



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## eAF – Questions & Answers

Questions and answers relating to practical and technical aspects of the Electronic Application Forms (Human and Veterinary).

**Please send any questions to**

**<https://servicedesk.ema.europa.eu> or the responsible NCA contact**



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## IMPORTANT INFORMATION

Users should continue to refer to [EudraLex Volume 2 \(Human\)](#) and [EudraLex Volume 6 \(Vet\)](#) for detailed guidance on completing the content of the application forms.

In addition, the regulatory USER GUIDE FOR THE ELECTRONIC APPLICATION FORM FOR A MARKETING AUTHORISATION which is available for human medicinal products at [CMDh](#) and for veterinary medicinal products at [CMDv](#) should be taken into consideration.

## OBJECTIVES OF THE eAF

### ***Q.1. What is the eAF? (H+V)***

**A:** The eAF is a collection of electronic Application Forms:

- Marketing Authorisation Application – Human
- Marketing Authorisation Application – Veterinary
- Variations – Human and Veterinary
- Renewals – Human and Veterinary

These forms are available to download from the EMA's eSubmission website, which is accessible through [EudraLex Volume 2](#) and [EudraLex Volume 6](#)

The website address is: <http://esubmission.ema.europa.eu/eaf/index.html>

### ***Q.2. How will the eAF be used? (H+V)***

**A:** The use of the electronic Application Forms is mandatory for all procedures (human and vet) exempting homeopathic products.

### ***Q.3. Will applicants be informed of upcoming updates to the AF some time in advance of it coming into force? (H+V)***


**A:** Yes, please check eAF – website for the release schedule.

### ***Q.4. What if we have prepared a variation with the electronic AF and while finalising all the documentation for the submission there is an update to the AF (a new version). For how long will the previous version be accepted for submission? (H+V)***


**A:** A transitional period is foreseen – please check eAF – website for details.

### ***Q.5. How can I keep up to date with changes to eAF? (H+V)***

**A:** Our Really Simple Syndication (RSS) feed provides users with notifications of changes made to eAF via their RSS reader.

- [Click to subscribe to the eAF RSS feed](#) .
- Users may also subscribe to the RSS feed on the eAF home page:



- **Click**  on the page itself to subscribe.
- For more information about RSS feeds, see *The EMA's Guide to RSS*.

**Q.6. In the case of a very urgent submission (the same day that the problem is encountered) and the eAF cannot be opened, nothing is not working properly, I cannot sign the document, etc... How long is the response time for the eAF team to come back to me and solve the problem? (H+V)**

**A:** Please contact EMA via the [service portal](#) immediately highlighting the urgency of the query in the message.

**Q.7. In case of a missing term how can I use the form without creating validation errors? (H&V)**

**A:** As a general rule, in order to achieve an additional value in the controlled term lists, please use the eAF Term Request Form. Once completed, you will need to submit your form via email to [mdms@ema.europa.eu](mailto:mdms@ema.europa.eu)

A provisional term may be added to the list within 5 working days; however, please note that there is a possibility that the term might not be approved and ultimately added to the list for future use. For further guidance please refer to [Term Request Process](#)

## ACCESSING THE eAF

**Q.8. How can I access the Electronic Application Forms (eAF)? (H+V)**

**A:** The eAFs are available for download from the eAF home page, which is part of the EMA's eSubmissions website: <http://esubmission.ema.europa.eu/eaf/index.html>

The eSubmissions website is also accessible through [EudraLex Volumes 2](#) and [6](#).

**Q.9. Why does it take so long to open the eAFs? The word version forms from NtA open a lot faster? (H+V)**

**A:** For a detailed explanation, please see section "Opening the form" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.10. I'm not able to open the eAF in the eCTD review tool? (H)**

**A:** If opening the eAF for the first time in the eCTD review tool, click "Allow content" when prompted, then click "Trust this document Always".

**Note:** To avoid any Adobe related plug-in issues, it is recommended that you (re)install your chosen review tool after any Adobe software related updates.

**Q.11. Is there a recommended version of Adobe Acrobat/Adobe Reader I need to use? (H+V)**

**A:** The minimum specification to use eAF is Adobe Reader/Acrobat version 10 or above. (It is always recommended to use latest version). For further details, please see section "Requirements on Adobe Reader and IT security settings" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.12. Is there a recommended proxy settings I need to use? (H+V)**

**A:** Please ask your IT department to check your network settings.

**Q.13. I cannot access the eAF using Mozilla Firefox / Google Chrome browsers. How can users of these browsers open the eAF? (H+V)**

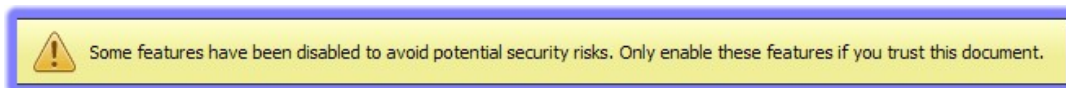
**A:** The built-in PDF viewer with Mozilla Firefox and Google Chrome do not support XFA - based PDF forms. Guidance to assist with resolving this issue can be found here:

<http://helpx.adobe.com/livecycle/kb/xfa-forms-firefox-chrome.html>

Please see section "Requirements on Adobe Reader and IT security settings" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.14. What should I do if I receive the message 'Some features have been disabled to avoid potential security risks. Only enable these features if you trust this document.' ? (H+V)**

**A:** The first time the form is opened, the following banner appears at the top of the window:



- Click the 'Options' button and select 'Trust this document always'.

**Note:** If your local IT policy forbids you from making changes to a security setting, it is recommended that you contact your local IT service desk and request that they allow access to the following url: <http://eaf.ema.europa.eu/eaf/services/EutctService?wsdl>

**IMPORTANT:** This web services location, managed by the EMA, enables many of the forms' fields, searches and drop-down lists to be populated dynamically. Without access, the form **CANNOT** be completed.

Please see section "Requirements on Adobe Reader and IT security settings" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.15. Does the eAF work in a Linux or Mac OS environment? (H+V)**

**A:** The operating system of the user should not matter, be it, Microsoft, Linux or Mac OS. However, it is important to note that Adobe reader and internet connection are required. Please see section “Requirements on Adobe Reader and IT security settings” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

## **GUIDANCE FOR COMPLETING THE eAF**

**Q.16. Where can I find guidance for completing the eAF? (H+V)**

**A:** This question and answer document is intended to cover anticipated questions relating specifically to the electronic forms. In addition, field level help is also available by moving the mouse pointer over each field of the electronic forms; these are called ‘tooltips’ (see Q.17).

Updated regulatory guidance on how to fill in the electronic Application Forms is published by the [CMDh](#) and [CMDv](#), continues to be the best way for users to ensure the content of the forms adheres to business requirements.

- If you encounter an issue with a specific field, please refer to the ‘Known Issues’ in the Release Notes for the specific form. These may be found on the [eAF pages](#) of the EMA’s eSubmission website. New issues may be raised via eAF service desk (<https://servicedesk.ema.europa.eu>).
- In case of any further technical queries, please contact us at: <https://servicedesk.ema.europa.eu>

**Q.17. What are tooltips and how to use them? (H+V)**

**A:** Tooltips are field level guidance available in the form - If you hover on the particular field/term you can see the field description/full term name description as a tooltip.

