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Information Technology
EMA/275948/2017

eAF Release Notes

This document lists and briefly describes the new features and fixed issues included in the release of the electronic application form: *Application for Renewal of a Marketing Authorisation*.

The most recent release appears first.

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

Version content

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

Change requests/Issues fixed for this version

id	Description	Comments
SD-45930	Section 3 - Add clone button in Qualitative and quantitative composition – active substance and excipients table.	In section 3 - 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-45920	Section 1 - Add selected and remove button should be added for MA number.	In section 1 - under pharmaceutical form section - "Add selected" and "remove all" buttons has been added above to the MA number
SD-45913	Section 1 – Concerned member state – when member state is removed here then it should refresh and automatically delete the corresponding member state in relevant sections	In Section 1 – Concerned member states – when "-" button is clicked it will refresh and delete the concerned member state in section 1 and also in other sections such as in "Invented Name section", "MA number section", "Name and address of MA holder section", "Name and address of contact person section" and "proof of payment section" if both sections have same number of member states selected.
SD-27691	For national procedure applications the Member State(s) fields should not be visible in proof of payment section	In Section Declaration and signature section – Member states field is hidden when National procedure is selected in section 1.

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 1.20.0.4 (Release Date: 07/02/2017)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	This release note is for the 1.20.0.4 (previously known as 1.20) technical release, for the eAF forms.

Issues fixed for this version

id	Description	Comments
SD-60221	Section 3 - It is not possible to select more than two Overages.	In section 3 – the issue has been resolved to select more than two overages.
SD-45880	Declaration section – Active substance – If 2 nd 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 2 nd active substance. The 'Ok' button does not clear the row if the 2 nd active substance isn't selected.	Declaration section – Active substance – Ok button clears the 2 nd 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-45885	Section 2 - When multiple manufacturers and laboratories are added empty pages are added.	Section 2 – Now we can add multiple manufacturers & laboratories and it won't generate empty pages.
SD-45935	Declaration and Signature - Proof of Payment - Tooltip for this section missing, wording unclear.	Declaration and Signature - 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"

id	Description	Comments
SD-45916	Section 1 – 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 – for Concerned Member States (CMS) – pop up message in delete button has been removed.
SD-45911	Section 3 - Active Substances are cropped for overages section.	Section 3 - Active Substances field width is increased in overages section to display long active substance names.
SD-45898	Section 3 - Qualitative and quantitative composition – Quantity/Unit field - When “quantity sufficient” term is selected then quantity and unit fields should be optional	Section 3 - 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.	<p>“Add selected” button removed in section 1 – Concerned Member States (CMS)</p> <p>Add All button removed in the following sections</p> <p>section 1 –</p> <ul style="list-style-type: none"> • Invented name section, • Name and address of MA holder, • Name and address of contact person <p>Declaration section – proof of payment</p>
SD-45910	In Section 2, ‘’. It would be helpful if there is also a button for “Copy address details from ‘Batch control’” in Medicinal product manufacturing sites	In Section 2 – Manufacturer of the Medicinal product – new “copy contact details from batch control” 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.

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

Id	Description	Workaround/Comment
		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: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	This release note is for the 1.20.0.3 hotfix, for the eAF forms.

Issues fixed for this version

id	Description	Comments
SD-52718	More than nine Overages in section 3 cause hidden overflow and generate multiple empty pages	In Section 3 - Now we can add more than 9 Overages and it won't hidden overflow and/or generate multiple empty pages
EAF-2217	In Section 1 - remove the 'add all' button in the 'is the product currently marketed' and select 'Yes'.	In Section 1 - "Add all" is removed from the section "is the product currently marketed".

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.
EAF-2219	'Add all' button does not add all member states in section 1, Invented name. Please use 'add selected' to ensure that RMS and all relevant CMS are added in this section.	

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

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	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 2.6.1: Decimal separators and commas: The only change should have been not to allow a comma.	In section 2.6.1 all numeric fields have been reverted to text fields, and a message has been added, reminding the user to use a full stop as the decimal separator.

