PLM Portal eAF Q&A Document
Questions received during eAF events in 2025

Updated in December 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Contents

Acronyms

Acronym	Definition
API	Application Programming Interface
CAP	Centrally Authorised Product
eAF	electronic Application Form
eCTD	electronic Common Technical Document
EoP	End of Procedure
EU IG	EU IDMP Implementation Guide, a set of 9 documents ('chapters') that form the basis for submitting and exchanging medicinal product data in the EU, in an IDMP-standardised way
FHIR	Fast Healthcare Interoperability Resources
IDMP	(unique) Identification of Medicinal Product Data, by following a set of ISO (IDMP) standards
MAH	Marketing Authorisation Holder
NCA	National Competent Authority
non-CAP	Products authorised through Mutual Recognition Procedure/Decentralised Procedure, purely nationally authorised (NAP) product
PLM	Product Lifecycle Management, here referring to the EMA PLM portal
PUI	PMS/Product User Interface
RMS/CMS	Reference Member State / Concerned Member State
UI	User Interface
XML	Extensible Markup Language

Definitions

PLM Portal eAF *(or PLM Portal web-based eAF or web-based eAF)*	PLM Portal web-based eAF user interface; from this user interface, a PDF containing a FHIR XML can be exported
Interactive PDF eAF *(or interactive pdf or PDF based eAF)*	For details about the interactive eAF PDF, please consult the eSubmission page: eSubmission: eAF
European Commission Notice to Applicant (NTA) – eAF European Commission– Application Form	https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-2_en
Non-Centrally Authorised Products (non - CAP)	Medicinal products for human use, other than Centrally Authorised Products (CAP) which are handled/authorised by EMA.
Fast Healthcare Interoperability Resources	The FHIR standard defines how healthcare information can be exchanged between different computer systems regardless of how it is stored in those systems. It entails an API. Data are normally in XML format.

Extensible Markup Language	The PLM Portal eAF can be exported at any time to generate a pdf. The form data is written in an FHIR XML. The pdf is a human readable rendition of this XML which is attached to the pdf.

1. Support and Documentation

1.1. Where can I find documentation on the PLM Portal eAF?

The PLM Portal eAF, same as the Interactive PDF eAF, follows the **EU variation regulation**. At the moment, in the PLM Portal eAF, only the human variation forms can be created on the PLM portal (all the other forms are to be created using the interactive eAF PDF). **Procedural guidance** for both Interactive PDF eAF and the PLM Portal eAF can be found under the CMDh procedural guidance: https://www.hma.eu/human-medicines/cmdh/procedural-guidance.html

Documentation and news related to the PLM Portal eAF application can be found on the PLM portal (Home PLM) and on the "eSubmission: eAF" webpage:

Item	LINK
eAF NEWS	https://plm-portal.ema.europa.eu/Guidance/article/KA-01006/en-us
eAF (user interface) release notes	https://plm-portal.ema.europa.eu/Guidance/article/KA-01011/en-us
eAF FHIR release notes	https://plm-portal.ema.europa.eu/Guidance/article/KA-01030/en-us
eAF - Guidance Documents and Training Videos	https://plm-portal.ema.europa.eu/Guidance/article/KA-01012/en-us
eAF registration guide	PLM Portal (eAF) guide to registration.pdf
eAF user navigation guide	PLM Portal eAF guide to navigation - eAF user guide.pdf

1.2. How does eAF use SPOR data?

The PLM Portal eAF uses more controlled vocabularies (SPOR) than the Interactive PDF eAF, allowing for less human errors than typing data in free text fields.

- PLM Portal eAF consumes data from **PMS.** Today PMS data is mostly used in the 'product selection' section of the PLM Portal eAF form. With the use of structured data (under analysis and development) in the PLM Portal eAF "Present and Proposed" section, more PMS data will be used e.g. ATC code.
- PLM Portal eAF consumes data from **RMS** (e.g. the variation scope list)
- PLM Portal eAF consumes **OMS** data through PMS (e.g. the MAH for a specific product) and from OMS through dataverse layer (e.g. organisation of contact person)
- PLM Portal eAF consumes **SMS** data through PMS (e.g. current product ingredient, in the UI 'product selection' section). In the future, with structured changes, data may be consumed from SMS directly (e.g. proposed ingredient/active substance).

1.3. Where can I find more information about SPOR?

SMS, OMS, RMS data and documentation can be found in the SPOR UI portal:

Item	LINK
SPOR data services on-boarding	On-boarding of users to SPOR data services
SPOR UI portal	https://spor.ema.europa.eu/sporwi/
Substances management services (SMS)	https://spor.ema.europa.eu/smswi/#/
Organisation management services (OMS)	https://spor.ema.europa.eu/omswi/#/
Referentials management services (RMS)	https://spor.ema.europa.eu/rmswi/#/

PMS/Product UI data and documentation can be found on the PLM portal:

Item	LINK
PMS/Product UI NEWS	https://plm-portal.ema.europa.eu/Guidance/article/KA-01031/en-us/
PMS/Product UI guidance documents	KA-01032 · PLM KA-01039 · PLM
EU Implementation Guides (EU IG), intro & chapter 1 through 9	**guidance documents on the submission of Art57 data** Chapter 3.I Technical specifications of the Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004
Q&A documents	**product-management-service-pms-frequently-asked-questions-faqs_en.pdf** JOINT_eAF - PMS Questions & Answers_v5

1.4. Where can I find more information on products with status "valid - pending national approval?

The relevant Q&A document describing what to do if a product was authorised through MRP procedure, however, the national authorisation is still pending is available at:
https://www.ema.europa.eu/en/documents/other/electronic-submission-article-572-data-questions-answers_en.pdf

1.5. Is it correct that new guidelines classification won't be included in the "old" application form? (Nov '25)

The new variation classification will be available in both PLM Portal eAF (the version is called "January 2026") and interactive PDF eAF (Human Variation v 1.28.0.0) Please check the eSubmission for more details on the interactive eAF PDF.

