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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.

## Table of Contents

## Version 1.28.1.0 (Updated version, Release Date: 29/05/2026)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the new checkbox "Annual update" and the auto calculated "Earliest implementation date". |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 306784 | [eAF] eAF VARIATION Human 1.28.1.0 – Annual update | <u>New Feature: Annual Update Checkbox</u><br>A new optional checkbox "Annual update" has been introduced in Section 1.<br>• Default state: unticked<br>• Visible for all procedure type combinations selected in Section 1<br><br><u>When "Annual update" is ticked:</u><br>a) In Section 1, selectable variation types are limited to:<br>• Type IA<br>• Type IAIN<br><br>b) A new field "Earliest implementation date" is displayed in Section 1 (read-only). This field is automatically populated with the earliest implementation date from Section 3.<br>A new note is displayed: "Note: The implementation date of the earliest/first type IA/IAIN variation included in the annual update is autofilled with information from section 3".<br>Each time an implementation date is entered or updated in Section 3, the form identifies the earliest non-empty date across all scopes and this value is automatically reflected in Section 1.<br><br>c) In Section 3:<br>• Implementation note is optional<br>• Implementation date is mandatory |

| id | Description | Comments |
|---|---|---|
| | | When "Annual update" is unticked<br><br>The "Earliest implementation date" field is not displayed in Section 1. |
| ADO 314240 | [eAF] eAF VARIATION Human 1.28.1.0 – mandatory OMS | • For non CAPs all address fields are now populated via OMS selection only<br>• Manual free-text entry is no longer allowed<br>• This behaviour is aligned with the existing approach used for CAPs<br><br>Affected sections:<br>• Name and address of the MA Holder<br>• Name and address of contact person<br>• PROPOSED<br><br>Exception: OMS is not mandatory in Proof of payment. |
| INC0171635 | [eAF] eAF VARIATION Human 1.28.1.0 - extra long note - text hidden under the next page - formatting bug | An issue affecting the display of long notes in the Scopes section (Section 3) has been resolved. |

## Version 1.28.0.0 (Updated version, Release Date: 27/11/2025)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the new variation classification of 1.28.0.0 release. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 267390 | [eAF] New variation classification for Variation Human eaf form | **Human** variation form:<br><br>1. The date displayed in the cover letter has been updated to "January 2026"<br>2. In section 3, the connection to the previous list "variation classification" has been replaced with a new list "Variation Classification - Human" |
| ADO 282959 | [eAF] Human Variation form - new variation classification - UAT finding from EC - business rule change to the Changes concerns table (coronavirus tickbox) | **Human** variation form:<br>The option "Variation to changes related to the active substance of a human coronavirus vaccine" has been now available for selection for procedure Type IB, in addition to Type II. |

## Version 1.27.0.1 (Updated version, Release Date: 25/04/2025)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.27.0.0 release (go-live 25/04/2025). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 238440 | [eAF] eAF Variation Human 1.27.0.0 - Changes | **Human** variation form:<br><br>3. The note under the tick box "The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder *(only applicable for Type IB and/or Type II variations)"* is always mandatory at the case that this tick box is unticked<br>4. There is the possibility for 'National Authorisation' and 'Super-grouping' selected, to enter the name of the reference authority and the name of the CMS. |

| id | Description | Comments |
|---|---|---|
| | | 5. For typeIA and/or typeIAIN the section of harmonisation part that is part of SIGNATURE section is moved at the end of the DECLARATION OF THE APPLICANT section. Additionally the text of harmonization part of Type II or Type IB or Type IB unforeseen or Type II Art29 (or any combination of those e.g. Type IA and Type II) is changed to follow the text displayed for typeIA and/or typeIAIN |

## Version 1.27.0.0 (Release Date: 27/11/2024)

## Human variation form: for use from 1st January 2025

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the 1.27.0.0 release, for the Human variation eAFs. **This version of the form is aligned with the amended Human Variation Regulation entering into force on 1st January 2025.**<br>This version of the form should only be used for variations starting on or after 1st January 2025. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 216232 | [eAF] Variation regulation changes in human variation eAF form | **Human** variation form:<br><br>1) Changes related to Super-grouping:<br><br>• National Authorisation in MRP/DCP and/or National Authorisation OR<br>• EU Authorisation<br>a new "Super-grouping" checkbox has been added below the "worksharing" checkbox. |

| id | Description | Comments |
|---|---|---|
| | | The business rules related with this new check box are:<br>• this is a non-mandatory check box<br>• when the checkbox is selected, only Type IA or Type IAIN are enabled for selection<br>• the user is able to select either "group of variation" and "Super-grouping" or single variation" and "Super-grouping".<br>• It is not possible to select both "Worksharing" and "Super-grouping".<br><br>2) Change related to 'mandatory' worksharing:<br><br>When Type IB or Type IB unforeseen, or Type II or Type II Art29 (or any combination of those e.g. Type IA and Type II) is/are selected then the following apply:<br><br>The Parallel variations section under DECLARATION OF THE APPLICANT section is visible (The Parallel Variations and Harmonisation sections have been moved from the "SIGNATURE" section).<br>The visibility rule of the Parallel Variations section is modified in order to be displayed also when Type IB/Type IB unforeseen is selected and, also when on 'EU authorisation' is selected.<br>The radio buttons 'yes'/'no' have been changed to tickbox declaration.<br><br>For any authorisation type selected at section 1:<br><br>a) The label of the section bold header is "**Declaration of the application about the submission(s) of the same variation (or group of variations) in other Member States / EMA**"<br><br>b) The new tickbox is labelled: " The applicant confirms that the same variation (or group of variations) does not apply to any other marketing authorisation held by the same holder (only applicable for Type IB and/or Type II variations)".<br><br>c) A new "Note" field has been added.<br>EU Authorisations only or EU authorisations mixed with national authorisations: tickbox selected – note is optional, tickbox not selected – note is mandatory.<br>National Authorisation MRP and/or National Authorisation: if the tick box is selected – note is optional, tickbox is not selected, then details on parallel variations (fields "Country", "Invented name", "Date of submission" etc) are mandatory.<br>When tickbox is selected the fields for details on parallel variations are not displayed. |

