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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

Please refer to the NtA approved content of the application forms that are published in PDF format at the [EudraLex Volume 2 (Human)](#) and [EudraLex Volume 6 (Vet)](#).

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

OBJECTIVES OF THE eAF

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

A: The eAF stands for electronic Application Form and is the format that should be used for all applications concerning:

- 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 also accessible through [EudraLex Volume 2](#) and [EudraLex Volume 6](#)

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

A: The use of the electronic Application Forms is mandatory in all procedures (human and vet) excepting homeopathic products and MRL, where specific forms should be used.

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, there is always a 2-6 months transition period for any new version, depending on the changes and it will be announced in advance. 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. Also, the data can normally be exported and then imported into the new version if needed.

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:

  🔊 eAF RSS Feed

- **Click** on the page itself to subscribe.

- For more information about RSS feeds, see *The EMA's Guide to RSS*.

ACCESSING THE eAF

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 desk immediately highlighting the urgency of the query in the message.

Q.7. 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 eSubmission website is also accessible via EudraLex Volume 2 and EudraLex Volume 6.

Q.8. Why does it take so long to open the eAFs? (H+V)

A: For an explanation, please see section "Opening the form" in the Practical User Guide for eAF for human and veterinary medicinal products in the EU.

Q.9. 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 the 'exclamation mark' on the top of the left hand pane to 'trust' the document. Select "Trust this document Always". However, using Adobe Reader or any other PDF reader make sure that the application is allowed to open a connection to the internet to allow complete display. Browser plug-ins may be not compatible with PDF forms (see Q.13 below). Additional details can be found in the Practical User Guide for eAF for human and veterinary medicinal products in the EU.

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

A: The minimum specification to use for eAF is Adobe Reader/Acrobat version 11 or above. (It is always recommended to use latest version). Please note that applicants should use Adobe Reader or Adobe Reader DC for locking the forms. Adobe Acrobat or Acrobat Pro DC should not be used for filling and locking the forms as this may cause issues when the locked forms are opened/viewed by the recipient who may be using Adobe Reader/Adobe Reader DC.

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

A: If you cannot open/access the eAF, it might be due to the proxy settings so please ask your IT department to check your network settings.

Q.12. 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
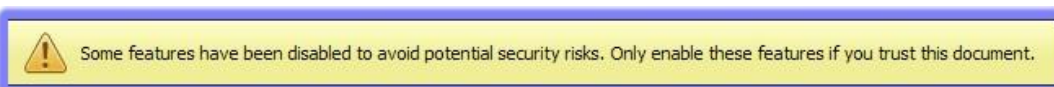Please see section "Requirements on Adobe Reader and IT security settings" in the Practical User Guide for eAF for human and veterinary medicinal products in the EU.

Q.13. Dropdown lists in the form do not work. What should I do? (H+V)

A: The first time the form is opened, an exclamation mark appears on the top of the left hand pane.
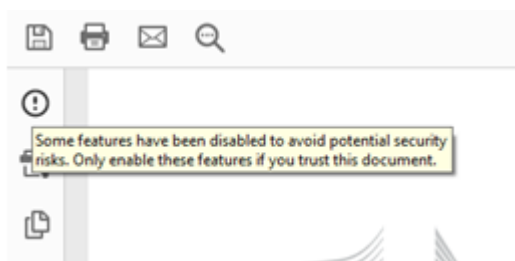
You will need to click the exclamation mark and the following banner appears at the top of the window:

- 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.14. 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.15. 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.16).

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 the EMA service desk, quoting "eAF" in subject (https://servicedesk.ema.europa.eu).

In case of any further technical queries, please contact us at: https://servicedesk.ema.europa.eu

Q.16. 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 your query to https://servicedesk.ema.europa.eu.

Q.17. 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.18. 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 normally not required for human or veterinary submissions, as long as a scanned signature or a text snippet in the required format is included in the electronic form and the submission is sent electronically using the eSubmission Gateway/Web Client/CESP/Eudralink (where accepted). Please note, that this signing off is rather to close the eAF properly when completed.

