



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

15<sup>th</sup> December 2017

Information Technology  
EMA/830627/2017

## eAF Release Notes – Before and after screenshots

This document is to accompany the eAF v1.22 release notes and intended on visually illustrating the differences between eAF **v1.21** and **v1.22** by using before and after screenshots. This list only contains changes where there is a clear visual difference between the old and new version; for a complete list of all changes refer to the release notes.

## eAF 1.21

## eAF 1.22

SD-65517 – eAF-OMS integration of organisation/address fields in all 4 forms.

Release scope for the 1.22.0.0



### Summary of OMS integration change (SD-65517):

Address fields in the below sections have been amended in line with OMS data in each form.

#### Human Form

Declaration Section  
Declaration Section (on behalf of Applicant)  
Section 2.2.4.1  
Section 2.4.1 Address  
Section 2.4.1 - Proof of payment  
Section 2.4.2  
Section 2.4.3  
Section 2.4.4  
Section 2.4.4 (Pharmacovigilance)  
Section 2.4.5  
Section 2.5.1.a Admin & Manufacturer  
Section 2.5.1.b  
Section 2.5.1.1  
Section 2.5.1.2  
Section 2.5.2 Admin & Manufacturer  
Section 2.5.3 Admin & Manufacturer  
Section 2.5.4

#### Veterinary Form

Declaration Section  
Declaration Section (on behalf of Applicant)  
Section 2.4.1  
Section 2.4.1 - Proof of payment  
Section 2.4.2  
November 2017 - eAF UAT closure meeting

Section 2.4.3

Section 2.4.4

Section 2.4.4 (Pharmacovigilance)

Section 2.4.5

Section 2.5.1.a Admin & Manufacturer

Section 2.5.1.b

Section 2.5.1.1

Section 2.5.1.2

Section 2.5.2 Admin & Manufacturer

Section 2.5.3 Admin & Manufacturer

Section 2.5.4

#### Renewal Form

Declaration Section  
Section 1 – Address of MA holder  
Section 1 – Name of contact Person  
Section 2 – Batch Control Testing Admin & Manufacturer  
Section 2 – Medicinal Product Admin & Manufacturer  
Section 2 – Active Substance Section 2 – Batch Release  
Section 2 – Batch Release Admin & Manufacturer  
Section 2 – For blood Products Admin & Manufacturer

#### Variation form

Section 1 – Name of contact Person  
Section 1 – Address of MA holder  
Signature section - Payment - Address

<p>Applicant [redacted]  Title [redacted]  First Name [redacted]  Surname [redacted]  Address 1 [redacted]  Address 2 [redacted]  <small>(name of: city, town, village, etc)</small>  Postcode [redacted]  Country [redacted] ▾  Telephone [redacted]  Telefax [redacted]  E-mail [redacted]</p>	<p>Applicant [redacted]  Title [redacted]  First Name [redacted]  Surname [redacted]</p> <div style="border: 2px solid red; padding: 5px;"> <p><i>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: <a href="http://spor.ema.europa.eu/omswi/#/">http://spor.ema.europa.eu/omswi/#/</a></i></p> <p style="text-align: right;">Find Address</p> <p style="text-align: right;">Clear Address</p> </div> <p>Address  Address 1 [redacted]  [redacted]  [redacted]  [redacted]  City/Locality/Town/Village [redacted]  State [redacted]  County [redacted]  Postcode [redacted]  Country [redacted] ▾  Telephone [redacted]  Telefax [redacted]  E-mail [redacted]</p>
<b>HUMAN FORM</b>	
	<b>SD-81544 – In section 2.5.3 - Active substance – a new free text field has been added to describe “company role” (intentionally does not include Label)</b>