| id | Description | Comments |
|---|---|---|
| | | 3) In the "Declaration of the Applicant" list the last tickbox label is updated to reflect mandatory worksharing and super-groupings: For mandatory worksharing or (super-)grouped variations affecting more than one MA: the MAs concerned belong to the same MAH.<br><br>4) The following notes are updated:<br>• The veterinary medicinal product part of Note 1 is deleted and replaced with "A MAH shall follow the worksharing procedure, where applicable. The worksharing procedure is optional where it involves more than one MA not belonging to the same GMA"<br>• Wording under note 5, note 6 and Declaration of the applicant to be updated as "grouped variations' to become "(super)-grouped variations"<br>• Wording under note 13 to be updated as "(super-)grouped variations affecting more than one MA, if appropriate.<br>• Note 7 is updated to delete the text: "Veterinary products only: If this list is very extensive it may be added as annex to the application form." And "For MRP/DCP procedures, "list of concerned products" can be provided as Annex to the application form". |

## Version 1.26.0.0 (Updated version, Release Date: 28/11/2023)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 28/11/2023). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 133942 | [eAF] Add Non-Current terms for Variations and Renewals (Human and Vet) for "Pharmaceutical Form" list | **Human and Veterinary** variation form:<br><br>There is a possibility to select also non-current terms from the "Pharmaceutical form" drop-down list. |

## Version 1.26.0.0 (Updated version, Release Date: 28/11/2023)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 28/11/2023). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| ADO 133942 | [eAF] Add Non-Current terms for Variations and Renewals (Human and Vet) for "Pharmaceutical Form" list | **Human and Veterinary** variation form:<br><br>There is a possibility to select also non-current terms from the "Pharmaceutical form" drop-down list. |

## Version 1.26.0.0 (Updated version, Release Date: 14/11/2023)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 14/11/2023). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| INC0050754 | Issue with the variation application form - reigniere | **Human** variation form:<br><br>The following issue was resolved:<br>When a variation application form for several changes of manufacturing sites (replacements/additions) was completed although OMS was used to enter the sites in the present and proposed section, a validation error was displayed and the box 'I declare this variation does NOT result in any changes in manufacturers (i.e. name/address change, addition or replacement of manufacturing site) or the Marketing Authorisation Holder'<br>was highlighted, even though it shouldn't be ticked.<br><br>This was an issue that happened when the user selected multiple scopes.<br>Specifically, if in the first instance in the proposed section the user has not selected an address then the validation rule of the checkbox breaks for the rest instances and it checked if address is completed only for the first instance.<br>For example, in the form the user has attached in the selected scope "B.II.e.1.a.3" in the proposed section the address was not completed, in the next scope "B.II.b.1.f" even if the address was properly completed the validation rule checked if the address was completed in the scope "B.II.e.1.a.3". |

### Version 1.26.0.0 (Updated version, Release Date: 24/07/2023)

#### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 24/07/2023). |

#### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| INC0018243 | Display issue with section 2 of veterinary variations eAF | **Veterinary** variation form:<br><br>The following issue was resolved:<br>In section « 2. Products concerned by this application", when data for a given country (MA number, invented name, MAH, etc…) were to be entered on the last row displayed on a page, a shift occured : the MAH name appeared in the 1st left column on the next page. |

## Version 1.26.0.0 (Updated version, Release Date: 31/05/2023)

#### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 31/05/2023). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| INC100509 | Human eAF variation form - business rule error in section 4b Paediatric Requirements. | **Human** variation form:<br>The business rule has been corrected to allow selection of more than one option in section 4b Paediatric Requirements. |

## Version 1.26.0.0 (Updated version, Release Date: 14/10/2022)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the minor fix version of 1.26.0.0 release (go-live 14/10/2022). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-665048 | Human eAF variation form - validation rule for mandatory use of OMS in 'proposed' section of the form. | **Human** variation form:<br>The text for the 'declariation' tickbox on the use of OMS has been amended to read "I declare this variation does NOT result in any changes in manufacturers (i.e. name /address change, addition or replacement of manufacturing site) or the Marketing<br>Authorisation Holder". |

# Version 1.26.0.0 (Updated version, Release Date: 14/06/2022)

## *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the BUGFIX version of 1.26.0.0 release (go-live 14/06/2022). |

## *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-665048 | Human eAF variation form - validation rule for mandatory use of OMS in 'proposed' section of the form. | **Human** and **Veterinary** variation form:<br>The tickbox "I declare this change does not affect organisations or the organisation is being deleted" will be displayed when the form is signed even if the form hasn't been validated. |
| SD-647719 | Business rule error in section 4b of the human variation form | **Human** variation form:<br>This change affects section 4b. When the applicant has selected the first option "This application relates to a new indication for an authorised medicinal product which:"; then the one of the sub options should be mandatory<br>• "is protected by a supplementary protection certificate under Regulation (EC) No 469/2009."<br>• "is protected by a patent which qualifies for the granting of the supplementary protection certificate."<br><br>The same applies with the 2nd option, if the applicant has selected 'This application relates to a previous/ongoing/parallel procedure which triggered Article 8 requirement.', then the "Competent authority/EMA procedure number" is mandatory.<br><br>With regards to the overall business rule, when paediatric has been selected in section 1, at least one of the five options below needs to be selected from section 4b:<br>• Radio button: "Article 8 of Paediatric Regulation applies to this variation application since."<br>• Radio button: "Article 8 of the paediatric regulation does not apply to this application, since." |

| id | Description | Comments |
|---|---|---|
| | | • Radio button: "This application relates to a new indication for a paediatric use marketing authorisation (PUMA)."<br>• Tick box: "This application relates to paediatric studies submitted according to Article 45 or 46 of the paediatric regulation"<br>• Tick box: "This application relates to paediatric studies included in a paediatric investigation plan" |