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

There are, however, still some NCAs that require the eAF of applications in NP, MRP and DCP to be printed, signed and sent in paper to the NCA. Please, find the details in the published documents on Requirements on Submissions (number and format) within MRP, DCP and National Procedures on the [CMDh](#) and [CMDv](#) website.

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

A: The release notes list all 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.20. 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 any sections by yourself.

Q.21. 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 in the dossier, clearly named (for example 'ema-form-annex-presentandproposed') in Module 1.2 (H) or Part IA (V).

SUBMITTING THE eAF

Q.22. What is the file naming format for submitting the eAF in an eCTD or a VNeeS? (H + V)

A: The file name for the eAF in an eCTD should be **cc-form-eaf-var.pdf**, where the **cc** is the country code and **-var** being the optional variable part. The variable part should only be used if more than one eAF is included in the eCTD (e.g. one separate eAF per included strength or form) to indicate the different forms (e.g. common-form-eaf-tablet.pdf).

Annexes to the eAF should be named **cc-form-annex-var.pdf** (e.g. common-form-annex-01.pdf. 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

The variable component, if used, should be a logical name and should be added without spaces.

In case of veterinary submissions, please consult the VNeeS guidance (section on file naming).

Generally, for VNeeS, any information that may help identify the contents of the file is encouraged to be included in the file name (e.g. as the given examples above). Preferably, the file name should include the part of the dossier where the document is located, but this is not mandatory. Valid file names for the eAF and annexes in a VNeeS are e.g. application-form.pdf, application-form-annex.pdf, p1-1a-admin-info-eAF.pdf and p1-1a-admin-info-eAF-annex.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.23. How can I sign the eAF? (H+V)

A: As the application form must always be signed, this means in the case of the eAF an implementation of an image of a scanned signature. Additionally, 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.' is also accepted. 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 the eAF.

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

Q.24. Scanned signature is not a real electronic signature, so 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 authority doesn't require wet signature/signature this field can be considered as symbolic confirmation that the form has been finalised and locked. It is also 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.25. 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 or see published documents on Requirements on Submissions (number and format) within MRP, DCP and National Procedures on the [CMDh](#) and [CMDv](#) website.

The signature image will not work as a digital advanced or qualified electronic signature, nor can it replace requirements of wet signed forms. There is no need to use qualified signatures or wet 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. If a wet signature is needed, eAF can be printed, signed and submitted to the requested NCA 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.26. 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 in the dossier. For requirement on a signed added paper copy for some NCAs, please see questions on wet signature above.

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.27. 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.28. 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.29. 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** 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 **renewal** and **variation** form allow inclusion of all forms and strengths. However, for the renewal some MS still require a single form to be submitted for each strength and pharmaceutical form (for details please see: CMDh list - [Data requested for Variations and/or Renewal Applications in the MRP/DCP](#) and CMDv list - [Format and no. of copies post-authorisation procedures](#)). 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.30. 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. 01.23) improves the possibilities to state all the included products in section 2 and different MAH names in section 1. 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. 01.23) 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.31. Is one single (common) form in English language accepted? (H+V)

A: In CP, MRP and DCP all member states should accept the application form and its content in English. There will be no national translations of the eAF provided by EMA or European Commission. In case of purely national applications, most NCAs accept the English eAF, but different requirements might exist, so please consult respective NCA websites.

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.32. Can I provide a scanned eAF? (H+V)

A: Printing and scanning the signed form should only be done for paper submissions (where acceptable) 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 or in part 1A of a VNeeS. The unsigned eAF can be printed, signed and submitted as per the NCA requirements in addition.

Q.33. Do I always have to use eAF? (H+V)

A: Yes, eAF has completely replaced the NTA word application forms (except for homeopathics and MRL, where specific forms should be used). The eAF can be printed and signed if required.

Q.34. 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, so the XML data should not be extracted and stored separately. This PDF document should be included within the eCTD structure in m1.2.