If you cannot see the tooltips when you ‘hover’ the mouse on the fields/over terms in the form please contact your IT support.

Please see section “Purpose of the document” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

If you cannot find the answer from tooltips please send email to <https://servicedesk.ema.europa.eu>.

**Q.18. What is the ‘Update lists’ button used for? (H+V)**

**A:** Please see section “Update of the XML data” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.19. Is there a requirement to deliver a signed paper copy of the application form? (H+V)**

**A:** No, a signed paper copy of the eAF is not required for human or veterinary submissions, as long as a scanned signature or an accepted equivalent in the required format is included in the electronic form and the submission is sent electronically using the eSubmission Gateway/Web Client/CESP.

- See '[How can I sign the eAF?](#)' question below for further guidance on including a scanned signature image file.

For veterinary submissions, a hard copy of the cover letter is not required if the submission is sent using the eSubmission Gateway/Web Client/CESP or Eudralink (for post-authorisation procedures only). A signed hard copy cover letter is required when the submission is sent via CD/DVD.

For further instructions on how to sign the eAF, please see section "Signature" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#)

**Q.20. What are the release notes and how should I use them? (H+V)**

**A:** The release notes list new functionality provided by the forms when new versions of the forms become available. It is strongly recommended to always review the release notes when new version of the forms becomes available.

You can find information relating to the use of the forms from the release notes, for example some workaround solutions are described in the release notes.

For further details, please also see section "Purpose of the document" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.21. How do I delete sections that are not relevant? (H+V)**

**A:** The eAFs are intelligent forms where a lot of business rules have been built in and some sections are only displayed depending on previous selections. It is not necessary or even possible to delete not required sections.

**Q.22. How do I include additional information/tables in fields that do not support tabular format? (H+V)**

**A:** The main workaround solution for providing information is attaching an annex to the application form. The annex should be attached as a separate PDF document, clearly named (for example 'ema-form-annex-presentandproposed') in the folder 1.2.

## SUBMITTING THE eAF

### Q.23. What is the file naming format for submitting the eAF? (H + V)

**A:** The file name will be **common-form-var.pdf**, the variable part should be used as outlined in the file & folder naming convention of the updated eCTD validation criteria version 6.1 resp. NeeS validation criteria version 4.1. In case you have to annex parts from the Classification Guideline for variations, this should become part of the 'var'-section, e.g. **common-form-annex-classgl.pdf**

Recommended usage of the variable part of the file name in this section:

**cc-form-eaf-var.pdf**  
**cc-form-annex-var.pdf**

Please see also section "File naming convention" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

### Q.24. How can I sign the eAF? (H+V)

**A:** As the application form must always be signed, which means in the case of the eAF an implementation of an image of a scanned signature. EMA additionally accepts an image of a text snippet about who has signed the form, e.g. stating 'This form was approved/authorised following company policies by [Mr. Nick Name; Head of Reg. Affairs] with authorisation to sign. The signature is in file.' Any image should be included as part of each of the eApplication Forms. Brief instructions how to insert an image are contained within the tooltip for all signature fields within the eAFs.

**Note:** In order to ensure that the signature scan image is displayed accurately, the signature image should be the following size:

Unit of Measurement	Width	Height
centimetres	12.70	2.54
Inches	5	1
pixels	1500	300

- For guidance on how best to create a high quality scanned signature image file, the following search 'string' (within Google, for example) returns good results: Create scanned signature image.

**Note:** Digital signatures (as opposed to scanned signatures) are not currently within the scope of this project.

For further information, please see section "Signature" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).



**Q.25. Scanned signature is not real electronic signature, why should I sign the form? (H+V)**

**A:** The signatures in the eAFs are not validated like real electronic/digital signatures, however, the eAF signature is not only a signature but also used to lock the form to prevent further modification of the data entered. If the receiving MS doesn't require wet signature/signature this field can be considered as symbolic confirmation that the form has been finalised and locked). It is important to lock the forms to prevent accidental changes to the form data by the recipient.

For further information, please see section "Signature" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.26. Are additional paper forms (with wet-ink signature) required in any Member State and what does this mean regarding the legal relevance? (H+V)**

**A:** The eAF does not change the wet signature requirements at the NCAs. Please contact the relevant NCA whether there is a need for a wet signed form in parallel.

The signature image will not work as a digital advanced or qualified electronic signature nor can replace requirements of wet signed forms. There is no need to use qualified signatures for eAFs submitted to the EMA for Centralised Procedure applications.

**Note:** Scanned eAF are invalid and will be rejected if included in section *m12* of the CTD structure in electronic format. The unsigned eAF can be printed, signed and submitted as per the NCA requirements in addition.

For further information, please see section "Signature" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.27. How many copies are to be submitted? Will two copies be delivered - the "PDF form" and a paper original/copy of signed version? (H+V)**

**A:** Only the PDF created using the electronic forms should be submitted. No other form created using Word may be submitted.

For further information, please see section "Integration of the forms into dossier" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.28. Should I include the extracted xml of the application form data in the submission? (H+V)**

**A:** Only the PDF created using the electronic forms should be submitted. The receiving authority will extract the xml from the PDF if required.

For further information, please see section "Integration of the forms into dossier" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.29. Can I submit a MRP/DCP/National application to the Member states using the eAF? (H+V)**

**A:** Yes, the eAF is accepted by all Member States. Please note that the use of the eAF has become mandatory for all types of European procedures (MRP/DCP/National) as of 1 January 2016.

For further information, please see section “Access to the forms and news on update” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.30. Can we submit a single (common) eAF for MRP/DCP? How will it be managed and who is the signatory? (H+V)**

**A:** For new **MAA** and **renewals** in MRP/DCP a single form should be submitted for each strength and pharmaceutical form (and not for each country). The signature can be included by the applicant or any authorised representative. The current policy will not change by using eAFs.

The **variation** form allows to include all forms and strengths. Again, the signatures should be provided by the MAH. If different national companies are involved it is recommended to add power of attorney as required by member states appropriately.

For further information, please see section “Access to the forms and news on update” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.31. Using a single (common) eAF for MRPs/DCPs: the Applicant/MA holder may differ per member state and the eAF may be signed by multiple responsible persons needed for communication with specific Authorities. How can this be done with a single eAF? (H+V)**

**A:** The variation form (v. 01.20) improves the possibilities to state all the included products and different MAH names in section 1.2. There is no need to repeat the section for applicant details as the NCA will keep the current rule that one applicant is sufficient.

The initial form and the renewal form (v. 01.20) improve the possibility to repeat the section for MA holder details and contact person details for each MS.

Additional signatory is possible for variation and renewal.

**Q.32. Is one single (common) form in English language accepted? (H+V)**

**A:** In MRP/DCP all member states should accept the application form in common language. There will no national translations provided by EMA or European Commission. In case of purely national applications different requirements exist, please consult respective NCA web-sites.