## Version 1.26.0.0 (Updated version, Release Date: 26/04/2022)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the BUGFIX version of 1.26.0.0 release (go-live 26/04/2022). |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-642359 | eAF (human and VET) - validation rule for mandatory addresses in the eAFs | **Human** and **Veterinary** variation form:<br>When EU authorisation only, or EU authorisation and any combination with MRP/DCP or NP is selected; then the address search from OMS in 'Proposed' field of Present and Proposed section should be triggered.<br>A new validation rule is triggered if no organisation has been selected in the 'proposed' field using OMS and user clicks validate. A new checkbox is visible in proposed Organisation search area and the user must declare this change does not affect organisations or the organisation concerned is being deleted to stop displaying the validation error.<br>The validation rule at the end of the form, when triggered reads 'At least one organisation should be selected from OMS or a declaration by application must be made that the change does not affect organisations or the organisation concerned is being deleted.' |

| id | Description | Comments |
|---|---|---|
| SD-634403 | UPD Product Identifier field | **Veterinary** Variation form<br>In Section 2, the UPD Product Identifier field is not displayed anymore in the Variation veterinary form. |
| SD-519223 | Form validation rule missing | **Human** Variation form<br>A missing validation rule has been added to the human variation form.<br>When Type IA or Type IAIN is selected in section 1, fields implementation date and implementation note appear in section 3. A validation rule has been added to make these mandatory in the following way;<br>If Type IA or Type IAIN is selected, the implementation date should be mandatory, if no date has been selected, the implementation note field is mandatory. |
| SD-626262 | eAF (human and VET) - validation rule for mandatory addresses in the eAFs | Validation rule for mandatory use of OMS has been accidentally removed and is returned.<br>Specifically, when the free text address fields were removed when mandatory use of OMS was implemented for CAP only submissions, the validation rule was accidentally removed. The fields are now shown however, they are read only and cannot be manually edited. The address when selected from OMS will be shown in these fields.<br><br>**Veterinary** Variation form<br>• Section 1: Name and address of MA holder<br>• Section 1: Name and address of contact person<br>• Section 3: Proposed<br><br>**Human** Variation form<br>The above applies to the following sections of Variation Human form taking into account that the applicant has selected EU authorisation in the form:<br>• Section 1: Name and address of the MA Holder, Name and address of contact person<br>• Section 3: Proposed.<br>• Section 4d: Manufacturer of the device, Notified Body, Companion diagnostic<br><br>**Human** Variation form<br>A new tooltip is added in the Human variation form which is relevant when EU authorisation only, or EU authorisation and any combination with MRP/DCP or NP is selected; the a new tool tip is shown when the user is hovering over the 'Summary of product characteristics, Labelling or Product Information tick boxes in the Annexed documents section. The following text has been added in the tool tip;<br>The link to the document is<br>here: https://www.ema.europa.eu/en/documents/template-form/checklist- |

| id | Description | Comments |
|---|---|---|
| | | submission-type-ia-type-ib-without-linguistic-review-product-information-annexes-annex-if_en.pdf<br>Please ensure Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable) is included to your submission (if applicable). Missing checklist is considered validation issue.<br>Please be reminded that in accordance with Union data protection requirements, no personal data should be included in the annotated PIs. This applies to the English version submitted at the time of opinion, the draft translation versions of the PI in all the languages submitted at D+5 as well as the final translations submitted at D+25. Please submit annotated PIs in an anonymised format (i.e. names of the reviewers removed from the track-changes). If you do not wish to do so, please ensure that the individuals whose data is included consented to its sharing with EMA and its further sharing by EMA with third parties such as other marketing authorisation applicants, marketing authorisation holders and National Competent Authorities, as relevant. EMA expressly disclaims any liability or accountability for the presence of unnecessary personal data in the annotated PI submitted by the marketing authorisation holder.<br><br>**Note:** The tool tip may not be fully readable depending on the position of your mouse pointer. If you cannot see the full text on the screen, please move the pointer to a different position. It is not possible to open the link directly from the tooltip or copy past the tooltip text due to limitation in the Adobe technology used in the forms. |
| SD-589125 | VMP-Reg related improvements/corrections | **Veterinary** Variation form, when MRP has been selected in section 1;<br>• In section for parallel variations; when Yes is selected, the value 'European union' has been removed.<br>• In the proof of payment section, when 'yes' is selected, then values 'European Union' and 'EMA' have been removed.<br>• When 'add all' option is used to add previously used member states, an empty entry in the end of the list has been removed.<br>• When 'grouping' is selected in section 1, but only one variation is selected in section 3 and the form is validated, when you are on top of that validation error and click jump to selected, it does jump to the label of the selected bug. |

