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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: *Application for Variation to 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release note is for the 1.21.0.0 release, for the eAF forms. |

Issues fixed for this version

| id | Description | Comments |
|-----------|---|--|
| SD-27791 | Signature section – copy personal information (title, first name and surname) from section 1 (Name and address of contact person) to signature section. | In Signature section – “Copy contact person details from section 1” button has been added to copy details from section 1 (Name and address of contact person). |
| SD-27725 | Section 4b – when “PIP decision number” or “product-specific waiver decision number” is unticked the corresponding text field should be hidden. | In section 4b – the text fields are hidden when “PIP decision number” or “product-specific waiver decision number” is unticked. |
| SD-27659 | Section 3 - Sometimes a present/proposed text covers two variations (classifications), but only one can be chosen | In section 3 – present/proposed - “+” and “-” button has been added to add more than one variation classification. |
| SD-91251 | In Section 3 – Types of scopes - eAF Version 1.20.0.5 –category A.4 is not appear in short list table after export and import. | In section 3 – Types of scopes – When Category A is selected it appears in the table after export and import e.g A.4. |
| SD-88370 | In section 2 - Page break issue in eAF variation form 1.20.0.5 | In section 2 – Page break issue has been resolved. |
| SD-102517 | When National Procedure is selected with Worksharing an option to select RMS and CMS should be available in section 1 and section 2. | In section1 and section 2 - When National Procedure is selected with Worksharing an option to select RMS and CMS 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 |

| Id | Description | Workaround/Comment |
|----|---|---|
| | | experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| | 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release note is for the 1.20.0.5 hotfix release, for the eAF forms. |

Issues fixed for this version

| id | Description | Comments |
|----------|---|---|
| EAF-2236 | In 1.20.0.4 version: Section 2- invented name box overlaps variation number box | In Section 2 - Invented name box overlaps defect has been resolved 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. |
| | When importing xml from v1.20.0.3 or previous version to v1.20.0.4 the imported scopes cannot be deleted in version 1.20.0.4 due to the removal of the 'bracket' in the scope name e.g. A.1) is now A.1. See SD-67377 above. | Untick (unselect) all variation scopes in the 'source' form before exporting the xml to prevent this issue. The xml will not include any scopes and these should be selected in v.1.20.0.4. |
| | 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release note is for the 1.20.0.4 (previously called v1.21) technical release, for the eAF forms. |

Issues fixed for this version

| id | Description | Comments |
|----------|--|---|
| SD-67377 | Question about eAF forms – discrepancy with variation guideline and xml for scopes in Section 3 – Types of change(s) Expected Result should be as below A.z) should display as A.z in the table B.1.a z) should display as B.1.a.z in the table | In Section 3 – types of change(s) – click “show all types” – then select different scopes. E.g. A.z), A.1, B.1.a z) The Result now shows in table as below A.z) should display as A.z in the table B.1.a z) should display as B.1.a.z in the table |
| SD-68186 | Section 2 – MA Numbers is not overflowing to next page, not able to add more than 22 MA numbers | In Section 2 – resolved the issue to add more than 22 MA numbers and overflowing to next page. |
| 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-45868 | Declaration of the Applicant section – implementation date fields should be hidden when Type IAIN or Type1A is selected in section 1. | Declaration of the Applicant section – Implementation date fields are hidden when Type IAIN or Type1A is selected in section 1. |
| 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-45914 | Section 2, The (i) button is missing for footnote 8 | Section 2, The (i) button is added next to MA number for footnote 8. |
| 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-45943 | Signature Section – new button “copy address details from section 1” should be added | Signature Section – new button “copy address details from section 1” has been added. |
| 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-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"> • Name and address of the Applicant/MA holder, • Name and address of contact person <p>Declaration section –</p> <ul style="list-style-type: none"> • proof of payment |
| EAF-1463 | It should be possible to indicate the Reference Authority for worksharing for procedures containing only Nationally Authorised products | In Section 1 – Reference Authority for worksharing field is visible when National Authorisation and worksharing is selected. |

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. |
| | When importing xml from v1.20.0.3 or previous version to v1.20.0.4 the imported scopes cannot be deleted in version 1.20.0.4 due to the removal of the ‘bracket’ in the scope name e.g. A.1) is now A.1. See SD-67377 above. | Untick (unselect) all variation scopes in the ‘source’ form before exporting the xml to prevent this issue. The xml will not include any scopes and these should be selected in v.1.20.0.4. |

| Id | Description | Workaround/Comment |
|----|--|---|
| | 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release note is for the 1.20.0.3 hotfix, for the eAF forms. |

Issues fixed for this version

| id | Description | Comments |
|----------|--|---|
| EAF-2214 | Section 2 - Variation number field should be optional for national variations. | In Section 1 and 2- Variation number is not mandatory for National Procedure. |

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-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. |
| | It should be possible to indicate the Reference Authority for worksharing for procedures containing only Nationally Authorised products | In order to indicate the Reference Authority for worksharing both National Authorisation in MRP/DCP and National Authorisation should be selected in section 1. |

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

Version content

| Functionality / use case | Comments |
|---|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release note is for the 1.20.0.2 hotfix, for the eAF forms. |

Issues fixed for this version

| id | Description | Comments |
|----------|--|--|
| SD-37070 | B.III.1 classification from eAF does not match with the variation guideline | In Section3, Scope B.III.1 had the word "Ph." Added to the initial sentence. The missing scope as stated was found to exist in all previous and current versions of the form. |
| SD-35462 | eAF not allowing addition of multiple products in case of worksharing application that contains only Centrally Authorised products | In Section2, the red +/-/clone button's now are displayed when EU authorisation is selected along with grouping and/or worksharing, or worksharing by itself. |
| EAF-2207 | Not able to Add or delete the product after clicked on Clone button which is in red or green. | In Section 2 the clone buttons are working as expected and delete button is not hidden after clone button clicked. |
| SD-35467 | Variation number shifts up when a scope is deleted | Section 3 – Types of Scopes – It is no longer to delete the original scopes from this section, additional scopes entry can be deleted as expected. |
| SD-35754 | Spelling mistakes in the variation form scopes. | In Section3, Scope A.2.b, the wording is correctly defined. No change has been made. In addition to this few typos has been rectified in scope A.8, B.I.A.1 c), B.I.A.1 f), B.I.A.3, B.III.1 a) 4, C:I.11.b) and C:II.7. |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | 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 |
|----|--|---|
| | The proof of payment not expanding sections yes or no correctly. | 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 Proof of payment 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 when copying from a Word document into the eAF | Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat. |

