EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Technology
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eAF Release Notes

This document lists and briefly describes the new features and fixed issues included in the release of the electronic application form: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information*.

The most recent release appears first.

Table of Contents

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Version 1.23.1.0 (Release Date: 28/09/2018)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for*: Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1.2: Administrative information, February 2018, Revision 13.*	This release note 1.23.1.0 is for high priority bug fixes. (No change requests are included)

Issues fixed for this version

Id	Description	Comments
EAF-2785	Section 2.5.3 - copy contact button details not copied to second section instead replacing first part.	In the MAA Human & MAA Vet forms – In sections 2.5.2 and 2.5.3; when pressing the button “copy contact details from 2.5.1.a” – if there are multiple sections\addresses present they shall all now be correctly copied into the respective sections.
EAF-2786	Section 4.2 - “Procedure number for MRP/DCP (if applicable)” caused validation errors however it says “if applicable”.	In the MAA Human & MAA Vet forms – In sections 4.2; when the user selects the checkbox “Withdrawn (by applicant before authorisation)” The “Procedure number for MRP/DCP” has now been corrected to be an optional field rather than a mandatory field.
EAF-2814	Initial maa eaf form bug - section 4.1.3/4.2.	In the MAA Human form – In sections 4.1.3; If the user selects “Yes” to “Is there another Member State(s) where an authorisation was refused/suspended/revoked by competent authorities for the same product” and then enters any combination of values in section 4.2 (Authorised\Submitted\Refused\Withdrawn (by applicant before authorisation)\Withdrawn (by applicant after authorisation)\Suspended/revoked). The selection shall be retained after saving, closing and reopening the form.
EAF-3003	XML Import Bug	This change is a minor change to the XML import process for correctly importing country codes – there is no visible change in the form.

Id	Description	Comments
SD-183493	UAT_eAF_1.23_Base/active Moiety mandatory	In the MAA Human & MAA Vet forms – In sections 2.6.1; If the active substance is a base without any salt or hydrate, there is no need to provide the base/active moiety again i.e. The base/active moiety fields (including the strength & unit fields) are now optional.
SD-184890	UAT_eAF_1.23_ 2.5.3 section MAA_H - ASMF EU number val error	In the MAA Human form – In sections 2.5.3; when the user selects “Yes” for "Is a Active Substance Master File to be used for the active substance(s)" The field “EU ASMF reference number if available” has been fixed so it is no longer mandatory.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields.	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the ‘symbols’ menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology.	Always ‘trust’ the form prior to importing xml from previous forms.

Version 1.23.0.0 (Release Date: 13/07/2018)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for*: Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1.2: Administrative information, February 2018, Revision 13.*	This release note is for the 1.23.0.0 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-145156	NTA changes for All 4 eAF forms.	All changes described in the NTA form specification have been implemented. Please refer to the user guide and Release Notes summary for detailed changes.
SD-159756	In section 2.5.1.b - Add Switzerland (CH) to drop-down countries list.	In section 2.5.1.b - Switzerland has been added to the drop-down country list.
SD-165173	In Section 4.1.2 when completing this section and saving\closing\reopening form. The contents of this section shall remain unchanged.	In Section 4.1.2 – Values are saved after reopen the form.
SD-182135	In All OMS address sections - “Org-modified date’ field is required only in xml and should not be visible in pdf.	This issue has now been resolved now by hide the field in the pdf.
SD-156002	In All Address section - format of the email address is not recognized and invalid if the name of the company is more than 9 characters.	Email address can be entered more than 9 characters of company name.
SD-184881	In section 1.6.1 note numbers are not aligned to the text.	In section 1.6.1 – Note numbers are aligned accordingly to NTA change.
SD-184876	In section 1.4 – “Note 1” is missing in the pdf.	In section 1.4 – “Note 1” has been added.
SD-186883	Remove\Hide OMS entry related fields from eAFs where no OMS data exists	In section 2.4.1 - payment section and 2.5.4 section - OMS address search is hidden, only manual entry is allowed in this section.

Id	Description	Comments
SD-182135	In all OMS address sections - “Org-modified date’ field is required only in xml and should not be visible in pdf.	In all OMS address sections – “Org-modified date” has been added to schema and this field is not visible in the pdf.
EAF-2933	Section 1.4.2 - "Copy data from above section" tooltip needs to be amended.	Section 1.4.2 - "Copy data from above section" tooltip has been amended.
EAF-2939	In section1.1.1 ,Overlapping of text with outline box after locking	In section 1.1. – Layout issue regarding the text overflowing outside its display area has been fixed.
EAF-2943	In section 2.6.1, one of dropdown of “Quantity/Unit” Highlights as yellow without any validation error in error section “validation error”.	In section 2.6.1 – The validation error has been fixed for Quantity/Units fields.
EAF-2944	In section 1.2 - Overlapping of text “Name of MA holder’ with textbox while validation.	In section 1.2 - “Name of MAH” field Layout issue has been fixed.
EAF-2984	In section 2.5.1 a - Space is missing between label “Manufacturing facility Telephone” and text box.	In section 2.5.1.a – “Manufacturing facility Telephone” layout issue has been resolved.

Known issues

Id	Description	Workaround/Comment
SD-183493	Base/active Moiety – Quantity/units fields should be optional.	For the Base/active Moiety field the associated Quantity/unit is mandatory when an entry is provided in this section, however currently the form validation returns an error when the Base/active Moiety is not provided, Users are advised to ignore this error.
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields.	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the ‘symbols’ menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.5 or previous version to latest version (1.23.0.0/1.21.0.1/1.22.0.0) additional digits are added to	Always ‘trust’ the form prior to importing xml from previous forms.

Id	Description	Workaround/Comment
	terms selected from controlled terminology.	

Version 1.22.0.1 (Release Date: 16/02/2018)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.22.0.1 hotfix release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
EAF-2812	Section 2.4.1 – proof of payment - LogID/OrgID missing in the within the pdf once saved and reopen.	In section 2.4.1 – Proof of payment - LogID/OrgID is visible after saved and reopen.
EAF-2811	Section 2.6 – “Clone” button - After export the XML from the EUTCT code is missing in substance and excipient sections.	In section 2.6 – when “Clone” button is clicked - EUTCT code is available in substance and excipient sections after export the XML.
EAF-2810	Empty Tag <rdm:org-modifiedDate> in eAF MAA should be removed.	Empty Tag <rdm:org-modifiedDate> in eAF MAA has been removed from schema.
EAF-2809	Missing timestamp in loc-modifiedDate when copy contact details button is clicked in Declaration section, section 2.4 and 2.5.	In sections Declaration, 2.4 and 2.5 – when copy contact details button is clicked – loc-modifiedDate timestamp is available.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the ‘symbols’ menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.

Version 1.22.0.0 (Release Date: 15/12/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.21.0.0 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-65517	eAF-OMS integration	All Address sections • Address fields has been amended to in line with OMS data. • OMS data can be searched now to fill address fields via search button. For all address fields users can now choose to either enter an OMS organisation thus auto populating address fields or they can choose to enter the address details manually.
SD-81544	Section 2.5.3 - Problem with filling intermediate manufacturer's role.	In section 2.5.3 - Active substance – a new free text field has been added to describe "company role". This intentionally does not include a label.
SD-124981	XSD - error - Section 1.1.2 - "Proposed/Agreed common renewal date" field type should be string and not date	Section 1.1.2 - "Proposed/Agreed common renewal date" field type has been changed to string in xsd.
SD-115249	In section 1.3 - formatting issue in Yes radio button	In section 1.3 – "Yes" – formatting issue has been resolved.
EAF-2761	Section 2.2.3.1 - Package size - numbers are not appearing in order	In section 2.2.3.1 - package size (label) field - numbers had been removed when more rows added.
EAF-2762	Section 1.4.2 - "Medicinal product authorised in the Union/Member	In Section 1.4.2 - "Medicinal product authorised in the

Id	Description	Comments
	State where the application is made or European" – "Date of authorisation" field should not appear when + button is clicked in subsequent rows.	Union/Member State where the application is made or European" – "Date of authorisation" field is not visible when subsequent rows added.
EAF-2764	The 'Update Lists' Button's tooltip needs to be updated as it incorrectly displays the 'Import XML' tooltip	Validation section – "Update lists" button - tooltip has been amended as "Click to update/reload the control lists".
EAF-2767	Section 2.6.1 – tooltip should be amended in units field to in line "Pharmaceutical form" - Units field	In Section 2.6.1 – "Units" field tooltip has been amended has "Click the arrow button to select unit of measurement for the Pharmaceutical form".
EAF-2769	Section 2.5.3 - Manufacturers active substance - free text field - tool tip should be amended.	In Section 2.5.3 - Manufacturers active substance - free text field - tool tip has been amended as "Click to enter information on active substance related to this manufacturer."
EAF-2773	Section 2.4.1 - Proof of payment - When export and import in the new version, the field proof of payment does not permit select different tax for different countries. Member states field is hidden which is wrong.	Section 2.4.1 - Proof of payment - When export and import in the new version, the field proof of payment allows to select different tax for different countries.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.5 or previous version to latest version (1.21.0.1/1.22.0.0) additional digits are added to terms selected from controlled terminology.	Always 'trust' the form prior to importing xml from previous forms.

Version 1.21.0.1 (Release Date: 30/06/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.21.0.1 hotfix release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-35463	The form was not retaining the title, first name and surname of the PRAC Rapporteur entered in the relevant field in section 1.1.1 when the form was saved and re-opened.	The form retains data after save and reopen in section 1.1.1 for PRAC Rapporteur.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.3 or previous version to latest version (1.21.0.0/1.20.0.5/1.20.0.4) additional digits are added to terms selected from controlled terminology.	Always 'trust' the form prior to importing xml from previous forms.

Version 1.21.0.0 (Release Date: 20/06/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.21.0.0 release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-82569	Section 2.6.3 –"Active substance" field label should change to "substance" to in line with NTA form.	In Section 2.6.3 –"Active substance" field label has been changed to "substance".
SD-79626	Section 2.2.3.6/2.2.3.5 – option "NA" should be added to the dropdown list.	In Section 2.2.3.6/2.2.3.5 – option "NA" has been added to the dropdown list.
SD-45930	Section 2.6.1 - Add clone button in Qualitative and quantitative composition – active substance and excipients table.	In section 2.6.1 - Qualitative and quantitative composition – clone button is added in active substance and excipients tables (two clone buttons - inner and outer section of the table).
SD-45834	Section 1 - Numeric value text should be added in strength field.	In Declaration section – "For numeric values, please use the full stop as the decimal separator. i.e. 0.002, rather than 0,002" text has been added in strength field.
SD-27733	Section 1.5.3 - Accelerated Review - the form requires to add the date that the request was accepted by the CHMP	In section 1.5.3 - Accelerated Review – the free text field has been added.
SD-27731	Section 1.3.2, 1.4.2, 1.4.3, 1.4.4, 1.4.7 and 1.6.1 – "unit field" should be added.	In section 1.3.2, 1.4.2, 1.4.3, 1.4.4, 1.4.7 and 1.6.1 – "Unit field" has been added next to "strength" field.
SD-27730	This usability improvement applies to human sections 1.4.2, 1.4.3, 1.4.4 In the second and third boxes, add a button at the top that says 'Copy data from above section'.	In sections 1.4.2, 1.4.3, 1.4.4 – "Copy data from above section' button has been added in second and third boxes to copy data from first box.