The receiving NCAs can extract the xml data directly from the forms.

Note: It is **not supported** to include the raw xml extraction within the eCTD 1.2 structure. 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.35. 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 / VNeeS submission.

DATA ENTRY

Q.36. How can I see which fields are mandatory? (H+V)

A: Click the **Validate Form** 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.37. 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.38. 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.39. 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.40. 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.41. 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.42. 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).

Q.43. How do I fill in the contact person address in the eAFs? (H+V)

A: For 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.44. How do I add 'salt/hydrate' form in to section 2.1.2 and/or 2.6.1? (H+V)

A: Please see detailed answer in the Practical User Guide for eAF for human and veterinary medicinal products in the EU, section 2.1.2 and 2.6.1.

Q.45. 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 describing 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	
⌄	⌄	⌄

approximately equal to
equal to
equivalent to
less than
less than or equal to
more than
more than or equal to
quantity sufficient
range

Q.46. 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.47. 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 the product, which we would like to register? (H+V)

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

Q.48. 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? (H+V)

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 and 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. Other third country sites 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.
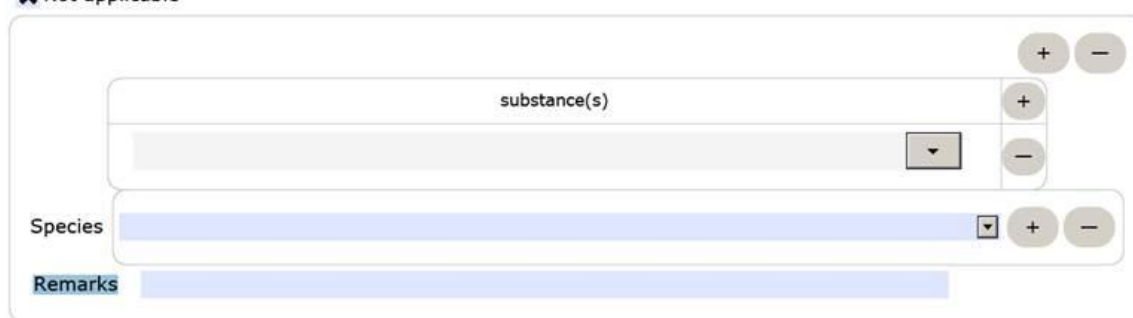
Q.49. How do I add excipients not listed and their justification in the 1.4 MRL section of the VET initial MAA? (V)

> **A:** The form requires that excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification is given. In case an MRL applica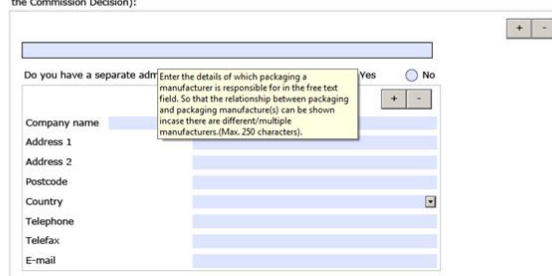tion is still under evaluation, reference should be made to the submission made to the EMA. In case MRLs are considered by the applicant to be "not applicable" to a substance, the corresponding box should be ticked. The appropriate justification should be provided under the "remarks" section, e.g. "included in out-of-scope list (EMA/CVMP/519714/2009)", "not pharmacologically active" etc.

Application for a Maximum Residue Limit has been made to the EMA

☐ Yes

✖ Not applicable

[1]*All substances contained in the product are subject to this requirement if they are pharmacologically active in the dose in which they are administered to the animal. Excipients not included in Regulation (EU) No 37/2010 should also be listed and an appropriate justification given.*

Q.50. 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 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.

Q.51. 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.52. 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.

Q.53. 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.

