EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15th 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

EUROPEAN MEDICINES AGENCY

Summary of OMS integration change (SD-65517):

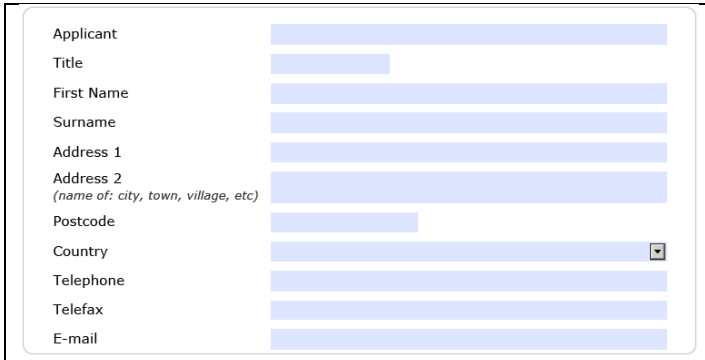
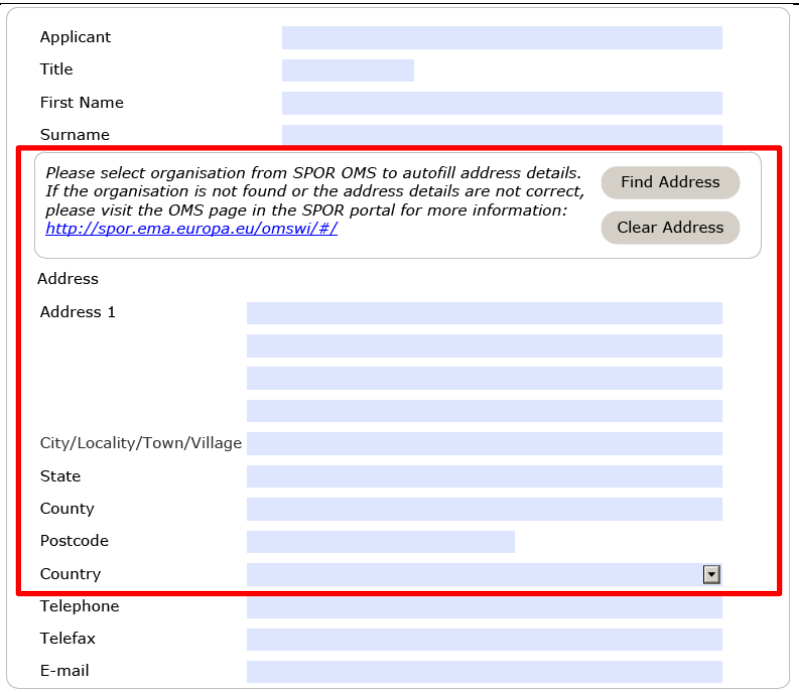
Address fields in the below sections have been amended in line with OMS data in each form.