For further information, please see section “Access to the forms and news on update” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.33. Can I provide a scanned eAF?**

**A:** Printing and scanning the signed form should only be done for paper submissions as this way the eAF will become a flat PDF.

**Note:** Scanned eAF are invalid and will be rejected if included in section *m12* of the CTD structure in electronic format. The unsigned eAF can be printed, signed and submitted as per the NCA requirements in addition.

**Q.34. Do I always have to use eAF? (H+V)**

**A:** Yes, eAF has completely replaced the NTA application forms. Please check national submission requirements if parallel paper submission is required. The eAF can be printed and signed for paper submissions.

**Q.35. Can I submit via the eSubmissions Web Client or Gateway if I am using the eAF? (H+V)**

**A:** The EMA strongly recommends the use of the Web Client or Gateway for Human and veterinary product submissions. The use of the eAF is mandatory from 1 July 2015 for all Centralised Procedure submissions (Human and Vet). After this date the paper forms will no longer be accepted (see <http://esubmission.ema.europa.eu/esubmission.html>).

**Q.36. eAF is mandatory for all types of licenses from 01 January 2016. Will any national requirements to use a national portal be maintained? (H+V)**

**A:** National portals can optionally be used in addition to the eAF.

**Q.37. Where is the correct place within the eCTD dossier to store the XML data? (H)**

**A:** The eAF form (.pdf) itself contains the xml data. This PDF document should be included within the eCTD structure in folder 1.2.

The receiving NCAs can extract the xml data directly from the forms. In the unlikely case that a local NCA requires a separate raw xml file, this may be added in a new folder outside the eCTD structure (similar to the current 'workingdocuments'- folder).

**Note:** It is **not supported** to include the raw xml extraction within the eCTD 1.2 structure due to restrictions in the acceptable file formats for EU Module 1. Such a sequence will become technically invalid.


For further information, please see section "Integration of the forms into dossier" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.38. Is there a requirement for the eAF to be supplied in a published submission only (i.e. eCTD /NeeS)? Or can the eAF be submitted via CD as a standalone document too? (H+V)**

**A:** Please submit the eAF always within an eCTD / NeeS / VNeS submission. However, if your dossier format is still paper based, a separate electronic submission may be appropriate if agreed with the responsible NCA.

## DATA ENTRY

**Q.39. How can I see which fields are mandatory? (H+V)**

**A:** Click the  button, which is on the last page of each of the eAFs as soon as you open the document. All mandatory fields are then highlighted and are accessible through the validation errors window. You can validate the form as many times as required.

Please note that if you validate the form before you start entering data, the form performance will be slightly slower as each field is validated as you fill them in.

For further information, please see section “Validating the form” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.40. Why are there free text fields in the eAF? (H+V)**

**A:** Free text fields have been implemented in a number of sections of the forms where no controlled terminology is available. We are currently working on finding best solution to implement structured data fields throughout the form. In some sections free text fields provide additional options to describe e.g. roles of a manufacturer as long as no controlled terminologies are available.

For further information, please see section “Data fields and formats” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Note:** If you have any comments or proposals for a best practice solution based on your experiences please send these to <https://servicedesk.ema.europa.eu> for consideration.

**Q.41. Can I leave mandatory fields empty? (H+V)**

**A:** If you are providing a separate annex instead of entering the information directly in a particular mandatory field, enter a space, N/A (not applicable) or a full stop to bypass the current minimum validation requirements. If the field does not allow text/full stop ignore the validation error and note this in the application cover letter.

**Note:** Applicants are encouraged to contact EMA technical help (<https://servicedesk.ema.europa.eu>) if currently implemented business rules should be reviewed and/or changed.

**Note:** The validation rules are imposed to ensure that a good quality submission is facilitated for all concerned parties.

**Q.42. Will leaving mandatory fields empty cause business validation issues? (H+V)**

**A:** In certain cases it might not be possible to fill in all 'mandatory' fields in the eAFs. This means leaving some form validation errors. If the information required in such fields is provided via an annex for example or the fact that the information is not available is mentioned in the cover letter this doesn't normally cause any issues during content validation phase. However, if information required in the mandatory section is not filled in and no annex is provided the application cannot be processed and a content validation issue might be triggered.

The form validation is simply a feature that enables use of business rules and guides the MAA/MAH to fill in the form correctly to avoid content validation issues once the application has been submitted.

The validation errors are not visible in the form after it is locked and signed, however, the number of remaining errors will be shown in the validation screen of the locked form.

**Q.43. Can I include rich text (formatted) in any fields within the forms? (H+V)**

**A:** This option is available only in the present and proposed product information fields of the variations form. All other free text fields in the forms allow only plain text.

Some text formatting features are available when using the navigation to 'Hyperlink' in the forms. Additional tabs are then provided to format text as well. A further workaround solution for insertion of certain special characters/strike through can be used via editing the text in rtf format (e.g. in Word or Outlook) and copy/paste the text/terms in to the eAF. It is also possible to use the superscript/subscript using rtf format in the present and proposed.

**Note:** The workaround solution for entering formatted text using rtf format and copy pasting the edited text does not work in the Initial MAA form when sections 2.1.2, 2.2.1 and 2.6.1 when the details are populated from 'Declaration' section. If you require special characters in these sections, please add an annex and mention this on the cover letter.

For further information, please see section "Data fields and formats" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Note:** Please inform <https://servicedesk.ema.europa.eu> if there are certain character sets that you'd hope to be supported in any future implementation.

**Q.44. Can I use track changes in the variation eAF? (H+V)**

**A:** Yes, but only in the present and proposed product information fields

**Note:** It is not possible to copy track changes from word document into the eAFs.

**Q.45. How do I use the billing address fields in the eAF? (H+V)**

**A:** If the fees have not been paid in advance and an invoice is going to be sent out you should select 'No' and indicate the billing address (even if it has not yet been relevant to pay a fee as it will be invoiced later).

Proof of payment (when relevant)

Have all relevant fees been prepaid to competent authorities?

Yes (for fees paid, attach proof of payment in Annex)

No

For Member State(s)

Please specify the reasons according to National requirements (exemption or later payment).

Billing address (when relevant)

Company name

VAT number

Address 1

Address 2

(name of: city, town, village, etc)

Postcode

Country

Telephone

Telefax

E-mail

Purchase order(PO) number

**Q.46. How do I fill in the contact person address in the eAFs? (H+V)**

**A:** For further information, please see section 2.4. initial MAA "MARKETING AUTHORISATION HOLDER / CONTACT PERSONS / COMPANY" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.47. How do I add 'salt/hydrate' form in to section 2.1.2 and/or 2.6.1? (H+V)**

**A:** Search and select the active substance(s) in the 'Declaration' section of the form and populate the sections in the form where active substance is required by using 'Populate data in section 2.2.1 and 2.6.1' button. In version 1.20 a text field for an additional description is provided.

**DECLARATION AND SIGNATURE**


Active Substance(s):  
AMLODIPINE  
VALSARTAN

The chosen active substance(s) is automatically displayed in section 2.6.1 on the 'Name of active substance field(s)'.