Q.54. If "State/County" information is not mentioned on official documents such as extracts from the Chamber of Commerce, MIAs or GMP certificates for manufacturers, but appears in the eAF due to OMS data, or the other way around, is there a risk for the apparent discrepancy to trigger validation comments? (H+V)

A: In case the "State" or "county" information comes up automatically in the eAF but is not listed on the MIA/GMPc/official document:

Information coming from OMS into the eAF is not editable as they are locked fields. However, if the applicant thinks that the information from OMS is wrong then they have to click "clear address" button and enter the address manually, or submit a change request to change the data in OMS in advance.

Please note that it should not trigger validation comment if the "county" or "state" field is populated in eAF but not listed on the MIA/GMPc/official doc.

In case the "State" or "county" information does not upload automatically in the eAF but is listed in the official documentation:

In that scenario, the applicant will have to click "clear address" button and enter the address manually, and in parallel or in advance submit a change request to change the data in OMS.

The ideal scenario is to have the same name and address throughout the dossier as per official documentation so if it contains a county as additional organisation information, then it should be included and if not included then should not be added to the eAF.

However, as long as the main information regarding the site is consistent then if the county/state is missing for countries other than USA and 3rd countries, then it won't come up

during validation. If this is the only discrepancy for the site information, then there should not be a validation query raised but if there are other issues with address, then it may be included in the questions. In any cases, it is really not a blocking issue, just an administrative matter.

SPECIFIC QUESTIONS ON THE VARIATION FORM

Q.55. 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? (H+V)

A: The section 2 of the variation form supports 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.

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.

Please note that for veterinary products however, if the list of products concerned is very extensive, it may be added as an annex to the application form.

For medicinal products for human use, the table should always be completed, however, "list of concerned products" can be provided as Annex to the application form if agreed by the relevant NCA/RMS.

For products authorised via the Centralised Procedure, the Annex A of the product(s) concerned should be provided as an Annex to the application form.

For worksharing procedures submitted to the EMA, which include nationally authorised products, relevant product and Member States details should be provided as an Annex B to the application form (using the template [Human](#) or [Veterinary](#) on the EMA website).

Q.56. 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

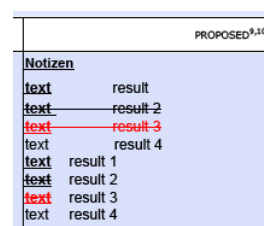### Q.57. For variation eAF how the Classification Guideline table will be added? (H+V)

A: The classification 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 [Classification 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.22
Please see section "Types of change" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

Q.58. 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)

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.22
Please see section "Types of change" in the [Practical User Guide for eAF for human and veterinary medicinal products in the EU.](#)

Q.59. 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.60. 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.61. 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 to not confuse people.

Q.62. 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. An empty data field will not cause a validation error for this procedure type.

Q.63. 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 in case several scopes will focus on the same present/proposed combination you should highlight this in the precise scope text field.
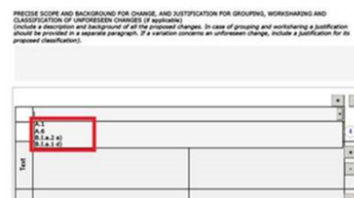
Q.64. How can we reflect "Editorial Changes" in the present-proposed table and which drop-down option we choose for this type of changes? (H+V)

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

Q.65. 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.22

SPECIFIC QUESTIONS ON THE MARKETING AUTHORISATION APPLICATION FORM

Q.66. 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+V)

> **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.67. 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+V)

> **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.68. A product which has two active substances Substance A / Substance B (8mg/5mg): In the composition of tablet are:
- **Substance A 8* mg** [**8.00 mg of Substance A is equivalent to 6.xx mg of Substance A active moiety]
- **Substance B 6,xx** mg** [*6.xx mg of Substance B is equivalent to 5.00 mg of Substance B active moiety]

What/how should be filled in:
- **Section declaration and signature**
  Substance A and second API Substance B or it's salt?
- **Section 2.1.2 (H+V)**

