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:

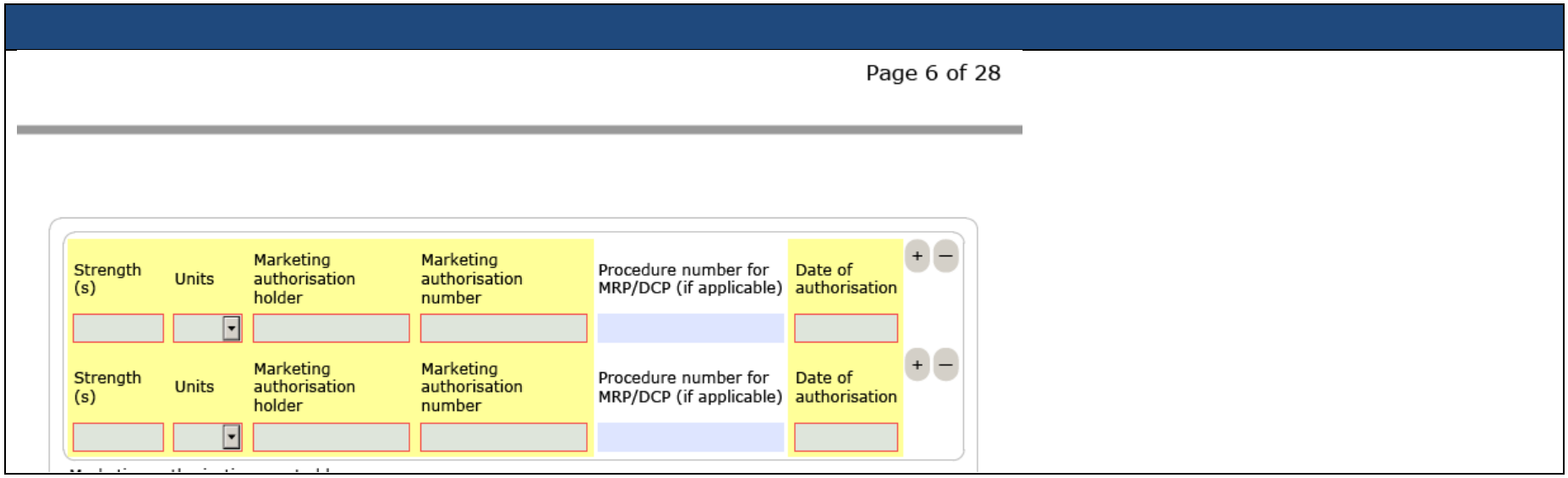
1. EAF-3031 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.4 and 4.2
2. EAF-3052 Validation error message in section 2.5.2 is incorrect in MAA Human and MAA Vet forms
3. EAF-3053 In Section 1.3.4 in Veterinary form and section 1.4 in Human form , only Unit field is mandatory 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.

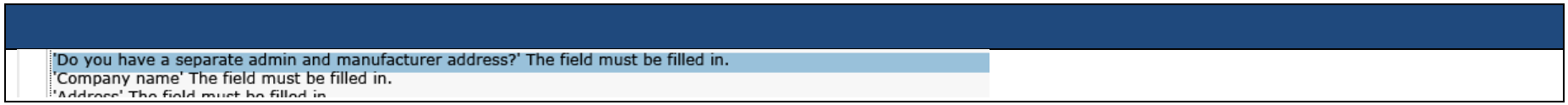
1. **EAF-3031 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.4 and 4.2**