Id	Description	Comments
SD-27699	To repeat section 2.2.4.2 for a second (or more) Medical Device	In section 2.2.4.2– Medical device – "+" and "–" buttons has been added to add more than one medical device
Sd-97945	In section 2.5.3 – Annex 5.11 check box is not visible after save and reopen the form.	In section 2.5.3 – Annex 5.11 check box is now visible after save and reopen the form.
EAF-2402	Section 1.3.2, 1.4.2, 1.4.3, 1.4.4, 1.4.7 and 1.6.1 – "Date of authorisation" field is overlapped after form is locked.	In Section 1.3.2, 1.4.2, 1.4.3, 1.4.4, 1.4.7 and 1.6.1 – "Date of authorisation" field overlapped issue is fixed now.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.3 or previous version to latest version (1.21.0.0/1.20.0.5/1.20.0.4) additional digits are added to terms selected from controlled terminology.	Always 'trust' the form prior to importing xml from previous forms.

Version 1.20.0.5 (Release Date: 23/02/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.20.0.5 hotfix release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-79077	Incorrect behaviour in section 1.1.1 When importing xml details from v1.20.0.3, the information regarding Co-Rapporteur is not carried over to the new form.	In section 1.1 – the details filled in 1.1.1 are imported correctly from xml.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the 'symbols' menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.3 or previous version to v.1.20.0.4 additional digits are added to terms selected from controlled terminology.	Always 'trust' the form prior to importing xml from previous forms.

Version 1.20.0.4 (Release Date: 07/02/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.20.0.4 (previously known as 1.21) technical release, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-45896	Incorrect behaviour in section 1.1.1 When section 1.1.1 is selected and filled with data and if the user goes with option 1.1.2 then - Date of acceptance/confirmation by CHMP: - CAT Rapporteur details are not cleared.	In section 1.1 – the details filled in 1.1.1 are cleared when 1.1.2 or 1.1.3 is selected.
SD-27760	Section 1.1.1 – if we select Annex 3(2)(a) and then select annex(1a) then 3(2)(a)is not unselected .. same for 3(2)(b) is not unselected when annex(1a) is selected.	In Section 1.1.1 – if Annex 3(2)(a) or 3(2)(b) is selected and then annex(1a) is selected then values in 3(2)(a) / 3(2)(b) is cleared.
SD-68395	Additional "copy contact details from 2.4.2" button should be added in Section 2.4.3 in MAA	In section 2.4.3 – new “copy contact details from 2.4.2” button has been added.
SD-60492	Section 1.2.2: '-' button always removes the first Pharmaceutical form entry no matter which button is clicked	In section 1.2.2 – Pharmaceutical field –the issue has been resolved in remove button to delete corresponding row.
SD-60221	Section 2.6 - It is not possible to select more than two Overages.	In section 2.6 – the issue has been resolved to select more than two overages.
SD-45939	Title, first name and surname are not in line with company and address fields	In Sections – Declaration, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.5.1.a, 2.5.1.b, 2.5.2 and 2.5.3 Title, first name and surname are aligned with company and address fields

Id	Description	Comments
		now.
SD-45957	In Section 2.4.1 – “Copy contact details from declaration section” button should copy details from “person authorised” rather than “Applicant part” of Declaration section.	In Section 2.4.1 – the issue has been fixed in “Copy contact details from declaration section” button now copy details from “on behalf of the applicant” rather than “Applicant part” of Declaration section.
SD-45923	Section 2.4.2 – “copy contact details from 2.4.1 section” tool tip is incorrect	Section 2.4.1 – “copy contact details from 2.4.1 section” tool tip is changed to “Click to auto-complete the contact details in section 2.4.2 with those already added in section 2.4.1”.
SD-45880	Declaration section – Active substance – If 2nd active substance is searched however selected button is not pressed, but ‘Populate date in sections 2.1.2, 2.2.1 and 2.6.1 is pressed an empty row is created in 2.6.1 for the 2nd active substance. The ‘Ok’ button does not clear the row if the 2nd active substance isn’t selected.	Declaration section – Active substance – Ok button clears the 2nd active substance if it is not selected with value. When ‘Populate’ button is pressed after ‘Ok’ the empty row in section 2.6.1 is deleted.
SD-45862	Address Fields in the form, Address Line 2, It may be clearer if the comment were beneath the caption instead of beneath the field.	All address Fields in the form, Address Line 2, the comment is beneath the caption now.
SD-45884	Address Fields in the form – ‘European Union’ should not displayed in the dropdown list as this is not a country.	All Address Fields in the form – ‘European Union’ is removed from the drop down list.
SD-45935	Section 2.4.1 - Proof of Payment - Tooltip for this section missing, wording unclear.	Section 2.4.1 - Proof of Payment - Tooltip for ‘No’ is amended as “If exemptions from fees have been given or an invoice is expected from the NCA, please select No”
SD-45916	Section 1.1.2 and 1.1.3 – CMS - Each time we want to delete a country from the concerned member states list we receive the pop-up “do you want to delete…” where we have to click yes or no. This is time consuming. Remove pop up message.	Section 1.1.2 and 1.1.3 – for Concerned Member States (CMS) – pop up message in delete button has been removed.
SD-45911	Section 2.6 - Active Substances are cropped for overages section.	Section 2.6 - Active Substances field width is increased in overages section to display long active substance names.

Id	Description	Comments
SD-45890	When parts of section 2.4.1 are duplicated for multiple MS and “no” is selected for the first MS then the checkbox for Annex 5.1 will not be activated in section 5 even if “yes” is selected for fees for any other MS in section 2.4.1.	In Section 2.4.1 – proof of payment - when “no” is selected in first instances and “yes” is selected in multiple instances then Annex 5.1 is selected in Annex 5 section.
SD-45917	Section 2.5.3 – annex 5.11 check box is not visible when Ph.Eur certificate of suitability is selected.	Section 2.5.3 – annex 5.11 check box is visible for ph.Eur certificate is selected “yes” or “no” and ASMF is selected as “yes”
SD-45898	Section 2.6 - Qualitative and quantitative composition – Quantity/Unit field - When “quantity sufficient” term is selected then quantity and unit fields should be optional	Section 2.6 - Qualitative and quantitative composition – Quantity/Unit field - When “quantity sufficient” term is selected then quantity and unit fields are optional now.
SD-58464	“Add All” and “Add selected” buttons should be reviewed in all relevant sections.	“Add selected” button removed in section 1.1.2 & 1.1.3 – Concerned Member States (CMS) “Add All” button removed in the following sections • section 2.3.1, 2.3.2, 2.3.3, 2.3.4 • section 2.4.1, 2.4.1 – proof of payment, 2.4.2, 2.4.3, 2.4.4 2.4.5
SD-45873	Section 2.4.5 - there is no possibility to copy data from section 2.4.3 to 2.4.5	In section 2.4.5 - new “Copy contact details from 2.4.3 section” button has been implemented.
SD-58708	Copy contact details buttons in all sections needs to review and fix the issue which are not copying all instances	In Section 2 - Copy contact details buttons are now copy’s all instances and don’t delete the data which is already filled in. For more than one instance it is possible to select which contact details to be copied. Section 2.4.2, 2.4.3, 2.4.4, 2.4.5, 2.5.2, 2.5.3
SD-45863	In section 1.1.1 • “If applicable, PRAC Co- Rapporteur” check box should not be mandatory • If “Generic of a centrally Authorised Medicinal Product” is selected then “CHMP Co-Rapporteur” check box should not be mandatory	In section 1.1.1 • “If applicable, PRAC Co- Rapporteur” check box is optional now. • If “Generic of a centrally Authorised Medicinal Product” is selected then “CHMP Co-Rapporteur” check box is optional now.
SD-73800	Section 2.6.1 When a second strength is added and ‘copy data’ button is used, only first instance on the active substance is copied. Not all data.	In Section 2.6.1 – ‘Copy data’ button is working for more than one instance.

Id	Description	Comments
EAF-2231	Section 2.5.3 - For CEP, the field “Name of the manufacturer if different from the above” is mandatory, but should be optional.	Section 2.5.3 - For CEP, the field “Name of the manufacturer if different from the above” is optional now.
SD-68660	After locking the form, some text in section 2.5.3 gets dislocated (Annex 5.8 and 5.22)	Once the form is locked - In Section 2.5.3 – dislocation of Annex 5.8 and 5.22 is fixed now.
SD-45864	Tick box for annex 5.22 should not be mandatory in section 2.5.3	In Section 2.5.3 – annex 5.22 is optional now.
SD-73810	section 2.2.3.1 - 2nd pack type added, it is not possible to select “N/A” in the closure and administration device in the second instance	In Section 2.2.3.1 – “N/A” is available in the drop down list to select in more than one instance now.

Known issues

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.
SD-47398	To allow 'superscript' in Section 2.6.1 - Overage and Quantity/Unit boxes.	To add superscript use the ‘symbols’ menu (from Insert menu) in word to select the relevant superscript numbers and copy and paste this to the eAF.
	When importing xml from v1.20.0.3 or previous version to v.1.20.0.4 additional digits are added to terms selected from controlled terminology.	Always ‘trust’ the form prior to importing xml from previous forms.

Version 1.20.0.3 (Release Date: 18/10/2016)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.20.0.3 hotfix, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-27799	Section 4.2 "Submitted" disappears if form is saved/locked	Section 4.2 is now correctly displayed when section 4.1.1, 4.1.2, 4.1.3 is selected and when the form is opened after a save.
SD-27807	In section 2.5.3 – Is a Active Substance Master File to be used for the active substance(s), applicant part version number field - the tooltip says that 100 characters can be added but in fact it is only 30	In Section 2.5.3 – "Applicant part number field" now allows 100 characters.
SD-42542	When compiling section 1.1.2 for a RUP, the option of wave number disappears when the changes are saved	In section 1.1.2 for a RUP, the option of wave number displays correctly after save and reopen the form.
SD-52718	More than nine Overages in section 2.6.1 cause hidden overflow and generate multiple empty pages	In Section 2.6.1 - Now we can add more than 9 Overages and it won't hidden overflow and/or generate multiple empty pages

Known issues

Since it is a hot fix the known issues identified in 1.20.0.1 still remain and therefore not repeated here, so please refer to Version 1.20.0.1 (Release Date: 30/06/2016), see below. In addition there is one more defect identified and mentioned here.

Id	Description	Workaround/Comment
SD-35463	Adobe Reader displaying forms as not being locked down and with red fields	The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue.

Version 1.20.0.2 (Release Date: 19/08/2016)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.20.0.2 hotfix, for the eAF forms.