| Id | Description | Workaround/Comment |
|----------|--|---|
| | 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 of the eAF. |
| EAF-1919 | it was possible to give information (MA number, MA holder) for a CMS that was not selected in the part 1 | For consideration in a future release of the eAF. |
| EAF-1926 | The inserted image file cannot be deleted from the image field ◆ the deletion of the image file should be possible here. | For consideration in a future release of the eAF. |
| 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 of the eAF. |
| EAF-1968 | No Suggestions Provided on typing units next to Quantity in all Forms | For consideration in a future release of the eAF. |
| EAF-1972 | Country filed does not provide suggestion when the first letter is typed. Refer other forms where on typing first letter we get suggestions | For consideration in a future release of the eAF. |
| EAF-1973 | Issue with validation during saving forms | For consideration in a future release of the eAF. |
| EAF-2002 | Tool Tips not in sync with the change made by Jira issue 1673 | For consideration in a future release of the eAF. |
| EAF-2008 | Present and Proposed content overflows and disappears below the margin if it is over certain amount of content | For consideration in a future release of the eAF. |
| EAF-2046 | Member states not refreshed - variation form | For consideration in a future release of the eAF. |
| EAF-2047 | Missing Validation for Add all function of CMS in section 1 of variation form | For consideration in a future release of the eAF. |
| EAF-2054 | member state values are shown as none None and so on after saving the Variation form and opening again | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|---|---|
| EAF-2082 | Section: Signature (Proof of Payment) - Tooltip for this section missing, wording unclear | For consideration in a future release of the eAF. |
| EAF-2083 | Section 2. Clone products to next member state. | For consideration in a future release of the eAF. |
| EAF-2084 | Declaration of the Applicant. Type IA - no need for implementation date. | For consideration in a future release of the eAF. |
| EAF-2092 | Section 3, To have ability to jump between different scopes more easily. | For consideration in a future release of the eAF. |
| EAF-2093 | Section 1 – Name and address of the Applicant/MA Holder, Country field contains value 'European Union' | For consideration in a future release of the eAF. |
| EAF-2095 | Section 1, contact person selection for member states and proof of payment member states selection | For consideration in a future release of the eAF. |
| EAF-2101 | Section 3 Types of change, usability is poor. | For consideration in a future release of the eAF. |
| EAF-2103 | Section 3 Types of change, There should be a navigation aid on the variation form to ease the finding of scopes in the eAF | For consideration in a future release of the eAF. |
| EAF-2106 | Section 2, That the MA Number is recognized by the form and the pick lists for invented name and MA holder name are filled. | For consideration in a future release of the eAF. |
| 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 | For consideration in a future release of the eAF. |
| EAF-2109 | In section 2, no additional "strength" item can be added in case of several active substances, with different units | For consideration in a future release of the eAF. |
| EAF-2110 | In Signature section, for the proof of payment, it could be helpful to add a button to copy contact details from section 1 into billing address | For consideration in a future release of the eAF. |
| EAF-2111 | 3 Present and Proposed, Able to select delete when right click on image section Should be able to paste a table including formatting | For consideration in a future release of the eAF. |
| EAF-2112 | Proof of payment cannot be edited once form signed – for a WSP/MRP where a single signature is required for all forms the PoP section cannot be completed by the CMSs after RMS has | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|--|---|
| | signed | |
| EAF-2114 | Section 2: Products concerned by this Application, delete Annex A tooltip references | For consideration in a future release of the eAF. |
| EAF-2116 | Have a copy button in the Signature Section | For consideration in a future release of the eAF. |
| EAF-2117 | It should be possible to list all member states selected in section 1 automatically in section 2. | For consideration in a future release of the eAF. |
| EAF-2118 | Relevant sections from the guideline including the boxes to be ticked regarding conditions to be met and documentation to be provided should be integrated in the eAF. | For consideration in a future release of the eAF. |
| EAF-2120 | The MA Number, Invented Name, MA Holder Name, Pharmaceutical Name, Strength and Unit fields are not clearly identified. | For consideration in a future release of the eAF. |
| EAF-2121 | Section 2, Is it possible to get for MA Holder Name a suggestion, as this is filled out previously in section 1: Name and address of the Applicant/MA Holder | For consideration in a future release of the eAF. |
| EAF-2122 | Signature, I was looking for a button: copy details from contact details (Section 1: Name and address of contact person) | For consideration in a future release of the eAF. |
| EAF-2127 | Section 2, The (i) button is missing for footnote 8 | For consideration in a future release of the eAF. |
| EAF-2128 | Section 2, Footnote 7 still encourages the use of annexes for section 2. | For consideration in a future release of the eAF. |
| EAF-2133 | It is time-consuming when selecting specific unit (e.x. mg). Possibility to type first letter of Specific Unit is not enough helpful. | For consideration in a future release of the eAF. |
| EAF-2137 | Section 1, If "National Authorisation" is selected a Variation procedure number should be entered. | For consideration in a future release of the eAF. |
| EAF-2140 | Section 2, For some countries the procedure number and variation number are different. It would be useful to have a | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|---|---|
| | field to include the individual variation number in this section. | |
| EAF-2145 | Section 1/2, Once CMS and RMS selected, they should auto-populate throughout the form. | For consideration in a future release of the eAF. |
| EAF-2149 | Section 3, It is possible to skip selecting a change type (e.g. not clicking 'Show All Types' to check boxes). | For consideration in a future release of the eAF. |
| EAF-2150 | Address Fields in the form, Address Line 2, It may be clearer if the comment were beneath the caption instead of beneath the field. | For consideration in a future release of the eAF. |
| EAF-2151 | Section 3, It is not very obvious that the "Scope" section of the table should be populated using a drop down list. | For consideration in a future release of the eAF. |
| EAF-2152 | Validation, A user is able to apply a signature – and lock a form – even if there are validation errors with the form. | For consideration in a future release of the eAF. |
| EAF-2158 | All Sections, When you delete something by mistake using the "-" button, it is not possible to use the "undo" button. | For consideration in a future release of the eAF. |
| EAF-2160 | Section 1, It would be good when pressing - on a MS, that it deleted it from all subsequent MS lists throughout the form. | For consideration in a future release of the eAF. |
| EAF-2161 | Section 1, Date of First Authorisation shows is MS's which are not CMSs | For consideration in a future release of the eAF. |
| EAF-2164 | Section 1, MAH copy button only copies the first entry. Would expect to be able to pick what was copied. | For consideration in a future release of the eAF. |
| EAF-2169 | Section 3, We find that the image section of the present/proposed section is currently not user- or reader friendly. | For consideration in a future release of the eAF. |
| 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 of the eAF. |
| EAF-2176 | If we select "copy contact details from previous section", there doesn't seem to be any possibility to remove the data from the section if this button was clicked by error. This means that the data needs to be manually deleted or typed over. | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|---|---|
| EAF-2177 | Section 1, Each time we want to delete a country from the concerned member states list we receive the pop-up "do you want to delete..." | For consideration in a future release of the eAF. |
| EAF-2178 | Section 3, The present/proposed table in section 3 is not very user friendly to complete. | For consideration in a future release of the eAF. |
| EAF-2179 | Section 3, Name of the excipient is not easily retrieved due to multiple synonyms and sometimes very long pick lists where we need to scroll a lot to find the correct excipient. | For consideration in a future release of the eAF. |
| EAF-2181 | Section 1: Type of application, Not able to indicate 'Notification' as the type of application (Only applicable for Belgium). | For consideration in a future release of the eAF. |

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.