2. PLM Portal eAF applicability

2.1. Is the web-based eAF applicable to all EU authorisation types?

Yes, all products authorised through any EU regulatory procedure, such as CP/MRP/DCP/NP are in scope of the web-based eAF.

2.2. Will national MAH Transfers also be handled via PLM?

Some NCAs may require that an eAF is submitted as a part of an MAH transfer. The PLM Portal eAF can be used if an eAF is required by the regulator. Alternatively, for national MAH transfers, existing national procedures outside the PLM Portal eAF should continue to be followed.

2.3. Is the web-based eAF suitable for local (e.g. Greece) national requirement in local language?

The PLM Portal eAF supports submission for national procedures, including for example Greece. However, the form itself is in English, and while product data can reflect local language content (e.g. substance names), the interface does not currently support full localization. National requirements for language-specific documentation should still be met through annexes or supporting documents.

2.4. Are there European countries refusing PLM Portal eAFs? What are the reasons and recommended ways of working?

All EU countries should be able to accept the PLM Portal eAFs into their systems. For any difficulty in this regard, please let us know by opening a service desk ticket. The request can be done here: https://support.ema.europa.eu/esc?id=sc_cat_item&sys_id=f1cf56baeb954210495ffb0dcad0cd94

2.5. If I have an MRP product with UK as Concerned Member State (CMS), can I use web-based eAF?

Yes, the PLM Portal eAF can be used, as long as the concerned products are available in the PLM Portal. In order to include UK products in PMS, a submission to xEVMPD is required, as PLM Portal eAF consumes product data from PMS.

2.6. Is the eAF applicable for homeopathic registrations?

The PLM Portal eAF is consuming data from PMS, and, at the same time, PMS is fed by xEVMPD. Therefore, any product that is needed in eAF can be submitted to xEVMPD. xEVMPD already allows the submission of these type of products, so please, review Chapter 3.II of XEVMPD to understand how to submit these products. Once submitted, they will be available in the PLM portal (Product UI and eAF).

2.7. Can you select multiple MAHs for one MRP/DCP in multiple countries? For example, we have DCP with 8 countries and 5 MAHs? (Nov '25)

Yes, the details of the MAHs will appear at the level of each selected product. Also, the contact details can be added for multiple MAHs, and the Proof of Payment. The only aspect you need to keep in mind is that only one reference MAH can be selected, when creating the form.

2.8. Additional contact points for a procedure are not included, which leads the RMS/Applicant to receive NCA mails (afterwards), even though they are not the MA owner in the country. Will this be changed? (Nov '25)

In the Contact page of the PLM portal eAF, when several member states are part of a variation, contact persons can be added for each member state if desired. Please consult chapter 2.4.3 of the user guidance https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20eAF%20guide%20to%20navigation%20-%20eAF%20user%20guide.pdf and should you still have questions about this topic, kindly raise a service desk ticket.

2.9. Does eAF supports all EU languages? (Nov '25)

Yes, the products are shown in the PLM Portal with the languages that are added in xEVMPD. The only language of the portal (for example, the navigation menu, the documentation etc.) is English.

2.10. In product details tab, the MA (marketing authorisation) number is visible. However, the Greek Health Authority have requested to use EOF product code in the eAF (the code remains unchanged throughout the lifecycle of the medicinal product). Can the EOF code be accommodated in eAF in place of MA number? (Nov '25)

The MA number comes from xEVMPD. The information that is provided in xEVMPD is the one that will be shown in the PLM Portal. Should you want to change this information, please consult first with the PMS EMA team and they will guide you if this information can be changed (and still IDMP compliant) and how to change it.

2.11. How to use the web form for National submission in DCP procedure, if the country of submission is CMS? (Nov '25)

When creating a variation for MRP/DCP products, the member states which are available in the dropdown menu(s) in Procedural Information (Reference member state and Concerned Member state) will be the member states from the selected products in the variation. The RMS/CMS in this case are the member state responsible and concerned for the current procedure, not the RMS/CMS of the product(s). We understand the way the member states appear in the dropdown selection for RMS/CMS could create concerns and following discussions with subject member experts and national authorities, we will proceed to either expand the selection with more Member States or further explain the terms and their applicability.

2.12. If only 50 products can be selected does that mean we have to create 2 or more forms? Will NCAs accept this approach? Will CESP system accept this? Why there is a limit of 50 in product selection? (Nov '25)

The limit of 50 products is only applicable when adding products in one go. This means, you can only add 50 products at once. After that, you can add 50 products more, and after that, 50 more products and so on. More than 50 products can be added in one form. The reason for it is to shorten the wait time after adding 50 products (there are multiple actions in the background for each added product).

2.13. If you can only select MP for non-CAPs, how can you deregister or change a pack size? (Nov '25)

The current setup, as decided together with Subject Matter Experts and CMDh, does not allow the un-selection of packages for non-CAPs. We are re-discussing the topic with the same groups, and potential changes will be made and announced on the PLM Portal.

2.14. Is the use of web-based eAF for purely national procedures agreed with all NCAs? Some HAs (e.g. Polish) require the AF in local language. How this can be approached at the "mandatory" stage? (Nov '25)

The web-based eAF is accepted by all member states, and it replaces the interactive PDF eAF. The web-based eAF does not interfere with any other local requirements, which will remain in the remit of the local authorities, and these additional forms should follow local regulation.

2.15. National contacts should be added in the eAF as contacts. If contacts are freelance consultants, they cannot have ORG/LOC-ID (was inactivated by EMA). How can these be included? ORG is a mandatory field in eAF for contacts. (Nov '25)

We will re-discuss with relevant groups this topic (the mandatory selection of OMS organisation), knowing that OMS has very clear rules for creating a new entity (it does allow a few types of non-organisations to be created in OMS)). Please first raise a ticket with OMS and follow their guidance. If the creation is not granted, a potential workaround is to select the Reference MAH of the for and add in the Cover letter the correct details.