Issues fixed for this version

Id	Description	Comments
SD-35460/ SD-35466/ SD-36435	Sections 2.2.3.2/3/4, 2.6.1: Decimal separators and commas: The only change should have been not to allow a comma	In Section 2.3.2.2/3/4 and 2.6.1 all numeric fields have been reverted to text fields, and a message explaining to use full stop as decimal separator has been added.
SD-40214/ SD-40467	In section 2.5.3, the field National ASMF reference number: (when applicable and only if EU ASMF reference number is not available) contains a limit of 30 characters	In Section2.5.3, the EU ASMF Reference and the National ASMF Reference have been extended to allow 100 characters, up from 30.
SD-42553	Section 4.1 disappears upon saving/closing/opening the form	Section 4.1 is now correctly displayed when the form is opened after a save.
SD-35464	Sections 2.5.2 and 2.5.3 - manufacturer(s) boxes overflow and stay hidden if more than 4 boxes are added	Section 2.5.2/2.5.3 – manufacturer(s) boxes are now able to add more than 4 boxes which is not hidden and flows to next page.

Known issues

Since it is a hot fix the known issues identified in 1.20.0.1 still remain and therefore not repeated here, so please refer to Version 1.20.0.1 (Release Date: 30/06/2016), see below. In addition there are two more defects are identified and mentioned here.

Id	Description	Workaround/Comment
SD-42542	When compiling section 1.1.2 for a RUP, the option of wave number disappears when the changes are saved	Pending review for inclusion in next release.
EAF-2211	Copy contact details 2.5.1.a button functionality not working when we add multiple manufacturer(s) in section 2.5.2 and 2.5.3	Pending review for inclusion in next release.

Version 1.20.0.1 (Release Date: 30/06/2016)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note is for the 1.20.0.1 hotfix, for the eAF forms.

Issues fixed for this version

id	Description	Comments
	In Section 2.4.1, the proof of payment not expanding sections yes or no correctly.	In Section 2.4.1, the proof of payment sections for yes and no are now correctly displayed when the form is reopened.
	In Section 2.6.1 the numeric fields do not allow more than 2 decimal places.	In Section 2.6.1, all numeric fields now support up to eight decimal places.
	In proof of payment section the “add all” button was not required.	In section 2.4.1 the “add all” button has been removed since it was no longer required.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Id	Description	Workaround/Comment
	prevent the application from progressing through the application workflow).☐	
	There is a known issue opening eAF forms using reader, when non-traditional or special characters are used (this has been observed when copying from a Word document into the eAF form). These characters might cause reader to request the installation of the Chinese character set pack. This issue is not observed in Adobe Acrobat which will open the file without issue.	Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat.
EAF-1654	section 1.1. of Human form - PRAC Rapporteur and Co-Rap shown as mandatory	Pending review for inclusion in next release.
EAF-1729	Import of form with signatures locks new form	Pending review for inclusion in next release.
EAF-1883	Section 1.1.1 CP, Generic Business Rule Error	Pending review for inclusion in next release.
EAF-1893	Section 2.6.1: it does not make sense to auto populate "min" when using range operator	Pending review for inclusion in next release.
EAF-1968	No Suggestions Provided on typing units next to Quantity in all Forms	Pending review for inclusion in next release.
EAF-1962	Ok Button does not verify the active substance selected or not.. Clear Button does not clear the data	Pending review for inclusion in next release.
EAF-1963	Incorrect behaviour -- Radio buttons are not cleared	Pending review for inclusion in next release.
EAF-1964	Incorrect behaviour in section 1.1.1 of Human form	Pending review for inclusion in next release.
EAF-1965	Human form - Section 2.4.1 The radio buttons for Centralised procedure and National procedure including mutual recognition/decentralised procedure are not selectable	Pending review for inclusion in next release.
EAF-1966	Human form -- Copy button does not copy the contact details -- Section 2.4.4 & 2.5.1.a	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
EAF-1971	Unable to export the role data in 2.5.1.2	Pending review for inclusion in next release.
EAF-2002	Tool Tips not in sync with the change made by Jira issue 1673	Pending review for inclusion in next release.
EAF-2013	Section 2.5.3 - Annex 5.11	Pending review for inclusion in next release.
EAF-2014	Section 1.3 for the legal basis cannot be completed and there is a mismatch in Annexes 5.9 and 5.10	Pending review for inclusion in next release.
EAF-2034	Error while copying the data in section 2.4.2 - Human Form	Pending review for inclusion in next release.
EAF-2035	Error Message on Clicking Populate data in section 2.1.2, 2.2.1 and 2.6.1 requires a change	Pending review for inclusion in next release.
EAF-2048	Copy function in section 2.4.4 does not work as expected	Pending review for inclusion in next release.
EAF-2054	member state values are shown as none|None and so on after saving the Variation form and opening again	Pending review for inclusion in next release.
EAF-2086	CMSs mentioned twice and empty rows showing no CMS are also listed	Pending review for inclusion in next release.
EAF-2087	Is it possible to include select and delete all for CMS countries/copy contact details, like for the Variation eAF?	Pending review for inclusion in next release.
EAF-2104	Declaration and Signature - When having fix dose combinations it is not possible to select the correct units, e.g. 10 mg and 5 mg.	Pending review for inclusion in next release.
EAF-2105	For fixe dose combinations: When adding the second strength and want to copy the data for the substances it copies only the data for the first substance.	Pending review for inclusion in next release.
EAF-2107	Section 2, It is not possible to insert a line into the active substance list, only at the end of the list, but not in between	Pending review for inclusion in next release.
EAF-2113	To add information regarding the procedure number and to list the MS in the above mentioned sections.	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
EAF-2130	There are buttons to allow copying the information from either 2.4.1 or from declaration section.	Pending review for inclusion in next release.
EAF-2131	When parts of section 2.4.1 are duplicated for multiple MS and “no” is selected....	Pending review for inclusion in next release.
EAF-2132	Section 2.4.5, However, there is no possibility to copy data from section 2.4.3 to 2.4.5.	Pending review for inclusion in next release.
EAF-2138	Section 2.5.2, The free text field is mandatory, if all activities are available in the drop down list it should not be mandatory to fill in this field.	Pending review for inclusion in next release.
EAF-2142	Section 2 – batch control/testing site, It is possible to add a field, where you can specified the role of the control/testing site like in the section 2 – medicinal product?	Pending review for inclusion in next release.
EAF-2146	Section 2.1.3, It is possible to both indicate the ATC code and to check the box that no ATC code has been assigned.	Pending review for inclusion in next release.
EAF-2147	In Section 1, the EAF-1752 functionality for "Add All" should be made available in section 1.1.3, and in 2.4.1, 2.4.2 and 2.4.3.	Pending review for inclusion in next release.
EAF-2148	Section 2, Clicking the button once should add the contact details, clicking the button twice should trigger nothing as the contact details are already added.	Pending review for inclusion in next release.
EAF-2154	Please could new buttons be added for the Member States- Add All, Remove All – for the Pharmaceutical Form and also for Name and Address of MA holder as done earlier in section 1	Pending review for inclusion in next release.
EAF-2164	Section 1, MAH copy button only copies the first entry. Would expect to be able to pick what was copied.	Pending review for inclusion in next release.
EAF-2173	To have the “N/A” in all drop down lists for all eAFs, to can be selected for special cases (purposes / special cases can be defined in the CL as advised in Q32 of Q&A on eAF).	Pending review for inclusion in next release.
EAF-2174	Signature, When one selects the country of the applicant there are "European Union" and "Switzerland".	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
EAF-2186	Active Substances are cropped for overages of Human, VET & Renewal forms	Pending review for inclusion in next release.
EAF-2211	Copy contact details 2.5.1.a button functionality not working when we add multiple manufacturer(s) in section 2.5.2 and 2.5.3	Pending review for inclusion in next release.

Additional information

NOTE: On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23rd October 2015 the new ID will be used for all new changes raised against eAF forms.

NOTE: To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

NOTE: From the beginning of January 2016 the eAF forms became Mandatory and the word version of the forms is no longer accepted.

Version 1.20.0.0 (Release Date: 14/06/2016)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release note contains the original release made on the 15/04/2016 and also the post UAT fixes that were applied for the release on the 14/06/2016.

Issues fixed for this version

id	Description	Comments
EAF-1673	Section 2.4.2. The tooltip should express that the address from the first iteration in 2.4.1 can be used only	In section 2.4.2 the tooltip for the “Copy contact details from 2.4.1 section” button to read: “This will only copy the details to the first instance of the address in section 2.4.2”
EAF-1752	The list of MS could be executed by the form if 'all' is selected. Depending from the case, the deletion of a few MS not involved will be quicker than to add MS by MS. New button - select all button to populate all member states field and option to clear them too.	In section 2.3.1, 2.3.2, 2.3.3 and 2.3.4 new buttons (Add All, Remove All) have been added to each section and will add the elements of the drop down list. If the checkboxes for each of these sections is unticked, the concerned member states are removed automatically.
EAF-1845	General usability: Data filled in from the applicants should be coloured darker than the filed names so it will be easier to review.	In all forms, the colour for the locked grey is now darker, and the caption for each field is now made bold to ensure a distinction.
EAF-1884	When MRP, DCP or NP are selected in section 1.1, the section 2.4.1 is not selected (but it works for CP).	In Section 1.1, the selection of the procedures now correctly defines the correct procedure in section 2.4.1.
EAF-1895/EAF-1985	When MRP, DCP or NP are selected in section 1.1, the section 2.4.1 is not selected (but it works for CP).	In Section 1.1, the selection of the procedures now correctly defines the correct procedure in section 2.4.1.
EAF-1896	in DE we use "," for decimal separator (e.g. quantity) in "EN" we have "." for that. We suggest to restrict all numeric input fields to allow only "." as decimal separator.	In Sections 2.2.3.2/3/4 the duration fields are now numeric, and in section 2.6.1 the Low and High Strength numerator and the 2.6.1 Substance Overage fields are also numeric.

id	Description	Comments
EAF-1924	2.5.1.a, 2.5.2, 2.5.3 Manufacturers. Telefax is a mandatory field however neither of other section is needed to fill	In Section 2.5.1a, 2.5.2 and 2.5.3 the telex field has been made non-mandatory.
EAF-1928	Name and address of the applicant “Address 2” (= confusing) – could it be changed to” City”	An additional sub-line has been added below Address Line 2 which reads “(Name of: city, town, village, etc)”
EAF-1932	We frequently submit DCPs/MRPs/RUPs in which several MAHs are included per procedure. This implies that more than 1 qualified person for pharmacovigilance (QPPV) and pharmacovigilance system master file (PSMF) need to be specified in section 2.4.4 of the application form, since every MAH has its own QPPV and own PSMF. It has been noticed that the current electronic application form allows to have more QPPVs per procedure, however, unfortunately there is no option to add additional PSMFs. We therefore would like to ask if it is possible to implement the option to add more PSMFs with the next update of the eAF?	In Section 2.4.2 the addition of a + and – button have been added to all input of multiple pharmacovigilance system master files. **NOTE**: *The MAA HUMAN DES has been changed as part of this request*.
EAF-1933	Problem short: XML contains data which is not visible in the form. Why a problem: data from re-used forms or closed sections will be submitted to NCAs/EMA via XML-import. The XML does not know that a section is closed (not visible) Causes: data quality problems Solution: delete all “non-visible” data from the XML.	In all sections, the form removes data from nodes that have been closed after having had data input.
EAF-1982/EAF-1987	This change was implemented in v.1.19 of the eAF with the ‘business rule’ if 1.4.1 is selected, then ‘claim for new active substance’ is mandatory field. Please advise if the ‘claim for new active substance’ should be optional selection when 1.4.1 is selected?	In Section 1.4.1, the “Claim for new active substance” is no longer mandatory.
EAF-1984/EAF-1988	With reference to the last couple of emails below from Tatyana, an issue is being encountered with section 3 Scientific Advice of v1.19 of the MAA eAF.	In Section 3.1, it is now possible to have duplicate member states selected.

