



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14<sup>th</sup> September 2018

Information Technology  
EMA/598622/2018

## eAF Release Notes v1.23.1.0

The scope of release v1.23.1.0 contains the following high priority bug fixes, (no change requests are included in this release):

1. EAF-2785 - section 2.5.3 - copy contact button details not copied to second section instead replacing first part.
2. EAF-2786 - section 4.2 - "Procedure number for MRP/DCP (if applicable)" caused validation errors however it says "if applicable".
3. EAF-2790 - Section 1 – name and address of the contact person - Clicking "copy contact details from previous section" only one company details are copied even though multiple companies are included.
4. EAF-2791 - Contact details for Applicant/ MAH have been entered. When copying "contact details from previous section" for "Name and address of contact person", telephone and e-mail information is not transferred.
5. EAF-2792 - Signature Section - Copy contact person details from section 1 does not work when more than one contact person details is available.
6. EAF-2995 - Section 1.2: Validation Error of Section 1.3 remains same even if Radio button is changed from "No" to "Yes".
7. EAF-2814 - initial maa eaf bug section 4.1.3/4.2.
8. EAF-3002 - Additional signature adding only possible after first signature.
9. EAF-3003 - XML Import Bug.
10. SD-183493 - UAT\_eAF\_1.23\_Base/active Moeity mandatory?
11. SD-184890 - UAT\_eAF\_1.23\_2.5.3 section MAA\_H - ASMF EU number val error.

12. SD-192861 - Electronic Application form Version 1.23.0.0.

Further details can also be found in the accompanying release notes accessed via the [eAF esubmission website](#).

**1. 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.



**2. 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In the MAA Human & MAA Vet forms – In sections 4.2; when the user selects the checkbox “**Withdrawn (by applicant before authorisation)**” The “**Procedure number for MRP/DCP**” has now been corrected to be an optional field rather than a mandatory field.

A screenshot of a web form section titled "4.2 MARKETING AUTHORISATION APPLICATIONS FOR THE SAME PRODUCT IN THE EEA (SAME QUALITATIVE AND QUANTITATIVE COMPOSITION IN ACTIVE SUBSTANCE(S) AND HAVING THE SAME PHARMACEUTICAL FORM FROM APPLICANTS BELONGING TO THE SAME MOTHER COMPANY OR GROUP OF COMPANIES OR WHICH ARE 'LICENSEES')". Below the title is a note: "Note: refer to Commission Communications 98/C229/03". There are four checkboxes: "Authorised", "Submitted (which are not considered as a multiple/duplicate application - see Section 4.3)", "Refused", and "Withdrawn (by applicant before authorisation)" which is checked. Below these is a form container with a "+ -" button in the top right. Inside the container are five input fields: "Country" (a dropdown menu), "Date of withdrawal", "Invented name", "Reason for withdrawal", and "Procedure number for MRP/DCP (if applicable)". The "Procedure number for MRP/DCP (if applicable)" field is highlighted with a red border. Below the form container are two more checkboxes: "Withdrawn (by applicant after authorisation)" and "Suspended/revoked (by competent authority)".

3. **EAF-2790 - Section 1 – name and address of the contact person - Clicking “copy contact details from previous section” only one company details are copied even though multiple companies are included.**

In the Variation form – In sections 1; when pressing the button “**copy contact details from previous section**” – if there are multiple sections\addresses present they shall all now be correctly copied into the respective section.



4. **EAF-2791 - Contact details for Applicant/ MAH have been entered. When copying “contact details from previous section” for “Name and address of contact person”, telephone and e-mail information is not transferred.**

In the Variation form – In sections 1; when pressing the button “**copy contact details from previous section**” –all fields shall now be correctly copied into the respective section including the Name, Address, Telephone and Email fields.



5. **EAF-2792 - Signature Section - Copy contact person details from section 1 does not work when more than one contact person details is available.**

In the Variation form – In the Signature section; when pressing the button “**copy contact person details from section 1**” and there is more than one contact present in section 1 – the form shall now prompt the user with the option of selecting exactly which contact they wish to copy.



**SIGNATURE**

Proof of payment (when relevant)

**Copy contact person details from Section 1**

Select contact details you wish to copy

- Mr, Asim, Qureshi
- Mrs, Menaka, Subramanyam

**select** **close**

Title

First name

Surname

Status (Job title)

**6. 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.

**7. EAF-2814 - initial maa eaf bug section 4.1.3/4.2.**

In the MAA Human form – In sections 4.1.3; If the user selects “Yes” to “Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same product” and then enters any combination of values in section 4.2 (Authorised\Submitted\Refused\Withdrawn (by applicant before authorisation)\Withdrawn (by applicant after authorisation)\Suspended/revoked). The selection shall be retained after saving, closing and reopening the form.

**8. EAF-3002 - Additional signature adding only possible after first signature.**

In the Variation & Renewal forms - This change was introduced to allow full flexibility for signatories to add their signatures in any order, i.e. Main signatory first and then additional signatories or Additional signatories first and then the main signature, the form shall no longer enforce any order for this. Note: The MAA Human & Vet forms also work in the same way.

**9. 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.

**10. SD-183493 - UAT\_eAF\_1.23\_Base/active Moeity 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 moeity again i.e. The base/active moiety fields (including the strength & unit fields) are now optional.

**11. SD-184890 - UAT\_eAF\_1.23\_ 2.5.3 section MAA\_H - ASMF EU number val 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.

**12. SD-192861 - Electronic Application form Version 1.23.0.0.**

In the Variation form – In the Present-Proposed section; when selecting a Country from the dropdown using the free text field entry – the list shall now display the International country codes list rather than just EU country codes list.

eAF 1.23.0.0	eAF 1.23.1.0
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PRESENT<sup>9,10</sup>

*Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/oms/wi/#/>.*

Find Organisation  
Clear Address

Company name

Address

City/Locality/  
Town/Village

State

County

Postcode

Country

Telephone

E-mail

D-U-N-S number<sup>11</sup>

EU or National ASM reference number<sup>1</sup>

PRESENT<sup>9,10</sup>

*Please select organisation from SPOR OMS to autofill address details. If the organisation is not found or the address details are not correct, please visit the OMS page in the SPOR portal for more information: <http://spor.ema.europa.eu/oms/wi/#/>.*

Find Organisation  
Clear Address

Company name

Address

City/Locality/  
Town/Village

State

County

Postcode

Country

Telephone

E-mail

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