## Version 1.26.0.0 (Updated version, Release Date: 20/01/2022)

## Human variation form: for use from 1st December 2021. Veterinary variation form: for use from 28th January 2022.

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the 1.26.0.0 release, for the human and veterinary variation eAFs. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-603296 | eAF VMP-Reg release v1.26.0.0 - update of the label name for the UPD product identifier | **Veterinary** Variation form:<br>In section 2, the label for UPD product information has been updated to read; "UPD Product Identifier[6] (only relevant for MRP, DCP, SRP and CP)" instead of the current UPD Product Identifier[6] (only relevant for MRP and CP). |
| SD-610514 | eAF VMP-Reg release v1.26.0.0 optional harmonisation/parallel variation section with new tooltip | **Human** variation form:<br>The "Yes/No" radio buttons of "Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products" and "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products" are now optional.<br>A new tooltip providing additional information is displayed when the user hovers over the section header "Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products"<br><br>**Veterinary** veterinary form:<br>The "Yes/No" radio buttons of "Declaration of the applicant about submission(s) of the same type of variation requiring assessment application for the same product in other Member States – for MRP/DCP/purely nationally authorised products" and |

| id | Description | Comments |
|---|---|---|
| | | "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products" are now optional. |

## Version 1.26.0.0 (Release Date: 1/12/2021)

## Human variation form: for use from 1st December 2021. Veterinary variation form: for use from 28th January 2022.

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document:<br>APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION | This release note is for the 1.26.0.0 release, for the human and veterinary variation eAFs. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-562925 | Mandatory OMS in eAF (for EU authorisation) | **Human** Variation form: the use of OMS is mandatory for Centralised Procedure applications.<br>When EU authorisation is selected, or if both, EU authorisation and MRP/DCP and/or National has been selected, the use of OMS is mandatory.<br>When MRP/DCP and/or National has been selected, the optional use of OMS continues to apply.<br>More specifically:<br>• The user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". These fields will become visible when the user selects an organisation from OMS.<br>• Add "find organisation" button when this is missing. |

| id | Description | Comments |
|---|---|---|
| | | • The user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.<br><br>The above applies to the following sections of Variation Human domain form when the applicant has selected EU authorisation in the form:<br>• Section 1: Name and address of the MA Holder, Name and address of contact person<br>• Section 3: Proposed. The OMS entry in 'present' is optional so free text fields need to be kept. Should be mandatory in 'proposed' (remove free text fields)<br>• Section 4d: Manufacturer of the device, Notified Body, Companion diagnostic<br><br>OMS is not mandatory in Proof of payment for billing (OMS search is available and recommeded for use). |
| SD-508617 | eAF – Veterinary variation form updated to reflect requirements VMP-Reg | Split the Human/Veterinary form to two (2) Variation forms.<br>• The Variation-Human form will have checkbox "Human" in Section 1 selected, read-only. The Veterinary checkbox will be hidden.<br>• The Variation-Veterinary form will have checkbox "Veterinary" in Section 1 selected, read-only. The Human checkbox will be hidden.<br><br>**Veterinary** Variation form includes the following changes:<br><br>**Cover page**:<br>Update cover page to reflect the new form version 1<br><br>**Section 1**:<br>• Add "/SRP" at the check box "National Authorisation in MRP/DCP"<br>• Delete the selection of procedure type (e.g. Type IAIN, Type IA, IB etc)<br>• Update "changes of concern(s)" list to reflect the update (check boxes should always be visible)<br>  ○ Quality<br>  ○ Indication<br>  ○ Safety<br>  ○ Non-food producing target species<br>  ○ Other<br><br>Name and address of MA holder: The address must be retrieved from OMS: |

| id | Description | Comments |
|---|---|---|
| | | • the user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". Also, these fields will become visible when the user selects an organisation from OMS.<br>• the user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.<br><br>Name and address of contact person: The address must be retrieved from OMS:<br>• the user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". Also, these fields will become visible when the user selects an organisation from OMS.<br>• the user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.<br><br>**Section 2**:<br>• Add the "UPD Permanent Identifier for the concerned national product(s):" and the "UPD Product Identifier (only relevant for MRP and CP):"<br>• Pharmaceutical form column reduced in size so the 2 UPD fields can fit<br>• A '?' button to be added next to UPD fields that will show the footnote, related to these 2 new UPD fields<br><br>**Section 3**:<br>• Scope selection from the new Veterinary Variation Classification list is established<br>• Procedure type section has been removed<br>• New extended attribute 'Timetable' with possible values R or S or E (one possible value each time) will be displayed as text field (not as a check box). The "timetable" information is part of "Application Submission Type" attribute.<br>• Variations that their timetable is "VNRA", are filtered out<br>• Implementation Date and Note are deleted<br>• Article 5 tick box is deleted<br>• Update the text into "Precise scope and background for change, and justification for a z) classification, grouping, worksharing (as applicable) (Include a description and background of all the proposed changes. In case of a z) scope, grouping and worksharing a justification should be provided in a separate paragraph.)."<br>• PRESENT/PROPOSED: For the present the user will be able to enter address in free text fields. Use of OMS is optional.<br>• In the Proposed address fields, the address must be retrieved from OMS: |

| id | Description | Comments |
|---|---|---|
| | | ○ the user cannot manually enter "Company name", "address", "City", "State", "County", "postcode", "Country". Also, address details in these fields is displayed when the user selects an organisation from OMS.<br>○ the user should be able to find the address using "Loc ID/Org ID" or "Organisation name/Country" or previously selected address.<br><br>**Section 4c**:<br>• Section 4c should be always visible<br>• Update the label of the text "Consideration of this application is also requested under the following article in directive 2001/83/EC or regulation (EC) No 726/2004:" into "Consideration of this application is also requested under the following article of Regulation (EU) 2019/6:"<br>• Update section by removing the old radio buttons and replace with updated (mutually exclusive) radio buttons.<br>• There will not be business rule related with the new radio buttons.<br>○ Article 40(1) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 1 year for each additional target species, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (a) or (b) of Article 39(1)).<br>○ Article 40(2) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 4 years, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (d) of Article 39(1)).<br>○ Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out.<br>○ Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection). |