<p>2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture  <i>Note: All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant. For each site provide the relevant information.</i></p> <p>(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Active Substance</p> <div style="border: 1px solid #ccc; height: 40px; margin: 5px 0;"></div> <p style="text-align: right;">Select</p> </div> <p style="text-align: right;">Copy contact details from Declaration Section Copy contact details from 2.5.1.a</p> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p>	<p>2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture  <i>Note: All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control/ in-process testing sites, should be listed. Broker or supplier details alone are not acceptable. For biotech products include all sites of storage of master and working cell bank and preparation of working cell banks when relevant. For each site provide the relevant information.</i></p> <p>(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p>Active Substance</p> <div style="border: 1px solid #ccc; height: 40px; margin: 5px 0;"></div> <p style="text-align: right;">Select</p> </div> <p style="text-align: right;">Copy contact details from Declaration Section Copy contact details from 2.5.1.a</p> <div style="border: 2px solid red; width: 100%; height: 15px; margin-top: 5px;"></div> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p>
<p><b>SD-115249 – In section 1.3 – “Yes” radio button formatting issue has been resolved</b></p>	
<p>1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?</p> <p><input checked="" type="radio"/> Yes (complete sections below and also complete 1.4 + 1.6) <input type="radio"/> No (complete section 1.4 + 1.6)</p> <p>1.3.1 <input type="radio"/> Please specify:</p> <p>1.3.2 <input checked="" type="radio"/> « Article 29 application » (Article 29 of Regulation (EC) No 1901/2006)</p>	<p>1.3 APPLICATION FOR A CHANGE TO EXISTING MARKETING AUTHORISATION LEADING TO AN EXTENSION AS REFERRED TO IN ANNEX I OF REGULATIONS (EC) NO 1234/2008, OR ANY NATIONAL LEGISLATION, WHERE APPLICABLE?</p> <p><input checked="" type="radio"/> Yes (complete sections below and also complete 1.4 + 1.6) <input type="radio"/> No (complete section 1.4 + 1.6)</p> <p>1.3.1 <input type="radio"/> Please specify:</p>
<p><b>EAF-2764 - The 'Update Lists' Button's tooltip needs to be updated (applies to Human, Vet &amp; Renewals)</b></p>	
<p><b>Update lists</b></p> <p>Click to import a XML file.</p>	<p><b>Update lists</b></p> <p>Click to update/reload the control lists.</p>
<p><b>EAF-2767 – In Section 2.6.1 – tooltip should be amended in units field to in line "Pharmaceutical form" - Units field (applies to Human, Vet &amp; Renewals)</b></p>	
<p>Click the arrow button to select unit of measurement for the active substance.</p>	<p>Click the arrow button to select unit of measurement for the Pharmaceutical form.</p>
<p><b>VETERINARY FORM</b></p>	
<p><b>SD-105001 – Section 4.1.1 - 'not applicable' radio button has been removed</b></p>	

<p>4.1.1 Is there another Member State(s) where an application for the same* product is pending**?</p> <p>If yes, section 4.2 must be completed</p> <p> <input type="radio"/> Yes         <input type="radio"/> No         <input checked="" type="radio"/> Not Applicable       </p>	<p>4.1.1 Is there another Member State(s) where an application for the same* product is pending**?</p> <p>If yes, section 4.2 must be completed</p> <p> <input type="radio"/> Yes         <input type="radio"/> No       </p>
<p><b>SD-106023 In section 1.4 redesigned MRL:</b></p>	
<p>Application for a Maximum Residue Limit has been made to the EMA <input type="radio"/> Yes <input type="radio"/> Not applicable</p>	<p>Application for a Maximum Residue Limit has been made to the EMA</p> <p> <input type="checkbox"/> Yes  <input type="checkbox"/> Not applicable       </p> <p><i><sup>1</sup>All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.</i></p>

	<p>Application for a Maximum Residue Limit has been made to the EMA</p> <p><input checked="" type="checkbox"/> Yes</p> <div data-bbox="1115 268 2040 735"> <p>substance(s) + -</p> <p>MELOXICAM +</p> <p>MELOXICAM Select -</p> <p>Date of Submission</p> <p>Species + -</p> <p>Remarks</p> </div> <p><input checked="" type="checkbox"/> Not applicable</p> <div data-bbox="1115 783 2040 1034"> <p>substance(s) + -</p> <p>MELOXICAM + -</p> <p>Species + -</p> <p>Remarks</p> </div>
	<p><b>SD-124640 – NTA changes have been implemented:</b></p> <p><b>Section 1.1.4 “If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birth-date, please specify” text field has been implemented</b></p>