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | 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-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-1950 | Section 3 "Type of change(s)": A heading for the following z-variations is missing: <ul style="list-style-type: none">• B.I.e• B.II.f• B.II.g• B.II.h• B.III. | In Section 3, the five sections: B.I.e, B.II.f, B.II.g, B.II.h, B.III now displays the correct title. |
| EAF-1828 | More than one MAH, for MRP/DCP variations more than one MAH is affected. At the moment we are able to include more than one MAH in the | In Section 1, the Name and Address of the Applicant/MA Holder now has a +/- button to allow for multiple addresses to be added. Note: The Variation DES has been changed to accommodate this |

| id | Description | Comments |
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| | word document. (See screenshot 2). This is not possible in the eAF. | change. |
| EAF-1754 | 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 of the renewal form.) | In Section 2, the member state now only allows the selection of States entered from section 1. |
| EAF-1931 | Section 2 "concerned products" is still a pain to work with. The information regarding concerned products should not be grouped by invented name for MRP/DCP/CP/NP | In Section 1, the "Click here to populate variation number in section 2" button is only displayed for MRP/DCP options. In Section 2, the whole section has been remodelled to improve user input. No new fields have been added and none have been taken away. There is a new Clone button which will create a copy of the current row as a new row. The variation number and member state options will only be displayed for MRP/DCP. When opening a new form, Section 2 fields will not be displayed by default, until the user has selected a corresponding authority type: MRP/DCP/NP/CP. A message will be displayed informing them of this. Finally, the member state will present only those countries selected in Section 1. |
| EAF-1933 | Applies to all section of all forms where additional information is optionally displayed/hidden. | In all sections, the form removes data from nodes that have been closed after having had data input. |
| EAF-1958 | In Validation section, the tooltip for the "Update Lists" button is incorrect. | In Validation Section, the tooltip for the Update List Button now reads: click to update/reload the control lists. |
| EAF-1992 | If some of specific classifications are selected and all other types are collapsed, it is not identifiable which type is applied for. | In Section 3, scope titles are now shown for all z) scopes. |
| EAF-2010 | The attached eAF puzzles us, however. It is clearly not locked, but still the applicant has managed to include a signature. I was under the impression that the signature was what locked the eAF, but that doesn't seem to be the case here. Is there something I miss? Or did the applicant somehow find a way to include the signature without locking the eAF? | In the Signature section, the Proof of Payment is now correctly locked when the form is signed. |
| EAF-2028 | None is added as a Member state when Add all button is clicked in section 1 of variation form. | In Section 1, the Add All button no longer automatically includes None. |

| id | Description | Comments |
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| EAF-2029 | When None is added as Concerned Member state in section 1. In section 2 Member states selection is shown with text Empty | In Section 1, when selecting "None" as a member state, in Section 2, the available member state is now "None". |
| EAF-2030 | When the user goes straight to section 2, having selected human MRP/DCP, but does not select a member state. When in section 2, they use the down arrow to see the selected states, a message is displayed: Please select a member state from Section 1. However, the message is not cleared down when a member state is selected from Section 1. Instead the user can select the member state, but the message "Please select..." is still displayed. | In Section 2, the member state selection now correctly closes/hides the messages when the user clicks away from the field. |
| EAF-2032 | When using the add all button in the section 1 Concerned Member state. In section 2 Member states selection is shown with text Empty for each member state added. | In Section 1, the add all button now correctly populates the list of concerned member states, so that in Section 2, when the correct member states are listed. |
| EAF-2033 | Section-1 Form does not clean the data if user selects MRP/DCP and then later remove MRP/DCP | In Section 1, the concerned member states are now only displayed for MRP/DCP. |
| 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-2053 | In the C.I scope, the IA-IN category is required in addition to the IA, IB, II. Both must be considered z) scopes and not given a normal index letter. | In Section 3, the C.I.z now appears twice, once for the IA-IN and again the IA, IB, II. This is to support both entries being z) level. |
| EAF-2068 | In Section 2, the member state list does not include the RMS. | In Section 2, the Member States list now includes the RMS (if applicable) as well as the CMS (if applicable). |
| EAF-2069 | For some z) variations still no heading (in this case C.I.4) is displayed. | The UAT build of the forms was using the wrong variation data. The process has been updated to ensure the correct variation data is now supplied, where the all scopes have a header. |
| EAF-2070 | In Section 2, the invented name and MA Holder name fields are not wide enough. | In Section 2, the Invented Name and MA Holder name will now flow onto multiple lines if the characters entered exceed the enterable width. The associated selection boxes for each have also been made wider to support the longer user input. |
| EAF-2071 | When removing member states, after using add all an error is displayed. | In Section 1 the Add All button now omits the RMS when selected, the behaviour is as expected. |

| id | Description | Comments |
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| EAF-2072 | In Section 1, the first name field in the Name and Address of contact does not wrap when the name is long than the field. | In Section 1 the first name field in the Name and Address of Contact person now displays text if the user enters more characters than the width of the field allows. |
| EAF-2073 | In Section 2, no ability to close the selection box when no option is wanted. | In Section 2, the Invented Name and MA Holder Name selection boxes now have a close button. |
| EAF-2074 | Issue with the B.I.c.3 scope order. | In Section 3, the B.I.c.3 scope has now been correctly alphabetised. |
| EAF-2075 | In section 3, The B.I.d name of scope is missing | In Section 3, the B.I.d title now reads: Stability. |
| EAF-2076 | In Section 1, CMS when loading XML, and pressing Add all, first item is missing. | In Section 1, the CMS add all functionality now handles the introduction of a blank first item in the drop down list, and renders correctly. |
| EAF-2077 | Section 2 products concerned by this application | In Section 2, the MA Number and Strength fields now allow multi-lines. The Strength selection panel has been expanded and now also has a close button. |
| EAF-2078 | When the second product is to be added i.e. + button is used in section 2 fields for 'variation number' and 'member state' appear. | In Section 2, when NP/CP has been selected, the variation number and member state now are removed in all new instances, not just the first. |
| EAF-2080 | In Section 2 the message says select member states, but when member states are entered they are not shown in section 2 | In Section2, the member state message was incorrect, and has now been updated to correctly request the usage of the reference member state and/or the concerned member state. |
| EAF-2081 | The list refresh button is not present on the bottom of the form, and is not consistent with other forms | In Form Validation Section, a new button has been added to allow "Update Lists". |
| EAF-2090 | New section 2 cannot be used for vaccines | In Section 2, Additional of a flag to indicate form and strength data will be stored in an associated footnote, and a footnote section. Additionally, while the flag is checked, the strength and unit fields will no longer be mandatory. |
| EAF-2091 | Active Substance name not fully shown. | In Section 2, the active substance field now expands to allow for long Active Substances to be displayed. |
| EAF-2102 | Have a "top" button added to each of the scopes to allow return to top of section 3. | In Section 3, a "top" button has been added to each scope, which will return the user to the top of Section 3. |