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



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

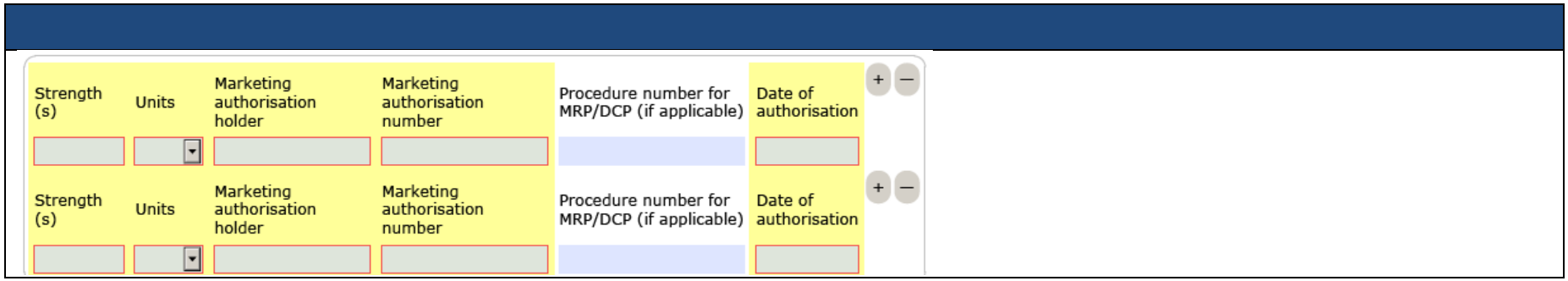
Filling the whole form except the field "Do you have a separate admin and manufacturer address?" in section 2.5.2, the validation error message has been changed from: "Site is in/outside the EEA" to: "Do you have a separate admin and manufacturer address?"



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 (+)

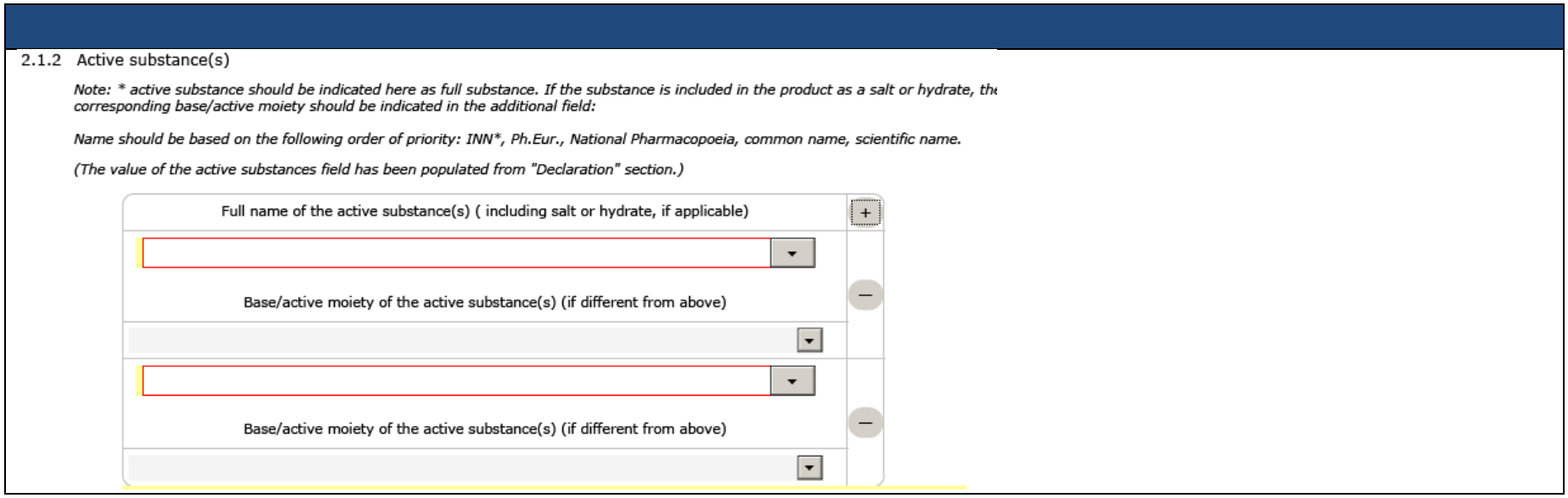
In MAA Human form – section 1.4 now when adding additional strength blocks the fields: Strength(s), Units, Marketing authorisation holder, Marketing authorisation number, Date of authorisation are Mandatory.

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.



