



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

October 2019

Information Technology  
EMA/517361/2019

## eAF Release Notes v1.23.1.3

The scope of release v1.23.1.3 covers the following high priority fixes:

1. SD-267318 Incorrect tooltips in section 2.5 of initial MAAs (H&V) and section 2 of renewal form
2. SD-249735 New eAF NTA changes
3. SD-271374 Query re variation eAF Version Number: 1.23.1.0 - present/proposed table(s)
4. SD-172754 Remove hard coded values from the drop down "country list" and replace with RMS entry
5. SD-271358 Copy function in section 2.4.3 of maa\_human\_v1.23.1.1
6. EAF-3197 Data not copied appropriately to 2.2.1 from declaration section
7. EAF-3199 Field is still mandatory even after adding a value for target species in section 2.1.4
8. EAF-3200 Tooltip value limit is 50 characters however more than 50 characters can be entered
9. EAF-3201 Copy details from section 2.4.1 is not working as expected

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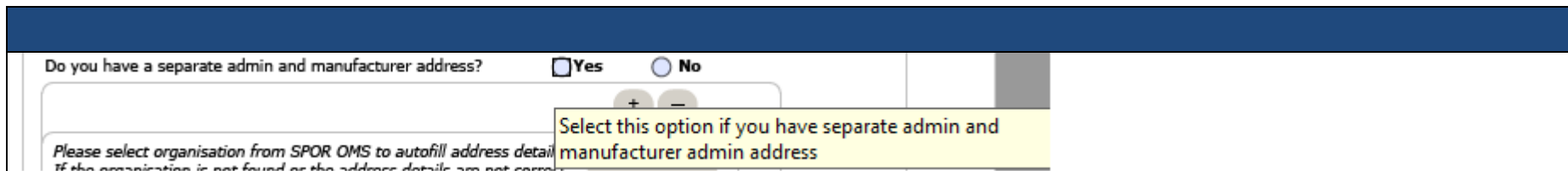
- 10. EAF-3204 Incorrect validation message appearing on clicking "Click here to populate data in section 3"
- 11. EAF-3205 Data not copied appropriately from section 1 to section 3 in renewal form
- 12. EAF-3207 Maximum character limit exceeded in Declaration and Signature section
- 13. EAF-3208 Unexpected behaviour for Variation procedure number(s) when multiple fields added by clicking (+) button
- 14. EAF-3209 Unexpected behaviour when copy data from section 1 to section 3
- 15. SD-293082 Problem with Application Form for Renewal

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

**1. SD-267318 Incorrect tooltips in section 2.5 of initial MAAs (H&V) and section 2 of renewal form**

Tooltip now has been changed to:

- For 'yes' - select this option if you have separate admin and manufacturer admin address
- For 'no' - select this option if the admin and manufacturer addresses are the same





## 2. SD-249735 New eAF NTA changes

On Veterinary form section 2.5.4, the descriptive title is as follows:  
"Contract companies used for clinical trial(s) on bioavailability or bioequivalence."

2.5.4 Contract companies used for clinical trial(s) on bioavailability or bioequivalence.	
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## 3. SD-271374 Query re variation eAF Version Number: 1.23.1.0 - present/proposed table(s)

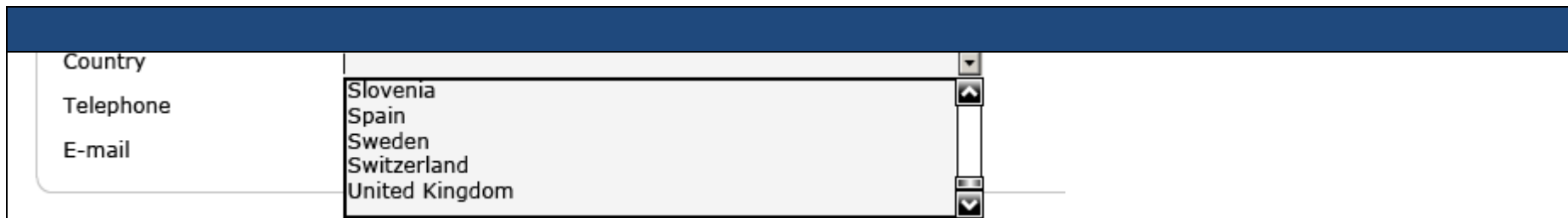
Texts are no longer hidden under next pages in section 3 "Present / Proposed Tables"

Page 7 of 14	
TEST TEST TEST TEST TEST TEST a Text continues to next page without being hidden.	
PRESENT <sup>9,10</sup>	PROPOSED <sup>9,10</sup>
TEST b TEST c TEST	