2.16. The web-based eAF will become mandatory for MRP/DCP including UK as CMS but also with UK registered nationally? (Nov '25)

The eAF will become mandatory (will be announced at least 9-12 months in advance) for all the products currently covered by the interactive PDF eAF (including UK Northern Ireland).

2.17. What if a certain variation is applicable for only one strength of the MRP/DCP, can you select only the one strength for that variation? (Nov '25)

The current setup, as decided together with Subject Matter Experts, does not allow the un-selection of packages for non-CAPs. We are re-discussing the topic with the same groups, and potential changes will be made and announced on the PLM Portal.

2.18. Will be able to use PLM based eAF for variations that are due to be submitted shortly after EoP of DCPs, i.e. when nor the RMS neither any CMS MA is granted. The valid pending national phase xEVMPD status cannot be used in such cases now. (Nov '25)

The 27 October release brought a change that allows the selection of products in the "Pending national phase" authorisation status; therefore, you can start using the eAF for these cases as well.

2.19. Will the PLM form allow its use in other non-EU HA submissions (e.g. UK MHRA) or will the system prevent selections of information that is not valid in EU, like MAH address or product name? (Nov '25)

The PLM Portal eAF (like the interactive PDF eAF) covers only EU products and only EMA and EU Members States are receivers of the PLM Portal eAFs.

2.20. How fast will the eAF portal be updated when a new Article 5 recommendation is issued? (Nov '25)

If there are any updates in RMS lists (the variation classifications), the PLM Portal will be updated the day after.

2.21. Is the web-based eAF more stable than the current eAF? The non-web-based is very instable especially when you make changes in the present and

proposed section. It often suddenly closes the eAF and in worst case changes are not saved. (Nov '25)

The replacement of the PDF based eAF with the web-based one brings a completely different technology and the web-based eAF is a stable tool and it is continuously improving. We are monitoring the performance, and actions are taken to improve it, if necessary. I hope you will have a much better experience with the web-based eAF.

3. Timeline

3.1. Where can we find the timelines and major milestones for PLM Portal eAF implementation (Updated)?

Updates about the PLM Portal eAF are published on the PLM Portal. The latest update was published in September 2025 and can be accessed her: PLM Portal eAF timeline or here: PLM Portal eAF news It is recommended to monitor the portal regularly for the latest news and guidance (eAF News).

3.2. When will the formal transition period towards mandatory web-based variations eAF use for CAPs/ non-CAPs start (Updated)?

The PLM Portal web-based eAF sequential use levels are the following:

- **Optional** Use: Both the interactive PDF and the web-based eAF are available. Applicants may choose either format, and no preference is expressed.
- **Recommended** Use: The use of the web-based eAF is encouraged. However, applicants may continue to use the interactive PDF if they are not yet ready to adapt their internal processes.
- **Strongly Recommended** Use: The web-based eAF should be used in most cases. The interactive PDF should only be used if specific constraints prevent the use of the web-based eAF (e.g., technical issues or missing features).
- **Mandatory** Use: The use of the web-based eAF is required. Submissions using the interactive PDF will not be accepted. Mandatory use will only be introduced after a formally announced transition period.

The situation today is the following: **strongly recommended** use of the PLM Portal eAF for **all** procedures (CAP and non-CAP). Keep track on any update in this regard through the **eAF News webpage** in the PLM portal, accessible through this link:
https://plm-portal.ema.europa.eu/Guidance/article/KA-01006/en-us

The formal transition period (following a completion of successful UAT/final confirmation by the users, in the PLM Portal eAF production environment) in-between highly recommended and mandatory status, will begin once all necessary features to support all use cases are available in the PLM Portal eAF. This means the PLM Portal eAF (minimum viable product) must be ready to fully replace the Interactive PDF eAF. The exact timing depends on the findings during the (strongly) recommended use phases and cannot yet be confirmed.

3.3. Is it recommended to use the web-based eAF for non-CAP procedures before a UAT is launched?

Yes, it is very much advised to start using the PLM Portal eAFs as soon as possible for all procedures and products. This allows users to become familiar with the PLM Portal application form. It also gives an opportunity to provide feedback and report issues –if any- so as to pave the way to mandatory use. The UAT transition period will serve as a final confirmation step, however, waiting until transitional period or the mandatory use is not advised as this could lead to issues being found at very close to the mandatory use.

Note that the production environment will be used as the environment where the final UAT/user confirmation test will take place. Even today, it is recommended to do 'testing' in the production environment.

3.4. When will the new variation classification guideline become available, and will the eAF reflect it (Updated)?

For guidelines and timelines on the amended variation regulation, please consult the CMDh website, more specifically Procedural Guidance -> Variation ->Revised Variations Framework.

The European Commission has published an updated draft version of the classification guideline in June 2025. Final version is expected to be published in the Official Journal in the coming months and it is expected to take effect in early 2026.

PLM Portal eAF will support the change in the Classification Guidelines. Further details will be released when available and relevant guidance documents will be made available.

Update: the form is now available in the PLM Portal by selecting the version "January 2026". Doing so, the scopes which are applicable to the new variation classification can be used. For the timeline, please consult the following page: Guidance on the application of the revised variations framework | European Medicines Agency (EMA)

3.5. At this stage, where the web-based eAF is only recommended, is this format also accepted on the AIFA (Italy) front-end portal?

Yes, we have received a confirmation from AIFA that the technical limitation that was affecting their local portal has been removed and AIFA can now receive the PLM Portal web based eAFs.

3.6. Can "non-mandatory" use of AF for non-CAPs be a justification to not add CAP to mandatory worksharing and submit separately?

No, unfortunately that could not be used as justification. Sometimes there may be some technical limitations with regards to the PLM Portal eAF and in those cases you would need to use the interactive pdf variation eAF, but the mandatory use of the PLM Portal vs pdf eAF is not a reason.