id	Description	Comments
	Within v1.18 of the form, Tatyana had been able to repeat a Member State where Scientific Advice had been given on multiple dates. However, within v1.19, an error message occurs when you try to select the same member state. This error box repeats many times once you've tried to repeat a member state and now, when you open the form, this same error box pops up a number of times before loading the form.	
EAF-1986/EAF-1977	The current 2.1.2 section no longer permits the user to add active substances. This prevents the addition of ad-hoc active substances to be added from the excipients lists. This requires the active substances panel to now allow manual adding of substances.	In Section 2.1.2, the active substances panel now allows for additional substances to be selected. The populate data button now no longer removes the +/- and Find buttons in section 2.1.2.
EAF-1995	We noted that an email address of a colleague has been rejected as invalid by the eAF: The address includes the character "'". Obviously the form does not accept all allowed characters. Beyond uppercase and lowercase letters (A–Z, a–z) (ASCII: 65–90, 97–122) and digits 0 to 9 (ASCII: 48–57) and the "." These are also the special characters: !#$%&'*+-/=?^_`{|}~ (ASCII: 33, 35–39, 42, 43, 45, 47, 61, 63, 94–96, 123–126)	In Section 3, the Email validation now allows for ' ! . # & % $ * + _ -. This applies to all email addresses used in the form (it is not limited to section 3).
EAF-2026	The tooltips between the two buttons is not consistent in its message.	In Section 2.4.2 the "Copy contact details from Declaration Section" button tooltip now explains: this will only copy the details to the first instance of the contact details in section 2.4.2.
EAF-2037	No restrictions on adding same MS as seen in Renewal and Variation forms. Users will be able to add same member states.	In Section 2.3.1, 2.3.2, 2.3.3, 2.3.4, the add All button's now correctly assign the member state, and now prevents duplicates from being selected.
EAF-2039	Quantity filed ins section 2.6.1 has more than 2 decimals	In section 2.6.1 the pharmaceutical form quantity field has now been changed from a text field to a decimal field to ensure 2 decimal place

id	Description	Comments
		support, and usage of the . as a decimal separator.
EAF-2041	Date of Authorization is missing for default but available on clicking + button in section 1.3.2	In Section 1.3.2, the Date of Authorisation field is now displayed in the first and all subsequent instances.
EAF-2042	Forms not very well formatted as a result of 1845 fix	In all sections, the caption space has been increased to allow for bold text to be displayed when the form is locked.
EAF-2043	Overage and excipient quantity fields still accept " ,"	In Section 2.6 the overage fields are now decimal fields and will only accept numeric values, and only allow a . as decimal field separator.
EAF-2097	2.6.1, 2.1.2, 2.2.1 - Active Substances are cropped	In Section 2.6.1, 2.1.2 and 2.2.1, the active substance fields now expand to show the whole active substance name.
EAF-2159	The add all buttons in subsequent sections should only add the RMS and CMS from section 1.	In all sections where appropriate, an “add selected” button will be visible when MRP/DCP is selected. The new button now adds the RMS and CMS identified in section 1. Note: the RMS will be added to the bottom of the member state list, after all selected CMS have been added.
EAF-2182	Update the appearance of all buttons (excluding drop down lists) to have rounded corners with no borders.	In all sections, the look and feel of the buttons in the form has been upgraded to give them soft rounded corners. Drop down lists and selectors have been left with a square.
EAF-2183	All Sections, Footnote links are ineffective and need to be improved.	In all sections, the footnote “i” button has been replaced with a “?” and now the footnote text appears within the context of the section it is in. The footnotes are still included at the bottom of the document for consistency.
EAF-2185	Copy function for pharmacovigilience does not work	In section 2.4.4, the pharmacovigilance ’copy contact details from 2.4.2 section’ button now correctly copies the address details.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.
	There is a known issue opening eAF forms using reader, when non-traditional or special characters are used (this has been observed when copying from a Word document into the eAF form). These characters might cause reader to request the installation of the Chinese character set pack. This issue is not observed in Adobe Acrobat which will open the file without issue.	Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat.
EAF-1654	section 1.1. of Human form - PRAC Rapporteur and Co-Rap shown as mandatory	Pending review for inclusion in next release.
EAF-1729	Import of form with signatures locks new form	Pending review for inclusion in next release.
EAF-1883	Section 1.1.1 CP, Generic Business Rule Error	Pending review for inclusion in next release.
EAF-1893	Section 2.6.1: it does not make sense to auto populate "min" when using range operator	Pending review for inclusion in next release.
EAF-1968	No Suggestions Provided on typing units next to Quantity in all Forms	Pending review for inclusion in next release.
EAF-1962	Ok Button does not verify the active substance selected or not.. Clear Button does not clear the data	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
EAF-1963	Incorrect behaviour -- Radio buttons are not cleared	Pending review for inclusion in next release.
EAF-1964	Incorrect behaviour in section 1.1.1 of Human form	Pending review for inclusion in next release.
EAF-1965	Human form - Section 2.4.1 The radio buttons for Centralised procedure and National procedure including mutual recognition/decentralised procedure are not selectable	Pending review for inclusion in next release.
EAF-1966	Human form -- Copy button does not copy the contact details -- Section 2.4.4 & 2.5.1.a	Pending review for inclusion in next release.
EAF-1971	Unable to export the role data in 2.5.1.2	Pending review for inclusion in next release.
EAF-2002	Tool Tips not in sync with the change made by Jira issue 1673	Pending review for inclusion in next release.
EAF-2013	Section 2.5.3 - Annex 5.11	Pending review for inclusion in next release.
EAF-2014	Section 1.3 for the legal basis cannot be completed and there is a mismatch in Annexes 5.9 and 5.10	Pending review for inclusion in next release.
EAF-2034	Error while copying the data in section 2.4.2 - Human Form	Pending review for inclusion in next release.
EAF-2035	Error Message on Clicking Populate data in section 2.1.2, 2.2.1 and 2.6.1 requires a change	Pending review for inclusion in next release.
EAF-2048	Copy function in section 2.4.4 does not work as expected	Pending review for inclusion in next release.
EAF-2054	member state values are shown as none|None and so on after saving the Variation form and opening again	Pending review for inclusion in next release.
EAF-2086	CMSs mentioned twice and empty rows showing no CMS are also listed	Pending review for inclusion in next release.
EAF-2087	Is it possible to include select and delete all for CMS countries/copy contact details, like for the Variation eAF?	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
EAF-2104	Declaration and Signature - When having fix dose combinations it is not possible to select the correct units, e.g. 10 mg and 5 mg.	Pending review for inclusion in next release.
EAF-2105	For fixe dose combinations: When adding the second strength and want to copy the data for the substances it copies only the data for the first substance.	Pending review for inclusion in next release.
EAF-2107	Section 2, It is not possible to insert a line into the active substance list, only at the end of the list, but not in between	Pending review for inclusion in next release.
EAF-2113	To add information regarding the procedure number and to list the MS in the above mentioned sections.	Pending review for inclusion in next release.
EAF-2130	There are buttons to allow copying the information from either 2.4.1 or from declaration section.	Pending review for inclusion in next release.
EAF-2131	When parts of section 2.4.1 are duplicated for multiple MS and “no” is selected....	Pending review for inclusion in next release.
EAF-2132	Section 2.4.5, However, there is no possibility to copy data from section 2.4.3 to 2.4.5.	Pending review for inclusion in next release.
EAF-2138	Section 2.5.2, The free text field is mandatory, if all activities are available in the drop down list it should not be mandatory to fill in this field.	Pending review for inclusion in next release.
EAF-2142	Section 2 – batch control/testing site, It is possible to add a field, where you can specified the role of the control/testing site like in the section 2 – medicinal product?	Pending review for inclusion in next release.
EAF-2146	Section 2.1.3, It is possible to both indicate the ATC code and to check the box that no ATC code has been assigned.	Pending review for inclusion in next release.
EAF-2147	In Section 1, the EAF-1752 functionality for "Add All" should be made available in section 1.1.3, and in 2.4.1, 2.4.2 and 2.4.3.	Pending review for inclusion in next release.
EAF-2148	Section 2, Clicking the button once should add the contact details, clicking the button twice should trigger nothing as the contact details are already added.	Pending review for inclusion in next release.
EAF-2154	Please could new buttons be added for the Member States- Add All, Remove All – for the Pharmaceutical Form and also for Name and	Pending review for inclusion in next release.

Id	Description	Workaround/Comment
	Address of MA holder as done earlier in section 1	
EAF-2164	Section 1, MAH copy button only copies the first entry. Would expect to be able to pick what was copied.	Pending review for inclusion in next release.
EAF-2173	To have the “N/A” in all drop down lists for all eAFs, to can be selected for special cases (purposes / special cases can be defined in the CL as advised in Q32 of Q&A on eAF).	Pending review for inclusion in next release.
EAF-2174	Signature, When one selects the country of the applicant there are "European Union" and "Switzerland".	Pending review for inclusion in next release.
EAF-2186	Active Substances are cropped for overages of Human, VET & Renewal forms	Pending review for inclusion in next release.

Additional information

NOTE: On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID’s have been kept for continuity and are prefixed with ‘emea’, the new ID’s used with the system all begin ‘EAF’. Effective from the 23rd October 2015 the new ID will be used for all new changes raised against eAF forms.

NOTE: To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

NOTE: From the beginning of January 2016 the eAF forms became Mandatory and the word version of the forms is no longer accepted.

Version 1.19.0.2 (Release Date: 23/02/2016)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This hotfix release addresses a critical issue.

Issues fixed for this version

id	Description	Comments
EAF-2050	The cover page for the Human form does not show the full and complete eAF version number, it only shows 1.19. Please can it show the full version.	The cover page now correctly reflects the eAF version number, and now shows 1.19.0.2.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

NOTE: On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23rd October 2015 the new ID will be used for all new changes raised against eAF forms.

NOTE: To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

NOTE: From the beginning of January 2016 the eAF forms became Mandatory, and the word version of the forms is no longer accepted.

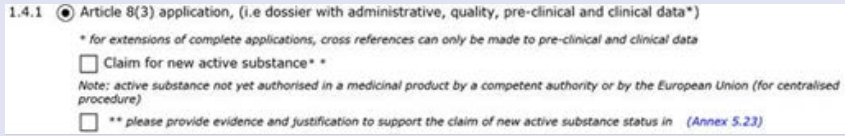
Version 1.19.0.1 (Release Date: 30/11/2015)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This hotfix release addresses a critical issue.