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.

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

Version content

Functionality / use case	Comments
Implementation as electronic form of the document for: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	This is a hotfix release for version 1.20.0.0.

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 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 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	Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat.

Id	Description	Workaround/Comment
	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, when the form is reopened. This issue is not observed in Adobe Acrobat which will open the file without issue.	
EAF-1729	Import of form with signatures locks new form	For consideration in a future release.
EAF-1962	Ok Button does not verify the active substance selected or not.. Clear Button does not clear the data	For consideration in a future release.
EAF-1968	No Suggestions Provided on typing units next to Quantity in all Forms	For consideration in a future release.
EAF-1973	Issue with validation during saving forms	For consideration in a future release.
EAF-2002	Tool Tips not in sinc with the change made by Jira issue 1673	For consideration in a future release.
EAF-2025	Error displayed when clicked on (Click here to populate data in to section 3)	For consideration in a future release.
EAF-2085	After selecting all CMS, one has to again select from the whole list of countries the Member states in which the product is marketed.	For consideration in a future release.
EAF-2086	CMSs mentioned twice and empty rows showing no CMS are also listed	For consideration in a future release.
EAF-2088	Member States have to be entered twice. After Invented Name and later in conjunction with the MA number.	For consideration in a future release.
EAF-2089	In Section 2, ‘’. It would be helpful if there is also a button for “Copy address details from ‘Batch control’”	For consideration in a future release.
EAF-2094	Section 2, Approved Manufacturers, copy address details only works for first instance.	For consideration in a future release.
EAF-2099	Section 3. Qualitative and quantitative composition, When quantity sufficient is selected the quantity and unit fields should be optional	For consideration in a future release.

Id	Description	Workaround/Comment
EAF-2100	Section 1, Selection for member states across the section 1, in some fields for MS section there is a limitation that the same member state cannot be selected twice, in some there isn't	For consideration in a future release.
EAF-2134	Section 1 and 2, The RMS should also be a member state that could be selected.	For consideration in a future release.
EAF-2139	Section 1, Date of expiry of current authorisation in concerned member state: it automatically appears all CMS.	For consideration in a future release.
EAF-2145	Section 1/2, Once CMS and RMS selected, they should auto-populate throughout the form.	For consideration in a future release.
EAF-2153	Member states where the product is currently marketed: would be nice if using 'Add all' added only those member states selected earlier.	For consideration in a future 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	For consideration in a future release.
EAF-2155	Section 1, This section should be reformatted conform this same section in the variation form.	For consideration in a future release.
EAF-2171	Section 1, Possibility to list several active substances in the section and to provide strength for each AS.	For consideration in a future 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).	For consideration in a future release.
EAF-2186	Active Substances are cropped for overages of Human, VET & Renewal forms	For consideration in a future 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: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	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-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-1917	Would be great having the possibility to copy address details from "Name and address of MAH (marketing authorisation holder)" also for "Name and address of contact" with a button.	In Section 1, a new button has been added which will copy the address details from the MAH section above, and the tool tip has now describes the behaviour.

id	Description	Comments
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-1894	<p>We would like to ask, if there is the possibility to add different responsible persons in the application form for the renewal, similar to the different responsible persons possible in the variation application form?</p> <p>We have got this request during the validation phase of one of our procedures and are facing now problems to solve this:</p> <p>Please amend AFs including Oana Maria Pop (Partners Consulting Services SRL, Romania) as contact person for RO as CMS according to e-version PoA.</p> <p>Unfortunately it is not possible to duplicate the section for the contact in the renewal form.</p>	<p>In Section 1, the contact name and address have been modified to allow multiple responsible person details.</p> <p>NOTE: This has caused a change to the Renewal DES which has been updated.</p>
EAF-1844	It´s not possible to fill in more than one name of the medicinal product even when authorisation in MRP/DCP is selected. We couldn´t find a corresponding answer in the draft Q&A document	In Section 1, it is now possible to have multiple invented names. For each invented name defined, the member state that it is applicable to should be displayed.
EAF-1933	<p>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</p> <p>Solution: delete all "non-visible" data from the XML.</p>	In all sections, the form removes data from nodes that have been closed after having had data input.
EAF-1978	The Reference Member State needs to be added to the existing auto-populated member state list.	In Section 1, the Concerned member state +/- buttons no longer added/remove member states to the later section. The later Member state/Ma Number section is now controlled manually.