3.7. Until when the pdf eAF will be available, also will the strongly use will be converted to mandatory use of web based eAF for non-CAPs? (Nov '25)

The target is to make the web-based eAF mandatory for all product types. But the timeline is not yet established, mostly due to dependency with PMS and OMS known issues and limitations. The Mandatory use will be announced well in advance (9-12 months).

4. Identity and Access Management, MAHs

Most questions regarding Identity and Access Management are answered in the eAF Portal Guide to Registration.

4.1. Is it possible for an National Competent Authority eAF user to see all eAFs and their status using the view "eAF List" in the PLM Portal?

No, only EMA authorised users have this possibility today, as they provide support for all eAF support tickets.

This functionality is not available for National Competent Authorities (NCA). An NCA eAF user can only see the forms generated by themselves - mostly for testing and familiarisation purposes.

4.2. If the MA for a MRP/DCP product is owned by two different companies, is it still possible to prepare one eAF? Can the form be signed by both RA (Regulatory Affairs) representatives?

Yes, one eAF form can be prepared and all products from different MAHs can be included in the same form, depending on the affiliation/roles available for the persons filling in the eAF. In such cases, a reference MAH needs to be assigned per dossier (footnote 5 in the PDF). Inside the form, several MAHs can be mentioned, e.g. contact persons in procedural information section, Proof of Payment in finalisation section. Please ensure that you and/or dossier collaborators have the correct roles for the concerned companies.

Even one person could complete the web-based form (depending on the roles affiliation), and then the eAF can be digitally signed by the two RA representatives (see chapter Integrity Stamp, signatures7.). Alternatively, if you wish people from other companies contributing to the form, please ensure that you have either Industry Manager or Industry Coordinator role, and that the co-authors have the correct roles with the concerned organisation(s). Please check out which scenario fits you most, in the use cases of the "eAF Portal Guide to Registration" e.g. use case 3.3.1.1.3 or 3.3.1.1.4.

4.3. Can I see all MAH's in the eAF (all countries of an MAH). Currently, I can only see the Reference MAH.

Yes, you can add information from all MAHs in the PLM Portal eAF User Interface, e.g. contact persons in procedure section, Proof of Payment in finalisation section, products from different MAHs (depending on the affiliation/roles), up to two names in the signature part and multiple digital signatures on the PLM Portal eAF pdf.

Whether you can see other MAHs in the PLM Portal eAF user interface, depends upon your affiliation and your role. Please check the "eAF Portal Guide to Registration" to decide what role you need. To export and finalise the PDF you need the eAF applicant manager or eAF applicant manager role with the various MAHs that are mentioned in the PLM Portal eAF UI.

4.4. We are MAH for only one country in an MRP and can only provide details for this country in the web form. Will the web form be updated to allow us to include the MAH information and payment for the other countries where we are not the MAH?

Whether you can yes/no include information on other MAHs in your form, depends on your affiliation with the other MAH, and on your specific role. See eAF Registration Guide, and please check out table 3, which describes the different rights per applicant role.

In the PLM Portal eAF form, information on other MAHs can be easily added in various places (like "contact person", "proof of payment", "additional signatory"). For example, the Proof of Payment section supports the addition of payment details for other MAHs, to ensure that all necessary financial information can be included even if the MAH is not the "Reference MAH".

4.5. Can CROs (consultant companies) get access/roles on behalf of an MAH, or only an MAH employee can get access/roles?

CROs and other consultants can be affiliated with a MAH's organization to gain access to the relevant products. This affiliation allows them to work on eAFs on behalf of the MAH. Details are available in the "eAF Portal Guide to Registration".

4.6. If I work in a Consulting Company and I must create an eAF on behalf on different MAHs, do they need to authorize me, or should I ask their approval by means of Admin Roles/Industry Roles?

As a consulting company, you must be properly affiliated with each MAH for which you need to create a PLM eAF. You do not need to be an administrator, but you must have the appropriate applicant role, such as Industry eAF Applicant Manager or Coordinator. The affiliation process is outlined in the "eAF Portal Guide to Registration".

4.7. In the same organisation, can we see the eAF created also by other colleagues?

As an industry user, yes, though visibility depends on the assigned user role. Users with the "eAF Applicant Coordinator" role can see all forms created within their organization. Users added as co-authors can also access the form.

Relevant guides should be consulted: Guide to registration, for more details on the various eAF roles, and the eAF user guide.

4.8. How can I create an eAF for MRP/DCP when the MAH / Organisation is different country by country, considering that at the beginning I can select only one Organisation?

You must select a 'Reference MAH' when creating the form. To include products from other MAHs, you need to be affiliated with those organizations and have the appropriate user roles. You can then add co-authors from those organizations so they can collaborate on the form, or you can add the products yourself if you do have the proper roles. See the "eAF Portal guide to registration" to set this up.

4.9. Once completed the eAF, is there a specific role to sign it?

No, there is no specific role to sign the PLM Portal eAF pdf. You can add a digital company signature –one or more- to the pdf, in addition to the EMA technical 'integrity stamp'.

4.10. As consultants, we prepare eAFs for customers. How can we have access to their product list? (Nov '25)

Please consult the guide to registration here:
https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

Based on the access that you can receive (for example to all products of an organisation or just the products that were added by another user), you can have for example the Application Manager for an organisation (and have access to all products), or Application Contributor (with limited access).

After consulting the guidance, should you still have questions, please raise a Service Desk request for information.

4.11. Can contributor applicants see all products when they are added as co-authors? (Nov '25)

The contributors can only see the products that were added in a form where they are invited as co-author. They cannot add more products from the MAH which invited them, and they cannot export the form. They can products from the organisation where they have Manger or Coordinator roles.

Please see Table 3 of the "PLM Portal guide to registration":

https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

4.12. Can you add/delete co-authors once the form has been created? (Nov '25)

Yes, co-authors can be added or removed after the form is created. Please consult the guidance to learn more about the steps for adding/removing co-authors.