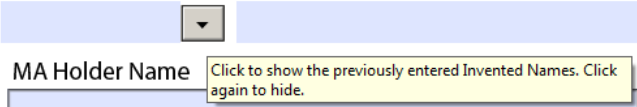
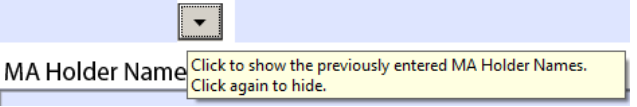
<input checked="" type="radio"/> 1.1.4 A NATIONAL PROCEDURE  Member state <input type="text"/> Application number <input type="text"/>	<input checked="" type="radio"/> 1.1.4 A NATIONAL PROCEDURE  Member state <input type="text"/> Application number <input type="text"/> <div style="border: 2px solid red; padding: 5px;"> If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify   <input type="text"/> </div>
	Section 1.5.4 “Article 77 (5) of Directive 2001/82/EC and Article 49 (3) of Regulation (EC) No 726/2004 (other requirements for the PSUR submission cycle”. The new Check box has been implemented
<b>1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004</b>  1.5.1 <input type="checkbox"/> Exceptional Circumstances Note: according to Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) No 726/2004  1.5.2 <input type="checkbox"/> Accelerated Review Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)  1.5.3 <input type="checkbox"/> Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for each extension to another food-producing species within five years of the initial authorisation)	<b>1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004</b>  1.5.1 <input type="checkbox"/> Exceptional Circumstances Note: according to Article 26(3) of Directive 2001/82/EC and Article 39(7) of Regulation (EC) No 726/2004  1.5.2 <input type="checkbox"/> Accelerated Review Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)  1.5.3 <input type="checkbox"/> Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for each extension to another food-producing species within five years of the initial authorisation)  <div style="border: 2px solid red; padding: 5px;"> 1.5.4 <input type="checkbox"/> Article 77 (5) of Directive 2001/82/EC and Article 49 (3) of Regulation (EC) No 726/2004 (other requirements for the PSUR submission cycle)  Please attach justification for requesting deviation from the ‘standard’ PSUR cycle as stated in legislation.” (Annex 5.24) </div>
	Section 4.1 – Label has been amended as “FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12 (N) OF DIRECTIVE 2001/82/EC.
<b>4.1 FOR NATIONAL APPLICATIONS ONLY, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(N) OF DIRECTIVE 2001/82/EC</b>	<b>4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(N) OF DIRECTIVE 2001/82/EC:</b>
	Section 4.3 “Multiple applications submitted simultaneously or subsequently to the initial application/MA for”. New radio buttons have been implemented