id	Description	Comments
EAF-2020	In Section 1, when a user selects the Reference Member State and then later in the Invented Names section, tries to use the the "Add All" button to populate the list with all member states, the button does not work. However if the Reference Member State is left blank the "Add All" button for Invented Names works as expected.	In Section 1, when pressing the Invented Names Add All button for member states, all member states are now added as expected.
EAF-2022	Section 1: Copy contact details from Previous section does not work in Name & address of contact person box. Fill in contact details in Name and address of MA Holder and click on Copy contact details from previous section. Here contact details are expected to be copied, but no details are copied.	In Section 1, the "Copy Contact Details from Previous Section" now copies the corresponding contact details from the previous section.
EAF-2024	First Authorization and Expiry of authorization for concerned are not created as added in section 1	In Section 1, the first authorisation and expiry of authorisation is now properly populated when using the add all, and remove all buttons.
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-2057	The field, Applicant's Reference is presently mandatory and it needs to be optional.	In Section 1, the Applicant's Reference Field is no longer mandatory.
EAF-2063	In Section 3, Pharmaceutical form is in the wrong place.	In Section 3, the pharmaceutical drop down list is now next to the caption instead of on the right hand side.
EAF-2096	The company name is much further in the left than other address fields.	In address blocks the company name and address field widths have been aligned to be the same, similar to the variation form.
EAF-2097	section 3 - Active Substances are cropped	In Section 3, the Quantitative and Qualitative active substance fields now expand to show the whole active substance name.
EAF-2141	Section 1, A country in the section where I add the date of the First authorisation and expiry date cannot be deleted.	In Section 1, when removing a concerned member state the corresponding first member state and expiry date of current is now removed correctly .
EAF-2143	Section "SIGNATURE" in the variation eAF (see screenshot hereunder), and equivalent in the human and	In Signature section ,The Job Title field now allows for longer job titles to be entered, expanding in height accordingly.

id	Description	Comments
	renewal eAFs.	
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.

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	Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat.

Id	Description	Workaround/Comment
	Chinese character set pack, when the form is reopened. This issue is not observed in Adobe Acrobat which will open the file without issue.	
EAF-1729	Import of form with signatures locks new form	For consideration in a future release.
EAF-1962	Ok Button does not verify the active substance selected or not.. Clear Button does not clear the data	For consideration in a future release.
EAF-1968	No Suggestions Provided on typing units next to Quantity in all Forms	For consideration in a future release.
EAF-1973	Issue with validation during saving forms	For consideration in a future release.
EAF-2002	Tool Tips not in sinc with the change made by Jira issue 1673	For consideration in a future release.
EAF-2025	Error displayed when clicked on (Click here to populate data in to section 3)	For consideration in a future release.
EAF-2085	After selecting all CMS, one has to again select from the whole list of countries the Member states in which the product is marketed.	For consideration in a future release.
EAF-2086	CMSs mentioned twice and empty rows showing no CMS are also listed	For consideration in a future release.
EAF-2088	Member States have to be entered twice. After Invented Name and later in conjunction with the MA number.	For consideration in a future release.
EAF-2089	In Section 2, ‘’. It would be helpful if there is also a button for “Copy address details from ‘Batch control’”	For consideration in a future release.
EAF-2094	Section 2, Approved Manufacturers, copy address details only works for first instance.	For consideration in a future release.
EAF-2099	Section 3. Qualitative and quantitative composition, When quantity sufficient is selected the quantity and unit fields should be optional	For consideration in a future release.
EAF-2100	Section 1, Selection for member states across the section 1, in some fields for MS section there is a limitation that the same	For consideration in a future release.