4.13. Will it be possible for an individual, who represent MAH but is not its employee, once linked to the MAH in OMS, to include different correspondence address from the address of the MAH? (Nov '25)

As long as the individual has an OMS entry, the contact details can be selected for that Organisation ID. Please review the user guidance for contact details (chapter 2.4.3):
https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20eAF%20guide%20to%20navigation%20-%20eAF%20user%20guide.pdf

4.14. Can a person added as contributor/coauthor in eAF, clone or copy form which is visible to them? (Nov '25)

No, the Application Contributor cannot clone applications. This role only allows for editing the application and adding scopes.

Please review Table 3 from the guide to registration:
https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

4.15. Is it possible to work with global and local colleagues on the same eAF? (Nov '25)

Yes, it is possible. Based on the structure of your organisation, different global and local colleagues can have different roles: Application Coordinator, Application Manger or Application Contributor. Please consult the guide to registration for all possible scenarios:
https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

4.16. For non-CAPs, is it necessary to register all our subsidiary companies at the initial stage of eAF creation? (Nov '25)

This depends on the way the MAH is organised and how the access is granted. It can be that some colleagues have access (Applicant Coordinator or Applicant Manager) to all the subsidiaries, and they can add any product in any eAF. Another scenario is that you create the eAFs for the main company, and invite as co-authors colleagues from the subsidiaries, and they can only add their own products. Please consult the guide to registration for all the possible options
(https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf)

4.17. In the MRP & DCP applications, if another company (not our legal entity) is designated as the CMS for a specific country, how should we input the product information and registration details in the electronic Application Form (eAF)? (Nov '25)

The PLM Portal eAF allows several users collaborate on a form. For example, you can invite the user from the other company to be a co-author, and they can request for Application contributor in your company. This way, they can add their own products, as long as they are at least Applicant manager in their own company.

Please refer to the guide below to review all the possible roles and the applicable scenarios: https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

4.18. We work with consultants in each EU country, who manage our national products. If we provide them with an eAF contributor access, is it possible to restrict their access so that they can only see the products of their own country? (Nov '25)

All the scenarios for roles and access are described in the following guidance:

https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

If you invite a national colleague and they will get Contributor access to your organisation, they will be able to add their local products, if they are Manager/Coordinator for their local companies. Should you still have questions on a specific scenario, please raise a Service Desk ticket.

4.19. I am affiliated with two independent organizations where I manage products. Can I assign myself to submissions I manage from other organizations and vice versa? This would save me the necessity of switching between my accounts / computers. (Nov '25)

You can ask the Application Coordinator role for both companies, and you will have access to all products of both companies. Please consult the guidance for more details and/or raise a Service Desk ticket giving more details on the MAHs that you need access to.

https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20%28eAF%29%20guide%20to%20registration.pdf

5. Navigation through the PLM Portal eAF

For more information on using the PLM Portal eAF, please read the eAF user navigation guide.

5.1. Is it possible to clone a whole eAF if I want to use it for a future variation with small changes, rather than creating a new one each time?

Yes, the PLM Portal supports a "Clone Application" function. This allows users to duplicate an existing PLM Portal eAF form, including all previously entered data such as products, scopes, and proposed changes. This is useful for versioning or reusing application details.

5.2. The application form allows me to include only one reference MAH name, however, there are multiple products from different MAHs included in the variation. Is that correct?

Yes, this is as per design. In case of multiple MAHs in one dossier/authorisation/procedure request, a single reference MAH for the procedure needs to be appointed. More information can be found in the CMDh guidance: 09 CMDh 133-2010 Rev11 2024 11 clean - Explanatory notes on Variation application form.pdf, in section "Name and address of the MA Holder" and "Name and address of contact person".

The information of the other MAHs can be added in other sections of the form, e.g. contact person or Proof of Payment.

5.3. If I need to change an eAF due to comments from authorities (NCAs/EMA) and import it into a next eCTD sequence, can I edit a previous version in PLM or do I have to create a new eAF?

You can always edit an existing PLM Portal eAF form. However, if you already finalised that form and sent the generated pdf to the NCA/EMA, the better process is to keep the original form, clone that form and then edit the clone. That way, you keep a full register of your communication with the authorities.

5.4. What is the maximum number of co-authors that can be added?

There is no maximum number of co-authors that can be added to a PLM Portal eAF. However, concurrent editing is not supported, so coordination among co-authors is essential to avoid data loss.

5.5. Why can I not add all colleagues who are coordinator as Co-Author to my draft eAF?

For a proper setup of the Industry applicant roles, please check the "eAF Portal guide to registration". You and your colleagues must be affiliated to the same organisation(s). In addition, a user must have maximum 2 roles per organisation (maximum 1 applicant role; and maximum 1 administrator role).

In case the guide doesn't solve the issue, please raise an EMA ServiceDesk - Incident.

5.6. Can consultants/companies also create test eAFs for training purposes?

Yes, test eAFs can be created in the production environment of the PLM portal. Please note that the eAF UAT environment is no longer in use. The eAF production environment is fit for testing purposes. Best to title your form as 'test'. Also, you can "deactivate" your forms to move them out of the listing of the real production forms.

5.7. What do I need to do if I only see CAPs in the PLM Portal, and no NAPs?

First check if you have the correct roles, for the PMS User Interface (PUI), and for the PLM Portal eAF User Interface. Please also check that you do not have duplicate applicant roles: for each application one should have one applicant role only. If you do have various applicant roles for the same application, it is best to keep the highest role and delete the others from your profile. For eAF role assignment, please check the "eAF Portal guide to registration".

Secondly, verify that you can see the NAPs through the PUI. If you can see the NAPs through the PUI, then you will be able to see them through the PLM Portal eAF User Interface.

If you have the correct roles, but cannot see the products, please raise a service-desk incident ticket with either the PMS/Product UI team (products not showing through PUI), or with the eAF team (products not showing through the PLM Portal eAF UI).

