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_humana_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 addind 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
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. |

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”

<table>
<thead>
<tr>
<th>TEST</th>
<th>TEST</th>
<th>TEST</th>
<th>TEST</th>
<th>TEST</th>
<th>a Text continues to next page without being hidden.</th>
</tr>
</thead>
</table>

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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 hardcoded values have been removed and a proper web service has been used (getEEACountries has been removed and getEuAndFreeTradeCountries have been used instead).

<table>
<thead>
<tr>
<th>Country</th>
<th>Slovenia</th>
<th>Spain</th>
<th>Sweden</th>
<th>Switzerland</th>
<th>United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Telephone</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E-mail</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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.

![Table showing pharmaceutical forms](image1)

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.

![Table showing pharmaceutical forms and species](image2)
8. EAF-3200  In Declaration section, On behalf of the applicant, Function -> Tooltip value limit is 50 characters however more than 50 characters can be entered

In Human and Veterinary maa forms maximum characters description removed from tooltip

9. EAF-3201  Copy details from section 2.4.1 is not working as expected

In veterinary maa form we updated the copy functionality so as to make the copy in respect of the instance it belongs to.
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.

<table>
<thead>
<tr>
<th>Name of active substance</th>
<th>Quantity / Unit</th>
<th>Reference / Monograph Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>BSINTHIUM D2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CACIA, SPRAY-DRIED</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABCOAT TC-WHITE</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

For numeric values, please use the full stop as the decimal separator, i.e., 0.002, rather than 0.002

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)."
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.

![Variation procedure number(s)](image)

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.
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.

<table>
<thead>
<tr>
<th>Product subject to shortened renewal</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Shortened Procedure Reason</td>
<td></td>
</tr>
</tbody>
</table>