| id | Description | Comments |
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| EAF-2108 | A clone button of the member state container to prevent repeating of information, and... | In Section 2, New clones buttons have been added to the member state and variation number containers. These buttons will create a copy of all the data in the corresponding section. |
| EAF-2115 | After choosing scopes, have to go back to top of section to collapse all, can we have a collapse all on each page | In Section 3, a "top" button has been added to each scope, which will return the user to the top of Section 3. |
| EAF-2120 | The MA Number, Invented Name, MA Holder Name, Pharmaceutical Name, Strength and Unit fields are not clearly identified. | In Section 2, the MA Number, Invented Name, MA Holder Name, Pharmaceutical Name Strength and Unit fields are now visible. |
| EAF-2129 | A clone button of the member state container to prevent repeating of information, and... | In Section 2, New clones buttons have been added to the member state and variation number containers. These buttons will create a copy of all the data in the corresponding section. |
| EAF-2143 | In the item "Status (job title)" of the variation eAF, and equivalent in the human and renewal eAFs, there is no room for a long job title. | In Signature section ,The Job Title field now allows for longer job titles to be entered, expanding in height accordingly. |
| EAF-2156 | In section 1 "name and address of the applicant/MA Holder" it should be possible to assign member states to the respective MAH. | In Section 1, the MAH contact details now support multiple member state selection. |
| EAF-2157 | Section 2, Footnote 8 not accompanied by a "i" button, linking to the corresponding footnote at the end of the application form. | In Section 2, there was an incorrect footnote reference, this has been removed. |
| 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-2165 | When locking the form, the captions turn bold, but there is some overlapping. | In Section 3, the Implementation Date now displays correctly when the form is locked. |
| EAF-2166 | Section 1, When numerous MA Holders are added to the extent that they should flow over to the next page, they appear to fall off the bottom of the page. | In Section1, The MA Holder address details now split across pages correctly. |
| EAF-2168 | Signature, Billing address fields are always displayed in the form, even have choosing "Have the fees been prepaid? No". | In Signature Section, The billing information panel is now no longer displayed by default, and now will only be displayed when the correct answer is given to the "Have all relevant fees been prepaid to |

| id | Description | Comments |
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| | | competent authorities?". |
| EAF-2170 | Section 1, Add "Add All" to the Name and Address of Contact Person or have them copied from the selected CMS. | In Section1, the name and address of contact person now has an "Add Selected" button which adds the concerned member state and reference member state selected earlier. |
| EAF-2175 | Section 1, It might not be clear on how to add several strengths if one has a product with multiple APIs. | In Section2, The Strength tooltip has been updated to provide instruction on how to enter multiple strengths for APIs. |
| EAF-2180 | In Section 2 of the variation form, as well as MRP/DCP the variation number needs to be present for National Procedure. | In Section2, The Variation number is now displayed for National Procedures, as well as for MRP and DCP. |
| 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 | Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat. |