| id | Description | Comments |
|---|---|---|
| | | **Annexed documents section**:<br>• Update the label of the text from "The following amended product information proposals are provided in the relevant sections of the EU-CTD format or NTA volume 6B format, where applicable:" into "The following amended product information proposals are provided in the relevant sections of the variation application dossier, where applicable:"<br>• Update the label of the check box "Manufacturing Authorisation Holder responsible for batch release and conditions of the Marketing Authorisation" into "Conditions of the Marketing Authorisation"<br><br>**Declaration of the applicant section:**<br>• Update the label of the text and label of check boxes<br>• Delete the check box "Where applicable, all conditions as set for the variation(s) concerned are fulfilled"<br>• Delete "Next production run/next printing"<br>• Update the label of the "Date" into "Proposed implementation date"<br><br>• Add two new separate sections under the existing section of declaration of the applicant. These 2 new sections should be appeared only if the user selects MRP or National authorisation. If only EU authorisation is selected these 2 new sections will not be appeared.<br>• Parallel variations section:<br>○ If no is selected then nothing will be displayed (below the radio buttons)<br>○ If yes is selected, then the fields below the radio buttons will be displayed in a frame and that will be repeatable. The list of Country field will be the EEA list including Nothern Ireland.<br>• Harmonisation section:<br>○ If the user selects yes to the questions 1) and/or 2) he has to fill in the following fields that will be appeared in a repeatable frame:<br>▪ Procedure(s) reference number:<br>▪ Specify the section(s) of SPC/PIL/labelling:<br>○ If the user selects no to to the questions 1) and/or 2) the fields below the radio buttons will not be appeared.<br><br>**Main Signatory section**:<br>• Update the label of the existing check box from "For worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4.3 in Part IA/Module 1 Application Form for each of the Mas concerned." into "For |

| id | Description | Comments |
|---|---|---|
| | | worksharing/grouping for more than one MA: the main signatory confirms authorisation to sign on behalf of the designated contacts as specified in section 2.4 in Part IA/ Application Form for each of the MAs concerned."<br><br>**Across the form:**<br>Update the footnotes |
| SD-574425 | eAF VMP-Reg release v1.26.0.0 update of the variation form section 'Extended data exclusivity/market protection' at Vet variation form | **Veterinary** Variation form: In section 4c on Extended data exclusivity/market protection:<br>• Add 3 new options with radio button selection (mutually exclusive) and the option which is already there needs to be modified slightly to replace the text 'four' with number '4'<br>• The new options to be added are;<br>Article 40(1) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) or (b) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 1 year for each additional target species, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (a) or (b) of Article 39(1)).<br><br>Article 40(2) of Regulation (EU) 2019/6 (where a variation is approved in accordance with Article 67 which adds another species referred to in point (a) of Article 39(1), the period of the protection provided for in Article 39 shall be prolonged by 4 years, provided that the variation application has been submitted at least 3 years before expiration of the protection period laid down in point (d) of Article 39(1)).<br><br>Article 40(4) of Regulation (EU) 2019/6 (where an applicant for a variation submits an MRL application in accordance with Regulation (EC) No 470/2009, together with safety and residues tests and pre-clinical studies and clinical trials during the application procedure, other applicants shall not refer to results of those tests, studies and trials for a period of 5 years from the granting of the MA for which they were carried out.<br><br>Article 40(5) of Regulation (EU) 2019/6 (if a variation involving a change to the pharmaceutical form, administration route or dosage is approved, and additionally assessed to have met a criterion within this Article, the results of |

| id | Description | Comments |
|---|---|---|
| | | the concerned pre-clinical studies or clinical trials shall benefit from 4 years protection). |
| SD-573178 | eAF VMP-Reg release v1.26.0.0 display the sms ID in the pdf at vet variation form | **Veterinary** Variation form:<br>In section 2, in the Active Substance field, display the SMS id in field called 'code'. |
| SD-587688 | eAF VMP-Reg release v1.26.0.0 variation form - alternative timetable tick box and field at vet variation form | **Veterinary** Variation form:<br>Timetable value should be displayed as text with value: "Default timetable: X" where X is the value of the timetable returned by RMS e.g. R.<br><br>A text with label "Alternative timetable agreed in advance:" should be displayed below "Default timetable" with 3 possible values "R", "E" and "S" displayed as radio buttons.<br><br>The radio button with the timetable value returned from RMS will be selected as default e.g. "R".<br><br>The new text "Alternative timetable agreed in advance:" will have a tooltip "Please select an alternative timetable if one has been agreed in advance of submission."<br><br>When the user selects an alternative value of the radio buttons e.g. "E" or "S" (different from the one returned from RMS list), a new mandatory check box will be displayed below with text "Please tick to confirm that the correspondence confirming the alternative timetable is included in the submission." When the user selects the default radio button value e.g. "R" this check box becomes hidden. |

### *Known issues/pending implementation*

| Id | Description | Workaround/Comment |
|---|---|---|
| | | |

| Id | Description | Workaround/Comment |
|---|---|---|
| | | |

### *Additional information*

None

## Version 1.25.0.0 (Release Date: 10/2021)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, September 2021. | This release note is for the 1.25.0.0 release, of the eAF variation form. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-403901 | **Human** domain only:<br>eAF – Medical Device Regulation related changes to align with the updated NtA form version September 2021 | **Human** domain only:<br>The variation form has been updated to align with the updated NtA form revision September 2021 to reflect the changes implemented as a result of the Medical Device Regulation Art 2(1) of Regulation (EU) 2017/745;<br>• New 'Changes concerns' tick box has been added to indicate 'Medical Device'. This new tick box is always visible and when selected, a new section 4.d is shown to include details on Medical Devices and Companion Diagnostics<br>• Addition of new section on Medical Devices (4.d) to reflect the changes from the Medical Devices regulation |