Id	Description	Workaround/Comment
	member state cannot be selected twice, in some there isn't	
EAF-2134	Section 1 and 2, The RMS should also be a member state that could be selected.	For consideration in a future release.
EAF-2139	Section 1, Date of expiry of current authorisation in concerned member state: it automatically appears all CMS.	For consideration in a future release.
EAF-2145	Section 1/2, Once CMS and RMS selected, they should auto-populate throughout the form.	For consideration in a future release.
EAF-2153	Member states where the product is currently marketed: would be nice if using 'Add all' added only those member states selected earlier.	For consideration in a future 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	For consideration in a future release.
EAF-2155	Section 1, This section should be reformatted conform this same section in the variation form.	For consideration in a future release.
EAF-2171	Section 1, Possibility to list several active substances in the section and to provide strength for each AS.	For consideration in a future 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).	For consideration in a future release.
EAF-2186	Active Substances are cropped for overages of Human, VET & Renewal forms	For consideration in a future 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: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	This hotfix release addresses a critical issue.

Issues fixed for this version

id	Description	Comments
EAF-2050	The cover page for the Renewal 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: <i>Notice to Applicants - Medicinal Products for Human Use - Volume 2B Module 1: Administrative information, May 2013, Revision 10.1.</i>	This hotfix release addresses a critical issue.

Issues fixed for this version

id	Description	Comments
EAF-1978	Not possible to add RMS and MA number for RMS in the auto-filled sections	In Section 1, the Concerned member state +/- buttons no longer added/remove member states to the later section. The later Member state/Ma Number section is now controlled manually.

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This release fixes various defects and change requests as outlined below.

Issues fixed for this version

id	Description	Comment
emea00038570	<ul style="list-style-type: none">The free text field for description of the active substance in section 3 incorrectly refers to "excipients"wrong tooltip for buttons Copy address details from batch release (3 times)	In Section 3 the tooltips have been updated.
emea00038698	First signature fields stay editable after the form is locked down with a signature	All fields should be read-only now.
emea00038629	2.6.1 - When the whole substance box is multiplied then the overages box show only the first one. When there are rows, the overages show correctly.	In Section 2.6.1 – The overages will now show all multiple active substance and excipients.
emea00036811	The strength is not controlled vocabulary. It is currently just free text field.	In Section 2.1.2 and 2.6. the strength field has been split into two fields: a free text field and a unit dropdown field.
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 Section1, section2 and proof of payment, the same member state if entered twice in CMS will now give an error message.
emea00037360	The MA numbers need to be assigned to the MS the number should be valid for. The list of MS involved should be taken from section 1. (Same solution as for authorisation date and expiry date)	In Section 1 - "First authorisation in Concerned Member State to which application is made" , "expiry date" and "concerned member state" are now presented in a be tabular format. and member state field values will populate from previous CMS.