Issues fixed for this version

id	Description	Comments
39303 / EAF-1895/1985	When MRP, DCP or NP is selected in section 1.1, the section 2.4.1 is not selected (but it works for CP).	In Section 1.1, the selection of the procedures now correctly defines the correct procedure in section 2.4.1.
EAF-1977/1986	The current 2.1.2 section no longer permits the user to add active substances. This prevents the addition of ad-hoc active substances to be added from the excipients lists. This requires the active substances panel to now allow manual adding of substances.	In Section 2.1.2, the active substances panel now allows for additional substances to be selected.
EAF-1982/1987	This change was implemented in v.1.19 of the eAF with the 'business rule' if 1.4.1 is selected, then 'claim for new active substance' is mandatory field. Please advise if the 'claim for new active substance' should be optional selection when 1.4.1 is selected?	In Section 1.4.1, the "Claim for new active substance" is no longer mandatory.
EAF-1984/1988	An issue is being encountered with section 3 Scientific Advice of v1.19 of the MAA eAF. However, within v1.19, an error message occurs when you try to select the same member state. This error box repeats many times once you've tried to repeat a member state and now, when you open the form, this same error box pops up a number of times before loading the form.	In Section 3.1, it is now possible to have duplicate member states selected.
EAF-1998/1999	The section 2.4.5 is hidden when CP is selected but it is a mandatory section for CP applications.	In Section 2.5.4, the section which was previously displayed only for MRP, DCP and National Procedures is now displayed for all procedure types.
	The NTA form introduced a change in the section 1.4 of the application form. Corresponding change has been	In Section 1.4.1, the form has been changed to this.

id	Description	Comments
	implemented in the Initial MAA human form; when Centralised Procedure is selected in section 1.1. and Art. 8(3) application is selected in section 1.4.1 the selection has changed from: • New active substance • Known active substance – which would be the case for our Extension Application, as we refer to the product already authorised in the EU	

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

NOTE: On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23rd October 2015 the new ID will be used for all new changes raised against eAF forms.

NOTE: To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

Version 1.19.0.0 (Release Date: 03/11/2015)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various change requests and defects as outlined below.

Issues fixed for this version

id	Description	Comments
emea00038531	Section 2.2.3.2 - 4 tooltips shows that only 30 chars. are possible. It is possible to copy-paste more. Boxes overflow.	In section 2.2.3.2, 2.2.3.3 and 2.2.3.4 - characters limit increased to 255 and it is flowable.
emea00038511	ATC code field is too short to select from the search result list.	ATC code field search results field length is increased
emea00038745	Regarding 2.2.4.4. (Notified Body), the Applicant is requesting that Switzerland be added in the list of countries. Regulatory Affairs have confirmed that legislation allows for a Notified Body to be located in Switzerland (see mail attached) so please ensure this country appears in the list at your earliest convenience.	In section 2.2.4.4. Switzerland has been added to the list.
emea00038749	NTA paper application version 11 update to eAF.	Paper version 11 changes has been be implemented in eAF
emea00038744	Regarding 2.2.4.1. (Manufacturer of the device), it says that for manufacturers outside the EEA, the authorised representative should be added. However the Country drop down list doesn't contain any of the EEA countries so this looks like an issue as EEA countries should also appear.	In Section 2.2.4.1 - country list now displays EU and free trade countries.
emea00038850	Annexes 5.9 and 5.6 won't select in 2.5.1.2 and 2.5.3 in any other than the FIRST box.	In Section 2.5.1, 2.5.2 and 2.5.3, when the checkbox is ticked, Annex 5.6 and 5.9 will be automatically checked.
emea00038704	Section 2.3.5: Annexes 5.10 and 5.11 won't get selected in Annex section if ticked in any other than FIRST box	In Section 2.5.3 - 5.10 and 5.11 when checkboxes ticked, the Sections 5.10 and 5.11 checkboxes are now automatically selected.

id	Description	Comments
emea00038629	2.6.1 - When the whole substance box is multiplied then the overages box show only the first one. When there's rows, the overages show correctly.	In section 2.6.1 - The overages will allow multiple active substance and excipients to be selected.
emea00026582	2.4 marketing authorisation holder : CMDv has received advice (attachment) from the European Commission that there can only be one (1) MAH for one VMP as a result of a single procedure. Therefore it is misleading to allow for multiple entries which currently is the case.	In Section 1, when centralised procedure is selected, the section 2,4,1 centralised procedure will be selected. If other procedures selected in section 1.1 section then in Section 2,4,1 the corresponding National, MRP, or DCP will be selected.
emea00036811	The strength is not controlled vocabulary. It is currently just free text field.	In Section 2.1.2 and 2.6.1. The strength field has been split into two fields in the declaration section: a free text field and a unit dropdown field.
emea00022291	2.5.3 Manufacturer(s) of the active substance(s) and site(s) of manufacture: information form DECLARATION AND SIGNATURE section should be copied via "update" button like in section 2.2	In Section 2.5.3. New button has been implemented - "copy contact details from declaration section". It will only appear for manufacturer section and not for the admin address section.
emea00037324	When populating fields with Member State information it is possible to assign the same Member State several times within one section. This does not make sense. Consider to include a rule which impedes this. Auto populate values from section 1	In Sections: 1.1.2, 1.1.3, 1.4.2, 1.4.3, 2.3.2, 2.3.3, 2.3.4, 2.3.5, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 3.1, It is no longer possible to enter the same member state in CMS section, if so an error message will be displayed.
emea00037347	section 2.4.5 centralised procedure hide this section	In Section 2.4.5 – The title will be visible and the content of the section will be hidden when Section 1 centralised procedure is selected.
emea00036815	Section 4.1 – when centralised procedure is selected this section is not mandatory. Hide this field.	In Section 4.1 The title will be visible and content of this section will be hidden when in Section 1 centralised procedure is selected.
emea00038328	2.4.1 - Billing address - new populate button to copy address from above address details	In section 2.4.1 - billing address - new populate button to copy address from above address details
emea00038341	2.4.2 – would it be possible to have 2 different populate buttons, one as it is 'copy contact details from 2.4.1' and one 'copy contact details from declaration section'. In my particular test case it was always the different section where I wanted to copy from. This would also help to align how the address is given, in both declaration section and 2.4.2 the address was given differently even it was the same address	In Section 2.4.2 and 2.4.3 - New populate button in to copy contact details from declaration section.
emea00038342	2.4.4 – button called, copy address details from 2.4.2 and also for the PhV system MF field, could have a copy from	In Section 2.4.4 – New Button added to copy address details from 2.4.2 has been added to the PhV system MF field section.

id	Description	Comments
	2.4.2	
emea00036813	To populate automatically information in section 1.6 based on the type of application in section 1.4	In Section 1.6 The check box will automatically be selected if Section 1.4 – the generic, hybrid, similar biological application and Article 16a Traditional use registration for herbal medicinal product are selected.
emea00038340	2.2.4 be made visible only if the product has medical device	In Section 2.2.4 – A New Check box has been implemented next to 2.2.4 title with the label "yes". If the new checkbox is selected, Sections 2.2.4.1 to Section 2.2.4.4 will appear. otherwise they will remain hidden.
emea00037338	user option to start or skip validation	Validation is required in the form.
emea00037438	Add warning note to confirm deletion of repeated section	All delete buttons in all sections now pop up with a message: "Do you want to delete this repeatable section". If the user selects yes the row/section is deleted, if they select cancel it is not deleted.
emea00038395	For every hyperlink to a footnote there should be a hyperlink back to the originating location	In the footnote section, each footnote when selected will return the corresponding section.
emea00035779	Admin and/or manufacturing address to be shown only if 'YES' is selected	In Section 2.5. - All Manufacturer address fields are now hidden at first, and it will only be made be visible when the user selects yes to the "do you have admin address and manufacturer address" question.
emea00035630	section 2.5.3 group until brief description with plus and minus buttons	In Section 2.5.3 – The section has been changed to allow for brief descriptions to be added using control buttons.
emea00038328	2.4.1 - Billing address - new populate button to copy address from above address details	In section 2.4.1 - billing address - new populate button to copy address from above address details
emea00038341	2.4.2 – would it be possible to have 2 different populate buttons, one as it is 'copy contact details from 2.4.1' and one 'copy contact details from declaration section'. In my particular test case it was always the different section where I wanted to copy from. This would also help to align how the address is given, in both declaration section and 2.4.2 the address was given differently even it was the same address	In Section 2.4.2 and 2.4.3 - New populate button in to copy contact details from declaration section.
emea00039143	When applicant fills in 2 pharmaceutical forms, a tablet with one active substance, and granules with two active substances, the function Populate data doesn't work properly for section 2.1.2 as it carries across only 2 substances.	In the Declaration page, when the "Populate data in Sections 2.1.2, 2.2.1 and 2.4.1 button is clicked it now populates the Section 2.1.2 "Name of Active Substances" list. In Section 2.1.2 the find, add and remove buttons have been removed.
emea00038570	Section "Person authorised for communication*, on behalf of the Applicant" the tooltip for populating details from	In Section "Person Authorised for Communication" the tool tip has been corrected, and in Section 2.6.1 the free text field has had the tooltip

id	Description	Comments
	previous section is incorrectly referring to sections 2.4.1 and 2 and the free text field for description of the active substance in section 2.6.1 incorrectly refers to “excipients”	corrected.
emea00039244	In the declaration section there is a full stop between paragraphs, as shown: It is hereby confirmed that all existing data which are relevant to the quality, safety and efficacy of the medicinal product have been supplied in the dossier, as appropriate and that such data are not subject to regulatory data exclusivity in the Union. . It is hereby confirmed that fees will be paid/have been paid according to the national/European Union rules**. On behalf of the applicant This will need to be removed.	In the Declaration section, the paragraph that begins "It is hereby confirmed..." the additional period has been removed.
emea00039224	In Section 2.4.3 need to remove hardcoded "Switzerland" and replace with web services	In Section 2.4.3 the country dropdown component has been replaced and now uses the EU and Free Trade Countries dropdown.
emea00039250	Marketing authorisation number field does not display all the text.	In Section 1.4.2. All Marketing Authorisation Number fields now display the complete field across multiple lines.
emea00039254	Section 2.4.4 – paper form doesn’t ask for telephone/email	In Section 2.4.4. the telephone number, fax number and email address have been removed, as they are not present on the paper form.
emea00039143	Section 2.1.2 doesn’t populate correctly when there's 2 pharmaceutical forms and 3 (and more) substances	In the Declaration and Signature section, all active substances now update the relevant sections. Section 2.1.2 is now populates with a unique list of active ingredient, sorted alphabetically. In Section 2.2.1, the products and active ingredient reflect those input in the Declaration section.
emea00039253	2.4.1 – company name = applicant in declaration section – field is not copied when copy contact details button is clicked	In Section 2.4.1, when the "Copy Contact Details from Declaration Section" button is pressed the company name is now populated with the Applicant details from the Declaration Section.
emea00039227	You can select different units when selecting the range operator this could lead to regulatory questions and import failures	In Section 2.6.1. The Quantity/Unit field has been changed when selecting a range. Now, whatever the principle unit selected in the "From" group, is repeated automatically in the "To" group.
emea00039307 / EAF-1899	Section 2.2.3, under „For each container give:“, the dropdown lists for „container“, „closure“ and „administration device“ contain „N/A“ twice.	In Section 2.2.3, the three drop down lists: Container, Closure and Administration Device now only contain a single instance of N/A.