| id | Description | Comments |
|---|---|---|
| | | • Addition of new section on Companion Diagnostics (4.d) to reflect the changes from the Medical Devices regulation<br>• Title fields in the form are now optional |
| SD-403901 | **Human** domain only:<br>Other (non-medical device related) changes to align with NtA version September 2021 | **Human** domain only:<br>• When Type of Application is 'Type II' a new value is available for selection in Changes concerns section: "Variation to changes related to the active substance of a human coronavirus vaccine"<br>• If "National Authorisation" or "National Authorisation in MRP/DCP" (or both) are selected and Type of Application is 'Type II' a new section under proof of payment has been added to allow the applicant to declare parallel variations; "Declaration of the applicant about submission(s) of the same type II variation application for the same product in other Member States – for MRP/DCP/purely nationally authorised products"<br>• If "National Authorisation" or "National Authorisation in MRP/DCP" (or both) are selected a new section "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products under proof of payment has been added to allow the applicant to provide information on harmonisation of product information "Information on harmonisation of product information for MRP/DCP/purely nationally authorised products' |
| SD-491930 | eAF - Proof of payment section should be more visible in the forms to ensure that it is filled in where needed | The Proof of payment checkbox is ticked as default to automatically display the Proof of payment section. It is possible to untick the box to hide the section if payment details are not relevant. |

### *Known issues*

| Id | Description | Workaround/Comment |
|---|---|---|
| | | |

| Id | Description | Workaround/Comment |
|---|---|---|
| | | |
| | | |

## Version 1.24.0.1 (Release Date: 12/2020)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.24.0.1 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-450512 | eAF - Brexit related change request - to be implemented in the eAFs | In all 4 forms, some country drop down lists will have dynamic values, depending on the Authorisation Selection in Section 1. |
| SD-465550 | Update of the eAF form validation rule to allow grouping of single scope for NAPs | In Variation form, there has been a change in the Validation rules of variations.<br>Now, when user selects National Authorisation, Grouping and only 1 type of procedure in Section 1, then if the user selects only 1 scope in Section 3, no validation error will occur. |

### *Known issues*

| Id | Description | Workaround/Comment |
|---|---|---|
| EAF-3196 | Text is hidden under the next page when a new product added. The issue insists only if you add a new product description and the description of the new product starts in the top of the next | User can fill in 1st description some empty lines. |

| Id | Description | Workaround/Comment |
|---|---|---|
| | page. If this is not the case, then the new product description is flowed across pages as expected. | |
| 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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

## Version 1.24.0.0 (Release Date: 09/2020)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.24.0.0 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-161811 | Variations scopes: eAF to Siamed and RMS - harmonisation of scope lists in both systems | Section 3 is significantly redesigned;<br>• Variations are now retrieved from SPOR System and the data shown is linked with the selections in Section 1.<br>• Where applicable, you can select the variation type, add implementation date/note (only for Type IA and $IA_{IN}$),<br>• Automated Article 5 applicability,<br>• Automated addition of relevant Documentations and Conditions (ability to select/add a free text note)<br>• For grouping addition/deletion and Clone buttons are also available (not available for Single Scope). |
| SD-375785 | eAF No Longer Validating Version | All forms check all digits of the form version. |

### *Known issues*

| Id | Description | Workaround/Comment |
|---|---|---|
| EAF-3196 | Text is hidden under the next page when a new product added. The issue insists only if you add a new product description and the description of the new product starts in the top of the next page. If this is not the case, then the new product description is flowed across pages as expected. | User can fill in 1st description some empty lines. |
| 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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

# Version 1.23.1.3 (Release Date: 09/2019)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.23.1.3 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-271374 | Query re variation eAF Version Number: 1.23.1.0 - present/proposed table(s) | Texts are no longer hidden under next pages in section 3 "Present / Proposed Tables" |

### *Known issues*

| Id | Description | Workaround/Comment |
|---|---|---|
| EAF-3196 | Text is hidden under the next page when a new product added. The issue insists only if you add a new product description and the description of the new product starts in the top of the next page. If this is not the case, then the new product description is flowed across pages as expected. | User can fill in 1st description some empty lines. |
| 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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

# Version 1.23.1.2 (Release Date: 03/2019)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.23.1.2 hotfix, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| EAF-3042 | In Section 3, After click at a particular place form goes to infinite loop of error message box | In section 3, the summary variations table is updated automated with no user action. |

### *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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

# Version 1.23.1.1 (Release Date: 01/2019)

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.23.0.0 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| EAF-3059 | eAF 1.23.1.0 for variations section 2: member state ERROR | Now in Variation form, the Member States of section 2, are now exported and imported as expected. |

### *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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

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

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release 1.23.1.0 is for high priority bug fixes. (No change requests are included) |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| EAF-2790 | Section 1 – name and address of the contact person - Clicking "copy contact details from previous section" only one company details are copied even though multiple companies are included. | In the Variation form – In sections 1; when pressing the button "copy contact details from previous section" – if there are multiple sections\addresses present they shall all now be correctly copied into the respective section. |
| EAF-2791 | Contact details for Applicant/ MAH have been entered. When copying "contact details from previous section" for "Name and address of contact person", telephone and e-mail information is not transferred. | In the Variation form – In sections 1; when pressing the button "copy contact details from previous section" –all fields shall now be correctly copied into the respective section including the Name, Address, Telephone and Email fields. |
| EAF-2792 | Signature Section - Copy contact person details from section 1 does not work when more than one contact person details is available. | In the Variation form – In the Signature section; when pressing the button "copy contact person details from section 1" and there is more than one contact present in section 1 – the form shall now prompt the user with the option of selecting exactly which contact they wish to copy. |
| EAF-3002 | Additional signature adding only possible after first signature. | In the Variation form - This change was introduced to allow full flexibility for signatories to add their signatures in any order, i.e. Main signatory first and then additional signatories or Additional signatories first and then the main signature, the form shall no longer enforce any order for this. Note: The MAA Human & Vet forms also work in the same way. |

| id | Description | Comments |
|---|---|---|
| EAF-3003 | XML Import Bug | This change is a minor change to the XML import process for correctly importing country codes – there is no visible change in the form. |
| SD-192861 | In the Present-Proposed section –country field is not displaying all countries. | In the Variation form – In the Present-Proposed section; when selecting a Country from the dropdown using the free text field entry – the list shall now display the International country codes list rather than just EU country codes list. |