id	Description	Comment
	Auto-populate from Section 1	
emea00038185	Annex 2.8 and 2.10 should not be mandatory. Both depend on the data entered (i.e. whether sites are located outside EEA or not in the territory of MRA partners, or whether batch release is done by a different Manufacturing Authorisation holder).	In Section 4 - Vet products - Annex 2.8 and 2.10 are no longer mandatory.
emea00037438	Add warning note to confirm deletion of repeated section	All delete buttons will now display a pop up with "Do you want to delete this repeatable section". If the user selected "yes" the row/section is deleted, otherwise the action is cancelled.
emea00037532	Approved Manufacturers: First line: not clear what to fill in	In Section 2 the tooltip has been changed to "click to enter role of the company, i.e - to describe which part(s) of the product are produced by this manufacturer"
emea00038395	For every hyperlink to a footnote there should be a hyperlink back to the originating location	In the footnote section all foot notes now link back to the corresponding section in the form.
emea00035779	Admin and/or manufacturing address to be shown only if 'YES' is selected	In Section 2.5. - All Manufacturer addresses will be hidden, and will be made visible when the user select "yes" to the question: "do you have admin address and manufacturer address".
emea00037338	user option to start or skip validation	The performance of the form has been greatly improved by focusing on validation of only user entered fields.
emea00039138	Existing Active Substances cannot be re-selected for any other consequent boxes.	In Section 1, when adding a new active substance, the user can now select a previously identified active substance if it is present in the list.
emea00039226	Renewal section 2: admin / manufacturing /and (company name if not have both)	In Section 2, Switzerland now appears only once in the country drop down lists.
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.
emea00039394 / EAF-1925	Page 4: The footnote if the MA number is not working:	In Section 1, Member State, MA Number (3), the Information (i) button has been removed, as it is not needed. The correct button is in the top right of the box

id	Description	Comment
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.
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.

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 (1.19) 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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This release fixes various defects and change requests as outlined below.

Issues fixed for this version

id	Description	Comment
emea00037448	Section 2 - 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 – Company name has been added to admin and manufacturer address. Manufacturer address has been implemented with +/- buttons to repeat section.
emea00037581	Section 2 - Guidance on how to complete the section should be added.	In Section 2 – 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/WC50004706.pdf "
emea00037471	In Section 3 - Add free text field to add description of active substances.	In Section 3 - new free text field has been added to provide description of active substance field with repeatable +/- buttons.
emea00037330	In Section 2 – add "populate button " to repeat the same addresses in this section.	In Section 2 "Copy address details from Batch release" button has been added.

id	Description	Comment
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 3 - for repeatable active substances and excipients should be added.	In Section 3 – 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 possible to add information on an Active Substance by clicking on - add active substance.	In Declaration section – grey active substance field is hidden and it will appear when active substance searched and added into the field.
emea00037517	Declaration and signature section - tooltip needs to be updated for payment section	In Declaration and signature section – Tooltips has been amended in the payment section.
emea00037775	Declaration and signature –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 Declaration and signature –payment section – now it is possible to select both “yes” and “no” option by repeating the section.
emea00037437	In Section 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 - 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 3 – Excipient/overage field is blank and cannot be populated	Resolved the defect in section 3 where excipient/overage field not displaying data.
emea00037428	In Section 2: Is it possible to associate each active substance to the corresponding manufacturer? At least a blank field associated to each manufacturer would be useful to add text to describe the corresponding manufactured active	In Section 2 - Manufacturer(s) of the active substance(s) - Active substance field has been added.

id	Description	Comment
	substance.	
emea00037430	In Section 1 - date of expiry of current authorisation - option to set as not applicable or make it to enter free text.	In Section 1 - Free text can be entered in the date field – “Date of expiry of current authorisation in Reference Member State/EU”.
emea00038337	Section 3 not all strengths have been populated from Declaration section, only first 2 are visible in the 2.2.1	Resolved the defect in “Section 3 – strength field” – where all values were not populated from declaration section.
emea00038327	Active substance in Section 2 - manufacturer - note should be added to mention that it is populating from declaration section	Resolved the defect in “Section 2 - manufacturer of the 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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This release fixes various defects and change requests as outlined below.

Issues fixed for this version

id	Description	Comment
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.
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 3 - 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)."
emea00035684	In word version we always put all MAs for the strength 2.5 mg (for example) into one sheet, so we have in the end only for each strength a separate form, but not for each country	In Section 1 - multiple strengths can be entered now and repeatable member states field has been added, where member states and MA number fields are grouped and repeatable.
emea00035643	In 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, a gas may have litre or kilogram.	In section 2.6 - free text field has been changed into 3 fields <ol style="list-style-type: none"> 1. Free text field to enter only numbers. 2. Dropdown field to select Units of Measurement. 3. Dropdown field to select Pharmaceutical form.

