



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

February 2019

Information Technology
EMA/81325/2019

eAF Release Notes v1.23.1.1

The scope of release v1.23.1.1 covers the following high priority fixes:

1. EAF-3031 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.4 and 4.2
2. EAF-3052 Validation error message in section 2.5.2 is incorrect in MAA Human and MAA Vet forms
3. EAF-3053 In Section 1.3.4 in Veterinary form and section 1.4 in Human form , only Unit field is mandatory when additional section is added
4. EAF-3010 Validation error in section 2.1.2 in MAA Human and MAA Vet forms
5. EAF-3036 Field for reasons for refused MAA too small in Human and Vet MAA forms
6. EAF-3061 Validation error in section 2.1.2 of MAA Human form
7. EAF-2786 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.3 and 4.2
8. EAF-2985 Section 2.4.1 Button is missing in original section but available in the added section
9. EAF-2987 Section 2.4.4 Added section have Member States as new field in MAA Vet form
10. EAF-2988 Section 2.5.3 mandatory fields in MAA Vet form
11. EAF-2990 "+" Button not working correctly in Sections 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5 and 2.4
12. EAF-2989 Section 2.6.3 link "Annex 5.13" is not clickable
13. EAF-3060 issue EAF-2995 was not fixed in the correct way

- 14. EAF-3058 eAF Renewal incorrect validation rule
- 15. EAF-3054 In Section 3, description blocks for Active Substance and Excipient fields are Mandatory
- 16. EAF-3055 In Section 3, Strength and Unit Fields are Mandatory even after filling correct Data
- 17. EAF-3059 Variation form section 2: member state error
- 18. SD-230717 Wave information in section 1.1.2
- 19. SD-234660 Text change on the cover page

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

1. EAF-3031 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.4 and 4.2

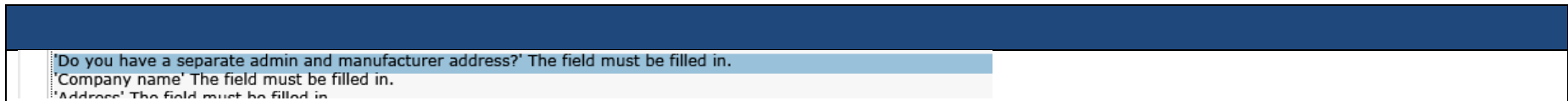
Example refers to MAA Human form – sections 1.4. field "Procedure number for MRP/DCP (if applicable)", is now optional on all instances.

Page 6 of 28

Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation		
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	+	-
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	+	-

2. EAF-3052 Validation Error message for section 2.5.2 in Human and Vet Forms is incorrect

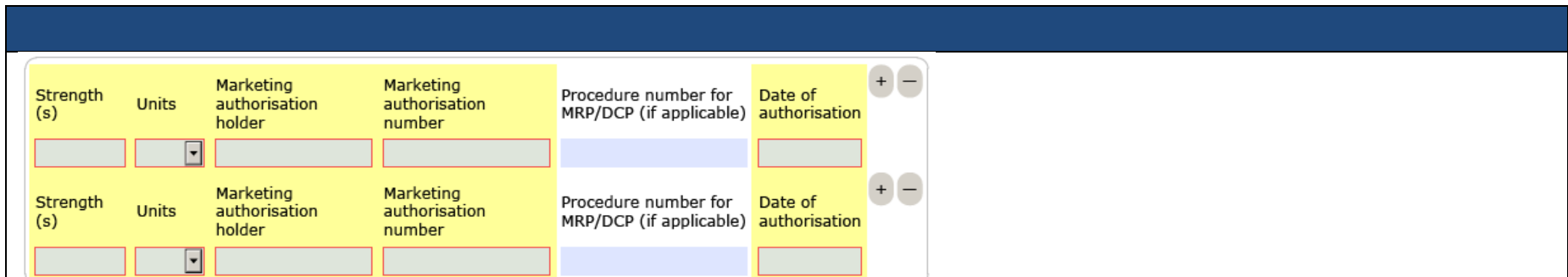
Filling the whole form except the field "Do you have a separate admin and manufacturer address?" in section 2.5.2, the validation error message has been changed from: "Site is in/outside the EEA" to: "Do you have a separate admin and manufacturer address?"



3. EAF-3053 In Section 1.3.4 in Veterinary MAA form and section 1.4 in Human MAA form, only Unit field is mandatory when clicked on (+)

In MAA Human form – section 1.4 now when adding additional strength blocks the fields: Strength(s), Units, Marketing authorisation holder, Marketing authorisation number, Date of authorisation are Mandatory.

In MAA Vet form – section 1.3 now when adding additional strength blocks the fields: Strength(s), Units, Marketing authorisation holder, Marketing authorisation number, Date of authorisation are Mandatory.



4. EAF-3010 Errors in MAA eAF

For MAA Human form, in section 2.1.2 , now when clicking the button to add additional active substance field, the fields "Base/active moiety of the active substance(s)(if different from above)" are not mandatory.

