to the active substance of a human coronavirus vaccine"
- If "National Authorisation" or "National Authorisation in MRP/DCP" (or both) are selected and Type of Application is 'Type II' a new section under proof of payment has been added to allow the applicant to declare parallel variations; "Declaration of the applicant about submission(s) of the same type II variation application for the same product in other Member States – for MRP/DCP/purely nationally authorised products"
- If "National Authorisation" or "National Authorisation in MRP/DCP" (or both) are selected a new section "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products under proof of payment has been added to allow the applicant to provide information on harmonisation of product information "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products'At Signature - Proof of payment section the Proof of payment checkbox should be ticked as default option and when this check box is unticked the section will be hidden

2. **SD-491930** [Renewal and Variation] Improvement of Proof of payment section in the eAF

In Renewal and Variation forms the following is implemented:

- The Proof of payment checkbox is ticked as default to automatically display the Proof of payment section. It is possible to untick the box to hide the section if payment details are not relevant.

3. SD-179089 [MAA human and MAA vet form] Proposed addition of new section for storage condition after Dilution /reconstitution

In the MAA Human form & MAA Vet form the following is implemented:

- Addition of a new repeatable section 2.2.3.7 Proposed storage condition after reconstitution or dilution

4. SD-121617 [MAA Human and MAA vet] Ability to indicate the Ph.Eur. Certificate of suitability for multiple active substances.

In the MAA Human form & MAA Vet form the following is implemented:

- 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 for the active substance(s)

5. SD-511614 [Renewal] Correction of a business rule in section 3. Qualitative and Quantitative composition

- The incorrect implementation of a business rule (issue introduced in v1.24.0.0) has now been corrected and excipient field is now optional for all types of procedures.

6. BUG FIX [Variation and Renewal] Proof of payment 'not relevant' tick box becoming unticked when form is saved/signed

In the Variation and Renewal forms the following bug fix has been implemented:

- The Proof of Payment section is always visible as the box is ticked by default. If the payment details are not relevant, for example for CP, the user can indicate this by unticking the box. The box now stays unticked when the form has been saved and reopened and signed and locked.

7. BUG FIX [MAA Human and MAA vet] 2.5.1.a admin address cannot be selected from OMS

In the Human and Veterinary MAA forms the following bug fix has been implemented:

- In section 2.5.1.a If both, the user has ticked 'yes' for both Admin and Manufacturer's address, it is now possible to select also the Admin address from OMS. The defect was allowing search from OMS but not selection. This has now been fixed.

8. BUG FIX [MAA vet] 2.4.3 LocID/OrgID of the selected address are not visible after the form is saved and reopened

In the Veterinary MAA form the following bug fix has been implemented:

- In section 2.4.3 when the form is saved and reopened the LocID and the OrgID fields are visible for addresses that have been selected using OMS search.

9. BUG FIX [Renewal] Proof of Payment section billing address fields visible when 'yes' when xml is imported

In the Renewal form the following bug fix has been implemented:

- In the Proof of Payment section, the billing address fields are not visible when 'yes' is selected when xml is imported from previously filled in form. The billing address fields are only visible when 'no' is selected.