| Id | Description | Workaround/Comment |
|----------|--|---|
| | 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 of the eAF. |
| EAF-1919 | it was possible to give information (MA number, MA holder) for a CMS that was not selected in the part 1 | For consideration in a future release of the eAF. |
| EAF-1926 | The inserted image file cannot be deleted from the image field ◆ the deletion of the image file should be possible here. | For consideration in a future release of the eAF. |
| 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 of the eAF. |
| EAF-1968 | No Suggestions Provided on typing units next to Quantity in all Forms | For consideration in a future release of the eAF. |
| EAF-1972 | Country filed does not provide suggestion when the first letter is typed. Refer other forms where on typing first letter we get suggestions | For consideration in a future release of the eAF. |
| EAF-1973 | Issue with validation during saving forms | For consideration in a future release of the eAF. |
| EAF-2002 | Tool Tips not in sync with the change made by Jira issue 1673 | For consideration in a future release of the eAF. |
| EAF-2008 | Present and Proposed content overflows and disappears below the margin if it is over certain amount of content | For consideration in a future release of the eAF. |
| EAF-2046 | Member states not refreshed - variation form | For consideration in a future release of the eAF. |
| EAF-2047 | Missing Validation for Add all function of CMS in section 1 of variation form | For consideration in a future release of the eAF. |
| EAF-2054 | member state values are shown as none None and so on after saving the Variation form and opening again | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
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| EAF-2082 | Section: Signature (Proof of Payment) - Tooltip for this section missing, wording unclear | For consideration in a future release of the eAF. |
| EAF-2083 | Section 2. Clone products to next member state. | For consideration in a future release of the eAF. |
| EAF-2084 | Declaration of the Applicant. Type IA - no need for implementation date. | For consideration in a future release of the eAF. |
| EAF-2092 | Section 3, To have ability to jump between different scopes more easily. | For consideration in a future release of the eAF. |
| EAF-2093 | Section 1 – Name and address of the Applicant/MA Holder, Country field contains value 'European Union' | For consideration in a future release of the eAF. |
| EAF-2095 | Section 1, contact person selection for member states and proof of payment member states selection | For consideration in a future release of the eAF. |
| EAF-2101 | Section 3 Types of change, usability is poor. | For consideration in a future release of the eAF. |
| EAF-2103 | Section 3 Types of change, There should be a navigation aid on the variation form to ease the finding of scopes in the eAF | For consideration in a future release of the eAF. |
| EAF-2106 | Section 2, That the MA Number is recognized by the form and the pick lists for invented name and MA holder name are filled. | For consideration in a future release of the eAF. |
| 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 | For consideration in a future release of the eAF. |
| EAF-2109 | In section 2, no additional "strength" item can be added in case of several active substances, with different units | For consideration in a future release of the eAF. |
| EAF-2110 | In Signature section, for the proof of payment, it could be helpful to add a button to copy contact details from section 1 into billing address | For consideration in a future release of the eAF. |
| EAF-2111 | 3 Present and Proposed, Able to select delete when right click on image section Should be able to paste a table including formatting | For consideration in a future release of the eAF. |
| EAF-2112 | Proof of payment cannot be edited once form signed – for a WSP/MRP where a single signature is required for all forms the PoP section cannot be completed by the CMSs after RMS has | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
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| | signed | |
| EAF-2114 | Section 2: Products concerned by this Application, delete Annex A tooltip references | For consideration in a future release of the eAF. |
| EAF-2116 | Have a copy button in the Signature Section | For consideration in a future release of the eAF. |
| EAF-2117 | It should be possible to list all member states selected in section 1 automatically in section 2. | For consideration in a future release of the eAF. |
| EAF-2118 | Relevant sections from the guideline including the boxes to be ticked regarding conditions to be met and documentation to be provided should be integrated in the eAF. | For consideration in a future release of the eAF. |
| EAF-2120 | The MA Number, Invented Name, MA Holder Name, Pharmaceutical Name, Strength and Unit fields are not clearly identified. | For consideration in a future release of the eAF. |
| EAF-2121 | Section 2, Is it possible to get for MA Holder Name a suggestion, as this is filled out previously in section 1: Name and address of the Applicant/MA Holder | For consideration in a future release of the eAF. |
| EAF-2122 | Signature, I was looking for a button: copy details from contact details (Section 1: Name and address of contact person) | For consideration in a future release of the eAF. |
| EAF-2127 | Section 2, The (i) button is missing for footnote 8 | For consideration in a future release of the eAF. |
| EAF-2128 | Section 2, Footnote 7 still encourages the use of annexes for section 2. | For consideration in a future release of the eAF. |
| EAF-2133 | It is time-consuming when selecting specific unit (e.x. mg). Possibility to type first letter of Specific Unit is not enough helpful. | For consideration in a future release of the eAF. |
| EAF-2137 | Section 1, If "National Authorisation" is selected a Variation procedure number should be entered. | For consideration in a future release of the eAF. |
| EAF-2140 | Section 2, For some countries the procedure number and variation number are different. It would be useful to have a | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|---|---|
| | field to include the individual variation number in this section. | |
| EAF-2145 | Section 1/2, Once CMS and RMS selected, they should auto-populate throughout the form. | For consideration in a future release of the eAF. |
| EAF-2149 | Section 3, It is possible to skip selecting a change type (e.g. not clicking 'Show All Types' to check boxes). | For consideration in a future release of the eAF. |
| EAF-2150 | Address Fields in the form, Address Line 2, It may be clearer if the comment were beneath the caption instead of beneath the field. | For consideration in a future release of the eAF. |
| EAF-2151 | Section 3, It is not very obvious that the "Scope" section of the table should be populated using a drop down list. | For consideration in a future release of the eAF. |
| EAF-2152 | Validation, A user is able to apply a signature – and lock a form – even if there are validation errors with the form. | For consideration in a future release of the eAF. |
| EAF-2158 | All Sections, When you delete something by mistake using the "-" button, it is not possible to use the "undo" button. | For consideration in a future release of the eAF. |
| EAF-2160 | Section 1, It would be good when pressing - on a MS, that it deleted it from all subsequent MS lists throughout the form. | For consideration in a future release of the eAF. |
| EAF-2161 | Section 1, Date of First Authorisation shows is MS's which are not CMSs | For consideration in a future release of the eAF. |
| EAF-2164 | Section 1, MAH copy button only copies the first entry. Would expect to be able to pick what was copied. | For consideration in a future release of the eAF. |
| EAF-2169 | Section 3, We find that the image section of the present/proposed section is currently not user- or reader friendly. | For consideration in a future release of the eAF. |
| 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 of the eAF. |
| EAF-2176 | If we select "copy contact details from previous section", there doesn't seem to be any possibility to remove the data from the section if this button was clicked by error. This means that the data needs to be manually deleted or typed over. | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|----------|---|---|
| EAF-2177 | Section 1, Each time we want to delete a country from the concerned member states list we receive the pop-up "do you want to delete..." | For consideration in a future release of the eAF. |
| EAF-2178 | Section 3, The present/proposed table in section 3 is not very user friendly to complete. | For consideration in a future release of the eAF. |
| EAF-2179 | Section 3, Name of the excipient is not easily retrieved due to multiple synonyms and sometimes very long pick lists where we need to scroll a lot to find the correct excipient. | For consideration in a future release of the eAF. |
| EAF-2181 | Section 1: Type of application, Not able to indicate 'Notification' as the type of application (Only applicable for Belgium). | For consideration in a future release of the eAF. |

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.

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release fixes various change requests and defects (see below). |

Issues fixed for this version

| id | Description | Comments |
|----------|---|---|
| EAF-2049 | When the variation form is locked, the second and subsequent payment sections in the "Proof of Payment" are not locked correctly when the form is locked ready for submission which is causing the forms to be rejected by NCAs | In the variation form, the Proof of Payment section now correctly locks when the form is locked ready for submission. |
| EAF-2050 | The cover page for the Variation 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

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

Version content

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release fixes various change requests and defects (see below). |

Issues fixed for this version

| id | Description | Comments |
|--------------|---|--|
| emea00038168 | some implementation dates in the variation section cannot be deleted after saving, closing and opening the form | In the Variation section, dates can now be deleted. |
| emea00037537 | In section 2 "Products concerned by this application" of the variations eAF: It is does not appear from the form for which countries the product information applies. The applicant may want to specify all product names in all involved countries of an MRP. Without a country attribute this makes it very difficult for us to identify the correct product(s) in question | In Section 1, when "National Authorisation in MRP/DCP" is selected, the Section 2 Member states will be visible above the MA holder field. |
| emea00036811 | The strength is not controlled vocabulary. It is currently just free text field. | In the products concerned by the application section, the strength fields 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 Section 1, Section 2 and Proof of Payment Section, the same member state cannot be entered twice in the CMS. |
| emea00038333 | populate button in section 1 - Name and address of the contact person | In Section 1 – A new button will populate contact details for "Name and address of contact person section" from the "Name and address of the Applicant/MA Holder" section. |
| emea00037438 | Add warning note to confirm deletion of repeated section | All delete buttons will pop up with a message: "Do you want to delete this repeatable section". If the user selected "yes" the row/section is deleted, otherwise no action is taken. |