2.1.2 Active substance(s)

*Note: * active substance should be indicated here as full substance. If the substance is included in the product as a salt or hydrate, the corresponding base/active moiety should be indicated in the additional field:*

Name should be based on the following order of priority: INN, Ph.Eur., National Pharmacopoeia, common name, scientific name.*

(The value of the active substances field has been populated from "Declaration" section.)

Full name of the active substance(s) (including salt or hydrate, if applicable)	
<input type="text"/>	+
Base/active moiety of the active substance(s) (if different from above)	-
<input type="text"/>	
Base/active moiety of the active substance(s) (if different from above)	-
<input type="text"/>	
Base/active moiety of the active substance(s) (if different from above)	-
<input type="text"/>	
Base/active moiety of the active substance(s) (if different from above)	-
<input type="text"/>	
Base/active moiety of the active substance(s) (if different from above)	-
<input type="text"/>	
Base/active moiety of the active substance(s) (if different from above)	-

5. EAF-3036 In section 4.2 the field for description for reasons for refused MAA is too short

MAA Human and MAA Vet forms– section 4.2 ‘Refused’ the ‘Reason of refusal’ field now supports up to 100 characters.

☒ Refused

Country

Date of refusal

Procedure number for MRP/DCP (if applicable)

Reason for refusal 123456789123456789123456789123789|

6. EAF-3061 Validation error for section 2.1.2 of MAAH eAF v.1.23

In MAA Human form – section 2.1.2 the part “For applications submitted in accordance with...” is mandatory by default and becomes non-mandatory if the user clicks on section 1.5.4

For applications submitted in accordance with Art. 8(3) or Art. 10a of Directive 2001/83/EC :

Claim for new active substance(s)

Note: active substance not yet authorised in a medicinal product by a competent authority or by the European Union (for centralised procedure)

Known active substance

please provide evidence and justification to support the claim of new active substance status in annex 5.23

7. EAF-2786 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.3 and 4.2

Example refers to MAA Vet form – section 1.3. The field "Procedure number for MRP/DCP (if applicable)", is now optional on all instances.

Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation	+ -
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	+ -
Strength (s)	Units	Marketing authorisation holder	Marketing authorisation number	Procedure number for MRP/DCP (if applicable)	Date of authorisation	+ -
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	+ -

8. EAF-2985 In section 2.4.1 'Add selected/Remove all' button is missing in original section but available in the added section

In section 2.4 the 'Add Selected and Remove All' buttons to add/remove Member States are visible only if the user has selected:

MRP – in Section 1.1.2; or

DCP – in Section 1.1.3

1.1 THIS APPLICATION CONCERNS

1.1.1 A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)

1.1.2 A MUTUAL RECOGNITION PROCEDURE (according to Article 32(2) of Directives 2001/82/EC)

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State:

Centralised procedure National procedure including mutual recognition/decentralised procedure

+ -

Copy contact details from Declaration Section

Add Selected Remove All ?

Member State(s) [dropdown] + -

9. EAF-2987 Section 2.4.4 Added section have Member States as new Field in Vet Form

Member States will be visible in section 2.4 only if the user has selected:

MRP - Section 1.1.2

DCP - Section 1.1.3

National - Section 1.1.4

1.1 THIS APPLICATION CONCERNS

- 1.1.1 A CENTRALISED PROCEDURE (according to Regulation (EC) No 726/2004)
- 1.1.2 A MUTUAL RECOGNITION PROCEDURE (according to Article 32(2) of Directives 2001/82/EC)

2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State:

Centralised procedure National procedure including mutual recognition/decentralised procedure

Copy contact details from Declaration Section

Add Selected Remove All ?

Member State(s) [dropdown] + -

10. EAF-2988 Section 2.5.3 mandatory fields in MAA Vet Form

In MAA Vet form section 2.5.3 under subsection "Is an active substance master file.." the fields "Name of the Manufacturer if different from Above" and "EU ASMF reference Number if Available" are now optional.

Telephone	<input type="text"/>
E-mail	<input type="text"/>
Name of the Manufacturer if different from the above	<input type="text"/>
EU ASMF reference Number if available	<input type="text"/>
National ASMF reference number (when applicable and only if EU ASMF reference number is not available)	<input type="text"/>

11. EAF-2990 "+" Button not working correctly in sections 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4

In MAA Vet form sections 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4 the [+] button next to Member States to add new instance is now working properly. Please note that in order for the button to be visible, the user must click first in section 1.1.2 or 1.1.3

