



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).



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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.

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 electronic Application Forms will be used instead of the existing MS Word version. It is mandatory to use the eAFs for Centralised Procedure submissions (human and vet) from 1 July 2015.

Q.3. 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*.

ACCESSING THE eAF

Q.4. 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.5. Why does it take so long to open the eAFs? The word version forms from NtA open a lot faster? (H+V)

A: [mailto:](#) Please see section "Opening the form" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.6. 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.7. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.8. Is there a recommended proxy settings I need to use? (H+V)

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

Q.9. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.10. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.11. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

GUIDANCE FOR COMPLETING THE eAF

Q.12. 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'.

Updated guidance on how to fill in the electronic Application Forms is published by the CMDh on 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 (eaf@ema.europa.eu).
- In case of any further technical queries, please contact us at: eaf@ema.europa.eu

Q.13. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

If you cannot find the answer from tooltips please send email to eaf@ema.europa.eu.

Q.14. What is the 'Update lists' button used for? (H+V)

A: Please see section "Update of the XML data" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.15. 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 in the required format is included in the electronic form and the submission is sent electronically using the eSubmission Gateway/Web Client.

- 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 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 Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.

Q.16. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.17. 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.18. How do I use the eAF for MRP/DCP submissions? Should I provide individual forms for each country or can one single form be used for all member states? (H+V)

A: This aspect is being discussed at the level of CMDh and CMDv, and updated guidance will be provided prior to the mandatory usage (January 2016).

Q.19. How do I include Annex A/Annex B in the variation form? (H+V)

A: Please see section “Variation form – 2. Products concerned by this application” in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.20. 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 or folder “1a-admin-info” for VNeS submissions.

FILENAMING CONVENTIONS

Q.21. What is the file naming format for submitting the eAF? (H + V)

A: Please see section “File naming convention” in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

SUBMITTING THE eAF

Q.22. 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/authorized following company policies by [Mr. Nick Name; Head of Reg. Affairs] with authorization to sign. The signature is in file.”, Any image should be included as part of each of the eAF 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.23. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.24. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.25. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.26. 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 will become mandatory for all types of European procedures (MRP/DCP/National) from 1 January 2016.

For further information, please see section “Access to the forms and news on update” in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.27. 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.28. 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 working documents folder).

Note: It is **not currently recommended** to include the raw xml extraction within the eCTD 1.2 structure.

For further information, please see section “Integration of the forms into dossier” in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

DATA ENTRY

Q.29. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.30. 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.

For further information, please see section “Data fields and formats” in the Harmonised Technical Guidance for Using of 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 requirements, please send these to eaf@ema.europa.eu for consideration.

Q.31. 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 (eaf@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.32. 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 a content validation issue might be triggered and the application cannot be processed.

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

A: Yes, but only in the present and proposed product information fields. All other free text fields in the forms allow only plain text.

Due to a technical limitation in the Adobe forms a workaround solution might be required for insertion of certain special characters/strike through. If you experience issues, edit the text in rtf format (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 from word or outlook 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.

Note: Please inform eaf@ema.europa.eu if there are certain character sets that you'd hope to be supported in any future implementation.

Q.34. 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.35. 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 Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.

Q.36. 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.

DECLARATION AND SIGNATURE

Active Substance(s):
 AMLODIPINE
 VALSARTAN

Add Active Substance(s)

Populate data in section 2.2.1 and 2.6.1

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 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)

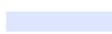
Name of active substance

AMLODIPINE MALEATE 

AMLODIPINE
AMLODIPINE MALEATE
VALSARTAN

Select

VALSARTAN 

Name of active substance	Quantity / Unit	Reference / Monograph Standard	
AMLODIPINE MALEATE 	  		
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 Harmonised Technical Guidance for Using of 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.37. How do I fill in the eAF if I need to express 'quantity sufficient' 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 this is not a unit/measure as it does not describe a precise measurement nor a quantity operator as it expresses the concept of "up to". It exists in the unit and measurements list only as a legacy term.

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

Ingredient = water
Quantity operator = "less than or equal to" = "up to";
Value = 100
Unit = "mL"

This logic should apply to any ingredient but in the case of excipients it hasn't yet been fully addressed in eAF. This will be done in the next version of eAF and in the meantime, as a workaround solution the eAF team kindly asks the applicants to provide a separate Annex called 2.6.1. Excipients in the same folder as the application form inside the eCTD / VNeES package.

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

Name of active substance	Quantity / Unit	Reference / Monograph Standard	+
	approximately equal to 0.6 ml		-

Name of Excipient	Quantity / Unit	Reference / Monograph Standard	+
	less than or equal to 0.6 ml		-

Note: * Only one name of each substance should be given in the following order: Ph. Eur., National Pharmacopoeia, common name, scientific name
** The active substance should be declared by its recommended name (for further details, consult the Guideline on the SPC)

* Ph. Eur., National Pharmacopoeia, common name, scientific name
or hydrate form if relevant

Q.38. How can I use the eAF more efficiently? Can I copy information from one field to another? (H+V)

A: We are introducing some 'copy from xx' buttons to allow copying information from previous sections to reduce the need to re-enter data multiple times. We are also working very hard to further improve the usability of the forms as much as possible, in order for these changes to meet your needs, please provide us your proposals for implementation of certain sections/fields via eAF@ema.europa.eu.

Q.39. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.40. 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 5.1)

No

For Member State(s)	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Billing address (when relevant)			
Company name	<input type="text"/>		
VAT number	<input type="text"/>		

Q.41. 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)	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Date of Submission	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Species	<input type="text"/>	<input type="button" value="+"/>	<input type="button" value="-"/>
Remarks	<input type="text"/>		

Q.42. 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.