| id | Description | Comments |
|-------------------------|---|--|
| emea00037315 | Variation form - Cannot put table into the present/proposed section | The present/proposed section is now landscape but it is not numbered. |
| emea00038335 | MA number and MA variation number should be in tabular format | In Section 2, when the "National Authorisation in MRP/DCP" in section 1 is selected, the MRP Variation number is now displayed at the top level and the member states, MA Holder and MA Number are now repeatable. |
| emea00038395 | For every hyperlink to a footnote there should be a hyperlink back to the originating location | In the footer section, all footnotes now contain a link back to the originating section. |
| emea00026341 | <p>Name and address of contact person - title should be an optional field, also, Signature - title should be optional</p> <p>The Title field is not defined in the specification, and therefore no requirement to be a Mandatory field. However, it may be desirable to retain this field after all. Consider whether a defect should be raised and as a minimum the optionality issue resolved.</p> | In the Signature section, the Title field is now mandatory. |
| 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. |
| emea00039109 | 'Change(s) will be implemented from' field, is very short | In the Section Declaration of Applicant the "Change(s) will be implemented from:" field length has been extended to allow 250 characters. |
| emea00039161 | The option to populate variation number in section 2 is a valuable approach, but seems to lack in implementation. When populating information, these are only populated in the first product. If a variation concerns several products, populating a procedure number to all products concerned does only work for the first product but not for all following products. | In Section 1, the "click here to populate variation number in Section 2" button now populates all section 2 instances with the variation number. In addition, in Section 2, when a new product is added by pressing the + button, it now automatically allocates the variation numbers to the new product. |
| emea00038996 | <ul style="list-style-type: none"> - The document can be correctly filled, validated, signed and saved under a different name. - However when opening the signed version Adobe opens a "save as" dialogue which has to be cancelled before the document can be opened - This occurs both after double-click in the file system or when clicking a hyperlink in the VNeS TOC. | This will occur the first time a form is copied to a new folder and is associated with the Adobe Trust Certificate needing to be applied to the document. |
| emea00039364 / EAF-1916 | Section 2: nothing happened when clicking annex A or annex b buttons (we do not see the content of these annexes) | In Section 2, the tooltip for annex A button has been updated to read "See Annex A" button: Populates/Clears necessary fields in the form with "See Annex A", The tooltip for annex B button has been |

| id | Description | Comments |
|-------------------------|--|---|
| | These buttons populate the necessary fields in the form with the statement: See Annex A or See Annex B, as is appropriate. This is to prevent validation errors in the form where Annex's have been used. | updated to state for "See Annex B" button: Populates/Clears necessary fields in the form with "See Annex B" |
| emea00039350 / EAF-1909 | <p>1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION The tooltip "Copy contact details from previous Section" reads "Click to auto-complete the contact details in section 2.4.2 with those already added in section 2.4.1", but whether section 2.4.2 nor section 2.4.1 can be found in this application form.</p> <p>2. PRODUCTS CONCERNED BY THIS APPLICATION The tooltip besides "Pharmaceutical Form" reads "Add additional medicinal product", but an additional pharmaceutical form appears when clicked.</p> | <p>In Section 1, the button "Copy contact details from previous section" the tool tip has been updated to read: Click to auto-complete the contact details from the section above.</p> <p>In Section 2, the + and - button tooltips have been modified to read: "+" : Add additional pharmaceutical form, and the "-" : Remove this pharmaceutical form, if required (One minimum). Additionally in Section 2, the + and - tooltips next to strength have been modified to read: "+":Add additional presentation, and the "-": Remove this presentation, if required (One minimum).</p> |
| 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. |
| emea00039447 / EAF-1935 | Strange behavior, tries to save the already opened document when it is re-opened. | In the variation form, once it has been signed and re-opened no longer requests for the user to save the form. |
| 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. |
| EAF-1969 | Please see the first screenshot of the eAF reading 'Variation included in this application'. There is an 's' missing from the word variations and the heading is no longer in bold as it should be. | In Section 3, the spelling mistake and formatting for the selected elements have been applied. |

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 | 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 |
|----|---|--------------------|
| | satisfy a best practice requirement (best practice failures result in a warning but do not prevent the application from progressing through the application 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 (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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release fixes various change requests and defects (see below). |

Issues fixed for this version

| id | Description | Comments |
|--------------|--|---|
| 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 | 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. |
| 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 ", |
| emea00037356 | In case of groupings per product for each selected change a "present & proposed"-section should be added related to the change selected (1:1 relationship). | In section 3 - drop down field added has been in present and proposed section which is readonly field and it show values which has been selected in "show all types". |

| id | Description | Comments |
|--------------|---|---|
| emea00037351 | Section 2 variation number can be copied from the section 1 | In Section 1 - populate button has been added populate variation number in Section 2. |
| emea00037900 | Section 2 - +/- buttons not working in strength and active substance repeatable group | Resolved defect in section 2 where +/- buttons not working |
| emea00036880 | Section 3 - to add option z) to section B.I.b.2 | In Section 3 - Scope list has been revised and z-scope has been added in relevant sections. |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release fixes various change requests and defects (see 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. |
| 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. |
| emea00035656 | The proposed situation should be filled up with structured data. | In Section 3 - Present and Proposed fields are grouped and repeatable with +/- buttons. |
| emea00035619 | In Declaration section - add multiple strengths for same active substance. | Declaration Section – “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. |
| emea00027290 | <p>In section 2 - Products concerned by this application. Footnote 7 under NOTES states further: "For products authorised via the Centralised Procedure, the Annex A of the products concerned should be provided as an Annex of the application form.</p> <p>So Annex A is for CP products, and further it states Annex B is for worksharing procedures submitted to the EMA. But there is</p> | In Notes Section - Note 7 - "For MRP/DCP procedures, 'list of concerned products' can be provided as Annex to the application form." has been added. |

| id | Description | Comments |
|--------------|---|---|
| | no clear mention if any particular form must be used for MRP eCTD. | |
| emea00037457 | Section 3: The only way to include tables in here is to paste a picture of them. It would be useful to have guidance on the resolution/size of pictures for their correct display, since some of them appear with the wrong size. Right now it seems that pictures are automatically re-sized to fit the image box. Would it be possible to deactivate this option? | In Section 3 – present and proposed – image field’s - automatic resized option has been disabled. |
| emea00037321 | When trying to enter an image to the table, it was only possible in the 2nd row, while in the first row only the upper half of the image was visible and it was not possible to extend the row. | In Section 3 – present and proposed – image fields - Resolved the defect which was not possible to see full image in the first row. |
| emea00037317 | Implementation date field is not long enough to fill all information | The “implementation date” field characters have been increased to 100. |
| emea00037433 | Clicking in the Company Name field, will show the pop up help for Surname | In Section 1 – “Company name” field tooltip has been updated. |
| emea00037322 | Add DCP to second row of section 1 for completeness | In Section 1 – “National authorisation in MRP” label has been changed to “National authorisation in MRP/DCP”. |
| emea00037458 | Special formatting for page 6 and 7 text boxes - precise scope and background | In Section 3 – “Precise and scope background” field is changed to rich text format which allows to enter superscript and subscript characters |
| 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. |
| emea00037525 | Signature section not locked after signed. | Resolved the issue in Signature section – which was not locked after signed the form. |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release fixes various change requests and defects (see below). |