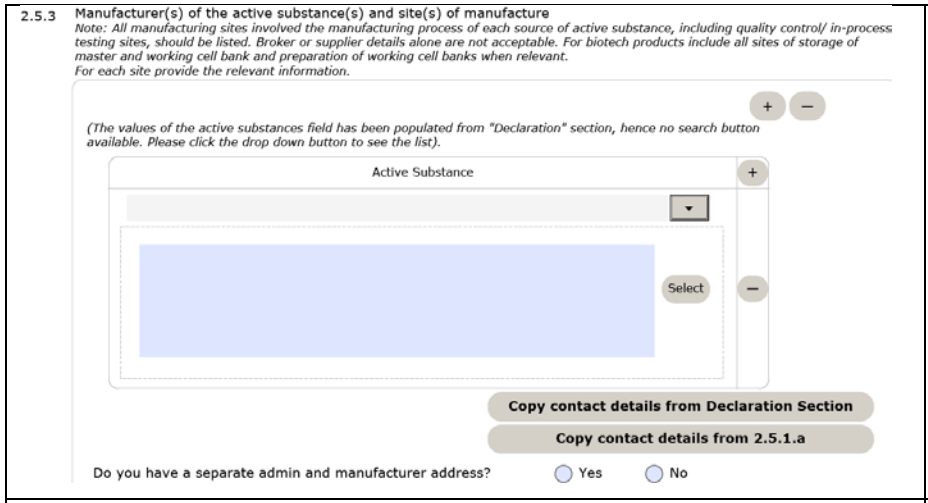
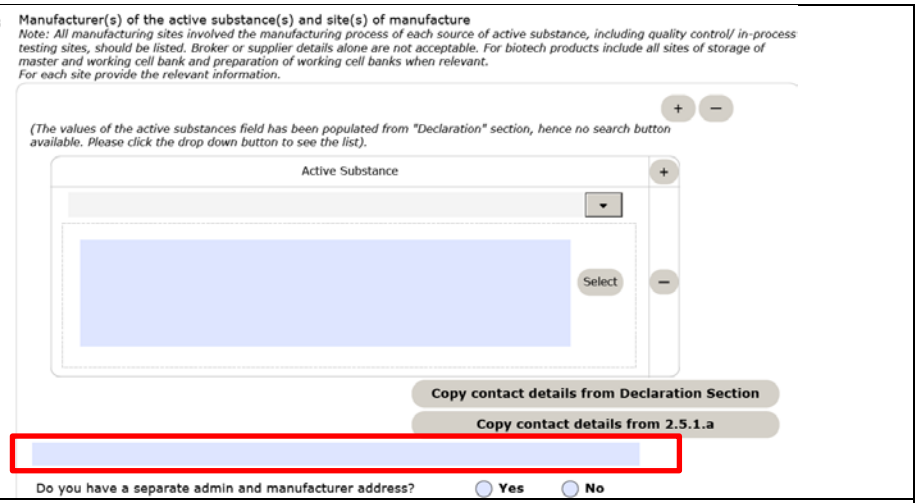
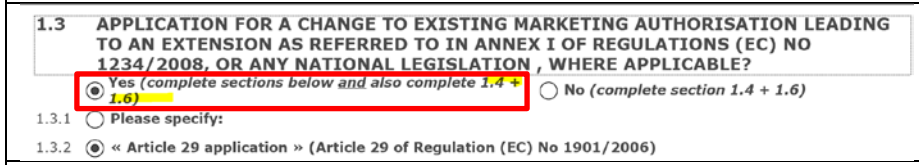
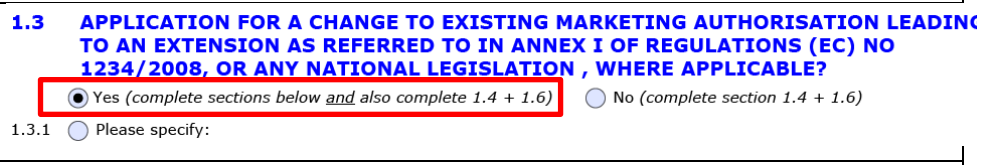
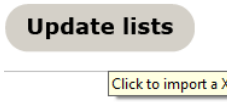
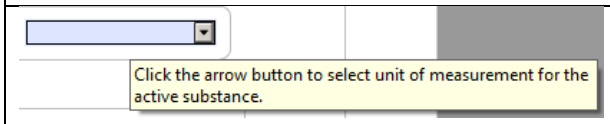
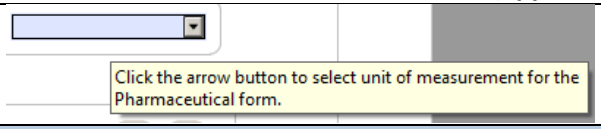
Human Form
Declaration Section
Declaration Section (on behalf of Applicant)
Section 2.2.4.1
Section 2.4.1 Address
Section 2.4.1 - Proof of payment
Section 2.4.2
Section 2.4.3
Section 2.4.4
Section 2.4.4 (Pharmacovigilance)
Section 2.4.5
Section 2.5.1.a Admin & Manufacturer
Section 2.5.1.b
Section 2.5.1.1
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
Section 2.4.3
Section 2.4.4
Section 2.4.4 (Pharmacovogilance)
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

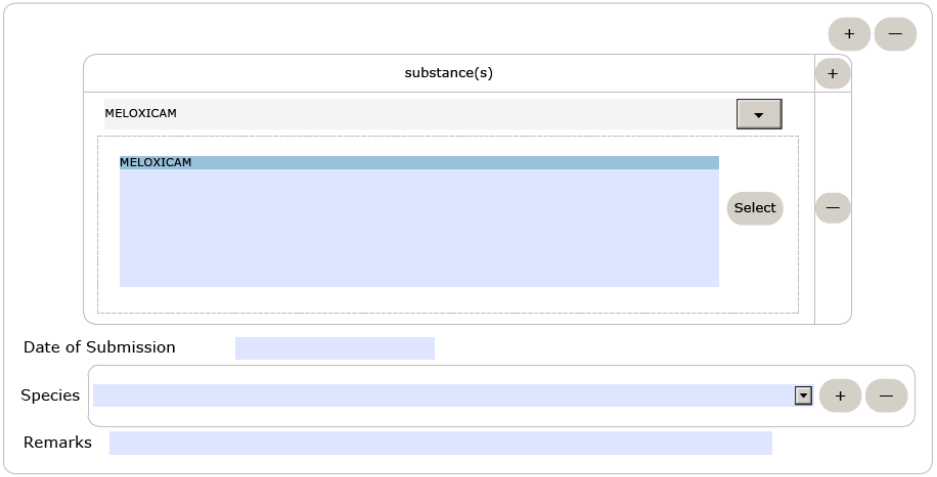
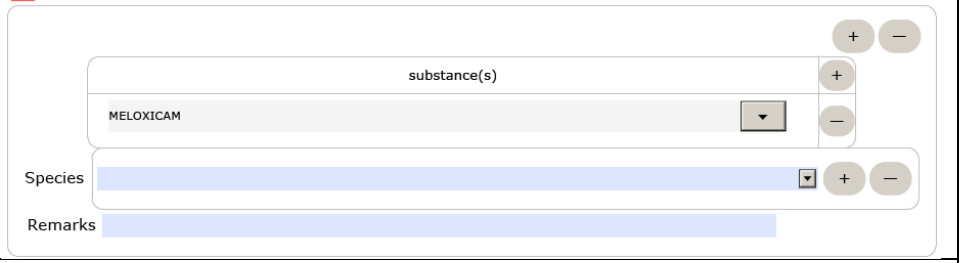
Renewal Form
Declaration Section
Section 1 – Address of MA holder
Section 1 – Name of contact Person
Section 2 – Batch Control Testing Admin & Manufacturer
Section 2 – Medicinal Product Admin & Manufacturer
Section 2 – Active Substance Section 2 – Batch Release
Section 2 – Batch Release Admin & Manufacturer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