id	Description	Comment
emea00035619	In section 1- add multiple strengths for same active substance.	In section 1- "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.
emea00035075	The overlap (i.e. the same substance being used in both Human and Vet products) is likely to occur mostly with excipients but it should not be exclusive to them. Please consider also using the same implementation for actives.	In section 1 – When Veterinary check box selected – Both Human and VET substances will be available in Active substance and excipient fields.
emea00034992	In section 3 - quantity/unit section in excipients – validation error.	In section 3 - quantity/unit section in excipients table has been implemented same as active substance table.
emea00034826	In section 3. Qualitative and quantitative comp; - Possible to change the Active substance from the initial selection in the section 1.	In section 3. Active substance field should be able to select only the substances which are selected in the section 1 now.
emea00034825	In section 3 – 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 3 – Excipients - free text field has been added in to specify coating.
emea00032938	In section 3 – 'Pharmaceutical form' and 'strength' needs to be populate from section 1.	In Section 3 - 'Pharmaceutical form' and 'strength' fields are populated by clicking populate button in section 1.
emea00026709	In Section 2 - Multiple batch control companies - In the past it has been sometimes a challenge to add multiple batch control/testing companies in the way the form is created, this is the case because for some of our products multiple companies are responsible and each only for specific parts. In the current eAF are able to add additional information to the form to separate between the responsibilities. It appears that this is no longer possible. Maybe it's possible to add a field similar as for section 12 (medicinal product manufacturer) to allow a similar way of separation.	In Section 2 - New free text field has been added to describe role of company.

id	Description	Comment
emea00026338	In Section 2 - If Laboratory name provided then make rest of sub-section mandatory (except Fax which should always be optional). Also, make sure that more than one laboratory can be included (additional instances).	In Section 2 - For blood products and Vaccines section - Once Laboratory field given then the rest of the sub section will become mandatory (except Fax).
emea00037531	ATC code search field tooltip needs to be updated.	In Section 2 - "ATC code" field tool tip has been updated.
emea00037479	Annex 2.6 - Should not be mandatory unless proof of payment has been selected in the Declaration and Signature section for Veterinary products.	In Declaration and Signature section - proof of payment - when "yes" is selected then Annex 2.6 is mandatory for Veterinary products.
emea00037334	Section 3 - Qualitative and quantitative first row tool tip needs to be updated.	In Section 3 - 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 Renewal form - In Section 1 - proposed common renewal date field should allow both text and date in this field, And tool tip needs to be updated.	In Section - "The proposed common renewal date" field now allows to enter text or date. And tooltip has been updated accordingly.

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This hotfix release addresses 2 critical issues.

Issues fixed for this version

id	Description	Comment
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.	In version number – space has been removed and rebuilds the forms.
emea00035778	In section 2, Approved Manufacturers for batch release in the EEA where the list of countries currently allows selection of any country in the world. The problem applies to the blood products/vaccines and the batch control/testing section also.	The country field in these sections are only allows EEA countries now.

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This release implements changes introduced in the latest revision to the Word form (July 2014). This release fixes other defects and change requests (see below).

Issues fixed for this version

id	Description	Comment
emea00026544	In section 2.1.3 The relationship between fields is not correct. The same applies to ACT VET code, some vet products have different ATC vet codes for different species, a relationship between these data should be established.	Sections 2.1.3 and 2.1.4 has been grouped together with repeatable +/- buttons
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"
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.
emea00033497	In the new MAA form it is now possible to enter an "Administrative" and "Manufacturing" site for the API supplier. However, in the renewal form this is not possible.	In Section 2 - Address fields are changed to Manufacturer address and Admin address. <ul style="list-style-type: none"> • "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.