5.8. If I am authorised as contributor for an MAH, I will not be able to select new products when I edit the form, correct? Will co-authors be able to add products?

With a contributor role, you cannot add products, but neither can you create a form/application either (see table 3 in the "eAF Portal guide to registration"). To perform the following actions (create a form, then add co-authors, then select products) you need eAF Applicant Manager or eAF Applicant Coordinator. Take care to only have one applicant role per organisation, otherwise your rights in the PLM Portal eAF won't work properly. Portal eAF won't work properly.

In the same "eAF Portal guide to registration", you will read that a co-author can only add products:

with the correct role level (Manager or Contributor) and

this role needs to be affiliated with the organisation to which the product belongs (roles are assigned per organisation, not per product).

See section 3.3.1.1. on different working models, from the same guide to registration.

5.9. How can the PLM Portal eAF be used for MRP/DCP if it is not possible to select multiple CMS (Concerned Member States)?

In the PLM Portal eAF, the concept of Reference MAH is used. The Reference MAH creates the form. The one person can:

- complete the full form, with sufficient affiliation roles with all concerned organisations,
- or can add co-authors who contribute in adding their information to the form.

Please consult the "eAF Portal guide to registration" on how to set up the roles, especially section 3.3.1.1 of real-case examples.

Also, inside the form, information from the CMS countries can be added: multiple products, from various organisations, in the product section (depending on the role/rights of the author), multiple contact persons in the procedural section, multiple Proof of Payment details in the finalisation section.

5.10. After EoP (end of procedure) for an MRP/DCP, it may take a while to receive all national MAs (RMS is not always 1st country to issue national MA). How can all affected countries (RMS + CMS) be selected in the eAF in case of a variation before all MAs available?

Specifically for such cases, PMS will allow the upload of "valid - pending national phase" products, which consequently can be selected in the PLM Portal eAF user interface.

The relevant Q&A document describing what to do if a product was authorised through MRP procedure, however, the national authorisation is still pending is available at:
https://www.ema.europa.eu/en/documents/other/electronic-submission-article-572-data-questions-answers_en.pdf

5.11. What number should be entered under 'MRP Variation Number', if the Product has a national marketing authorisation?

If the product has a national MA, the MRP Variation Number field can be left blank or marked as "Not applicable", as the MRP Variation Number is only mandatory for MRP/DCP products. If the NCA requests an MRP variation number for a national MA, please check the format with that NCA.

5.12. When we want to add an DCP to the form, is it sufficient to select the product from one country and the products from the other member states are automatically added?

No, products from each Member State must be selected individually. The PLM Portal eAF does not automatically add products from other MS even if they are part of the same DCP.

5.13. The regulation regarding variations has been revised, and among the changes, there are requirements related to annual update. Is there any change expected at the eAF level?

PLM Portal eAF and the interactive PDF eAF will be updated to support the new regulation, once the practical requirements are clear.

5.14. Is the procedure number a mandatory field for worksharing (WS) and super-groupings for NAPs included in a CP worksharing (WS) or super-grouping?

Yes, the procedure number is mandatory for worksharing (WS) and super-groupings. This ensures traceability and alignment across all involved products and procedures.

5.15. In which environment can I do some test eAFs?

The production environment can be used for testing, as it contains the full list of products. As long as the eAF is not sent to the regulatory authorities, the form is not considered as submitted.

5.16. Can I change the MAH after cloning in order to use the same application form easily also for other products with different MAH?

Yes, when cloning, the MAH can be changed. In case the MAH is changes, only part of the sections are kept in the cloned application, as a new set of products will need to be selected.

5.17. Can I add an "Alternative company name" and will this be used just as additional information?

The Alternative company name can be selected in the Procedural information section. More details can be found in the user navigation guide, chapter 2.4.2:

https://esubmission.ema.europa.eu/cessp/PLM%20Portal%20eAF%20guide%20to%20navigation%20-%20eAF%20user%20guide.pdf

The alternative company name is optional, and on the PDF both names will be displayed (the main name and the alternative name (if available and only if selected in the eAF)).

5.18. How to select that proof of payment is not relevant?

The PLM Portal automatically recognizes procedure types that do not attract a fee, for example CAP Type IA variations. For other procedures that do not have a fee, you do not fill in the proof of payment section, and pdf will display that Proof of Payment section is not applicable.

5.19. Does each section need to be Validated after filling it in?

You can validate each section at a time, but you do not have to; you can wait to run the full form validation at the time of the finalisation.

5.20. In case the web-based form cannot be edited further and a switch to the interactive PDF eAF is necessary, can this be pre-filled via data export?

No, the 2 technical solutions are completely different and there is no import available from and to the 2 versions of the forms (PLM Portal and interactive PDF), therefore when switching from one to another, the details need to be entered from scratch.

Before starting editing the PLM Portal eAF, please consult the guidance and the known issues (detailed in the release notes as well), just in case you might not be able to use if for your products.

5.21. After finalization of eAF form in PLM portal can we edit the application form further?

Yes, the form can be reopened for editing. This is done in the list of applications, 'Completed tab', you can use the action 'Reopen Application Form' and the form will move back to the draft tab. If you have already submitted the eAF, we recommend 'cloning' the application form instead if you need to edit the form to reflect validation feedback in the form. However, of course if the form has not been submitted yet, it can be finalised and reopened for editing as many times as needed.

5.22. Can we delete an eAF from the list when it is in draft and we don't need it ?

It is indeed possible to 'soft delete' draft applications by 'Deactivating' the form. This can be done from the Application form list by clicking the 3 dots at the end of the row and selecting option Deactivate Application form.

5.23. For a Type IA variation, if not all conditions for are met and I select "no" for one/some of them, will the variation automatically update to Type IB?

No, this functionality is not yet implemented as there may be some specific scenarios where this automation would not apply. The user needs to choose the correct variation type. More automated calculations can be considered for further development, based on the user feedback.