**4. SD-172754 Remove hard coded values from the drop down "country list" and replace with RMS entry**

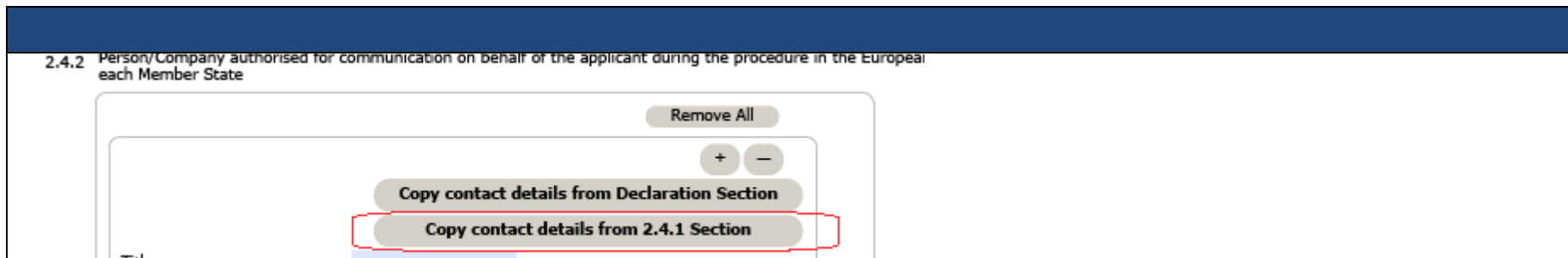
In the sections that have hardcoded values (Human and Veterinary maa forms section 2.5.1 b), the hardcode values have been removed and a proper web service has been used (getEEACountries has been removed and getEuAndFreeTradeCountries have been used instead).



The screenshot shows a form with a dropdown menu for 'Country'. The dropdown is open, displaying a list of countries: Slovenia, Spain, Sweden, Switzerland, and United Kingdom. The form also includes fields for 'Telephone' and 'E-mail'.

**5. SD-271358 Copy function in section 2.4.3 of maa\_human\_v1.23.1.1**

In Human form, copy buttons of sections 2.4.2, 2.4.3 are working as expected.



The screenshot shows a form section titled '2.4.2 Person/Company authorised for communication on behalf of the applicant during the procedure in the European each Member State'. It contains a 'Remove All' button, a '+' and '-' button, and two 'Copy contact details' buttons. The button 'Copy contact details from 2.4.1 Section' is highlighted with a red box.

**6. EAF-3197 Data not copied appropriately to 2.2.1 from declaration section**

In Human and Veterinary maa forms, code enhancements for appropriate data-copy. Pharmaceutical forms in section 2.2.1 are now filled in from declaration section as expected.

**2.2.1 Strength and pharmaceutical form (use current list of standard terms - European Pharmacopoeia)**

*(The values of the following fields have been populated from "Declaration" section.)*

Pharmaceutical Form:	Age-appropriate dosage form for parenteral use	+	-
Pharmaceutical Form:	Concentrate for nebuliser solution	+	-
Pharmaceutical Form:	Capsule, hard + tablet	+	-

**7. EAF-3199 Field is still mandatory even after adding a value for target Species in section 2.1.4**

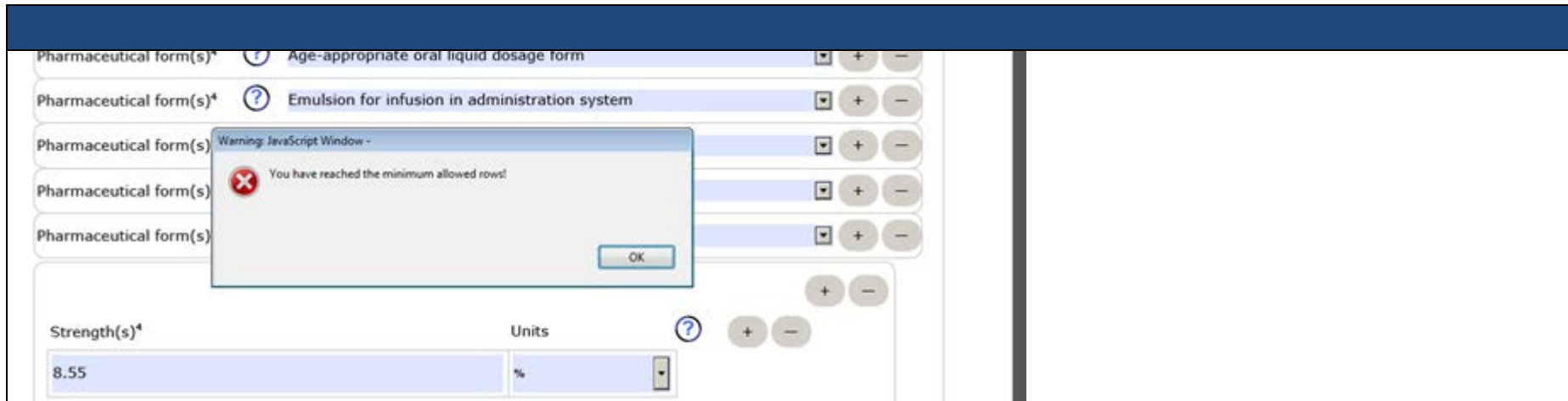
In Veterinary maa form code enhancement so as to make the particular fields mandatory / no-mandatory.