id	Description	Comment
emea00033533	Should the applicant just add all the numbers without details of which number refers to which country (user has 19 countries)? Should the user make an Annex as with the MS Word form?	In Section 1 – “member states” field has been added and grouped with MA numbers with repeatable +/- buttons.
emea00033799	Currently it is impossible to set certain information in the eAF for MRP/DCP initial applications. 5. Section 2.6.1 - For the composition of the product it is common to add comments and references to include additional information. In example additional information is provided for the composition of the ink that is printed on a capsule. If this information is not provided in the AF validation questions are raised by the NCA’s during validation.	In section 2.6.1 -A free text field has been added to enter composition details
emea00033921	For a particular product a company is the MAH in the RMS and most of the CMSs, whilst a third party holds the MA in one CMS. They would like to prepare one common form for the RMS and all CMSs. Currently there is no option to include the details of a second MA holder. On page 4 the user is only allowed to include the details of one MAH.	In Section 1 – “Name and address of MA holder” section is repeatable now with +/- buttons and “member states field” (repeatable inside) has been added in this section.
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
emea00035563	Requested to add “Company name” in In Section 1 – “Name and Address of Contact”	In Section 1 under Name and Address of Contact – “Company name” field has been added.
emea00035564	In Section 2- Admin/Manufacturer address fields should be in line with other address fields such as Address1 and Address 2	In Section 2 – 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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2014.</i>	This release implements changes introduced in the latest revision to the Word form (July 2014). This release fixes other defects and change requests (see below).

Issues fixed for this version

id	Comment
emea00033809	This release implements changes introduced in the latest revision to the Word form (July 2014). <ul style="list-style-type: none">In Signature section - Payment details have been updated.Footnote 1 has been amended.
emea00034011	Maximum length of "(Invented) Name" under "Section 2" has been increased from 250 to unlimited characters.
emea00033490	In Section 1 - "Strength" and "Active substance" fields have been grouped with repeatable + and - buttons.
emea00034677	Resolved the issue in email format - which was not able to enter .info and .asia
emea00034701	Telephone number field characters have been increased to 50 from 30.

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	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
	failures result in a warning but do not prevent the application from progressing through the application workflow).□	

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2013.</i>	This release fixes various defects as outlined below.

Issues fixed for this version

id	Comment
emea00031799	All forms, when opened, check the availability of the webservices, if webservices not available then the form gives error message.
emea00032901	In Section 1 – When EU authorisation is selected then the “Date of first authorisation in Reference Member State/EU” and “Date of expiry of current authorisation in RMS/EU” fields are visible now.

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2013.</i>	This release implements changes introduced in the substance list in EUTCT.

Issues fixed for this version

id	Comment
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. <ul style="list-style-type: none">The active substance fields and excipient field searches the relevant Human or Veterinary Substance list depending on whether the user has selected Human or Veterinary application.

Known issues

id	Description	Workaround/Comment

Additional information

None

Version 1.9.4 (Release Date: 25/07/2013)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision, July 2013.</i>	This release implements changes introduced in the latest revision to the Word form. The release also fixes various defects.

Issues fixed for this version

id	Comment
emea00031445	This release implements changes introduced in the latest revision to the Word form (July 2013) - Croatia has been added to the EU country list.
emea00026316	Version control has been implemented - when the RENEWAL 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.
emea00031538	The drop down list for the selection of units of measure in Section 3 now allows all available units to be selected.

Known issues

id	Description	Workaround/Comment

Additional information

None

Version 1.6.1 (Release Date: 01/03/2013)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision 10, October 2012.</i>	This hotfix addresses a critical issue in the form.

Issues fixed for this version

id	Comment
emea	In Section 1 – the following fields are visible in all cases <ul style="list-style-type: none">• "Date of first authorisation in Reference Member State/EU"• "Date of expiry of current authorisation in Reference Member State/EU"• "Proposed Common Renewal Date"

Known issues

id	Description	Workaround/Comment

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: <i>APPLICATION FORM FOR RENEWAL OF A MARKETING AUTHORISATION, Revision 10, October 2012.</i>	This release implements changes introduced in the latest revision to the Word form. The release also fixes various defects.