<p><b>4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT</b></p> <p>Multiple applications (submitted simultaneously or subsequent to the original product) for:</p>	<p><b>4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT</b></p> <p>Multiple applications <span style="border: 1px solid red; padding: 2px;">submitted Simultaneously <input type="checkbox"/> or Subsequently <input type="checkbox"/> to the initial application/MA for:</span></p>
	<p><b>Section 5.24 “Justification for requesting deviation from the ‘standard’ PSUR cycle as stated in legislation”. New annex 5.24 check box has been implemented</b></p>
	<p><input type="checkbox"/> 5.24 Justification for requesting deviation from the ‘standard’ PSUR cycle as stated in legislation.</p>
<p><b>END OF NTA Changes</b></p>	
<p><b>RENEWAL FORM</b></p>	
	<p><b>SD-105185 – In Section 2 – batch control/testing site - New free text field has been added. (intentionally does not include Label)</b></p>
<p>Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where <b>batch control/testing</b> takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: right;">+ -</p> <p style="text-align: center; background-color: #f0f0f0; border-radius: 5px;">Copy address details from 'batch release'</p> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p> </div>	<p>Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where <b>batch control/testing</b> takes place, as required by Article 51 of Directive 2001/83/EC as amended or Article 55 of Directive 2001/82/EC, if different from above</p> <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: right;">+ -</p> <p style="text-align: center; background-color: #f0f0f0; border-radius: 5px;">Copy address details from 'batch release'</p> <div style="border: 1px solid red; height: 15px; margin-bottom: 5px;"></div> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p> </div>
	<p><b>SD-105187 – In Section 2 – Active substance manufacturer - New free text field has been added. (intentionally does not include Label)</b></p>
<p>Manufacturer(s) of the <b>active substance(s)</b>  <i>Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient</i>  <i>(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).</i></p> <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: right;">+ -</p> <p style="text-align: center; background-color: #f0f0f0; border-radius: 5px;">Copy address details from 'batch release'</p> <p>Active Substance <span style="float: right;">+ -</span></p> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> <span style="background-color: #f0f0f0; display: inline-block; width: 100%; height: 15px;"></span> </div> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p> </div>	<p>Manufacturer(s) of the <b>active substance(s)</b>  <i>Note: All manufacturing sites involved in the manufacturing process of each source of active substance should be listed. Broker or supplier details alone are not sufficient</i>  <i>(The values of the active substances field has been populated from "Declaration" section, hence no search button available. Please click the drop down button to see the list).</i></p> <div style="border: 1px solid #ccc; padding: 5px;"> <p style="text-align: right;">+ -</p> <p style="text-align: center; background-color: #f0f0f0; border-radius: 5px;">Copy address details from 'batch release'</p> <p>Active Substance <span style="float: right;">+ -</span></p> <div style="border: 1px solid #ccc; padding: 2px; margin-bottom: 5px;"> <span style="background-color: #f0f0f0; display: inline-block; width: 100%; height: 15px;"></span> </div> <div style="border: 1px solid red; height: 15px; margin-bottom: 5px;"></div> <p>Do you have a separate admin and manufacturer address? <input type="radio"/> Yes <input type="radio"/> No</p> </div>
	<p><b>SD-105670 - In Section 1 - “If no ATC code has been assigned, please indicate</b></p>



<div style="border: 1px solid #ccc; padding: 5px;"> <div style="text-align: right;">+ -</div> <p>ATC code <input type="text"/></p> <p>Group <input type="text"/></p> <p><input type="checkbox"/> If no ATC code has been assigned, please indicate if an application for ATC code has been made</p> </div>	<div style="border: 1px solid #ccc; padding: 5px;"> <div style="text-align: right;">+ -</div> <p>ATC code <input type="text"/></p> <p>Group <input type="text"/></p> </div>
	<p><b>SD-125823 – In section 1 - When “National authorisation in MRP/DCP” or “National authorisation only” is selected – “Product subject to shortened renewal” check box will be visible in section 4. If checkbox is selected then “Shortened Procedure Reason” free text field will be visible and mandatory</b></p>
<p><b>4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY</b></p> <p><b>Module 1</b></p> <p><input type="checkbox"/> 1.0 Cover letter</p>	<p><b>4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY</b></p> <div style="border: 2px solid red; padding: 5px;"> <p>Product subject to shortened renewal <input checked="" type="checkbox"/></p> <p>Shortened Procedure Reason <input type="text"/></p> </div> <p><b>Module 1</b></p> <p><input type="checkbox"/> 1.0 Cover letter</p>
<b>VARIATION FORMS</b>	
<b>EAF-2771 - Section 1 - when “TypeIB unforseen”</b>	