Issues fixed for this version

| id | Description | Comment |
|--------------|---|--|
| 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" |
| emea00026378 | Section 1 - When MRP / or national is selected, it is not mandatory to fill in the list of countries, whereas it should be. | In Section 1 – "Concerned Member State(s)" field is mandatory when MRP selected. |
| emea00032616 | In the current version of the eAF it is not possible for purely national MAs to introduce a variation procedure number. Footnote in the paper version also to be amended to include also purely national MAs. | In Section 1 – "Variation procedure number" is visible and not mandatory when National procedure selected. |
| emea00035644 | Requested to update the Tooltip in Present and Proposed Image fields. | In Section 3 – Tool tips are updated in Present and Proposed image fields. |
| emea00035637 | Footnote 20 does not exist, therefore the description should be empty. | In Notes section – Foot note 20 is updated as ("empty") |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, June 2014. | This release implements changes introduced in the latest revision to the Word form (June 2014). This release fixes various other defects and change requests (see below). |

Issues fixed for this version

| id | Comment |
|--------------|--|
| emea00033808 | This release implements changes introduced in the latest revision to the Word form (June 2014). <ul style="list-style-type: none">• In Section 3 – Types of Scopes - B.I and B.II scopes have been implemented.• In Signature section - Payment details have been updated.• In Declaration Section – check box “Where applicable, national fees have been paid” has been amended to “Where applicable, national fees have been prepaid or will be paid in accordance with national requirements”.• Footnotes 1, 6, 8, and 18 have been amended.• Footnote 20 has been deleted. |
| emea00032617 | In Section 1 – “Name and address of the Applicant/MA Holder” made as repeatable group and Member states field has been added with repeatable + and – buttons. |
| emea00034011 | Maximum length of “(Invented) Name” under “Section 2” has been increased from 250 to unlimited characters. |
| emea00034405 | Resolved the issue in version control - which was not working in 1.14.1 version. |
| emea00033490 | In Section 2 – “Strength” and “Active substance” fields have been grouped with repeatable + and – buttons. |
| emea00034581 | In Section 3 – Types of scopes - C.1.11.b - implementation date field has been deleted. |
| emea00034683 | In Section 1 – “Variation procedure number” is visible when National Authorisation selected. |
| 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 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | This release fixed the defect as outlined below. |

Issues fixed for this version

| id | Comment |
|--------------|--|
| emea00034310 | Resolved an issue in section 3 – present and proposed images 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | 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 |
| emea00032898 | In section 4.b – The tick boxes are added to “PIP decision number” and “product specific waiver decision number” fields. |
| emea00030674 | In Section 4a - The orphan designation procedure number is now repeatable |
| emea00027531 | In Section 1 – When national authorisation and worksharing are selected for a veterinary product the “RMS/Reference Authority for worksharing” field is visible now. |
| emea00033595 | In Section 3 Types of change(s) – Image fields had been added to Present/Proposed Column |

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 1.12.0 (Release Date: 09/10/2013)

Version content

| Functionality / use case | Comments |
|---|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | This release fixes hot fix and other defect. |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00032143 | Resolved issue in "Section 3- Types of changes" - The full category for a variation not displayed correctly in the summary table. |
| emea00032362 | Resolved issue in "Section 3- Types of changes - Procedure types" - not displayed correctly after xml data imported. |

Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
| | | |

Additional information

None

Version 1.11.0 (Release Date: 10/09/2013)

Version content

| Functionality / use case | Comments |
|---|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | This release fixes hot fix and other defect. |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00032138 | Resolved the issue in section 2 – “MRP variation number field” is optional even after save and open the form when EU Authorisation selected in section 1. |
| emea00032095 | In Section 3 - Implementation date field is added in the following scopes. B.I.a.1.i, B.I.d.1.c, B.I.e.5.a, B.II.a.3.b.1, B.II.b.3.a, B.II.d.1.h, B.II.d.1.i, B.II.d.2.e, B.II.d.2.f, B.II.e.1.3, B.II.f.1.e, B.II.g.3, B.III.1.a.4, B.III.1.b.4, C.I.3.a, C.I.8.a, C.I.10, C.I.12, C.II.6.a, C.II.8 |

Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
| | | |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | 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 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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, July 2013. | This release implements changes introduced in the latest revision to the Word form (July 2013). The release also fixes various defects. |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00031436 | This release implements changes introduced in the latest revision to the Word form (July 2013). |
| emea00031493 | Resolved issue in section 2 – “MRP Variation number” not displayed after xml data imported. |
| emea00031641 | In section 2 – “MRP variation number field” made as repeatable group. |
| emea00031523 | In Declaration of the Application Section – “Date field” or “Free text field” made mandatory when check box selected. |
| emea00031585 | The tooltip for the “Free text” field in Declaration of the Application Section has been amended to read ‘Click to insert details regarding implementation date (Max. 50 chars).’ The tooltip for the “Member States” field in Signature Section has been amended to read ‘Click arrow button to select member state. With the drop-down list open, press the first letter of the item you wish to select. To cycle through other items beginning with the same first letter, press repeatedly.’ |
| emea00031638 | The heading in the cover page is changed to “EUROPEAN COMMISSION HEALTH AND CONSUMERS DIRECTORATE-GENERAL” which is same as marketing authorisations form. |
| emea00031640 | In Section 3 – Types of change(s), the footnote ‘If one of the conditions is not met and the change is not specifically listed as Type II’ is removed from categories B.I.a.z, D.5, D.7, D.8, D.9, D.10, D.12, D.16, D.18. |
| emea00031642 | In Section 1 - “Company name field” has been added in the “Name and address of the contact person” |
| emea00031643 | Resolve issue in Section 2 - when in the ‘Invented name’ field if you press ‘tab’ cursor jumps over the section to ‘MAH name field’ instead of next field. |
| emea00031644 | Maximum length of “PIP decision number”, “product specific waiver decision number” and “class waiver decision number” increased from 30 to 50 characters. |

| id | Comment |
|--------------|---|
| emea00030674 | In Section 4a – Designation procedure number and designation date field are made as repeatable field. |

Known issues

| id | Description | Workaround/Comment |
|----|-------------|--------------------|
| | | |

Additional information

None

Version 1.9.1 (Release Date: 12/06/2013)