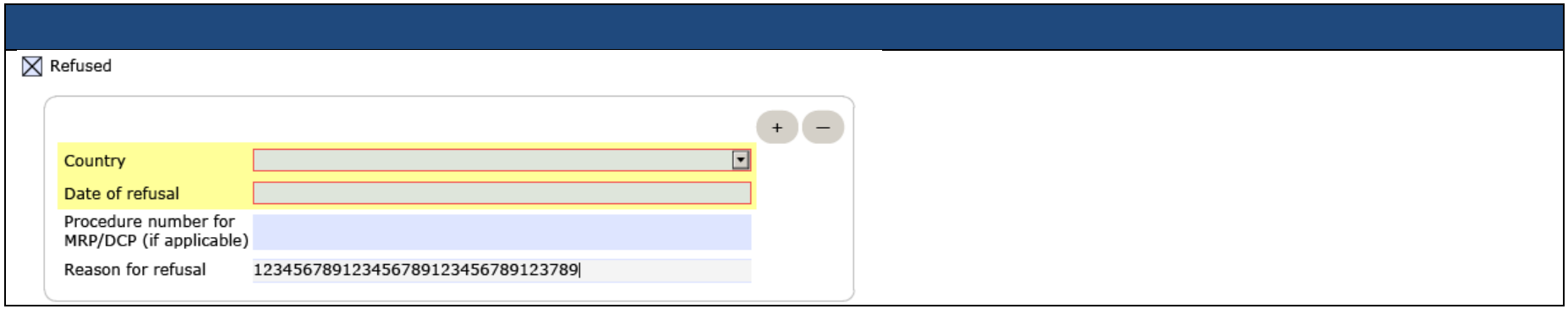
4. EAF-3010 Errors in MAA eAF

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.



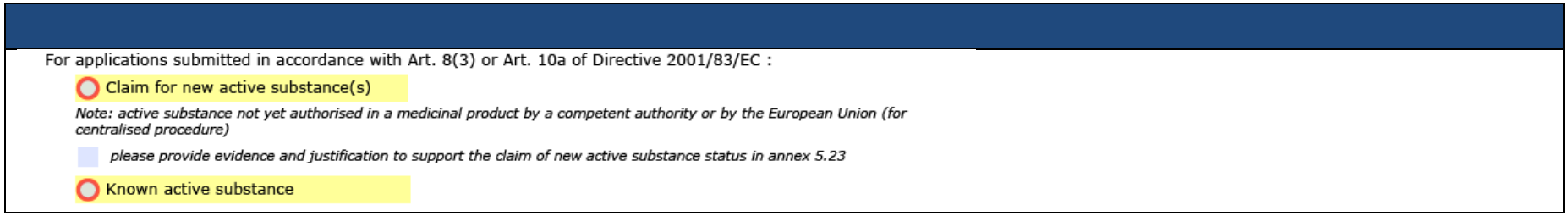
5. EAF-3036 In section 4.2 the field for description for reasons for refused MAA is too short

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



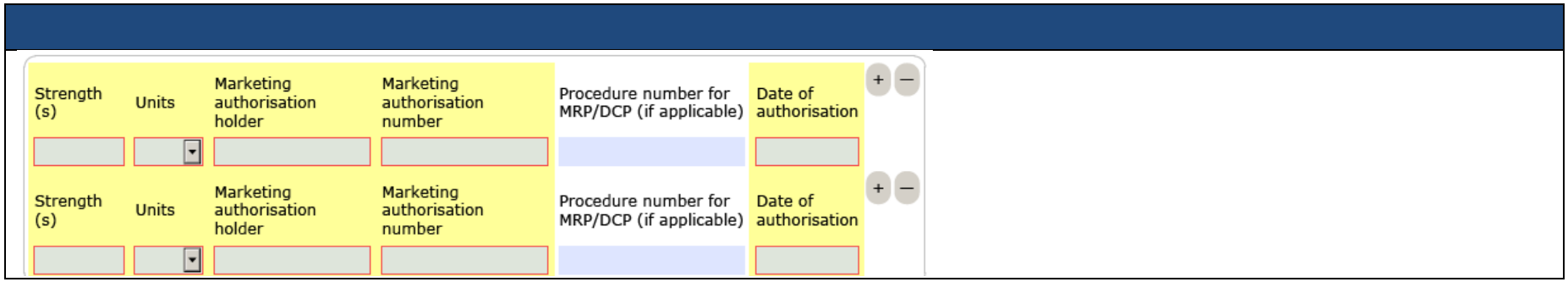
6. EAF-3061 Validation error for section 2.1.2 of MAAH eAF v.1.23