## 2.6 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of active substance	
AMLODIPINE	▼
VALSARTAN	▼


If a salt/ester/maleate/monohydrate etc. form is required either in 2.1.2 section or in 2.6.1 section, this can be added via the following workaround solution:

Go to section 2.6.1 and add a row in the 'Name of Excipient' section (in 2.6.1) by clicking  'plus' button at the end of the field.

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	
▼	▼	▼	+
			-

Search for the salt/ester/maleate/monohydrate relevant to this application and select it from the list to display it in the 'Name of Excipient' section.

Name of Excipient
AMLODIPINE MALEATE ▼

Return to section 2.1.2 and select the relevant terms from the list. Select it and if you need to add another active substance add an additional row by pressing .


### 2.1.2 Name of the active substance(s)

*Note: Only one name should be given in the following order of priority: INN\*, Ph.Eur., National Pharmacopeia, common name, scientific name;  
\* The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant (for further details, consult the Guideline on the SPC)*

Active Substance	
▼	+
AMLODIPINE AMLODIPINE MALEATE VALSARTAN	Select
	-

Select the active substance from the list to display them in the form.

Active Substance		
AMLODIPINE MALEATE	▼	-
VALSARTAN	▼	-

Return to section 2.6.1 and go to 'Name of active substance' section and add the relevant active substances by clicking the arrow and by adding extra row(s) if needed. Select the relevant salt/ester/maleate/monohydrate from the list and fill in the relevant information in the other columns. Delete any unnecessary fields displaying incorrect terms if relevant using  button.

List the active substance(s) separately from the excipient(s)

Name of active substance


AMLODIPINE MALEATE

AMLODIPINE  
AMLODIPINE MALEATE  
VALSARTAN

Select

VALSARTAN

Name of active substance	Quantity / Unit	Reference / Monograph Standard	
AMLODIPINE MALEATE			+
AMLODIPINE MALEATE			-
VALSARTAN			-

Return to the 'Name of excipient' section and remove the row with the selected salt/ester/maleate/monohydrate form by clicking the  ('minus') button at the end of the row.

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	
LACTOSE MONOHYDRATE			-

Remove excipient field, if req

If you have selected multiple active substances in the 'Declaration' section, these will be automatically displayed in dropdown menu.

Please also see section 2.2.1 initial MAA "Strength and pharmaceutical form (use current list of standard terms – European Pharmacopeia)" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Note:** Do not press 'populate in section 2.2.1 and 2.6.1' button while and after doing this step as it could add incorrect active substance in the form.

**Q.48. How do I fill in the eAF if I need to express 'quantity sufficient' / 'q.s.' amount? (H+V)**

**A:** "quantity sufficient" means adding enough of an ingredient to achieve a specific final volume or total weight. This term has been discussed extensively in the past and it was agreed that 'quantity sufficient' was introduced as quantity operator in the eAFs and will now allow to describe the limits precisely.

To express for example: "to five grams of NaCl add enough (quantity sufficient qs) water to make 100 ml"

Ingredient = water

Quantity operator = "quantity sufficient";

Value =100

Unit = "mL"



Name of active substance	Quantity / Unit	
<input type="text"/>	<input type="text"/>	<input type="text"/>
	<div style="border: 1px solid black; padding: 2px;">       approximately equal to        equal to        equivalent to        less than        less than or equal to        more than        more than or equal to        quantity sufficient        range     </div>	

**Q.49. How do I indicate the batch release in section 2.5 of initial MAA eAF? (H+V)**

**A:** Any manufacturer responsible for batch release in the EEA should be listed under section 2.5.1 of the application form. Since this is the only section where this information should be provided, the need for a drop-down menu has not been identified. If the site responsible for batch release in the EEA is also involved in batch control testing activities, the name and address of such site should be repeated in section 2.5.1.2.

Please see section “2.5.1 - Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA ” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.50. Part 2.5.1.2 Batch control/testing: Is it necessary to choose all possibilities as is stated in Manufacture License for company (if possible to find them there) or only for product, which we would like register? (H+V)**

**A:** Only the tests carried out for the products that the application is concerned should be listed here.

**Q.51. Regarding section 2.5.2 and 2.5.3: does the term “quality control” also includes release testing, and if so, when it comes to the release testing of the medicinal product, are then sites listed twice, once in 2.5.1.2 and 2.5.2?**

**A:** Yes, release testing of the finished product is part of Quality testing. This activity is only linked to sites performing Batch Control testing arrangements in relation to the Batch Release of the product as per requirements of Article 51 of Directive 2001/83/EC. As such a site may perform both release testing under 2.5.1.2 and “normal” QC-FP activities under 2.5.2 which are not linked to the batch release. In this case the site(s) will be listed twice i.e. under each section. However, if the site only performs one or the other quality control testing only, the site(s) will then need to be listed in the relevant section depending on the QC-FP activity. testing arrangements in relation to the Batch Release of the product. Sometimes, sites perform both kinds of testing activities however only sites located in the EEA or where an MRA or ACAA arrangement is in place can be listed in 2.5.1.2. Third country sites (USA and any other country outside the EEA/MRA/ACAA) cannot perform this activity and should therefore not be listed under 2.5.1.2. These sites are only authorised to perform QC-FP activities not related to the Batch Release.

**Q.52. How do I add excipients not listed and their justification in the 1.4 MRL section of the VET initial MAA? (V)**

**A:** The form requires that excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification is given. The appropriate justification should be provided under the “remarks” section. A short justification can be added e.g. “out of scope”, “not pharmacologically active” etc.

Application for a Maximum Residue Limit has been made to the EMA  Yes  Not applicable

Pharmacological active substance(s)	+	-
	+	-
Date of Submission		
Species		+ -
Remarks		

**Q.53. Section 2.5.1a Batch release: There is empty field: what is necessary to write here? Why is there information about packaging in help window? If I have different/multiple manufacturers responsible for batch release I can use + and add it (H)**

**A:** The free text field is included so that those applicants who have products with multiple packaging can include details of which packaging the manufacturer is responsible for i.e. to show the relationship between the packaging and the manufacturer. This is an optional field that can be left empty it is not needed.

**2.5 MANUFACTURERS**  
Note: ALL manufacturing and control sites mentioned throughout the whole dossier MUST be consistent regarding their names, detailed addresses and activities.

2.5.1 a Authorised manufacturer(s) (or importer(s)) responsible for batch release in the EEA in accordance with Article 40 and Article 51 of Directive 2001/83/EC ( as shown in the package leaflet and where applicable in the labelling or Annex II of the Commission Decision):

Do you have a separate address for each packaging manufacturer responsible for in the free text field. So that the relationship between packaging and packaging manufacturer(s) can be shown in case there are different/multiple manufacturers.(Max. 250 characters).	Yes <input type="radio"/> No <input type="radio"/>
Company name	
Address 1	
Address 2	
Postcode	
Country	
Telephone	
Telefax	
E-mail	

**Q.54. Section 2.6.1. of the initial MA eAF - For a multi-strain dossier, is there a requirement to list all possible combination of intended formulations on the e-AF or only include a list of all vaccine serotypes and/or vaccine strains and follow with the excipients/adjuvant? (V)**

**A:** For a multi-strain dossier each vaccine serotype and/or vaccine strain should be listed but not each possible combination of marketed products. Adjuvants and excipients for a standard batch should also be listed in section 2.6.1 below the active ingredients for a standard batch.