id	Description	Comments
emea00039369 / EAF-1918	I have reviewed the forms and under 2.2.3 for the MAA_human form noted that there is a duplication of NA under the “Administration Device” .	In Section 2.2.3, the three drop down lists: Container, Closure and Administration Device now only contain a single instance of N/A.
emea00039360 / EAF-1913	The field "Units" (following “strength”) offers a picklist but single symbol can be entered manually that is not checked against the CV	In Section 2, the unit’s field no longer allows users to type characters into the field.
emea00039362 / EAF-1914	In Section 2 or 3, the field "Units" should be mandatory since “strength” is mandatory, too	In Section 2, the unit’s field is now mandatory, and is highlighted when the validation button is pressed.
emea00039425 / EAF-1929	The handling of the title-field is inconsistent. It is mandatory everywhere but in 2.4.2 and 2.4.4.	In Section 2.4.2 and 2.4.4, the title field has been made mandatory.
emea00039448 / EAF-1936	the text. Do you have admin address and manufacturer address? Yes No. The text should be reverse.	In Section 2.5.1, the wording of the question has been changed to read: Do you have a separate admin and manufacturer address?
emea00039468 / EAF-1951	eAF version from June 2014, paper version June 2015 (http://ec.europa.eu/health/documents/eudralex/vol-2/index_en.htm)	The cover sheet on all four eAF forms have been updated to be consistent with the current versions of the eAF paper forms.
emea00039500 / EAF-1960	The page numbers are missing on section 2.6 when the format of the page changes from portrait to landscape. For the renewal form, it is on section 3.	In Section 2.6 the page number is now displayed on the page.
EAF-1970	1) Copy contact details from 2.5.1a does not copy the data. 2) copy contact details from declaration section does not copy the data	In Section 2.5.3, the buttons: copy from section 2.5.1a and copy from declaration section now behave as expected.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Id	Description	Workaround/Comment
	workflow).☐	

Additional information

NOTE: On the 23rd October 2015, the change control software used at EMA was changed. All existing entries were migrated and given new reference numbers. The old reference ID's have been kept for continuity and are prefixed with 'emea', the new ID's used with the system all begin 'EAF'. Effective from the 23rd October 2015 the new ID will be used for all new changes raised against eAF forms.

NOTE: To aid clarification of which version of the form is being used, the eAF Version Number is now displayed on the cover sheet for this electronic form.

Version 1.18.0.0 (Release Date: 07/07/2015)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various change requests and defects as outlined below.

Issues fixed for this version

id	Description	Comments
emea00036814	Section - 1.6.5 - HAS THIS APPLICATION BEEN SUBJECT TO PIP COMPLIANCE VERIFICATION? Not Applicable tick box option should be added.	In 1.6.5 section – “Not applicable” tick box option has been added
emea00037580	Section 2.5.2 - cannot differentiate between the manufacturer of the powder and diluent.	In Section 2.5.2 - Free text field has be added at the beginning of the section to describe the partial product. e.g vial with solvent, vial with powder, solvents"
emea00037513	Section 2.2.3 - The sub numbering “2.2.3.1” is missing	In Section 2.5.3 - the sub numbering “2.2.3.1” has been added.
emea00037336	Populate button should be added in sections 2.4.3 and 2.4.1	In Section 2.4.2 and 2.4.3 - "Copy contact details from 2.4.1 section" button has been implemented.
emea00037111	In Section 2.2.3 - Container, Closure and Administrative list returning same data set for dropdown where different dataset is required.	In Section 2.2.3 - Individual data set is now returned in Container, Closure and Administrative device dropdown list.
emea00037329	In Section 2.5.2 - “Enter EudraGMP Manufacturing Authorisation reference” field gives validation error appears after close and reopen the form	Resolved the validation error in 2.5.2 section which appears after close and reopen the form.
emea00037349	Several addresses need to be entered multiple times. Would it be possible that the first address in the Declaration section can be used to be populated at the	In Declaration section – “Copy contact details from previous section” button has been implemented. In 2.4.1 section - Copy contact details from declaration section” button

id	Description	Comments
	next section	has been implemented.
emea00034829	In Section 1.4 and 1.6.1 not possible to show the connection between the product strength and authorisation number.	In Section 1.4.2, 1.4.3, 1.4.4 and 1.6.1 - strength, ma holder, ma numbers date of authorisation has been implemented in a tabular format to relate between product strength and authorisation number.
emea00037448	Section 2.5.2 and 2.5.3 - it is not possible to include different company names in this section when there are different company names in the administration office (DMF holder) and the manufacturing address. It should be possible to add different company names. And it should be able to repeat manufacturer address (one admin address with many manufacturer address)	In section 2.5.2 and 2.5.3 – Company name has been added to admin and manufacturer address. Manufacturer address has been implemented with +/- buttons to repeat section.
emea00037581	2.5.1.2, 2.5.2 and 2.5.3 - Guidance on how to complete the section should be added.	In Section 2.5.1.2, 2.5.2, 2.5.3 – the below note has been added. "note: please see the `Compilation of Union Procedures on Inspections and Exchange of Information' document, (see pages - Interpretation of the Union Format for Manufacturer/Importer Authorisation): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf"
emea00037471	In Section 2.6.1 - Add free text field to add description of active substances.	In Section 2.6.1 - new free text field has been added to provide description of active substance field with repeatable +/- buttons.
emea00037330	In Section 2.5 – add "populate button " to repeat the same addresses in this section.	"Populate contact details in 2.5.2 and 2.5.3" button has been added in 2.5.1 section.
emea00037986	Admin and Manufacturer address tooltip needs to be amended.	All Admin and Manufacturer address in the form has been updated with corresponding tooltips.
emea00037456	Copy button for section 2.6.1 for repeatable active substances and excipients should be added.	In Section 2.6.1 – when active substances and excipients section repeated for different strengths then "copy data" button will appear to click.
emea00037319	In Declaration section - It is not clear why the field 'Active Substance(s)' is provided as a grey shaded field when it is not possible to insert text directly in that field. It was only	In Declaration section – grey active substance field is hidden and it will appear when active substance searched and added into the field.

id	Description	Comments
	possible to add information on an Active Substance by clicking on - add active substance.	
emea00037517	Section 2.4.1 - tooltip needs to be updated for payment section	In Section 2.4.1 – Tooltips has been amended in the payment section.
emea00037346	Auto populate from Declaration section as separate fields for each of the substances in Section 2.1.2	2.1.2 Section is now auto populated data form declaration section by clicking “populate” button in declaration section.
emea00037775	Section 2.4.1 –payment section - it is only possible to select either “yes“ or “no“ for the Proof of payment. We often have a situation when we submit the application for several countries and some require the payment in advance and some do not.	In Section 2.4.1 – proof pf payment section – now it is possible to select both “yes” and “no” option by repeating the section.
emea00037437	In Section 1.1 - did not reject RMS also included as CMS. If a country is chosen as a Reference Member State it should not be possible to select same member state as a Concerned Member State.	In Section 1.1 - term "None" has be added in the concerned member states dropdown field, and if CMS is selected same as RMS then error message will pop up as below. “CMS should not be same as RMS. If there is no CMS is involved then please select 'None' from the list ",
emea00037875	In Section 2.6.1 – Excipient/overage field is blank and cannot be populated	Resolved the defect in section 2.6.1 where excipient/overage field not displaying data.
emea00038310	Tooltip needs to be updated - For 2.4.4 ‘Summary of the applicant pharmacovigilance system’ - number field	Resolved the defect in “section 2.4.4 - Number field” – Tooltip has been amended
emea00038337	Section 2.2.1 not all strengths have been populated from Declaration section, only first 2 are visible in the 2.2.1	Resolved the defect in “Section 2.2.1 – strength field” – where all values were not populated from declaration section.
emea00038327	Active substance in 2.1.2 and 2.5.3 - note should be added to mention that it is populating from declaration section	Resolved the defect in “Section 2.1.2 and 2.5.3 – active substance field” – note “The value of the active substances field has been populated from Declaration section” has been added.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.17.0.0 (Release Date: 23/03/2015)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various change requests and defects as outlined below.

Issues fixed for this version

id	Description	Comments
emea00036835	eAF takes long time to open pdf even after the form is locked.	Resolved this defect – Now eAF takes lesser time to open pdf after it is locked.
emea00036262	Section 2.6.3 - after validated/saved the “Date of Submission” field is highlighted yellow and gives validation error when reopens.	Resolved defect in Section 2.6.3 – after validated/saved there won’t be any validation error for “Date of Submission” field when reopens.
emea00035944	When previous version of xml imported into latest version of eAF, there is error message says you are using old version.	Resolved this defect - When previous version of xml imported into latest version of eAF, there will be no error message box.
emea00035908	section 2.2.1 - superscript format is not working after populated data from Declaration Section	As superscript format is not copied across the other sections in pdf due to limited functionality in pdf, the below tooltip has been updated in the strength fields "Insert details regarding strength in the free text field. (Please enter strengths in separate fields if the composition is different for different strengths. And please insert superscripts and subscripts as symbols to maintain formatting)."
emea00035819	Section 2.2.3 - It is not possible to add additional rows in Section 2.2.3 for 'proposed storage conditions'	Section 2.2.3 – Resolved issue to add additional rows for “proposed storage conditions”.
emea00035818	Populate data' button in 'Declaration' section which leaves	Declaration Section – resolved issue in populate button which leaves

id	Description	Comments
	section 2.2.1 unpopulated	section 2.2.1 unpopulated.
emea00035643	Section 2.6 – free text field should be changed into 1 millilitre or 1 litre or 1 drop (no valid selection), all solid forms will be 1 piece, all powders can be 1 gram or kilogram, and a gas may have litre or kilogram.	Section 2.6 free text field has been changed into 3 fields 1. Free text field to enter only numbers. 2. Dropdown field to select Units of Measurement. 3. Dropdown field to select Pharmaceutical form.
emea00035620	Section 1.4.2: Article 10(1) generic application – Strength field needs to be repeatable.	Section 1.4.2 – "Strength" field is now repeatable with +/- buttons.
emea00035618	All of the drop down/selectable fields in eAF from EUTCT should allow to see Provisional terms.	Provisional terms of drop down/selectable fields in eAF from EUTCT are available now.
emea00035619	In Declaration section - add multiple strengths for same active substance.	Declaration Section – "Strength" field is now repeatable with +/- buttons.
emea00035605	Section 4.1 - yes/no check box has no option to be left blank.	Section 4.1 - "not applicable" option has been implemented.
emea00035196	Section 2.6.1 - quantity/unit section in excipients - validation error.	Section 2.6.1 - quantity/unit section in excipients table has been implemented same as active substance table.
emea00034825	Section 2.6.1 – Excipients - it seems still not be possible to divide the composition into tablet core, coating 1, coating 2 or capsule content and capsule composition.	In Section 2.6.1 – Excipients - free text field has been added in to specify coating.
emea00034822	Address fields are different format in different sections	Declaration section - address field section has been changed to common format. Section 2.4.4 – Pharmacovigilance system master file - address field section has been changed to common format.
emea00034738	Specific list of manufacturing functions list to be displayed as a drop-down lists in Manufacturers section.	2.5.1.2 - new dropdown list field has been implemented in "Brief description of control tests carried out by the laboratory(ies) concerned". 2.5.2 - new dropdown list field has been implemented in "Brief description of functions performed". 2.5.3 - new dropdown list field has been implemented in "Brief description of manufacturing steps performed by manufacturing site". • When Centralised procedure selected in Section 1 – Only drop