Issues fixed for this version

id	Comment
emea00028260	The latest revision to the Word form, revision 10, has been implemented in the eAF.
emea00026996	In section 1, when 'EU authorisation' or 'National authorisation only' is selected, the validation routine is run. Validation errors for the date of first authorisation and expiry date fields are now not displayed.
emea00026997	In section 4, the checkboxes 1.1, 1.4.2 and 2.4 are optional when the form is used for a medicine for human use. Checkboxes 1.1 and 2.4 are optional when the form is used for a medicine for veterinary use.
emea00026998	In section 1 when 'EU authorisation' is selected for a product that is currently marketed, a mandatory checkbox is displayed, which is labelled 'Attach annex'. This allows confirmation that the instructions in footnote 2 have been followed.
emea00027156	The tooltip for the payment status field has been amended to read 'Click to add payment status (Max. 100 characters).'
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.
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.

Known issues

id	Description	Workaround/Comment

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: <i>APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION, Revision February 2007.</i>	This release addresses the locking of the form fields after the form has been signed and a mandatory / not mandatory issue which was prevented certain types of submissions being made. 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.
emea00026298	If 2.1 = Community then sections 14.1 & 14.2 are no longer mandatory.

Known issues

id	Description	Workaround/Comment

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: <i>APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION, Revision February 2007.</i>	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.
emea00025197	Payment Status: Allow more characters and widen field. The payment status box should be longer as it is not readable. I entered 'To be paid on receipt of invoice from the EMEA' and most of it was not visible.

Known issues

id	Description	Workaround/Comment

Additional information

None

Version 1.2.23 (Release Date: 18/06/2012)

Version content

Functionality / use case	Comments
Implementation as electronic form of the document: <i>APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION, Revision February 2007.</i>	This hotfix release addresses 2 critical issues identified in the pilot phase plus a few quick wins. More details can be found in the section directly below.

Issues fixed for this version

id	Comment
emea00026405	The "Manufacturer of active substance" drop down list now uses the Worldwide list of countries instead of the European list.
emea00026296	Route of administration "Find" functionality has been redesigned to avoid a data loss defect that would impact XML export users.
emea00026103	Section 1 - "Concerned member state" no longer mandatory.
emea00026297	Section 1: "First authorisation in Concerned Member State to which application is made" and "Expiry date of current authorisation in Concerned Member State" are now mandatory (as per the specification ref: 7.3 and 7.4).
emea00025827	Section 4.1: Mandatory / optional behaviour of section 16.3.3 now correctly matches the specification i.e. When "Community authorisation" is selected section 16.3.3 is now mandatory. When "National authorisation in MRP" or "National authorisation" is selected 16.3.3 is optional.
emea00025182	"Marketing Member State" now is mandatory as per the specification.

Known issues

id	Description	Workaround/Comment
None		

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: <i>APPLICATION FOR RENEWAL OF A MARKETING AUTHORISATION, Revision February 2007.</i>	This implementation is the first version of the document as 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
emea00024567	Page 3 `1. Application for Renewal of a Marketing Authorisation` Active Substance(s): request to have a "Find" button for active substances.	The free text area allows entering any active substance. Free text area to be replaced by structured content.
emea00024746	Applicant's reference: This should be optional rather than mandatory.	Insert a space or full-stop to comply with the form's validation rules.
emea00025081	Use "Find" logic rather than a free text box for the Active Substance.	The free text area allows entering any active substance. Free text area to be replaced by structured content.
emea00025182	Member State: Field is specified as Mandatory in the specification but in the eAF it is currently optional.	Please ensure you have entered the mandatory information.
emea00025187	Section 1: Fields `First authorisation in Concerned Member State to which application is made` and `Expiry date of current authorisation in Concerned Member State` are specified as Mandatory in the specification (7.3 and 7.4) but are currently optional in the form.	Please ensure you have entered this mandatory information.

Additional information

None