**Q.55. In section, 2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s) there is no space to include a note to the Qualitative and Quantitative composition after the excipients list. (H&V)**

**A:** At the moment you have an option to add a note above of each list.

In section, 2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s) there is no space to include a note to the Quali		
Name of Excipient	Quantity / Unit	Reference / Monograph Standard

**Q.56. Documents appended to this application: There are some boxes we don't need to mark as they are not applicable for us. However, if we don't mark all of them a validation error appears. What should we do? (H+V)**

**A:** Occasionally the built in business validation rules have been interpreted incorrectly when the forms were built. You should report any unusual form validation errors to <https://servicedesk.ema.europa.eu>. Please note that the form validation errors are there to guide you to fill in the application correctly and sometimes it is perfectly acceptable to leave some validation errors especially when information is provided on a separate annex to the application form.

## SPECIFIC QUESTIONS ON THE VARIATION FORM

**Q.57. In an MRP variation, is the attachment to eAF, "list of concerned products" the best way to show multiple invented names in section "2. Products concerned with this application"? If we add several "2. Products concerned..." sections, the information regarding MA holder and MA number appear multiple times?**

**A:** The section 2 of the variation form has been completely changed in version 1.20. The new layout will support all options to enter multiple products with same or different product names, MAHs and MA numbers for MRP/DCP applications. Therefore, the annexes A or B are no longer necessary to be used.

2. PRODUCTS CONCERNED BY THIS APPLICATION? ?

Form and Strength information is provided in footnote

Variation Number DE/H/0212/001/1A/098 + -  
Clone

Active Substance  
IBUPROFEN (LYSINE) + -

Member State Germany + -  
Clone

MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
1234.00.00	Advil	Company	Tablet	200	mg	+ - Clone
1234.00.01	Advil forte	Company	Tablet	400	mg	+ - Clone

Member State Austria + -  
Clone

MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
PVK 1234	Advil	Company	Tablet	200	mg	+ - Clone
PVK 1235	Advil forte	Company	Tablet	400	mg	+ - Clone

Member State Netherlands + -  
Clone

MA Number(s)	Invented Name	MA Holder Name	Pharmaceutical Form	Strength	Unit	
RVG 120034	Advil	Company	Tablet	200	mg	+ - Clone
RVG 120035	Advil forte	Company	Tablet	400	mg	+ - Clone

Footnote  
This describes all employed strenghts

Please see section “Variation Form 2. – Products concerned by this application” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.58. In the variations eAF it is possible to select the types of change(s)/variation categories. Nevertheless the relevant page(s) from the Guideline for this/these change(s) still need to be attached and the relevant boxes for conditions and documentation (both for Type IA and Type IB) need to be ticked. Are there any plans to integrate this into the eAF? Any timelines available? (H+V)**

**A:** There is an existing change request to improve the variations form. The proposed change is however a major change to the variation form and it is likely that this will not be implemented before the introduction of the Single Submission Portal

**Q.59. For variation eAF how should the relevant Variations Guideline extract be added? (H+V)**

**A:** The Variations Guideline table should be added as a separate document annexed to the application form. It should be provided in the same folder as the application form, clearly named as [Variation Guideline](#). It is important not to attach the annexes in to the eAF itself, this will prevent proper locking of the forms. For file naming recommendations see Q.23  
Please see section “Types of change” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.60. Section 3: “Scope and background” and “Present and proposed”:  
Will it become possible to insert a table? It would create a better overview and ease the readability. (H+V)**

PROPOSED <sup>9,10</sup>	
Notizen	
text	result
text	result 2
text	result 3
text	result 4
text	result 1
text	result 2
text	result 3
text	result 4

**A:** Currently you can use text lines and insert blanks to structure the layout similarly. More complex descriptions can be provided in a separate annex to the eAF. This annex should be clearly named and should be provided in the same folder as the application form within the submission package. For file naming recommendations see Q.23  
Please see section “Types of change” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.61. How can we copy-paste an image? How can we add multiple pictures in the same image field and how can we adapt the picture to the size of the field? (H+V)**

**A:** You can select an image from the file system per each cell. Just one image per cell should be included. The cells are repeatable. The image cannot be enlarged. If the size needs to be adjusted please provide the image as an annex.  
Please see section “Types of change” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.62. How can we alternate text fields and image fields in the present-proposed-table (e.g. text-image-text-image-text)? (H+V)**

**A:** It is not possible within one section of the present/proposed table. You will need to repeat the section entirely.  
Please see section “Types of change” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

**Q.63. Section 1: Why does “variation procedure number” becomes visible when choosing national procedure? This is not applicable for national procedures? (H+V)**

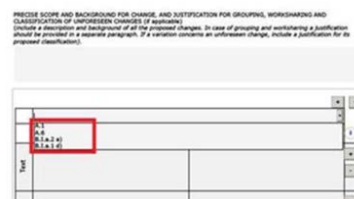
**A:** Purely national variation procedures will not use the MRP procedure number. However, a procedure number may exist for national procedures and it may be used as a tracking number. The data field will offer a place for it. An information note may be added to the form.

**Q.64. Section 2: For national procedures the set-up for MA holder name and MA number is not including Member state. The only section for national procedures where member state is present is in the section 1 “Name and address of contact person”. Why is it not aligned with the same set-up as for National Authorisation in MRP/DCP? (H+V)**

**A:** There is no need to include the member state name in the national procedure applications as the application is only provided to a single member state.

**Q.65. How can we select multiple variations for one section of the present-proposed table (e.g. several changes might be located in the same section of a document)? (H+V)**

**A:** There is only one reference option provided. but incase several scope will focus on the same present/proposed combination you should highlight this in the precise scope text field.



**Q.66. How can we reflect “Editorial Changes” in the present-proposed table and which drop-down option we choose for this type of changes? (H+V)**

**A:** Editorial changes should be described in the present-proposed table, but are not necessarily directly related to the variation editorial changes.

**Q.67. In situations that require an extensive explanation in a specific comment field, how can we proceed if we do not have enough space for our clarifications (e.g. some comment fields only accepts 50 characters)? (H+V)**

**A:** More complex descriptions and copies of the relevant conditions need be provided in an annex. For file naming recommendations see Q.23

## SPECIFIC QUESTIONS ON THE RENEWAL FORM

**Q.68. Section 2: Active substance manufacturers: it is not possible to add a function of the manufacturer – how do you discriminate between e.g. manufacturers of intermediates for API and the actual API manufacturer? (H+V)**

- A:** You can describe the role of the manufacturer in the first line. The section can be repeated as often as needed.