### *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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

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

### *Version content*

| Functionality / use case | Comments |
|---|---|
| Implementation as electronic form of the document: APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION, February 2018. | This release note is for the 1.23.0.0 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-145156 | NTA changes for All 4 eAF forms. | All changes described in the NTA form specification have been implemented. Please refer to the user guide and Release Notes summary for detailed changes. |
| SD-140624 | In present and proposed section OMS-integration should be implemented. | In "Present and Proposed" section – OMS search address has been added. |
| SD-182135 | In all OMS address sections - "Org-modified date' field is required only in xml and should not be visible in pdf. | In all OMS address sections – "Org-modified date" has been added to schema and this field is not visible in the pdf. |
| SD-175713 | In section 2 - When selecting "EU Authorization" under section 1 and trying to add second, the option to add more products using the + buttons disappears. | In section 2 – To add more products "+" button issue has been resolved. |
| SD-156002 | In All Address section - format of the email address is not recognized and invalid if the name of the company is more than 9 characters. | Email address can be entered more than 9 characters of company name. |
| SD-186883 | Remove\Hide OMS entry related fields from eAFs where no OMS data exists. | In payment section – OMS address search is hidden, only manual entry is allowed in this section. |
| SD-169798 | In section 2 - When you select the footnote, save the form and re-open the countries you have selected before saving disappear. | In section 2 – when you select the footnote – details are saved after reopen the form. |
| EAF-2977 | In signature section, "Main Signatory" is not allowed to signature (image) if user signed "Additional Signatory" first. | In signature section – Additional signatory cannot be added if main signatory is not filled. |

### *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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

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

### *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 1.22.0.1 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| EAF-2812 | Declaration and Signature section – proof of payment - LogID/OrgID missing in the within the pdf once saved and reopen. | In Declaration and Signature section – Proof of payment - LogID/OrgID is visible after saved and reopen. |
| EAF-2810 | Empty Tag <rdm:org-modifiedDate> in eAF MAA should be removed. | Empty Tag <rdm:org-modifiedDate> in eAF MAA has been removed from schema. |
| EAF-2809 | Missing timestamp in loc-modifiedDate when copy contact details button is clicked in section 1. | In section 1 – when copy contact details button is clicked – loc-modifiedDate timestamp is available. |

### *Known issues*

| Id | Description | Workaround/Comment |
|---|---|---|
| SD-35463 | Adobe Reader displaying forms as not being locked down and with red fields | The applicant/MAH must use Adobe Reader to sign and lock the forms. If the form has been locked using Adobe Acrobat and the receiving regulator views the form using Adobe Reader this issue is experienced. If the regulator views the form using Adobe Acrobat there is no issue. |
| | When importing xml from v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

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

### *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 1.22.0.0 release, for the eAF forms. |

### *Issues fixed for this version*

| id | Description | Comments |
|---|---|---|
| SD-65517 | eAF-OMS integration | All Address sections<br>• Address fields has been amended to in line with OMS data.<br>• OMS data can be searched now to fill address fields via search button. For all address fields users can now choose to either enter an OMS organisation thus auto populating address fields or they can choose to enter the address details manually. |
| EAF-2771 | Section 1 - when "TypeIB unforsceen" is selected then "Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)" section should be displayed. | In Section 1 - when "TypeIB unforsceen" is selected then "Change(s) concern(s) (for Type IB and Type II variations only, tick all changes applicable)" section will be displayed now. |
| EAF-2772 | Section 2 - "Form and Strength information is provided in footnote" check box field should move to end of the section and font should be reduced. | In Section 2 - "Form and Strength information is provided in footnote" check box field has been moved to end of the section and font has been reduced. |
| EAF-2774 | Section 1 - When selecting "Concerned member State(s)", the same state should not be selected more than once. | In Section 1 - When same "Concerned member State(s)" is selected, than it gives error message to select different CMS. |
| EAF-2775 | Section 2 - The pop-up message for the MA Holder name is the same as the one for the Invented names. | In Section 2 – "MA Holder Name" tooltip has been amended as "Click to show previously entered MA Holder Names. |
| EAF-2776 | When type IA variations selected in section 1 "Type of application" then in Declaration section "Change(s) will be implemented from" are removed after selection, but saving the | In Section 1 – Type of Application – When Type IA variations are selected then in Declaration section "Change(s) will be implemented from" field is displayed correctly when the form is reopened. |

| id | Description | Comments |
|---|---|---|
| | form and opening it again "Changes will be implemented from" re-appears. | |
| EAF-2777 | Section 3 - In the Present/Proposed table the exact width of column "PRESENT" and column "PROPOSED" slightly differs, leading to different line breaks in identical text used on both sides. Comparison of both columns can therefore be difficult if the reader is expecting that identical text appears identical | In Section 3 - Present/Proposed table - the width of the column "PRESENT" and column "PROPOSED" is same now. |
| EAF-2779 | Section 4.b, validation - Validation error still occurs if radial requiring additional text input is de-selected, and validation re-run | In Section 4.b – Validation error has been resolved. |