5.24. Does MRP number includes also DCPs? Do I need to include MPR procedure number for DCPs?

Yes, the DCP number is equal to the MRP number for this purpose, and it should be included if you usually include it in the interactive pdf eAF.

5.25. What to do if the billing address is not in the drop-down menu?

The organisations available in the Proof of Payment section are those from OMS. Please check if the organisation/location is available in OMS itself. If it is, however, you cannot see it in the list, please do let us know via a ServiceDesk ticket and we will investigate the issue.

5.26. Does the NCA's contact the MAHs directly if there are any problems/errors in SPOR data used in web based eAF? If not, how are the errors handled? Or Does it result in further eCTD submissions? (Nov '25)

Before sending an eAF, please verify the correctness and completeness of the data. This can be done either in ProductUI or in eAF. Once it reaches the authorities, the form might be rejected, and the products would have to be corrected, and a new form created and sent via eCTD.

The product data can be corrected by the marketing authorisation holder in xEVMPD, or by the PMS team if there is any mismatch between xEVMPD and PLM Portal (ProductUI of eAF). For this, please raise a ticket with SPOR->PMS.

5.27. For product selection, if we select medicinal products (MA) but not any of the "packaged medicinal product" associated to this MP, then is it considered that the application affect all packaging presentations? Or should we tick all of them? (Nov '25)

All the packages are selected by default in a form. Only for centrally authorised products it is possible to de-select specific packages in the Present/Proposed changes. For all other types of products (MRP/DCP, purely national products), all packages will be considered for a variation. There are ongoing discussions to adjust this behaviour. Should this change, the Release notes will be updated accordingly.

5.28. How to proceed for MRP/DCP when not all national MAs have been granted yet and we need to submit a variation. As only granted MAs are in XEVMPD, how to include the pending MAs? (Nov '25)

A recent fix has been deployed in the PLM Portal which will allow the users to select any products that was submitted in xEVMPD with the status "Pending national phase". They will be selectable as any other product in the PLM Portal.

5.29. If I have selected under product selection a wrong product by mistake, how can I delete it again? (Nov '25)

To remove a product, you need to access the "Product selection" tab, click on the line with the product that you want to remove (a red icon will be activated on the first column) and then click save.

5.30. Is there no testing environment available in PLM eAF portal? (Nov '25)

There is no separate test environment for the PLM Portal. You can use the Production environment to create test eAFs and to check the functionality. These test eAFs can be afterwards de-activated. As long as you do not send these eAFs in eCTD sequences, they will not be visible by the authorities.

5.31. Not all the MAs approved under single DCP and same MAH are visible under the product selection. How to request for the product database update? (Nov '25)

In case products are missing from the PLM Portal (ProductUI/PMS/eAF), please raise a ticket with EMA Service Desk ->SPOR->PMS

5.32. An MAH needs to submit the same variation for 2 marketing authorisations. According to the variation guide, since they are national registration of the same MAH, I can submit them as a grouping of IA. But when I fill the eAF, it is set as a single variation and not a grouping. Why? (Nov '25)

The grouped versus single regulatory activity will always be calculated based on the number of variations in a form. If there is only 1 variation, then it will always be a "Single regulatory activity".

Super-grouping refers to either several MAs or several Type IAs, and it can be "Single regulatory activity" or "Grouped regulatory activity". The rules for the super-grouping are detailed here: https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_296_2013_Rev.29_2025_02_clean_-_Chapter_6_-_BPG_for_the_Processing_of_Grouped_Applications_in_MRP.pdf (for several NAPs of the same MAH, the products must be authorised in several member states to be considered a super-grouping; please see Page 1, the paragraph 2 related to super-grouping).

5.33. What if the user missed a certain proof of payment and finalised the application form and submitted in eCTD format? What should the user do in order to add the proof of payment in this case? (Nov '25)

Please contact the product lead or the relevant health authority to get further guidance. In the case that you need to send a new sequence, you can clone the form, re-open the cloned one, and edit the missing details. You can also re-open the initial form you sent; it is up to you if you want to have all the sent versions in the PLM Portal.

5.34. Can all user-driven changes in the eAF be tracked? For instance, if a document is modified by another operator before final submission, how is the audit trail ensured? (Nov '25)

We do not currently have a report on all the changes done by the users on the forms, but we will take it as an input for future improvements in the PLM Portal, considering the added value and the cost of implementation.

5.35. Can I see somewhere how many products were selected finally for a procedure? Eg when I need to prepare a variation for 100 products, how can I check that all of them was selected? (Nov '25)

Yes, now there is a counter at the end of the table in the Product selection module.

5.36. Can we use already submitted web based eAF for new another variation by updating the existing? Or we must create new form every time? (Nov '25)

A form can be re-opened and edited; however, we recommend either creating new ones for new variations, or cloning the existing ones and editing the cloned version.

In this way, in case the initial eAF needs to be adjusted at the request of the authorities, it will still be available.

5.37. Can you delete a form once it's been created? (Nov '25)

The eAFs cannot be deleted, but they can be de-activated. A form that was de-activated will be automatically deleted after 1 year. As long as the form is still visible in the "de-activated forms" tab, they can be re-activated.

5.38. Can you please show us the Proof of Payment section, how to populate fees details ? (Nov '25)

To populate the Proof of payment, there are 2 main sections: fees paid, and fees not paid; you can add lines for each category, selecting the country to which it is applicable

Please watch this video to see it in practise: https://www.youtube.com/watch?v=hFGrV7YHJRo&t=1863s

5.39. If we only have one type IA in our annual update, justification for grouping becomes irrelevant, no? (Nov '25)

According to the regulation, the grouping refers to the grouping of several products. Super-grouping refers to grouping of products and/or grouping of variations.

Please consult the guidance and also contact the local authorities for more clarify on the type of application from the regulatory point of view.