id	Description	Comments
		down field will be visible & mandatory, free text field will not be visible. • When other procedures selected in Section 1– both free text field and drop down field will be visible and either one is mandatory
emea00033201	Section 2.2 - Container, material and closure needs to be repeatable.	Section 2.2 - Container, material and closure fields are now grouped and repeatable with +/- buttons.
emea00032941	In Section 2.2.3 - User should be able to select N/A from Container, Closure and Administration Device drop down lists.	In Section 2.2.3 – N/A option has been implemented in the drop down list for Container, Closure and Administration Device.
emea00030754	Section 1.4.3: Article 10(3) hybrid application – Strength field needs to be repeatable.	Section 1.4.3 – "Strength" field is now repeatable with +/- buttons
emea00027113	Repeated fields are not removed in a user friendly manner.	1.4.2, 1.4.3 1.4.4 and 1.6.1 sections have been amended with +/- buttons in relevant fields.
emea00022342	2.5.1.1 - Should there be a company field for this section as well in case the organisation is different from MAH.	In Section 2.5.1.1 – "Company name" field has been added.
emea00037524	In Proposed shelf life - dropdown list - N/A should be added.	In Section 2.2.3 – proposed shelf life – "N/A" has been added to standard time unit's dropdown list.
emea00037531	ATC code search field tooltip needs to be updated.	In Section 2 – ATC code field tool tip has been updated.
emea00037334	Section 2.6 Qualitative and quantitative first row tool tip.	In Section 2.6 – Qualitative and quantitative – quantity free text field tooltip has been updated.
emea00035561	eAF takes longer time to load and open.	The performance issue has been resolved which was slow to load and open eAFs. "Update list" button has been added in the validation section to reload the EUTCT list if needed.
emea00037528	In Human and VET - section 1.1 - proposed common renewal date field should allow both text and date in this field, And tool tip needs to be updated.	In Section 1.1 - The proposed common renewal date field now allows to enter text or date.
emea00037512	Section 2.4.5 - Name of contact person missing.	In Section 2.4.5 – "Name of contact person" label has been added.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.16.0.1 (Release Date: 02/10/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This hotfix release addresses a critical issue.

Issues fixed for this version

id	Description	Comments
emea00035755	In 1.16.0.0 forms - there is a space at the beginning of the version number in the XML which is causing an error message while export.	Resolved this issue in version number – space has been removed.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.16.0.0 (Release Date: 26/09/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various change requests and defects as outlined below.

Issues fixed for this version

id	Description	Comments
emea00022216	Request for a drop down field with standard time units list. e.g days, weeks, months etc.	In Section 2.2.3 –in “Proposed shelf life section” drop down field with standard units list has been implemented.
emea00026537	Annex 5.14 should be mandatory if scientific advice has been given - section 3.1.	In Section 3.2 – “Annex 5.14” check box becomes mandatory when yes is selected.
emea00026712	Some companies are located in Cities, Towns or Villages. City could be changed to City/Town/VillageCity/Town/Village.	“Address” field has been changed to “Address1” and “City” field has been changed to “Address2”
emea00031790	A free text field has been requested for section 2.5.1.a of the MAAA-H & MAA-V to enable users to specify which packaging a manufacturer is responsible for. A free text field already exists in 2.5.2 and could be used for this purpose.	In Section 2.5.1.a – free text field has been implemented toenter the details of which packaging a manufacturer is responsible for. So that the relationship between packaging and packaging manufacturer(s) can be shown in case there are different/multiple manufacturers.
emea00033037	The field 2.1.3 Pharmacotherapeutic group - The ATC code is selected from a dropdown list from EUTCT rather than free text field. This could be an issue as in many cases the ATC code has not been decided/allocated at the time of the application and the applicant will only propose higher levels. The field could be broken up to select some parts of the ATC code from a list and allow free text for the rest.	In Section 2.1.3 – ATC code is searchable field via EUTCT list.

id	Description	Comments
emea00033494	Add possible data-entry fields for administration and manufacturing location (as done in 2.5.3)	In Section 2.5.1.a, and 2.5.2 - Address fields are changed to Manufacturer address and Admin address. • "Do you have admin address and manufacturer address? Yes, No" has been added. • If 'yes' selected Manufacturer and Admin address are visible • If 'no' selected one address details are visible.
emea00033500	Rename button into "Add study" and make company information repeatable within a study.	In Section 2.5.4 – "Add study" button has been added and company details are grouped and repeatable with +/- buttons inside.
emea00034743	Some additional telephone number fields have been found to still only accept 30chars. for consistency they should all now be 50. Specific fields found are the admin and manufacturing numbers.	Maximum length of "Telephone number" has been increased from 30 to 50 characters.
emea00034923	Following problem with the eAF for Variations: In the section "Proof of payment" it is not possible to provide the different billing addresses for the MAs in the different countries in this section. Would it be possible to duplicate the section also for the address? So there would be the possibility to provide the Member states A and B for the MA holder X and the Member state C for the MA holder Y?	Resolved issue in Section 2.4.1 – Proof of payment section – "Billing address" has been repeatable with +/- buttons
emea00035076	Request to include more than one contact person in sections 2.4.2 & 2.4.3 of the MAA-H.	In Section 2.4.2 and 2.4.3 – "Contact details" are repeatable with +/- buttons
emea00035564	In Section 2.5.3 Admin/Manufacturer address fields should be in line with other address fields such as Address1 and Address 2	In Section 2.5.3 – Admin/Manufacturer Address field changed to Admin/Manufacturer Address 1 and Address 2.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.15.0.0 (Release Date: 10/06/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various defects and change requests as outlined below.

Issues fixed for this version

id	Comments
emea00022316	In Section 2.2 – “Strength” and “Active substance” fields have been grouped with repeatable + and – buttons.
emea00022347	In Section 2.6.1 – “Strength”, “Active substance” and “Excipients” are grouped together with repeatable + and – buttons to link with each other
emea00031054	In section 2.6.1 – the terms "less than or equal to" or “more than or equal to” are suggested to use for "Quantity sufficient".
emea00033428	Resolved issue in section 2.6.1 “strength” field - special characters such as super and subscript have been implemented to allow manual formatting.
emea00033489	In section 1.4.3 Hybrid application – under “Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product”, a “Member states” field has been added with repeatable + and – buttons. This field appears only if MRP/DCP procedure selected in Section 1.1.
emea00033490	In Declaration and Signature section – “Strength” and “Active substance” fields have been grouped with repeatable + and – buttons.
emea00033491	In section 2.3.1 - Radio buttons are changed to check boxes, and “member states” field has been added separately for both check boxes.
emea00033492	Sections 2.3.2 and 2.3.4 are visible when both check boxes selected in 2.3.1 section.
emea00033499	In Section 2.4.2 to 2.4.4 – “Member states” field has been added with repeatable + and – buttons.
emea00033723	Resolved defect in section 2.2.3 – “Material” field now displays full text.
emea00033724	Maximum length of Package size” field under “Section 2.2.3” has been increased from 50 to unlimited characters.

id	Comments
emea00033725	Resolved issue in section 2.5.3 – “country” field is now displays after “postcode” field.
emea00033726	Resolved issue in section 2.5.2 –if ‘Site outside EEA’ is selected, “If yes” text was missing in, “please provide summary information in Annex 5.9 (and, if available a GMP certificate or a statement from the competent authority which carried out the inspection)”
emea00033727	In section 2.5.3 - "Provide copy in Annex 5.10" appears only if yes is selected.
emea00033795	In section 1.4.2 generic application – under “Medicinal product authorised in the Union/Member State where the application is made or European reference medicinal product”, “Member states” field has been added with repeatable + and - buttons, and this field appears only if MRP/DCP procedure selected in Section 1.1.
emea00033796	In Section 2.3.3 and 2.3.4 - “member states” field has been added separately for both check boxes.
emea00033797	In section 2.3.1 – free text field has been added and grouped with member states field with repeatable + and – buttons.
emea00033798	In sections 2.5.1.a and 2.5.2 – “address” fields are amended as same as 2.5.3(admin and manufacturer address separately)
emea00033985	Resolved issue in section 2.4.1 – Billing address (when relevant) is now optional and is invisible when “yes” is selected under “Proof of payment”.
emea00034011	Maximum length of “(Invented) Name” field under “Section 2” has been increased from 250 to unlimited characters.
emea00034159	In Declaration and Signature section - "Applicant" text field has been added.
emea00034400	Resolved issue in 2.5.3 section - “Name of the manufacturer if different from above” field is optional now.
emea00034405	Resolved issue in version control - which was not working in 1.14.1 version.
emea00034677	Resolved the issue in email format - which was not able to enter .info and .asia
emea00034687	Resolved the issue in annex 5.1 - which was checked even it hasn’t been checked in Declaration or 2.4.1 section.
emea00034689	In Section 2.3.1 – tool tip has been amended.
emea00034690	In Section 2.3.1 – “Subject to medical prescription” label has been amended to “Subject to medical prescription (*complete section 2.3.2*)”.
emea00034699	Resolved issue in 2.2.3.1 – “proposed shelf life” section was not able to add multiple rows.
emea00034701	Telephone number field characters have been increased to 50 from 30.
emea00034702	In Section 3.1 – reference field characters limit has been increased to unlimited.
emea00034688	Annex 5.8 tick box in 2.5.2 section has been removed from repeatable section and appears only at end of the section.

Known issues

Id	Description	Workaround/Comment
emea00027134	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.14.1.0 (Release Date: 22/04/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various defects as outlined below.

Issues fixed for this version

id	Comments
emea00033916	Resolved an issue in section 2.5.3 – active substance field data not visible after a save, close and a reopen.
emea00033977	Resolved an issue in section 5.1 – tick box not selected after a save, close and a reopen.
emea00034281	Resolved an issue in section 5.9 and 5.10 – tick box not selected after a save, close and a reopen.
emea00034010	Resolved an issue in section 2.6.1 –composition free text field data not visible after a save, close and a reopen.

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.14.1 (Release Date: 06/02/2014)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release fixes various defects as outlined below.