> **A**: In section 2.6.1 as well as in section 2.1.2, you should complete details of both the active moiety and the full active substance (substance derivate), in the respective fields. Section 2.6.1 should also indicate the corresponding quantity of each substance per dosage form unit.
>
> In section 2.2.1 you should indicate the active substances as used for expression of strength (normally, in line with the guidance, these would be the active moieties) and the strengths corresponding to the contents of this substance.
>
> In section "Declaration and Signature", you should use the full name of the active substance including salt or hydrate, if applicable (i.e. the derivative of the active moiety, if the active substance contains not only the active moiety) and the strength as indicated in section 2.2.1. As this section is used only to identify the particular application, it may occur that the strength reflects the contents of active moiety, but the active substance field lists a salt or hydrate of this active moiety. More detailed information though is to be provided is subsequent sections of the Application Form.
>
> In case of fixed dose combination products this information should be completed for all active substances in the product concerned.

Q.69. The application is based on Art. 10b (fixed combination) [Dir 2001/83/EC]. Will this also require to tick one of check boxes in section 2.1.2 – claim for new active substance or second option known active substance? If one of the boxes is not ticked, the AF is wrongly validated. The same issue occurs for Art. 10(1), 10(3), 10(4) and 10c. Please advise what to do.(H)

A: Applications made under article 10b of Directive 2001/83/EC must pertain to products "containing active substances used in the composition of authorised medicinal products". Therefore the products applied for under such basis cannot contain new active substances and the claim of new active substance is not applicable to such applications. However, as the validation rules currently don't take into account the specified legal basis selected in section 1.4, validation errors can only be avoided by selecting "known active substance" although this is not needed from a regulatory point of view in case of other legal bases than Art. 8(3) and Art. 10a Dir 2001/83/EC. Please consider this as a workaround for the time being.

This workaround is also applicable for extension applications.

Q.70. In the MAA-Human eAF v1.23 issues occured to fill in section 1.3. "Application for a change to existing marketing authorisation leading to an extension". It is required to fill in the table under "for existing marketing authorisation in the EU/MS where the application is made". For product with more than one API: How do you list the strength of the product in this section? As it is now you only can list one strength with one unit?"(H+V)

A: It is definitely true, that only one unit of measurement (UoM) can be chosen. But normally the strength will use just that one UoM in case of fixed combinations.

In some rare cases where agreed, combination packs may contain e.g. tablets and cream or liquid multiple pharmaceutical forms. In those cases the pharmaceutical form can be duplicated and/or the strength line can be duplicated:

If these options will not be sufficient, an additional remark may be added to the cover letter. But this should apply to exceptionally rare cases only.

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 ORGANISATIONS, SUBSTANCES, EXCIPIENTS AND OTHER TERMS

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

A: If you need to request a missing substance in order to complete an eAF, please submit a request for substance insertion with the corresponding SmPC to the EMA Service Desk portal.

If you need to request a new term (e.g. pharmaceutical form or unit of measurement) or new organisation or a request for an update of an already existing term or organisation in order to complete the eAF, please submit a request through the SPOR Portal - http://spor.ema.europa.eu/rmswi/#/ providing as much supporting documentation as possible (e.g. name of the product concerned, SmPC, etc.). Please note you need to be registered with SPOR prior to submission of change requests: https://register.ema.europa.eu/identityiq/login.jsf. The user guide for managing referential and organisation data in eAF is available here.

OMS users are advised to become familiar with **Change requests validation in OMS** guidance, **Organisation data quality standards in OMS** guidance and **OMS Controlled Vocabularies (CVs)** guideline. The documents are available on the SPOR portal > Organisations > Documents > View.

Q.73. Is there some kind of overview which explains all abbreviations used in the drop down list? (H&V)

A: Values are re-used from SPOR-RMS. Details can be retrieved from term details.

TECHNICAL QUESTIONS/TROUBLESHOOTING

Q.74. 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.75. 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.76. 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.77. 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.78. 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,
v. 01.23 did change the DES.

Q.79. 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 undetake for your organisation.

