



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

September 2020

Information Technology
EMA/477434/2020

eAF Release Notes v1.24.0.0

The scope of release v1.24.0.0 covers the following fixes and features:

1. SD-375785 [All forms] eAF No Longer Validating Version
2. SD-404120 [Human, Vet] eAF - Bug in 2.5.1 when second instance is created then Annex 5.9 is not automatically ticked
3. SD-318708 [Renewal] Bug fixing when copying Excipients.
4. SD-161811 [Variation] Variations scopes: eAF to Siamed and RMS - harmonisation of scope lists in both systems

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

1. SD-375785 eAF No Longer Validating Version

All forms check all digits of the form version.

2. SD-404120 Defect in eAF (MAA form) section 1.5

[Human, Vet] eAF - Bug in 2.5.1 when second instance is created then Annex 5.9 is not automatically ticked

The screenshot shows a form section titled "2.5.1 b Official batch release for Blood products and Vaccines". Below the title is the text: "Details of the Official Medicines Control Laboratory (OMCL) or laboratory designated for the purpose of official batch release (in accordance with Articles 111(1), 113, 114(1)-(2) and 115 of Directive 2001/83/EC as amended)". Above this text is a rounded rectangular box containing the following options:

- If available
- Attach latest GMP certificate (Annex 5.9)
- Or
- Enter EudraGDMP document reference number

3. SD-318708 Renewal eAF issue with copy excipients

[Renewal] Bug fixing when copying Excipients.

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
<input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <i>For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002</i>	<input type="text"/>	-
			Clone

4. **SD-161811 Variations scopes: eAF to Siamed and RMS - harmonisation of scope lists in both systems**

[Variation] Section 3 is significantly redesigned;

- Variations are now retrieved from SPOR System and the data shown is linked with the selections in Section 1.
- Where applicable, you can select the variation type, add implementation date/note (only for Type IA and IA_N),
- Automated Article 5 applicability,
- Automated addition of relevant Documentations and Conditions (ability to select/add a free text note)
- For grouping addition/deletion and Clone buttons are also available (not available for Single Scope).

Please read the instructions in the top of Section 3 on how to use along with the field tooltips.

3. TYPES OF CHANGE(S)

Variations included in this application: Please follow instructions below to add variation *fill Section 1 of the form first, so as for the proper variations to be loaded. Navigate through the dropdown lists, in order to show the variation. You can select the variation by clicking the relevant checkbox of the variation box.*
Note: Any change in Type of Application in Section 1, will delete any selected variation!

Variation	Selected
-----------	----------

Show Selected Variations

Show Variation Lists

Grouping of variations is being selected. You may choose variation changes of types that are selected on section 1.

A. ADMINISTRATIVE CHANGES

A.4 Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an A

<input type="checkbox"/>	A.4 - ADMINISTRATIVE CHANGES - Change in the name and/or address of: a manufacturer (including where relevant quality control testing sites); or an ASMF holder; or a supplier of the active substance, starting material, reagent or intermediate used in the manufacture of the active substance (where specified in the technical dossier) where no Ph. Eur. Certificate of Suitability is part of the approved dossier; or a manufacturer of a novel excipient (where specified in the technical dossier)	<input type="button" value="+"/>	<input type="button" value="-"/>	<input type="button" value="Clone"/>
Procedure Types: IA <input type="checkbox"/> IB <input type="checkbox"/>				
<u>Conditions:</u>				
<input type="checkbox"/> The manufacturing site and all manufacturing operations must remain the same.				
Note: <input type="text"/>				
<u>Documentations:</u>				
<input type="checkbox"/> A formal document from a relevant official body (e.g. Chamber of Commerce) in which the new name and/or address is mentioned.				
Note: <input type="text"/>				
<input type="checkbox"/> Amendment of the relevant section(s) of the dossier (presented in the EU-CTD format or NTA volume 6B format for veterinary products, as appropriate).				
Note: <input type="text"/>				
<input type="checkbox"/> In case of change in the name of the holder of the Active Substance Master File holder, updated 'letter of access'.				
Note: <input type="text"/>				