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



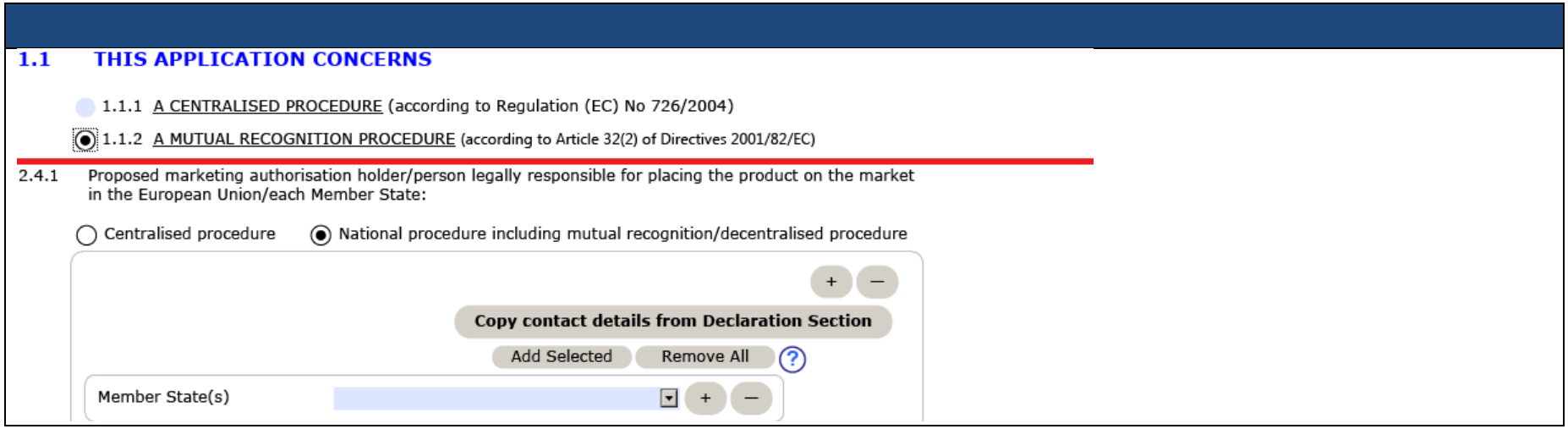
7. EAF-2786 Field "Procedure number for MRP/DCP (if applicable)" is mandatory in sections 1.3 and 4.2

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



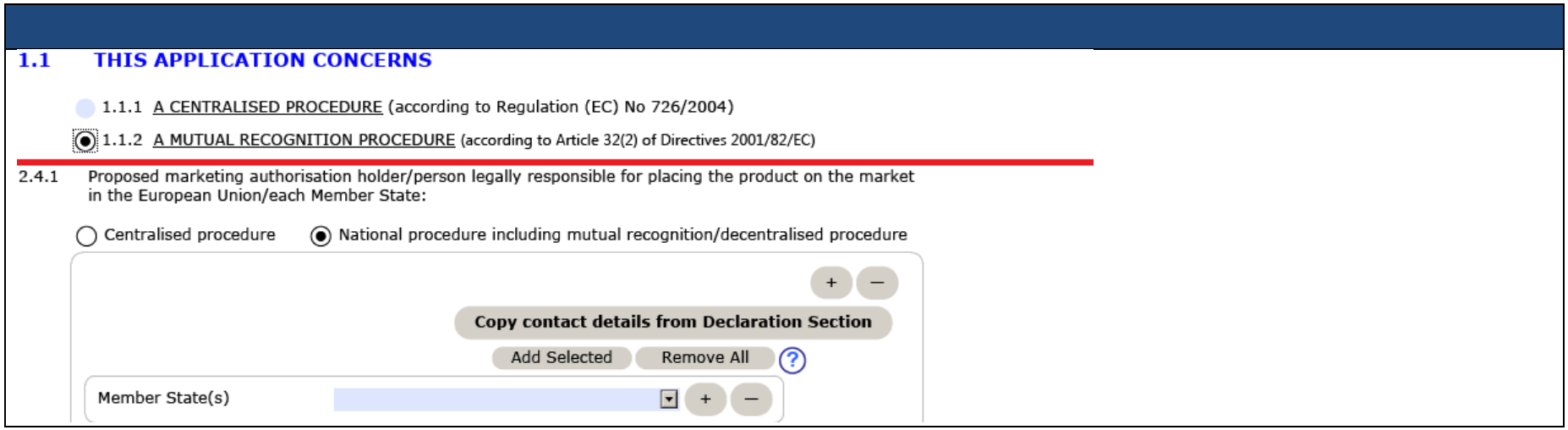
8. EAF-2985 In section 2.4.1 'Add selected/Remove all' button is missing in original section but available in the added section