### 2. APPROVED MANUFACTURERS

Authorised manufacturer(s) (or importer) responsible for **batch release** in the EEA (in accordance with Articles 40 and 51 of Directive 2001/83/EC, as amended, or Articles 44 and 55 of Directive 2001/82/EC (as shown in the package leaflet and where applicable in the labelling or Annex II of the Decision)

Company Role:

Do you have a separate admin and manufacturer address?  Yes  No

Company name

Address 1

Address 2   
*(name of: city, town, village, etc)*

Postcode

Country

Telephone

Telefax

Manufacturer Facility E-mail

Please see section “Approved manufacturers” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

## SPECIFIC QUESTIONS ON THE MARKETING AUTHORISATION APPLICATION FORM

**Q.69. Person authorised for communication\*, on behalf of the Applicant and Section 2.4.2 of the application form. We as generic company intend to submit MAA from India on EU based MAH in Europe. Till date, all the regulatory activities are managed by India office only wherein EU based MAH will provide the LOA to the responsible person for communication during the procedure. So we would to have a provision for the person who communicates on behalf of applicant from India. In the eAF for the section "Person authorised for communication\*, on behalf of the Applicant" the country India is not listed in the drop down list? (H)**


**A:** As a workaround solution you can enter the country name in the 'Address 2' field after the city/town element and leave the 'country' field empty. Please ignore the form validation error and mention this in the cover letter. Please get confirmation from the receiving MS whether a contact point outside the EEA is supported.

**Q.70. For the section 2.4.4 Summary of the pharmacovigilance system, in a community procedure with more than 1 MAH the section "Qualified Person in EEA for Pharmacovigilance " can be multiplied for more than one QPPV, but the location of the Pharmacovigilance system master file is only one section and cannot be multiplied as to indicate all locations per each pharmacovigilance system. Which location should be described here? (H)**

**A:** In this case section 2.4.4 needs to be repeated as different PV master files will be maintained. For each system the QPPV may be identical.

**Q.71. How should I add attachments/annexes to the forms? (H+V)**

**A:** Attachments to the form should be included as per the currently approved processes. Annexes to the application form should always be included in section 1.2 of EU Module 1 or for Veterinary applications the same folder where the application form is provided.

**IMPORTANT:** You must **NOT** use the attachment function within the forms to attach supporting documents. Whilst this feature is visible in the bottom left of the Reader/Acrobat window under a paper clip () , it should not be used. To avoid confusion, this functionality maybe removed as a future enhancement to the electronic forms.

**Note:** If, for any reason, you are sending an XML file, it is suggested you create a zipped archive (also known as a zip file) containing all supporting documentation.

For further information, please see section "Integration of the forms into dossier" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

## MISSING SUBSTANCES, EXCIPIENTS AND OTHER TERMS

**Q.72. What is the process to request a missing substance (active substance or excipient) or additional terms for drop-down lists? (H+V)**

**A:** If you need to request a missing substance or other term in order to complete an eAF, please use the [eAF Term Request Form](#). Once completed, you will need to submit your form via email to [mdms@ema.europa.eu](mailto:mdms@ema.europa.eu)

A provisional term may be added to the list within 5 working days; however, please note that there is a possibility that the term might not be approved in future. More information how to request additional terms in eAF can be found [here](#).

Please see section "2.6.1 Qualitative and Quantitative composition in terms of the active substance(s) and the excipient(s)" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.73. I need to use a standard term already sent and approved by EDQM. The EDQM database has been updated but the current electronic application form has not been updated to include this term. What shall I do? (H+V)**

**A:** Temporarily the EDQM lists (Dosage Forms, Routes of administration and Containers) are not automatically synchronised between EDQM and EUTCT. If you find any such cases, please send your query to [mdms@ema.europa.eu](mailto:mdms@ema.europa.eu). They will check the EDQM Register and update EUTCT accordingly. The term should be visible a few days after in the eAF.

If the pharmaceutical form is not listed in the term list, please follow the defined missing term request process and send the request to [mdms@ema.europa.eu](mailto:mdms@ema.europa.eu). Further details are available on the eAF website

**Q.74. Is there some kind of overview which explains all abbreviations used in the drop down list. For example, Renewal form – version 1.20, at section 1, when you need to complete the composition of the active substances for a tablet, you cannot choose xx mg/tablet. There is the possibility of U/g, but I'm not sure what the "U" stands for, is it unit? (H&V)**

**A:** Values are re-used from EUTCT. Details can be retrieved from term details. In general, the abbreviations should follow common standards, i.e. The International System of Units.

In the specific case, the strength of the product should be expressed by a value and a unit of measurement, e.g. Tablet – 200 – mg. It depends from the pharmaceutical form which unit of measurement is the appropriate one.



**Q.75. Active substance and excipients: When we click to the drop down window, there are no substances to choose. Not even with writing the substance name and clicking the bottom "search". What is the reason for and how can it be solved?**

**A:** Occasionally there are issues with the connection to the EUTCT web services. If this happens, please save the form and reopen to check if the connection has returned. If the issue persists, consult your IT support to check if your internet connection is working and there are no firewall settings preventing access to EMA webservices.

**Q.76. In case the name of the product is not compliant with the current standard terms for pharmaceutical form (ie. "Solution for dental use" instead of "dental solution"), should a eAF Term Request Form be filled to add this pharmaceutical form to the drop-down list or should the EDQM standard term be selected in the drop-down list?**

**A:** If a term is still missing in the Standard Term list, you should follow the eAF Term Request process. The agency will contact EDQM for a new term as appropriate and should inform you on the outcome of the process. However, if the proposed term is not accepted you will be referred to an alternative term, which then should be used and is to be accepted by agencies. The issue may be explained in the cover letter as appropriate.

## TECHNICAL QUESTIONS/TROUBLESHOOTING

**Q.77. What is the 'Export XML' function for? (H+V)**

**A:** Please see section "Export of the XML data" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.78. How will the XML contained within the form be used? (H+V)**

**A:** The EMA and NCAs only requires the PDF version of the eAF to be submitted. However, when you save the PDF, the XML is also saved as a part of the file. It is possible to extract and view the XML and to store the file for use later.

**Q.79. Can I export the XML contained within the form? (H+V)**

**A:** Please see section “Export of the XML data” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.80. Can I import previously completed XML data into the form? (H+V)**

**A:** Please see section “Import of the XML data” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.81. Will there be a technical possibility to update the AF to the new version without losing the variation/product/company specific data added?**

**A:** It is possible to export and import the user inserted data to the new version of the form, however, updates of the underlying data exchange standard (XML-data) can mean that some fields are not correctly imported.

Normally usability changes will have no impact on the data imports, however, e.g. v. 01.20 will change the DES.

**Q.82. How can I automate the extraction of XML in to our system? (H+V)**

**A:** Whilst the EMA and NCAs are aware of tools on the market that enable users to automatically extract xml data from the forms, these tools have not undergone formal testing.

As such, EMA are unable to provide support or recommendations for these tools, currently.

**Note:** A search query of “Export form data using the Java API” may be a good starting point for any investigations you may wish to undertake for your organisation.