<p>Type of Application (tick all applicable options)</p> <ul style="list-style-type: none"> <li><input type="radio"/> Single variation</li> <li><input type="radio"/> Grouping of variations</li> <li><input checked="" type="radio"/> Worksharing</li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> Type IA<sub>IN</sub></li> <li><input type="checkbox"/> Type IA</li> <li><input checked="" type="checkbox"/> Type IB unforeseen<sup>2</sup> <span>?</span></li> <li><input type="checkbox"/> Type IB</li> <li><input type="checkbox"/> Type II</li> <li><input type="checkbox"/> Type II Art. 29<sup>4</sup> <span>?</span></li> </ul> <p>Name and address of the Applicant/MA Holder<sup>5</sup> <span>?</span></p> <p>Member State <span>+</span> <span>-</span></p>	<p>Type of Application (tick all applicable options)</p> <ul style="list-style-type: none"> <li><input type="radio"/> Single variation</li> <li><input type="radio"/> Grouping of variations</li> <li><input checked="" type="radio"/> Worksharing</li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> Type IA<sub>IN</sub></li> <li><input type="checkbox"/> Type IA</li> <li><input checked="" type="checkbox"/> Type IB unforeseen<sup>2</sup> <span>?</span></li> <li><input type="checkbox"/> Type IB</li> <li><input type="checkbox"/> Type II</li> <li><input type="checkbox"/> Type II Art. 29<sup>4</sup> <span>?</span></li> </ul> <div style="border: 2px solid red; padding: 5px;"> <p>Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Indication</li> <li><input type="checkbox"/> Paediatric requirements</li> <li><input type="checkbox"/> Safety</li> <li><input type="checkbox"/> Quality</li> <li><input type="checkbox"/> Annual variation for human influenza vaccines</li> <li><input type="checkbox"/> Non-food producing target species</li> <li><input type="checkbox"/> Other</li> </ul> </div>												
<p><b>2. PRODUCTS CONCERNED BY THIS APPLICATION<sup>7</sup></b> <span>?</span></p> <div style="border: 2px solid red; padding: 2px;"> <input type="checkbox"/> Form and Strength information is provided in footnote     </div>	<p><b>EAF-2772 - Section 2 - "Form and Strength information is provided in footnote"</b></p> <p>2. PRODUCTS CONCERNED BY THIS APPLICATION<sup>7</sup> <span>?</span></p> <p>Active Substance <span>+</span> <span>-</span></p> <table border="1"> <thead> <tr> <th>MA Number(s)<sup>8</sup> <span>?</span></th> <th>Invented Name</th> <th>MA Holder Name</th> <th>Pharmaceutical Form</th> <th>Strength</th> <th>Unit</th> </tr> </thead> <tbody> <tr> <td><span>+</span> <span>-</span></td> <td><span>+</span> <span>-</span></td> <td><span>+</span> <span>-</span></td> <td><span>+</span> <span>-</span></td> <td><span>+</span> <span>-</span></td> <td><span>+</span> <span>-</span></td> </tr> </tbody> </table> <p><input checked="" type="checkbox"/> Form and Strength information is provided in footnote.</p>	MA Number(s) <sup>8</sup> <span>?</span>	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>
MA Number(s) <sup>8</sup> <span>?</span>	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit								
<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>	<span>+</span> <span>-</span>								
<p>Concerned Member State(s)</p> <p>Add All Remove All</p> <p>Austria <span>+</span> <span>-</span></p> <p>Austria <span>+</span> <span>-</span></p> <p>Austria <span>+</span> <span>-</span></p>	<p><b>EAF-2774 - Section 1 - When selecting "Concerned member State(s)"</b></p> <p>Concerned Member State(s)</p> <p>Add All Remove All</p> <p>Austria <span>+</span> <span>-</span></p> <p>Austria <span>+</span> <span>-</span></p> <div style="border: 1px solid gray; padding: 5px; width: fit-content;"> <p>Warning: JavaScript Window - Error</p> <p> Please select different member state from above</p> <p style="text-align: right;">OK</p> </div>												

	EAF-2775 - Section 2 - The pop-up message for the MA Holder name is the same as the one for the Invented names
<p><b>MA Holder Name    Pharmaceutical Form</b></p> 	<p><b>MA Holder Name    Pharmaceutical Form</b></p> 
<p><b>EAF-2777 - Section 3 - In the Present/Proposed table width differs</b></p> 