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



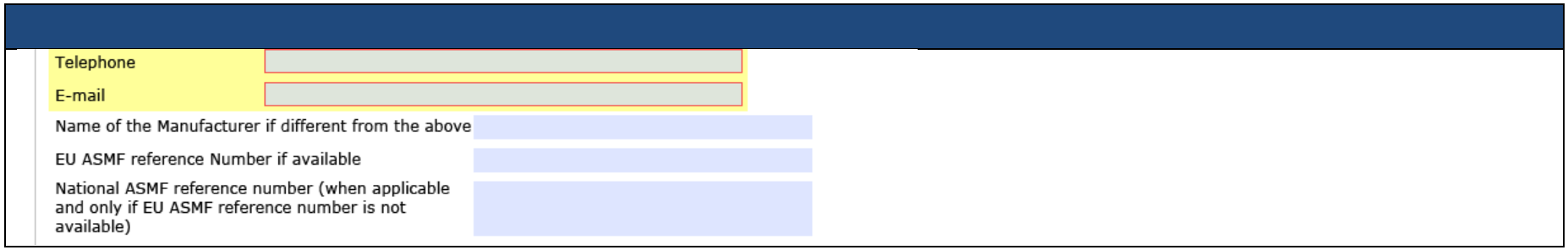
9. EAF-2987 Section 2.4.4 Added section have Member States as new Field in Vet Form

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



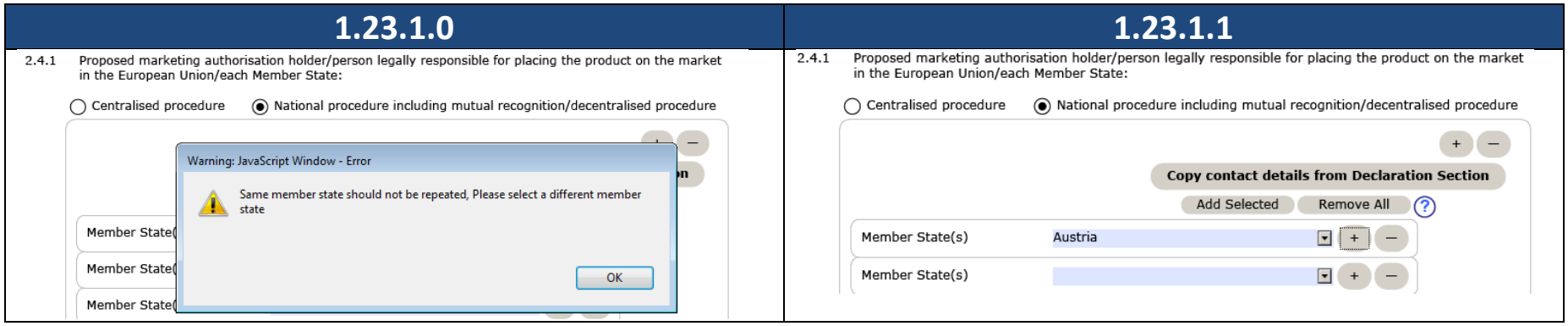
10. EAF-2988 Section 2.5.3 mandatory fields in MAA Vet Form

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.