	
HUMAN FORM	
	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)

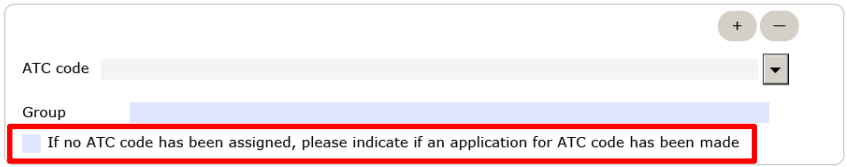
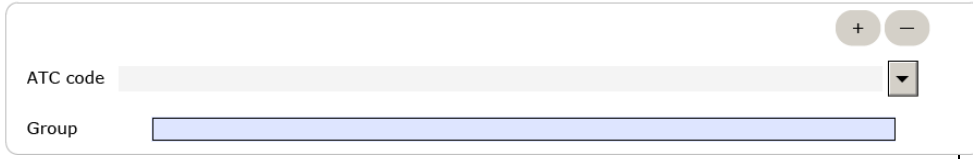
	
	SD-115249 – In section 1.3 – "Yes" radio button formatting issue has been resolved
	
	EAF-2764 - The 'Update Lists' Button's tooltip needs to be updated (applies to Human, Vet & Renewals)
	
	EAF-2767 – In Section 2.6.1 – tooltip should be amended in units field to in line "Pharmaceutical form" - Units field (applies to Human, Vet & Renewals)
	
VETERINARY FORM	
	SD-105001 – Section 4.1.1 - 'not applicable' radio button has been removed

4.1.1 Is there another Member State(s) where an application for the same* product is pending**? If yes, section 4.2 must be completed ○ Yes ○ No ○ Not Applicable	4.1.1 Is there another Member State(s) where an application for the same* product is pending**? If yes, section 4.2 must be completed ○ Yes ○ No
	SD-106023 In section 1.4 redesigned MRL:
Application for a Maximum Residue Limit has been made to the EMA ○ Yes ○ Not applicable	Application for a Maximum Residue Limit has been made to the EMA ☐ Yes ☐ Not applicable [1]*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.*

	Application for a Maximum Residue Limit has been made to the EMA ☒ Yes  ☒ Not applicable 
	SD-124640 – NTA changes have been implemented: **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**

1.1.4 A NATIONAL PROCEDURE Member state Application number	1.1.4 A NATIONAL PROCEDURE Member state Application number If a waiver or amendment of PSUR-cycle is applied for, to harmonise with a substance birthdate, please specify
	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
1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004 1.5.1 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 Accelerated Review *Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)* 1.5.3 Article 13(5) of Directive 2001/82/EC (one year of data exclusivity for each extension to another food-producin species within five years of the initial authorisation)	**1.5 CONSIDERATION OF THIS APPLICATION IS ALSO REQUESTED UNDER THE FOLLOWING ARTICLE IN DIRECTIVE 2001/82/EC OR REGULATION (EC) No 726/2004** 1.5.1 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 Accelerated Review *Note: centralised procedure only according to Regulation (EC) No 726/2004 Article 39(8)* 1.5.3 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) 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) Please attach justification for requesting deviation from the `standard' PSUR cycle as stated in legislation." (Annex 5.24)
	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.
4.1 FOR NATIONAL APPLICATIONS ONLY, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(N) OF DIRECTIVE 2001/82/EC	**4.1 FOR NATIONAL/MRP/DCP APPLICATIONS, PLEASE COMPLETE THE FOLLOWING IN ACCORDANCE WITH ARTICLE 12(N) OF DIRECTIVE 2001/82/EC:**
	Section 4.3 "Multiple applications submitted simultaneously or subsequently to the initial application/MA for". New radio buttons have been implemented