### *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 v1.20.0.5 or previous version to latest version (1.21.0.0/1.22.0.0) additional digits are added to terms selected from controlled terminology. | Always 'trust' the form prior to importing xml from previous forms. |

# Version 1.21.0.0 (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 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)<br>Expected Result should be as below<br>A.z) should display as A.z in the table<br>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)<br>The Result now shows in table as below<br>A.z) should display as A.z in the table<br>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. | "Add selected" button removed in section 1 – Concerned Member States (CMS)<br>Add All button removed in the following sections<br>section 1 –<br>• Name and address of the Applicant/MA holder,<br>• Name and address of contact person<br>Declaration section –<br>• 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 | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|---|---|---|
| | the PoP section cannot be completed by the CMSs after RMS has 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. |

| Id | Description | Workaround/Comment |
|---|---|---|
| EAF-2140 | Section 2, For some countries the procedure number and variation number are different. It would be useful to have a field to include the individual variation number in this section. | For consideration in a future release of the eAF. |
| 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 | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|---|---|---|
| | means that the data needs to be manually deleted or typed over. | |
| 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)":<br>A heading for the following z-variations is missing:<br>• B.I.e<br>• B.II.f<br>• B.II.g<br>• B.II.h<br>• 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. | In Section 1, the Name and Address of the Applicant/MA Holder now has a +/- button to allow for multiple addresses to be added. |

| id | Description | Comments |
|---|---|---|
| | At the moment we are able to include more than one MAH in the word document. (See screenshot 2). This is not possible in the eAF. | Note: The Variation DES has been changed to accommodate this 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.<br><br>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.<br>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. |

| id | Description | Comments |
|---|---|---|
| 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. |
| 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. |

| id | Description | Comments |
|---|---|---|
| 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. |
| 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. |

| id | Description | Comments |
|---|---|---|
| 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. |
| 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. |

| id | Description | Comments |
|---|---|---|
| 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 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. |

| Id | Description | Workaround/Comment |
|---|---|---|
| | There is a known issue opening eAF forms using reader, when non-traditional or special characters are used (this has been observed when copying from a Word document into the eAF form). These characters might cause reader to request the installation of the Chinese character set pack, when the form is reopened. This issue is not observed in Adobe Acrobat which will open the file without issue. | Download from the Adobe website the Chinese Language Pack for Adobe Reader, or open the file with Adobe Acrobat. |
| EAF-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. |

| Id | Description | Workaround/Comment |
|---|---|---|
| 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. |
| 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. |

| Id | Description | Workaround/Comment |
|---|---|---|
| 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 signed | For consideration in a future release of the eAF. |
| 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. |

| Id | Description | Workaround/Comment |
|---|---|---|
| EAF-2140 | Section 2, For some countries the procedure number and variation number are different. It would be useful to have a field to include the individual variation number in this section. | For consideration in a future release of the eAF. |
| 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 | For consideration in a future release of the eAF. |

| Id | Description | Workaround/Comment |
|---|---|---|
| | means that the data needs to be manually deleted or typed over. | |
| 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*

**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 1.19.0.0 (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.<br><br>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 | Name and address of contact person - title should be an optional field, also, Signature - title should be optional<br><br>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. | 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 | - The document can be correctly filled, validated, signed and saved under a different name.<br>- However when opening the signed version Adobe opens a “save as” dialogue which has to be cancelled before the document can be opened<br>- This occurs both after double-click in the file system or when clicking a hyperlink in the VNeeS 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 |

| 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. | been updated to state for "See Annex B" button: Populates/Clears necessary fields in the form with "See Annex B" |
| emea00039350 / EAF-1909 | 1. APPLICATION FOR VARIATION TO A MARKETING AUTHORISATION<br>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.<br><br>2. PRODUCTS CONCERNED BY THIS APPLICATION<br>The tooltip besides "Pharmaceutical Form" reads "Add additional medicinal product", but an additional pharmaceutical form appears when clicked. | 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.<br>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).<br>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). |
| 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.<br>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.<br>"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 | In section 2 - Products concerned by this application.<br>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.<br><br>So Annex A is for CP products, and further it states Annex B is for worksharing procedures submitted to the EMA. But there is | 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).<br>• In Section 3 – Types of Scopes - B.I and B.II scopes have been implemented.<br>• In Signature section - Payment details have been updated.<br>• 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".<br>• Footnotes 1, 6, 8, and 18 have been amended.<br>• 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.<br>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.<br>• 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).'<br>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<br>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.<br>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. Types of Change(s)* 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 *Declaration of the Applicant*: 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 | *Payment Status*: Allow more characters and widen field. The payment status box should be longer as it is not readable. I entered 'To be paid on receipt of invoice from the EMEA' and most of it was not visible. |

## *Known issues*

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

## *Additional information*

None

# Version 1.2.24 (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 *Annex A* and *Annex B*. |
| 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**<br>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 |
|---|---|---|
| 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. | The electronic application form can however be used for grouped variations where different scopes are applied for from the same Marketing Authorisation Holder.<br>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.<br>Meanwhile, if your variation includes repeats of the same scope you should use the word application form for such applications.<br>For example the scope C.1.2. a) cannot be repeated as in the sample below:<br>**TYPE(S) of CHANGE(S)**<br>☒ 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<br>**VARIATIONS INCLUDED IN THIS APPLICATION:**<br>*1. Implementation of change A in the SmPC*<br>**C.I.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**<br>☒ a) Implementation of change(s) for which no new additional data are submitted by the MAH — IB<br>☐ 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<br>*2. Implementation of change B in the SmPC*<br>**C.I.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**<br>☒ a) Implementation of change(s) for which no new additional data are submitted by the MAH — IB<br>☐ 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<br>/ |

## *Additional information*

None