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

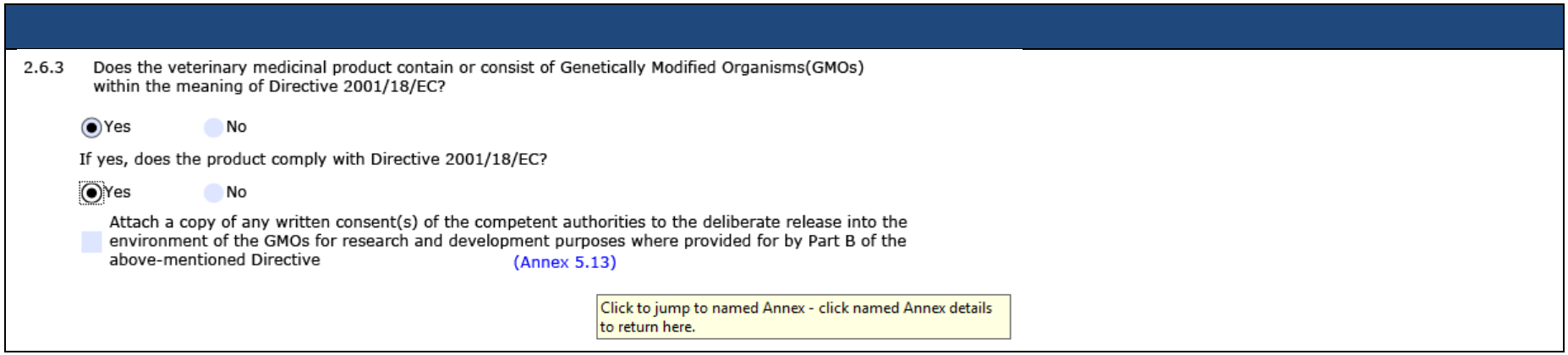
In MAA Vet form sections 1.3.2, 1.3.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4 the [+] button next to Member States to add new instance is now working properly. Please note that in order for the button to be visible, the user must click first in section 1.1.2 or 1.1.3



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

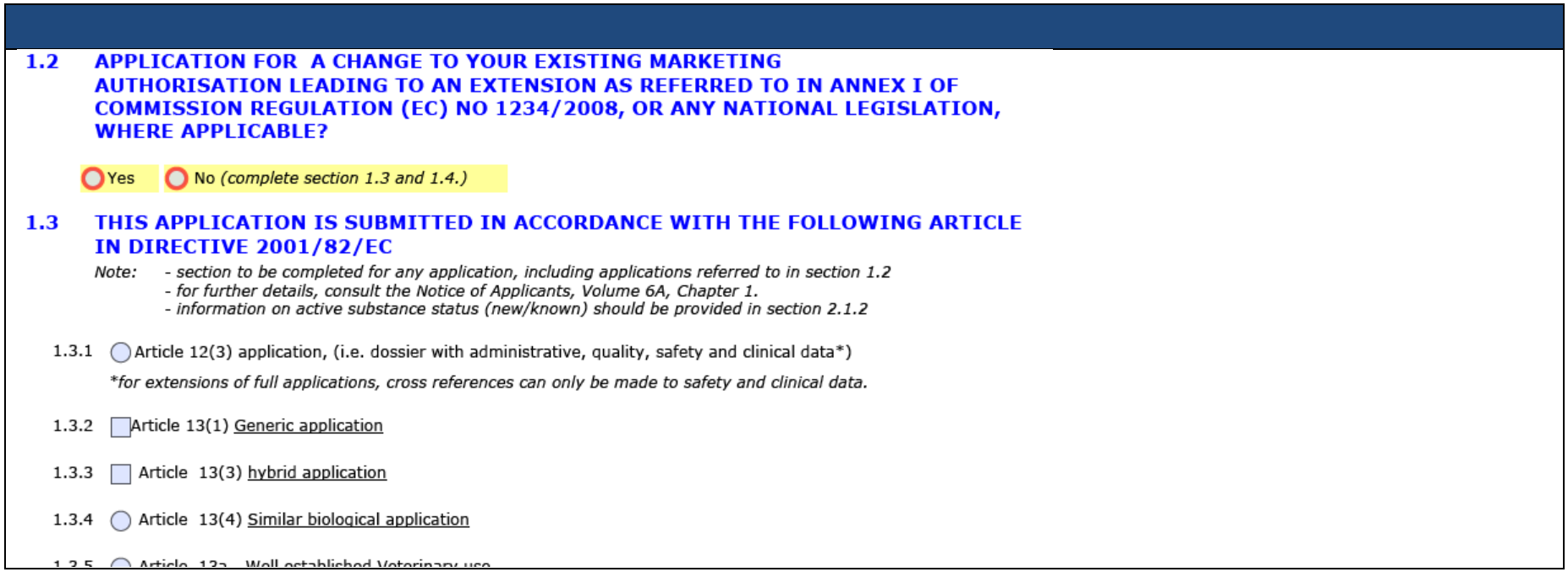
In MAA Vet form – section 2.6.3

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



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

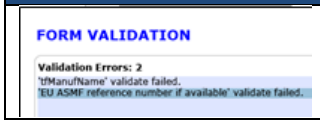
1.3.3 ☐ Article 13(3) hybrid application

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


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

No changes. Issue is considered resolved.