**Q.83. I have a problem with XML data import? (H+V)**

**A:** Please see section “Import of the XML data” in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.84. Why do the drop-down lists for certain fields not function? (H+V)**

**A:** Drop-down lists and search fields within the forms are populated dynamically from eAF’s web services (managed by the EMA).

Additional, dynamic information is 'called' by the form as soon as it's opened *and trusted*. This then populates certain drop-down option lists and searches with data from EMA's web services.

- If your local IT policy forbids you from making changes to a security setting, it is recommended that you contact your local IT service desk and request that they allow access to the following URL: <http://eaf.ema.europa.eu/eaf/services/EutctService?wsdl>

**IMPORTANT:** This web services location, managed by the EMA, enables many of the forms' fields, searches and drop-down lists to be populated dynamically. Without access, the form CANNOT be completed.

- To check in Acrobat 10 and above, select Edit>Preferences then choose the Security (Enhanced) category. If you are able to, add the full path of the file in the 'Privileged Locations' table. If you are not, contact your IT service desk and request that access for the form(s) to the EMA's web services (using the above URL) is allowed.

***Q.85. How do we get around the issue of enhanced security restricting the eAF from connecting to EUTCT? (H+V)***

**A:** Please see section "Requirements on Adobe reader and IT security settings" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

***Q.86. What do I do if the information I am trying to include cannot be added due to the limitations of the eAF's design and formatting? (H+V)***

**A:** If you feel that information cannot be included in the form, please review any workaround solutions provided in the release notes or use an annex. If you still feel you cannot include all relevant information, please contact us at <https://servicedesk.ema.europa.eu>.

***Q.87. Can I use bookmarks in the eAFs? (H+V)***

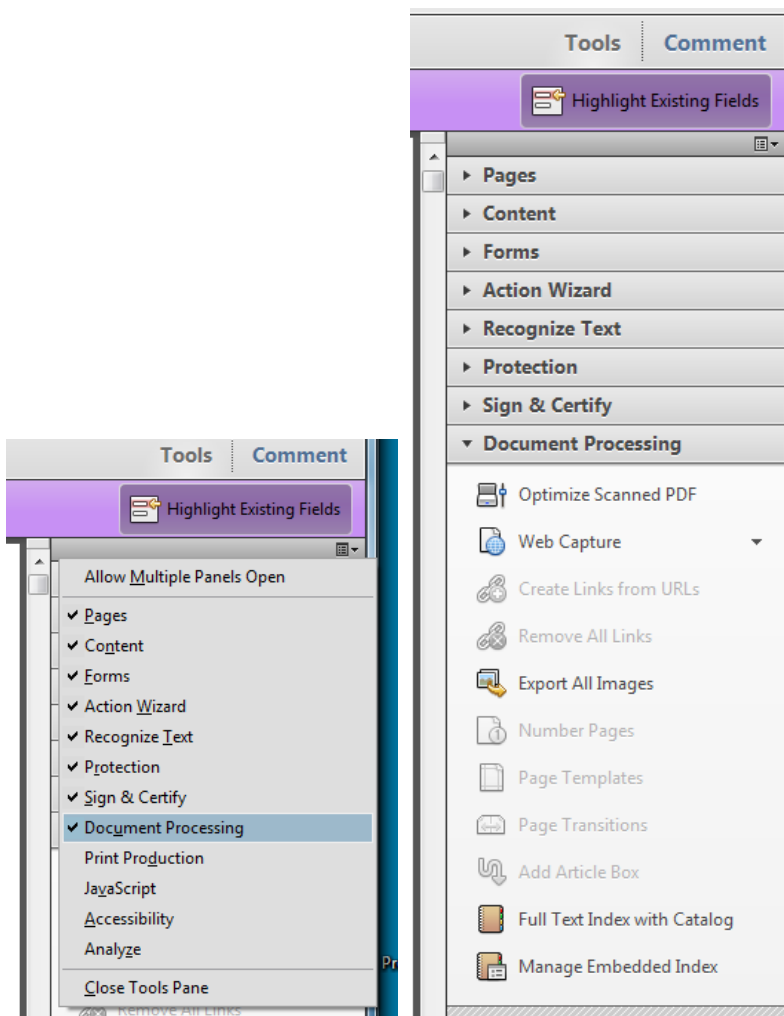
**A:** No, bookmarks may hinder to correctly lock the form.

***Q.88. How do I navigate to different sections of the form quickly? (H+V)***

**A:** Please see section "Navigation in the forms" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

***Q.89. What needs to be considered in case of rendering the eAF PDF file for eCTD purpose (H)***

**A:** Please be aware of the settings for optimising the PDF file in accordance with the eCTD specifications. Make sure, that the line 'Document Processing' is ticked on (as highlighted below) to allow full text index with catalogs and managing embedded indexes



**Q.90. Fast web view / Our eCTD generating software automatically saves all pdfs within the eCTD with fast web view enabled, however in the case of signed eAFs this renders them unviewable, there is no way to switch this off. (H)**

**A:** The eCTD / NeeS validation criteria have been updated. The eAF will no longer be tested for fast web view. However, a rendering should be able to switch off 'fast web view' rendering for eAF PDF files. Additional workarounds are no longer needed to overcome fast web view warnings.

## GENERAL QUESTIONS

**Q.91. Can I save the form and come back to it later if I haven't finished completing it? (H+V)**

**A:** To save the form, press **Ctrl + S** - progress is saved to the downloaded location. Note that if you have not saved it to a specific location, this action opens the 'Save As' dialogue to prompt saving in a particular folder other than the default location. Make a note of where the

document is saved to easily pick up where you left off. When you have completed the eAF please save it in your desired location.

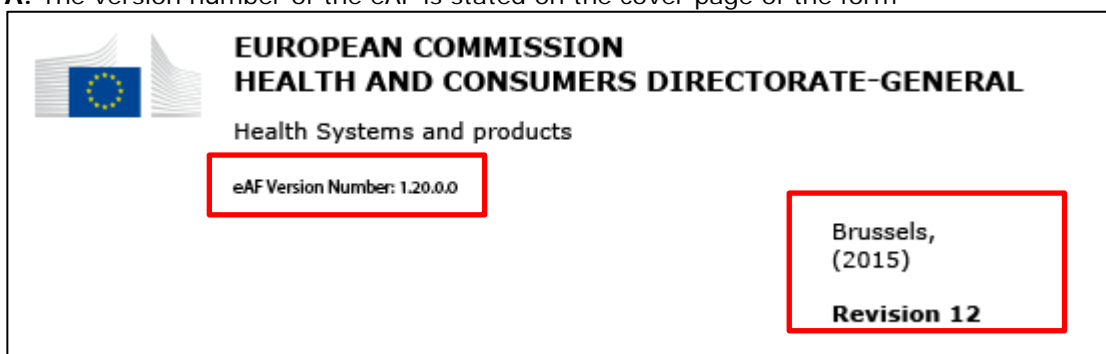
**Note:** When a signature file is attached to the eAF it will be **locked** and **no further changes are possible** (with the exception of the additional signatory section, where only this section is locked).