Pharmaceutical form(s)	Bee smoke stick	+	-
	Bee-hive solution	+	-
	Ear wash, solution	+	-
	Film-coated tablet + pessary	+	-
	Lyophilisate for solution for injection	+	-
	Bee smoke paper	+	-
	Intramammary suspension	+	-



**10. EAF-3204 Incorrect validation message appearing on clicking "Click here to populate data in section 3"**

A standard deletion method of instances is used in all forms, especially in the [-] buttons, where it first asks for confirmation from the user to delete the field. In Renewal form in this particular section/action confirmation is not needed as it is an automated process.





**11. EAF-3205 Data not copied appropriately from section 1 to section 3 in renewal form**

In Renewal form, code enhancements to make relevant fields (Quantity/unit) mandatory.

Name of active substance	Quantity / Unit	Reference / Monograph Standard	
BSINTHIUM D2	<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"/>	<input type="button" value="+"/> <input type="button" value="-"/> <input type="button" value="Clone"/>
CACIA, SPRAY-DRIED	<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"/>	<input type="button" value="+"/> <input type="button" value="-"/> <input type="button" value="Clone"/>
ABCOAT TC-WHITE	<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"/>	<input type="button" value="+"/> <input type="button" value="-"/> <input type="button" value="Clone"/>

**12. EAF-3207 Maximum character limit exceeded in Declaration and Signature section**

Maximum character limit has been removed from tooltip in "Please specify fee category under National rules" and "Status (Job Title)".

Status (Job Title)	<p>EngineerTest EngineerTest EngineerTest EngineerTest            EngineerTest EngineerTest EngineerTest EngineerTest            EngineerTest EngineerTest EngineerTest EngineerTest            EngineerTest EngineerTest EngineerTest EngineerTest            EngineerTest EngineerTest EngineerTest EngineerTest            EngineerTest EngineerTest EngineerTest EngineerTest</p> <div data-bbox="622 1107 1003 1145" style="border: 1px solid black; padding: 2px;">             Click to add job function of the authorised contact (Max. 50 characters).           </div>
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**13. EAF-3208 Unexpected behaviour for Variation procedure number(s) when multiple fields added by clicking (+) button**

In Variation form code enhancements so as the Procedure Numbers validation respect the Authorisation selection.

The screenshot shows a form titled "Variation procedure number(s)" with a help icon. Below the title are three input fields. The first field is empty and has a light blue background. The second and third fields are highlighted with a yellow border and contain a grey background, indicating they are active or selected. Each field has a "+" button on the left and a "-" button on the right.

**14. EAF-3209 Unexpected behaviour when copy data from section 1 to section 3**

In Renewal form when clicking the "Populate data in section 3 " button, all pharmaceutical forms of section 3 are being deleted before new data being copied.

The screenshot shows a form section titled "3. QUALITATIVE AND QUANTITATIVE COMPOSITION IN TERMS OF THE ACTIVE SUBSTANCE(S) AND THE EXCIPIENT(S)". Below the title is a note: "(For centrally authorised products the composition should be provided separately in tabular format as part of the Quality Expert Statement.)". A text area contains the instruction: "A note should be given as to which quantity the composition refers (e.g. 1 capsule)". Below this are three rows of data, each with a dropdown menu for the pharmaceutical form, a text input for the quantity, and a dropdown menu for the unit. The first row is "Pharmaceutical Form: Age-appropriate dosage form, other" with quantity "0.01" and unit "%". The second row is "Pharmaceutical Form: Bee-hive gel" with quantity "0.022" and unit "% (w/w)". The third row is "Pharmaceutical Form: Capsule, hard" with quantity "0.33" and unit "% (w/v)". Each row has a "+" button on the left and a "-" button on the right.

**15. SD-293082 Problem with Application Form for Renewal**

In Renewal form the shortened procedure reason and shortened renewal checkbox in section 4 are visible/hidden based on section 1 selections, even after reopening the form.

Product subject to shortened renewal <input checked="" type="checkbox"/>	
Shortened Procedure Reason	