1.23.1.0	1.23.1.1
<p>2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State:</p> <p><input type="radio"/> Centralised procedure <input checked="" type="radio"/> National procedure including mutual recognition/decentralised procedure</p> <div data-bbox="302 555 1075 783"><p>Warning: JavaScript Window - Error</p><p>⚠ Same member state should not be repeated, Please select a different member state</p><p>OK</p></div> <p>Member State(s) [+] [-]</p> <p>Member State(s) [+] [-]</p> <p>Member State(s) [+] [-]</p>	<p>2.4.1 Proposed marketing authorisation holder/person legally responsible for placing the product on the market in the European Union/each Member State:</p> <p><input type="radio"/> Centralised procedure <input checked="" type="radio"/> National procedure including mutual recognition/decentralised procedure</p> <div data-bbox="1209 555 2027 758"><p>[+] [-]</p><p>Copy contact details from Declaration Section</p><p>Add Selected Remove All ?</p><p>Member State(s) Austria [+] [-]</p><p>Member State(s) [+] [-]</p></div>

12. EAF-2989 Section 2.6.3 link "Annex 5.13" is not clickable

In MAA Vet form – section 2.6.3

The Annex 5.13 is now clickable and leads to section 5, annex 5.13.

2.6.3 Does the veterinary medicinal product contain or consist of Genetically Modified Organisms(GMOs) within the meaning of Directive 2001/18/EC?

Yes No

If yes, does the product comply with Directive 2001/18/EC?

Yes No

Attach a copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive [\(Annex 5.13\)](#)

Click to jump to named Annex - click named Annex details to return here.

13. EAF-3060 issue EAF-2995 was not fixed in the correct way

In MAA Vet form - section 1.3 is always visible. The rule for mandatory is the below:

section 1.3 is mandatory only when in section 1.2 the option 'No' is selected.

section 1.3 is not mandatory by default (cases of section 1.2 option 'Yes' is selected, or section 1.2 neither 'Yes','No' is selected.).

1.2 APPLICATION FOR A CHANGE TO YOUR EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF COMMISSION REGULATION (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?

Yes No (complete section 1.3 and 1.4.)

1.3 THIS APPLICATION IS SUBMITTED IN ACCORDANCE WITH THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC

Note: - section to be completed for any application, including applications referred to in section 1.2
- for further details, consult the Notice of Applicants, Volume 6A, Chapter 1.
- information on active substance status (new/known) should be provided in section 2.1.2

1.3.1 Article 12(3) application, (i.e. dossier with administrative, quality, safety and clinical data*)
*for extensions of full applications, cross references can only be made to safety and clinical data.

1.3.2 Article 13(1) Generic application

1.3.3 Article 13(3) hybrid application

1.3.4 Article 13(4) Similar biological application

1.3.5 Article 13a Well established Veterinary use

14. EAF-3058 eAF Renewal v23.0.1 Incorrect Validation error messages

The error messages 'tfManufName' and 'EU ASMF reference number if available' have been removed from the validation error message list.

View from 1.23.1.0

FORM VALIDATION

Validation Errors: 2
'Manufacturer' validate failed.
'EU ASMF reference number if available' validate failed.

15. EAF-3054 In Section 3, Description Blocks of Active Substance and Excipient Fields are Mandatory

No changes. Issue is considered resolved.

16. EAF-3055 In Section 3, Strength and Unit Fields are Mandatory even after filling correct Data

No changes. Issue is considered resolved.

17. EAF-3059 eAF 1.23.1.0 for variations error in section 2 'Products concerned by this application' when using export/import function.

The Member States in section 2 are now exported and imported as expected.

View from 1.23.1.0

Member State

MA Number(s) ?	Invented Name	MA Holder Name	Pharmaceutical Form
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Member State

MA Number(s) ?	Invented Name	MA Holder Name	Pharmaceutical Form
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

18. SD-230717 Wave information

In MAA Human form – section 1.1.2 “A MUTUAL RECOGNITION PROCEDURE”, now when click in “Repeat use...” the fields: Wave 1, [+] [-] Buttons and “Copy in all Waves” button, are no longer visible.

The screenshot shows the '1.1.2 A MUTUAL RECOGNITION PROCEDURE' section of the MAA Human form. It includes a sub-section '(according to Article 28(2) of Directive 2001/83/EC)'. The form contains several input fields: 'Reference Member State' (a dropdown menu), 'Date of authorisation' (a date field), and 'Marketing authorisation number' (a long text field). Below these is a note: '(* a copy of the authorisation should be provided - see section 4.2)'. There is a 'Procedure number:' field. Two radio buttons are present: 'First use' (unselected) and 'Repeat use (Please also complete section 4.2)' (selected). Below the radio buttons is a container with 'Add All' and 'Remove All' buttons. Inside this container, there is a 'Concerned Member State (specify)' dropdown menu with '+' and '-' buttons, and a 'Proposed/Agreed common renewal date' field.

19. SD-234660 Text change on the cover page MAA Human and Maa Vet

In MAA Human form on the first page, the text: From “This application form will be included in...” till “...Update from February 2018.” has been removed.

In MAA Vet form on the first page, the text: From “This application form will be included in:...” till “...Update from February 2018.” has been r-moved.