**IMPORTANT:** It is strongly recommended that you save the unsigned version of the form before locking it and that you save the signed version of the eAF with a new filename so that the original (un-signed) version may be used again if needed.

Please see section "Saving the form" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.92. How can I find out which version of the electronic form I am using? (H+V)**

**A:** The version number of the eAF is stated on the cover page of the form



**Q.93. What input did actual users of the form have in to the design of the final form? (H+V)**

**A:** The eAF was designed in conjunction with stakeholders from within the EMA, National Competent Authorities and industry. Throughout the life of the eAFs different User Acceptance Testing sessions have taken place to ensure that the eAFs reflect the needs of stakeholders while maintaining consistency with the current paper forms where possible.

Regular consultation with stakeholders is taking place to improve the eAF's usability. If you have any comments or proposals for improvements, please send these to <https://servicedesk.ema.europa.eu> for consideration.

**Q.94. Why is information in fields still visible when the corresponding fields are un-ticked? (H+V)**

**A:** A technical decision was made to ensure sections completed then hidden would persist to reduce the risk of accidental data loss. Once entered in the form, data may only be deleted on a field by field basis by users.

**Q.95. How do I jump to 'month/year' in the pop up calendar? (H+V)**

A: Please see section "Data fields and formats" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.96. How do I add a complex table as part of the present and proposed section in the variation eAF? The form doesn't allow me to include all of the necessary information? (H+V)**

A: Please see "3. Types of change(s)" in the variation form section of the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.97. How to use Manufacturing roles dropdown menu in the eAF? (H+V)**

A: Previously it was possible to provide very detailed level of information on the manufacturing roles in the eAF in the free text field. On the request from the inspections team this field is now a controlled terminology field with manufacturing roles provided through EUTCT list. The list might appear short and high level however; this is the sufficient level of information required by GMP inspections team and the terminology is based on the agreed terms used in the EU format for MIAs and GMP certificates included in the Compilation of Community Procedures on Inspections and Exchange of Information.

If you require any other new term please send us new term request form from this [link](#).

More information on details of the manufacturing functions required can be found from the ['Compilation of Union Procedures on Inspections and Exchange of Information'](#) (see pages 144-173).

Please see "2.5 Manufacturers" in the initial MAA section of the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.98. I cannot find role 'Manufacture of the finished product'? (H+V)**

A: Manufacture of the finished product is covered by 'Processing of medicinal product'

Please see "2.5.3 Manufacturers of active substance and sites of manufacture" in the initial MAA section of the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.99. Brief description of control tests carried out by the laboratory(ies) concerned" does not contain manufacturing of the VMP (only "processing" of the VMP)" (V)**

A: Manufacturing of the Veterinary Medicinal Product (VMP) is covered by the term 'Processing of medicinal product'.

Please see "2.5.3 Manufacturers of active substance and sites of manufacture" in the initial MAA section of the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.100. How to provide address details in the eAF? Can I leave 'Address 2' field empty? (H+V)**

**A:** Address details should be provided in the eAF in a harmonised way – the same address should be similarly filled when it's required in different sections of the forms. The latest version of the forms will allow some autopopulation of the address details from previous sections to improve usability.

It is very important to fill in both, Address 1 and Address 2 fields. The Address 2 field was previously called 'city'. Following a large number of queries, saying that the address was not in a city but in a town, borough, area etc. it was decided to replace City by Address 2. Address 2 field should be used to provide the 'postal location i.e. the city element of the address. This can be for example; village/town/city, etc. Street and number should always enter in Address 1 and city/town/village should be entered in Address 2 field.

"Address 1" field is to enter building name/number or street  
"Address 2" field is to enter city/town.

The information how the address details should be filled in are provided in the tooltips when you hover on the corresponding field.

Please see section "Providing address details" and "Declaration section" in the initial MAA section of the [Practical User Guide for eAF for human and veterinary medicinal products in the EU](#).

**Q.101. Is there a change impacting AF during the procedure, it would be a double work (first filling out paper version and then complete eAF from the scratch?)**

**A:** There is no need to change the format or the version of the application in the middle of the procedure. The same applies to previously submitted AF in different format at an earlier stage

**Q.102. We have understood that it is not required to change from a paper application form to the eAF, but our question is this: is it permissible to change to an eAF mid-procedure should one wish to do so?**

**A:** It is not recommended to change the format of the form in the middle of the procedure. In case of compelling reasons please contact the RMS, relevant NCA or the EMA for confirmation of acceptability of the format change in the middle the procedure.

**Q.103. Would the EMA agree that a master form can be prepared containing general entries that will not change, which can be 'Saved As' each time. This would remove the need for the author to update each of the drop downs etc. each time they need to complete the form? Only the details relating to the current submission would be required i.e. application number, description etc?**

**A:** It is recommended that a template is created by the MAHs/applicants that can be used over and again without a need to refill all the information. It is however very important to observe if new versions of the forms become available. In those cases the templates will need to be updated.

**Q.104. How to integrate the new VET regulation where vet variations will be disconnected from the human system? (V)**

**A:** It is foreseen that the proposal for the new veterinary Regulation, will be discussed extensively in the Council and the Parliament over the next 2 -3 years. This new regulation is proposed to come into effect two years after adoption, so the timescale of the finalisation is some 4-5 years from now. As we are still far from the final version of the text, we cannot take into account any of the new Regulation proposals into the current version of the electronic application forms. Once the Regulation will be adopted, relevant review and update will be carried out during the transition period until the Regulation comes into effect.

**Q.105. What should I do if my question isn't answered here? (H+V)**

**A:** If your question regarding the electronic implementation of these forms is not answered here, or in the tooltips, please send your question to <https://servicedesk.ema.europa.eu> for a response. Frequently asked questions will be added, as deemed appropriate.

## OPEN ISSUES

**Q.106. The section "Active Substance" is difficult to fill in especially for immunological products.**

**The AS descriptions available in the database most often do not match very well with the description in the product information. Clear instructions on the level of detail that is required should be given. Is a workaround available to indicate the immunological active substances in more detail?**

**A:** The same workaround principle applies as for other sections, please attach an annex to the application form. Please highlight a respective use of annex in your cover letter. Refer to term request process

**Q.107. Why is there no possibility any more to add a contact person for the Scientific Service for the CP? The Practical User Guide states the following: "In centralised procedure a single contact person should be indicated for the scientific service".**

**A:** For ease of contacting the applicant only single contact person for each procedure should be provided. Contact details can contain an email address to a shared mailbox if multiple persons are dealing with the application on the applicant side.

**Q.108. Could you probably address how notifications, e.g. art 61(3) will be handled in the future?**

**The eAF does not introduce change to how art. 61(3) notifications are handled.**

**A:** The existing paper form as published on the CMDh website has not been replaced and should be used as previously. There are no plans to replace this MS word template in near future.



***Q.109. We use a specific AF for Homeopathic medicinal products' Marketing Authorisation Applications. Will a specific eAF be published and when?***

**A:** This specific form is currently not adapted to an eAF. Existing differences and additional needs can be accommodated in the eAF MAA (hum and vet), but most likely at a later point in time.