Version content

| Functionality / use case | Comments |
|--|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | This release fixes hot fix and other defects |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00029514 | In "Section 1" the Validation error has been fixed when EU Authorisation and National Authorisation are selected. |
| emea00030889 | In "Declaration of the Application Section" - New free text field has been added under "Date field" to allow users to define the implementation date by its own words |
| emea00027879 | In "Signature Section" - Member states field has been added to allow Users to include which member state has been paid. |
| emea00028851 | In "Section 3- Types of changes" - The full category for a variation is given in the form's XML output. |
| emea00028457 | In "Section 3 - Types of changes" - The Alignment issue has been fixed when + sign is clicked to add additional variation. |
| emea00026316 | Version control has been implemented - when the VARIATION 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 |
|----|-------------|--------------------|
| | | |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | This release fixes various defects. |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00027517 | Where applicable a free-text field for a comment is included for procedures listed in section 3. |
| 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. |
| emea00027249 | In section 1 when 'EU authorisation' is selected, the field allowing entry of the variation procedure numbers is displayed. |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | This release addresses the locking of the form fields after the form is signed. 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. |
| emea00027217 | Under section "2. Products concerned under this application". The active substance fields are made optional when the "see annex A/B" buttons are clicked. When clicked the other fields will be automatically filled with the default text "see Annex A/B" unless already populated. |

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: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | 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. |
| emea00026354 | Validation allowed that section 3. <i>Types of Change(s)</i> the 'Present' and 'Proposed' free text fields may be left unpopulated. User feedback indicated that an entry should always be made for MRP variations so should be mandatory. |
| emea00026314 | Update footnote 7 with the extra information that exists in the paper form (page 3 of paper form), recommending the inclusion of an annex in case of applications including more than 20 products. |
| emea00026335 | Section <i>Declaration of the Applicant</i> : Marking of the checkbox "There are no other changes than those identified in this application..." was not mandatory. Should be changed to be mandatory. |
| emea00025197 | <i>Payment Status</i> : 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 1.2.24 (Release Date: 03/04/2012)

Version content

| Functionality / use case | Comments |
|--|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | This release addresses a number of issues identified in the early stages of the pilot phase. These are detailed in the section directly below. |

Issues fixed for this version

| id | Comment |
|--------------|---|
| emea00025188 | Tool tip comments have been added in various sections of the form. |
| emea00025586 | The form now supports repeats of the same scope from the same Marketing Authorisation Holder. |
| emea00025643 | The form now allows the user to enter a comment against the implementation date e.g. within 6 months after approval. |
| emea00025644 | The EMA can now be selected as reference authority for work sharing. |
| emea00025645 | The form now allows the user to add a reference to the attached <i>Annex A</i> and <i>Annex B</i> . |
| emea00025727 | The labels of variation types of the table in section 3 "Types of changes" are now correctly displayed after closing and re-opening the form. |
| emea00025728 | The form now supports adding and removing variation types, also after closing and re-opening. |
| emea00025731 | Administrative numbers in the tables of section 3 "Types of changes" are now displayed correctly when the type of change is repeated. |
| emea00025732 | Some checkboxes in section 3 "Types of changes" were not displayed as expected and this behaviour has now been addressed. |
| emea00025735 | Aesthetic fix of a border in section 4.a "Type II variations - new indications - orphan medicinal product information". |
| emea00025742 | Fix of inconsistencies in the mandatory status of procedure types in section 3 "Types of changes". |
| emea00025766 | The table height in section 3 "Types of changes" has been updated to avoid increasing when elements are added to the table. |
| emea00025778 | The variation counter table can now expand across multiple pages. |

Known issues

| id | Description | Workaround/Comment |
|--------------|---|---|
| emea00025755 | While the initial main signature field is not marked as mandatory, but when the user adds additional main signatories, these latter are marked as mandatory. | The signature is a mandatory element, although not marked as such by the electronic form. |
| N/A | Affects Adobe 8.1.0 Reader and Acrobat ONLY Two blank landscape pages incorrectly inserted after section 4C. Certain content may not appear as it should. | This is a known issue with version 8.1.0 of both Adobe Reader and Acrobat software, rather than with the form implementation. To resolve this issue, upgrade your Reader or Acrobat software to version 8.1.1 or later. |

Additional information

None

Version 1.0.0 (Release Date: 14/03/2012)

Version content

| Functionality / use case | Comments |
|--|--|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, May 2008. | 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 |
|----|-------------|--------------------|
|----|-------------|--------------------|

| id | Description | Workaround/Comment | | | | | | | | | | | | |
|--|--|---|--|----------------|--|----|--|----|--|----------------|--|----|--|----|
| emea00025586 | Please note that the current version of the Variations electronic application form, does not allow for any grouped variation application that contains repeats of the same scope from the same Marketing Authorisation Holder. | <p>The electronic application form can however be used for grouped variations where different scopes are applied for from the same Marketing Authorisation Holder.</p> <p>The technical team is currently working on solving this issue and it is expected that a new revision will be made available by 1st of April 2012.</p> <p>Meanwhile, if your variation includes repeats of the same scope you should use the word application form for such applications.</p> <p>For example the scope C.1.2. a) cannot be repeated as in the sample below:</p> <div data-bbox="1176 595 1865 1222" style="border: 1px solid black; padding: 5px;"> <p>TYPE(S) of CHANGE(S)</p> <p><input checked="" type="checkbox"/> Copy of the relevant page(s) from the Guideline for this/these change(s) is attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) are ticked</p> <p>VARIATIONS INCLUDED IN THIS APPLICATION:</p> <p>1. Implementation of change A in the SmPC</p> <table border="1" data-bbox="1182 758 1731 922"> <thead> <tr> <th>C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product</th> <th>Procedure type</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH</td> <td>IB</td> </tr> <tr> <td><input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)</td> <td>II</td> </tr> </tbody> </table> <p>2. Implementation of change B in the SmPC</p> <table border="1" data-bbox="1182 975 1731 1139"> <thead> <tr> <th>C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product</th> <th>Procedure type</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH</td> <td>IB</td> </tr> <tr> <td><input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability)</td> <td>II</td> </tr> </tbody> </table> <p>/</p> </div> | C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product | Procedure type | <input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH | IB | <input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability) | II | C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product | Procedure type | <input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH | IB | <input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability) | II |
| C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product | Procedure type | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH | IB | | | | | | | | | | | | | |
| <input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability) | II | | | | | | | | | | | | | |
| C.1.2 Change in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product | Procedure type | | | | | | | | | | | | | |
| <input checked="" type="checkbox"/> a) Implementation of change(s) for which no new additional data are submitted by the MAH | IB | | | | | | | | | | | | | |
| <input type="checkbox"/> b) Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH (e.g. comparability) | II | | | | | | | | | | | | | |

Additional information

None