MISSING SUBSTANCES, EXCIPIENTS AND OTHER TERMS

Q.43. 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

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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q. 44. 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. They will check the EDQM Register and update EUTCT accordingly. The term should be visible a few days after in the eAF.

Q.45. 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.

Note: Annex A and Annex B buttons in the form are not links. Clicking either of the buttons will simply add text 'See Annex A/B' in the relevant fields to indicate for the receiving authority that a separate Annex has been added to the application form and is available in the same folder (1.2) where the application form can be found.

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

TECHNICAL QUESTIONS/TROUBLESHOOTING

Q.46. What is the 'Export XML' function for? (H+V)

A: Please see section "Export of the XML data" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.47. 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.48. Can I export the XML contained within the form? (H+V)

A: Please see section "Export of the XML data" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.49. Can I import previously completed XML data into the form? (H+V)

A: Please see section "Import of the XML data" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.50. 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.51. I have a problem with XML data import? (H+V)

A: Please see section "Import of the XML data" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.52. 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.53. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.54. 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 eaf@ema.europa.eu.

Q.55. Can I use bookmarks in the eAFs? (H+V)

A: Yes, you can bookmark in the eAF. Please see this link.

http://help.adobe.com/en_US/acrobat/X/pro/using/WS58a04a822e3e50102bd615109794195ff-7cc6.w.html

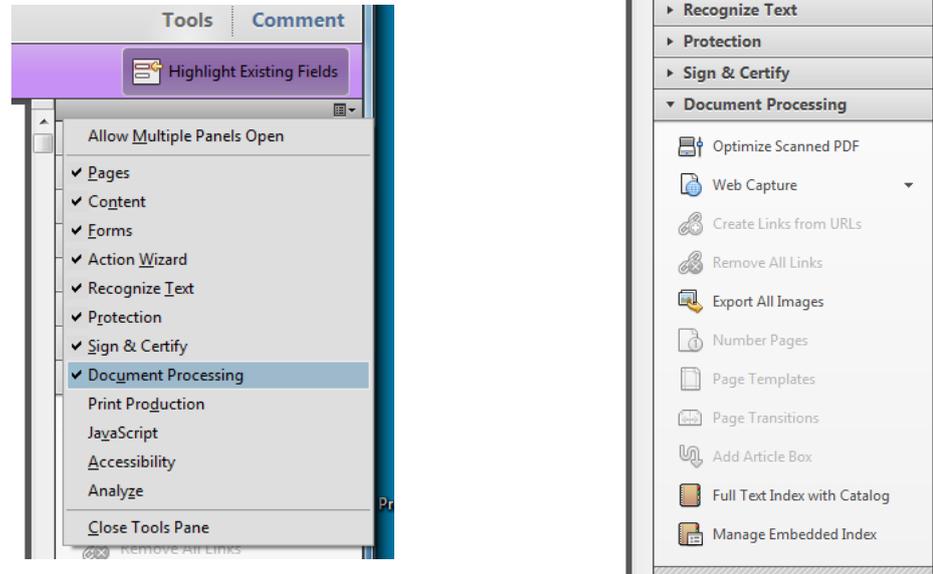
But this will work only after saving the file once data entry has been locked. Otherwise, validation errors will be stated.

Q.56. How do I navigate to different sections of the form quickly? (H+V)

A: Please see section "Navigation in the forms" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.57. 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.



GENERAL QUESTIONS

Q.57. Is this the complete and final version of the eAF? (H+V)

A: EMA is committed to ensuring that electronic Application Forms are aligned with the latest published versions of the paper-based forms on EudraLex. The eAFs are becoming mandatory for the centralised procedure applications from 1 July 2015 and 1 January 2016 for European procedures and in future they will be kept aligned with the requirements for a set of data deemed necessary by the European Commission Notice to Applicants. Regular updates to the electronic application forms are expected to ensure that they are aligned with any updates published by the European Commission, in consultation with the competent authorities of the Member States and the European Medicines Agency (EMA) through the [Notice to Applicants group](#).

Non content-related, format and functionality updates to the forms can be made if deemed necessary.

Note: If you have any comments or proposals for a best practice solution based on your requirements, please send these to eaf@ema.europa.eu for consideration.

Q.58. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.59. How can I find out which version of the electronic form I am using? (H+V)

A: When any of the eAFs are 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.

Users can also follow these steps to manually check the version:

1. Right-click on the body of the form and select 'Document Properties...' or on the Acrobat menu bar select: File>Properties (PC keyboard shortcut= CTRL+D).
2. The 'Document Properties' dialog window appears. Click the 'Custom' tab to find version information.

Note: The revision number of the form reflects the paper form on which the particular form is based. Please see the first page of each form for the precise revision number of the form.

Q.60. 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 eaf@ema.europa.eu for consideration.

Q.61. Is it possible to track changes within the electronic forms? (H+V)

A: This functionality is not currently available in interactive Acrobat forms.

Q.62. 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.63. How do I jump to 'month/year' in the pop up calendar? (H+V)

A: Please see section "Data fields and formats" in the [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.64. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.65. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.66. 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU.](#)

Q.67.: 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.68. 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 Address1 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 [Harmonised Technical Guidance for Using of eAF for human and veterinary medicinal products in the EU](#).

Q.69. What happens to the requirement for national requirements for translated application forms when the use of the eAFs becomes mandatory in January 2016? (H+V)

A: Currently there are no plans to provide translated versions of the eAF in other European Languages. All NCAs have agreed to the mandatory use of the eAFs. If there are any specific questions, please contact the concerned member state(s) as relevant.

Q.70. 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.71. 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 eaf@ema.europa.eu for a response. Frequently asked questions will be added, as deemed appropriate.