4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT Multiple applications (submitted simultaneously or subsequent to the original product) for:	**4.3 FOR MULTIPLE APPLICATIONS OF THE SAME VETERINARY MEDICINAL PRODUCT** Multiple applications submitted Simultaneously or Subsequently to the initial application/MA for:
	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
	☐ 5.24 Justification for requesting deviation from the `standard' PSUR cycle as stated in legislation.
	END OF NTA Changes
RENEWAL FORM	
	SD-105185 – In Section 2 – batch control/testing site - New free text field has been added. (intentionally does not include Label)
Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where **batch control/testing** 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 + – **Copy address details from 'batch release'** Do you have a separate admin and manufacturer address? ◯ Yes ◯ No	Site(s) in EEA or in countries where an MRA or other EU arrangements apply, where **batch control/testing** 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 + – **Copy address details from 'batch release'** Do you have a separate admin and manufacturer address? ◯ **Yes** ◯ **No**
	SD-105187 – In Section 2 – Active substance manufacturer - New free text field has been added. (intentionally does not include Label)
Manufacturer(s) of the **active substance(s)** *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* *(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).* + – **Copy address details from 'batch release'** Active Substance + – Do you have a separate admin and manufacturer address? ◯ Yes ◯ No	Manufacturer(s) of the **active substance(s)** *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* *(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).* + – **Copy address details from 'batch release'** Active Substance + – Do you have a separate admin and manufacturer address? ◯ **Yes** ◯ **No**
	SD-105670 - In Section 1 - "If no ATC code has been assigned, please indicate

	if an application for ATC code has been made" field has been removed
	
	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
4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY **Module 1** 1.0 Cover letter	**4. DOCUMENTS APPENDED TO THIS APPLICATION - FOR HUMAN MEDICINAL PRODUCTS ONLY** Product subject to shortened renewal ☒ Shortened Procedure Reason **Module 1** 1.0 Cover letter
VARIATION FORMS	
	EAF-2771 - Section 1 - when "TypeIB unforsceen"

Type of Application (tick all applicable options)

- Single variation
- Grouping of variations
- Worksharing
- Type IA_{IN}
- Type IA
- Type IB unforeseen[2]
- Type IB
- Type II
- Type II Art. 29[4]

Name and address of the Applicant/MA Holder[5]

Member State

Type of Application (tick all applicable options)

- Single variation
- Grouping of variations
- Worksharing
- Type IA_{IN}
- Type IA
- Type IB unforeseen[2]
- Type IB
- Type II
- Type II Art. 29[4]

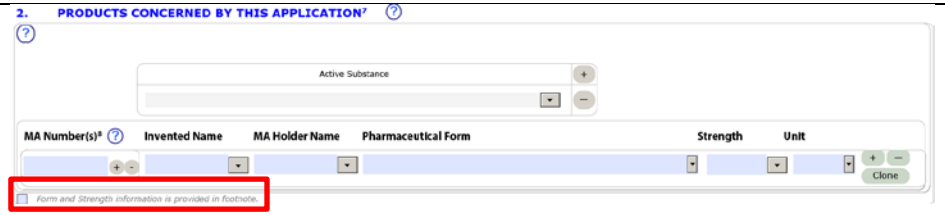
Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)

- Indication
- Paediatric requirements
- Safety
- Quality
- Annual variation for human influenza vaccines
- Non-food producing target species
- Other

EAF-2772 - Section 2 - "Form and Strength information is provided in footnote"

2. PRODUCTS CONCERNED BY THIS APPLICATION[7]

Form and Strength information is provided in footnote



EAF-2774 - Section 1 - When selecting "Concerned member State(s)"

Concerned Member State(s)

Add All | Remove All

Austria

Austria

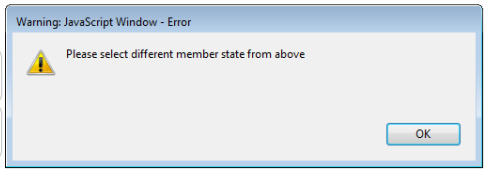
Austria

Concerned Member State(s)

Add All | Remove All

Austria

Austria



	EAF-2775 - Section 2 - The pop-up message for the MA Holder name is the same as the one for the Invented names
MA Holder Name **Pharmaceutical Form** MA Holder Name Click to show the previously entered Invented Names. Click again to hide.	**MA Holder Name** **Pharmaceutical Form** MA Holder Name Click to show the previously entered MA Holder Names. Click again to hide.
	EAF-2777 - Section 3 - In the Present/Proposed table width differs