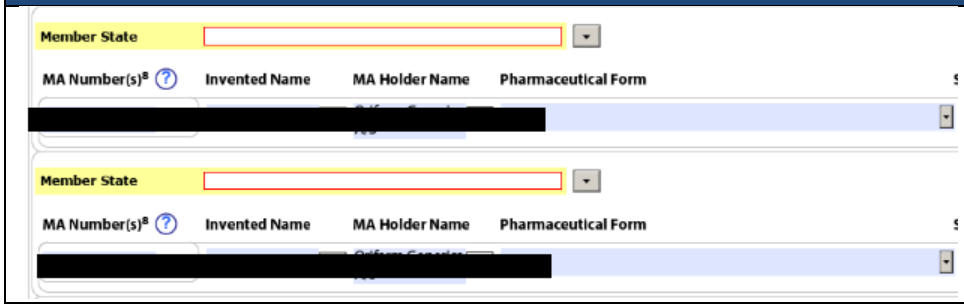
16. EAF-3055 In Section 3, Strength and Unit Fields are Mandatory even after filling correct Data

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.

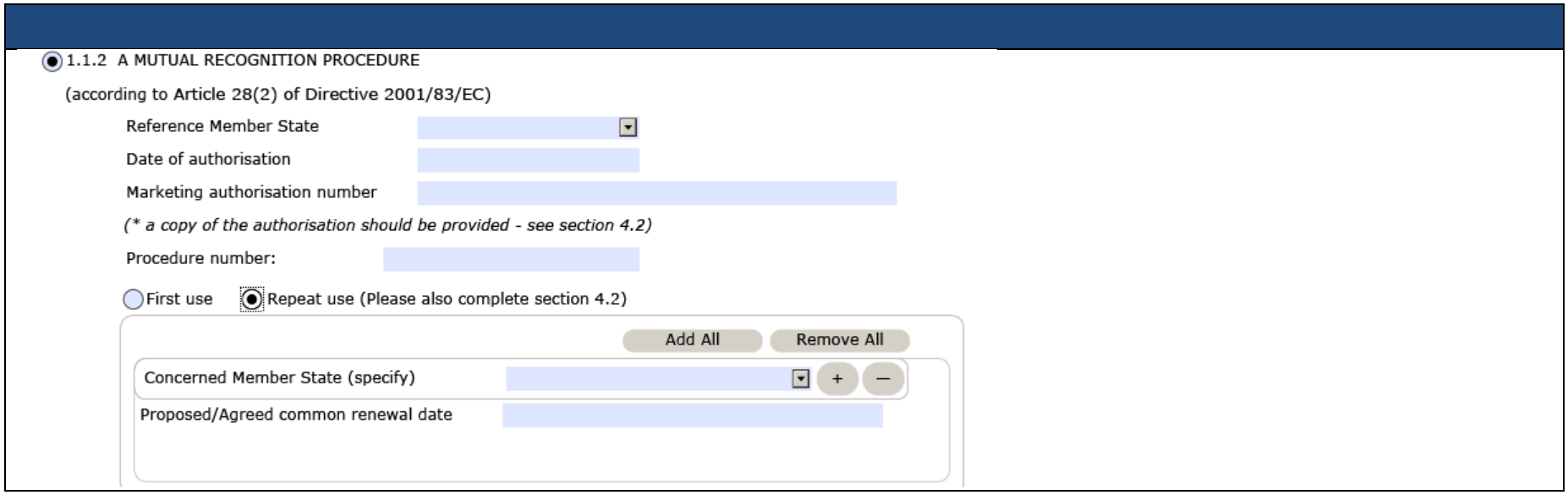
The Member States in section 2 are now exported and imported as expected.

View from 1.23.1.0



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.



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.