Q.80. 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.81. 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.82. How do we get around the issue of enhanced security restricting the eAF from connecting to SPOR-RMS? (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.83. 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.84. Can I use bookmarks in the eAFs? (H+V)

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

Q.85. 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.86. 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 belwo) to allow full text index with catalogs and managing embedded indexes
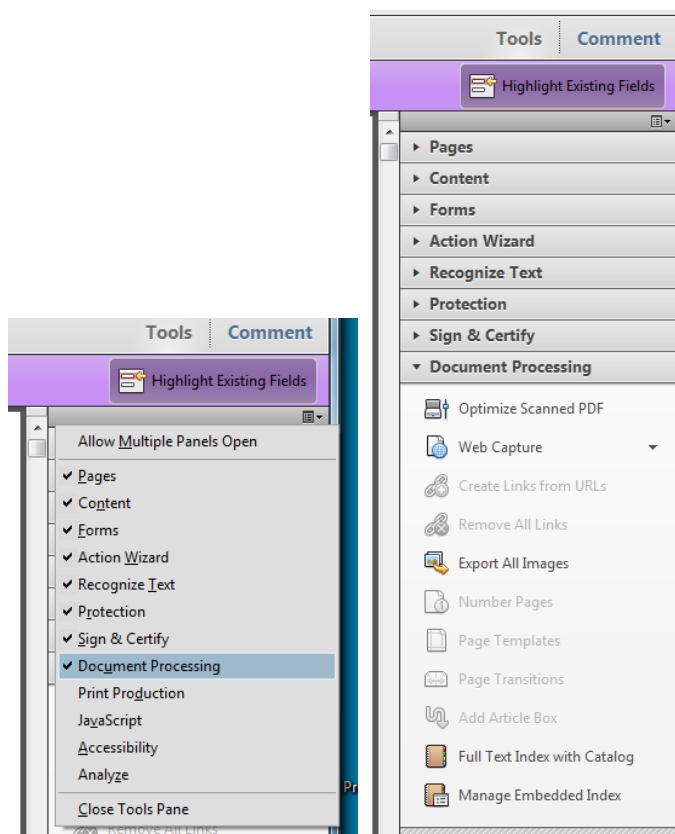
Q.87. Fast web view / Our eCTD generating software automatically saves all pdfs within the eCTD with fast web view enabled, however in the case of signed eAFs this renders them unviewable, there is no way to switch this off. (H)

> **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.88. 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.89. 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.90. 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.91. 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.92. 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.93. 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.94. 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.95. 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.96. How to provide address details in the eAF?? (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. In the latest version of all forms, OMS is used to retrieve organisation / address details using search function, or alternatively those details can be inserted manually.

It is very important to fill the mandatory fields, which are:

- the first line of the Address ;

- City/Locality/Town/Village;

- Country;

- Telephone;

- E-mail

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.97. Can a master form be prepared containing general entries that will not change, which can be 'Saved As' each time, at the applicant's side. 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? (H+V)

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 or updated references from master data ([SPOR](#)) become available. In those cases the templates will need to be updated.

Q.98. How to integrate the new VET regulation where vet variations will be disconnected from the human system? (V)

A: The new veterinary Regulation has been discussed extensively in the Council and the Parliament and should be adopted by the end of 2018 and shall be applicable 36 months from the entry into force. As we do not have 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.99. 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.100. 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? (H+V)

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.101. 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" (H+V).

A: Even if technically possible also for centralised procedure, for ease of contacting the applicant only single contact person for each centralised 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.102. 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. (H)

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.103. We use a specific AF for Homeopathic medicinal products' Marketing Authorisation Applications. Will a specific eAF be published and when? (H+V)

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.

Q.104. We would like to use our abbrieviated company name (e.g. the Acronym name as given in OMS) in the eAF, but this is not visible in the lists in the eAF. How should we handle this situation? (H+V)

A: The company name should be the same in the eAF as in the proof of establishment and therefore the acronym is not applicable in the eAF and should not be visible there. (Option for using a short name could, however, be relevant in the labelling and should then be discussed and agreed during the labelling review.)