Issues fixed for this version

id	Comments
emea00031163	An issue in the form which gave three validation errors relating to Title, First Name and Surname has been resolved.
emea00031234	An issue in section 5.1 - under 2.4.1. If you tick 'no' to the question "Have all relevant fees been prepaid to competent authorities?", the checklist at the end of the form for "5.1 Proof of payment" is now automatically updated.
emea00032109	Resolved an issue in section 2.5.3 which gave a validation error in "EudraGMP certificate Number" after a save, close and a reopen.
emea00032292	Resolved an issue in section 1.6.3 - under 1.6.1, if 'no' is selected it is not visible after a save, close and a reopen.
emea00027134	Resolved issue in section 2.2.1 – This section is now read only where the field is populated by clicking the "Populate" button in the Declaration Section.
emea00031799	All forms, when opened, check for the availability of the webservices, if the webservices are not available , an error message is displayed.
emea00032898	In section 1.6.3 – The tick boxes have been added to "PIP decision number" and "product specific waiver decision number" fields.
emea00031644	In section 1.6.3 - The maximum length of "PIP decision number", "product specific waiver decision number" and "class waiver decision number" has been increased from 30 to 50 characters.
emea00033684	In section 2.6.1 -A free text field has been added.
emea00033675	In section 2.1.2 and 2.5.3 active substance fields - The search button has been removed in order to select the active substance from previously selected list.
emea00032940	2.5.1.2 Section is now optional.

id	Comments
emea00033221	In section 2.4.1 Have all relevant fees been prepaid to competent authorities - billing address is now optional if 'No' selected.
emea00031791	In section 2.1 - The tick box for "Proposed (invented) name of the medicinal product in the Community/Member State/ Iceland/ Liechtenstein/Norway:" is only visible for MRP/DCP procedure.
emea00031793	In section 1.6.1 - A new active substance field has been added.
emea00031794	In Section 1.2.1 - The orphan designation procedure number is now repeatable.
emea00031796	In section 1.1.2 - – Implemented business rule: • When Repeat use is selected, Section 4.2 is now mandatory.
emea00032375	In Section 1.2 the title has been changed to “Orphan Medicinal Product Designation” from “Orphan Medicinal Product Information”.
emea00033680	In Section 2.5.3 – the active substance fields are now repeatable

Known issues

Id	Description	Workaround/Comment
emea00029681	The eAFs do not currently allow a user to enable fast web viewing - and are not built/saved with fast web viewing enabled. This is an issue as the eCTD criteria requires that all submitted PDFs are saved with fast web viewing enabled to satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application workflow).☐	User will see unexpected errors in eCTD technical validation. We are investigating ways in which the fast web viewing within the eAFs could be enabled. This issue does not prevent any forms from being used, as it is a best practice failure only.

Additional information

None

Version 1.10.1 (Release Date: 02/09/2013)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This release implements changes introduced in the substance list in EUTCT. This release fixes various other defects as well (see below).

Issues fixed for this version

id	Comments
emea00032078	This release implements changes introduced in the EUTCT substance list. The substance list now contains two separate lists; one for Human substances and one for Veterinary substances. • The active substance fields and excipients field now searched only Human substance list.
emea00031987	In section 2.4.2 – “Switzerland” has been added in the country list.
emea00031988	In section 2.2.4.1 – Resolved issue which was not able to select non EU/EEA country list.

Known issues

Id	Description	Workaround/Comment
emea00027134	It is still possible to add additional active substances in section 2.2.1. If active substance is added to 2.2.1 it will not be added to the Declaration section. Clicking the “Populate” button in the Declaration section will overwrite any data in section 2.2.1.	User should only add active substances to the declaration section of the form and then use “Populate data” button to copy automatically to sections 2.2.1 and 2.6.1.

Additional information

None

Version 1.8.2 (Release Date: 31/05/2013)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.*	This implementation is the version 10.1 of the NTA word document as an electronic form. This release fixes various other defects as well (see below).

Issues fixed for this version

id	Comments
emea00029257	The latest revision of the MAA H Word form, revision 10.1, has been implemented in the eAF.
emea00027275	In section 2.2.3 – Material field has been added.
emea00027351	Annex 5.6 selection now removes after checkbox is unselected in 2.5.1.2.
emea00028830	In section 2.6.2 The field called “Active Substance” is changed to “Name”.
emea00027360	Resolved issue in section 4.1.3 - elaborate entry field has been removed which is not in paper form.
emea00029357	Resolved issue in section 1.6.1 which failed to save data for more than one MA’s after save, close and reopen.
emea00026316	Version control has been implemented - when the MAA-H eAF is opened via a computer that is connected to the internet, an automated version check is performed to inform the user if a more recent version of the eAF is available for download. If the most recent version is not being used a warning window appears informing the user that a more recent version should be used.

Known issues

Id	Description	Workaround/Comment
emea00027134	It is still possible to add additional active substances in section 2.2.1.	User should only add active substances to the declaration section of the form and then use “Populate data” button to

Id	Description	Workaround/Comment
	If active substance is added to 2.2.1 it will not be added to the Declaration section. Clicking the “Populate” button in the Declaration section will overwrite any data in section 2.2.1.	copy automatically to sections 2.2.1 and 2.6.1.

Additional information

None

Version 1.6.0 (Release Date: 31/10/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2008, Revision 9.*	This release fixes various defects.

Issues fixed for this version

id	Comments
emea00027228	The drop down list for the selection of units of measure in section 2.6.1 now allows all available units to be selected.
emea00027363	In section 4.3 – The checkbox for annex 5.16 has been added to the repeating group, allowing it to be checked for each medicine.
emea00027693	The substance and route of administration search fields no longer accept a carriage return as input. Instead, if the 'Enter' key is pressed while one of these fields has focus, the search will be executed.
emea00027340	In section 2.4.1 – Implemented validation rule making the annex 5.7 checkbox mandatory, if SME status has been assigned.
emea00027343	In section 2.4.4 – Implemented business rules: • the 'Telefax' field now optional, • the checkbox for annex 5.5 now mandatory, • And the checkbox labelled 'The above mentioned qualified person resides in the EEA' now mandatory.
emea00027362	In section 4.2 – Implemented business rule: • All fields which appear below the 'Authorised' checkbox when it is selected are now mandatory.

Known issues

Id	Description	Workaround/Comment
emea00027134	It is still possible to add additional active substances in section 2.2.1.	User should only add active substances to the declaration section of the form and then use "Populate data" button to

Id	Description	Workaround/Comment
	If active substance is added to 2.2.1 it will not be added to the Declaration section. Clicking the “Populate” button in the Declaration section will overwrite any data in section 2.2.1.	copy automatically to sections 2.2.1 and 2.6.1.

Additional information

None

Version 1.5.3 (Release Date: 31/08/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2008, Revision 9.*	This release addresses the locking of the form fields after the form has been signed, an issue with annex 5.9 and incorrect data population with multiple active substances. In the following tables, more details can be found for this and other change requests that have been implemented in this release.

Issues fixed for this version

id	Comment
emea00026911	eAFs are now "locked" from further editing after completion. It is still possible to extract the form data as XML.
emea00027042	In section 2.5.2 - Resolved issue that prevented user accessing the check box indicating something has been added as annex 5.9 on section 5.
emea00027134	Resolved issue automatically copying multiple active substances from Declaration section when “Populate” button clicked.
emea00027237	Maximum length of “Applicant details name” increased from 50 to 100 characters.

Known issues

Id	Description	Workaround/Comment
emea00027134	It is still possible to add additional active substances in section 2.2.1. If active substance is added to 2.2.1 it will not be added to the Declaration section. Clicking the “Populate” button in the Declaration section will overwrite any data in section 2.2.1.	Only add active substances to the declaration section of the form then use “Populate” button to copy to all other sections (including 2.2.1).

Additional information

None

Version 1.4.3 (Release Date: 16/07/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2008, Revision 9.*	This release addresses the product section redesign which includes the replacement of the free text fields that were used for the description of the product, with structured fields and controlled term lists. In the following tables, more details can be found for this and other change requests that have been implemented in this release.

Issues fixed for this version

id	Comment
emea00026303	Product redesign to be implemented across all sections. Replacement of free text fields with controlled term lists wherever possible and restructuring of the sections and data model to be RDM compliant.
emea00026312	MAA Human form - TSE Number. Allow +/- repeat group for "TSE Number" field.

Known issues

Id	Description	Workaround/Comment

Additional information

None

Version 1.2.22 (Release Date: 18/06/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2008, Revision 9.*	This hotfix addresses a critical issue and a number of quick wins identified in the pilot phase. More details can be found in the section directly below.

Issues fixed for this version

id	Comment
emea00026296	"Find" functionality e.g. for "Route of administration" has been redesigned to avoid a data loss defect that would impact XML export users.
emea00025240	Section 1.1.1: When "Mandatory scope" is selected, one of the following must now also be selected: Annex (1) (Biotech medicinal product) Annex (3) (New active substance for mandatory indications) Annex (4) (Orphan designated medicinal product)
emea00025242	Section 1.1.1: When "Optional scope » (Article 3(2))" is selected, one of the following must now also be selected: Annex 3(2)(a) (New active substance) Annex 3(2)(b) (Significant innovation or interest of patients at EU level)
emea00025245	Section 1.1.1: "Date of acceptance/confirmation by CHMP" is now mandatory.

Known issues

Id	Description	Workaround/Comment
emea00022017	Inability to select "Attach marketing authorisation (Annex 5.15)" in section 4.2 for each of the marketing authorisations, when 'Authorised' option is checked.	Applications may indicate attachment within the 'Authorisation number' field e.g. by suffixing with the text "MA included". Please check the 'Attach marketing authorisation (Annex 5.15) option beneath the window only if ALL MAs are attached to the application.

Id	Description	Workaround/Comment
emea00025154	Section 2.5.2 “Site is in the EEA” radio button option: When the form is closed and re-opened the “Site is in the EEA” sub-section of 2.5.2 remains in the collapsed state.	Click on the 2.5.2 “Site is in the EEA” radio button to reopen the sub-section.
emea00025833	Section 1.1.2 The section of RUP is not identical to paper form. Section to identify procedure after first round MRP or DCP is missing and additionally a section.	Will be fixed in next release.

Additional information

None

Version 1.0.0 (Release Date: 29/02/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: *Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2008, Revision 9.*	This implementation is the first version of the document as an electronic form.

Issues fixed for this version

id	Comment
n/a	This implementation is the first version of the document as electronic form.

Known issues

Id	Description	Workaround/Comment
emea00021979	The 'Excipient(s): Name of excipient, Quantity, Unit, Reference/Monograph standard.' free text area in section 2.6.1 allows entering any excipient.	Free text area to be replaced by structured content.
emea00022017	Inability to select "Attach marketing authorisation (Annex 5.15)" in section 4.2 for each of the marketing authorisations, when 'Authorised' option is checked.	Applications may indicate attachment within the 'Authorisation number' field e.g. by suffixing with the text "MA included". Please check the 'Attach marketing authorisation (Annex 5.15) option beneath the window only if ALL MAs are attached to the application.
emea00025154	Section 2.5.2 "Site is in the EEA" radio button option: When the form is closed and re-opened the "Site is in the EEA" sub-section of 2.5.2 remains in the collapsed state.	Click on the 2.5.2 "Site is in the EEA" radio button to reopen the sub-section.

Additional information

None