5.40. Did I understand correctly that for a Super grouping of IA between CPs and NAPs we need to choose IB? (Nov '25)

The calculations are done automatically in the PLM Portal eAF, and some scenarios are not allowed (for example CAP+NAP and Type IA, indeed). Please review the regulation and contact the relevant authorities to understand which are the combinations that are allowed: https://health.ec.europa.eu/document/download/bab1cd14-f7ad-46f2-98d1-9b108b1df1d1_en?filename=mp_marketing-authorisations_variations-guidelines_en.pdf

5.41. Fee Payments: How should we handle if there are no fee payments necessary, because they are covered via annual fee? (Nov '25)

You can fill-in the section "No relevant fees have been prepaid to competent authorities". In the window with the payment details you can specify the member states where it is applicable and the reason for the lack of payment (for example "covered by annual fee").

5.42. In previous eAF, there were sections for documents and conditions after selection variation category? Is it not available here? (Nov '25)

They are available in the PLM Portal eAF as well, after selecting a scope, the type of variation (for example Type IA), as well as the conditions and documentation are shown of the page to be confirmed.

5.43. On the first page when you enter a "friendly name", is this name shown only for me as the author? (Nov '25)

The name is available for all the users who have access to the form. The friendly name will not appear in the PDF, it is simply used to easier identify the content of a specific form.

5.44. Will it be possible to save some kind of template eAF where we have added all products in the procedure to be able to easier start the next application? We have several procedures with many products included. (Nov '25)

Yes, you can create forms that you name in a meaningful way for you. You can leave these eAFs in draft, and you can clone them whenever you want to work on a new variation.

5.45. Is there a section available to complete the conditions and documentation requirements for the variation, as was provided in the previous version? (Nov '25)

Yes, they are available in the PLM Portal eAF as well. After selecting a scope, the type of variation (for example Type IA), as well as the conditions and documentation are shown on the page, and they must be confirmed (ticked), or a note can be added in case they are not applicable for the form.

5.46. One of our contact persons is a freelancer. The previous existing OMS account was deactivated because local contacts can be entered manually in pdf

eAF. How should we include this contact in web-based eaf as "company" is a mandatory field? (Nov '25)

We will re-discuss this topic and the mandatory selection of OMS organisation, knowing that it is not possible to add single persons as organisations. We hope to find a quick solution. As a workaround, please select the Reference MAH of the form and add in the Cover letter the correct details.

5.47. If there are several Company names registered with the same Loc-ID, can the alternative Company Names be chosen or is it always the "default" name as currently in the PDF eAF? (Nov '25)

For the reference MAH, in the Procedural Information tab, one Alternative name can be selected if desired and if available.

5.48. Will an old version of the eAF be available in the portal in case we need to submit responses during a procedure and will need to use an old version of the form? (Nov '25)

Yes, all the forms are available in the portal. If the eAF is in status "Completed", you need to navigate to that group of forms, re-open and edit the form or clone the form and edit the cloned version (which you can afterwards send as a response sequence).

6. Present and Proposed

6.1. Will the product variations always be included in the annex or will they be integrated into the eAF?

Not all variations will be integrated directly into the PLM Portal eAF. Some changes will still require annexes, especially when detailed descriptions or supporting documentation are necessary. Each case is unique, and while entry of structured data changes will be implemented, annexes remain essential for certain types of changes.

6.2. How can "editorial changes" be entered in the application form, for example to the product information, in addition to changes with a specific scope?

Editorial changes should be clearly identified in the PLM Portal eAF 'Present and Proposed' section. A brief description should be included in the Precise Scope, along with a declaration that the changes do not alter the content beyond the scope of the variation within which the editorial changes are being submitted. These changes should be listed in the Present/Proposed table, with justification for why they are considered editorial (i.e. why they should not trigger a specific variation). This can be done directly in the PLM Portal eAF or as an attachment to the PLM Portal eAF PDF.

Detailed guidance on editorial changes is available here: https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/classification-changes-questions-answers

6.3. Is there a plan to add in the eAF variation the manufacturing business operation type (like in section 2.5 of the eAF MAA) to capture the manufacturing change (addition/replacement/removal)?

Structured changes are a key objective for future developments. The plan is to allow users to propose updates in a structured manner as part of the eAF process. These changes will include also manufacturing business operation types*. Concrete dates for these implementations are not yet established.*

6.4. Is the declaration of the applicant about the submission(s) of the same variation in other Member States / EMA: "The applicant confirms that the same variation (or group of variations)…" also applicable for homeopathic products?

Following the amended variation regulation effective 1 January 2025, this declaration is included in the PLM Portal eAF. We are not certain that this applies also to homeopathic products. If you use the form for homeopathic products, please check the updated regulation, and in case of any deviations, please put an update in the "Note" field to avoid any unjust rejection by the relevant Member State.

6.5. Why do I see different OMS details in the present/proposed section, specifically in the "Add present/proposed organisation"?

There are currently some issues with the data layer that uses the OMS data in conjunction with the product data. We are currently working on a fix to ensure that the organisational data in the present and proposed section is read from a different table, and this will allow more direct updates of the OMS data.

6.6. The sections titles in the present/proposed section are not exported to the finalised eAF. Only 'Text' is displayed instead of the title. Is this a known issue?

This is the expected behaviour. The names of the sections are there only to help the user navigate through the sections. The "text" that appears in the first column is based on the existing NTA form (and interactive PDF).

We are working on changes to improve the visibility of the present/proposed, which will most likely omit the column containing only "text".

6.7. What is the process for an addition of an organization/manufacturer (ORG ID)?

The business rules in web-based form are currently like those in the interactive pdf: the present organisation field can be left empty, and the proposed organisation is mandatory and must be selected from OMS.

6.8. What is the process to specify that an organisation (ORG ID) is deleted, in the present/proposed section?

For a deletion of a manufacturer, the removed/deleted organisation ID must be specified in the present/proposed free text field. The "Add present and proposed organisation" must not be used for this case, as a deletion is not considered a standard change in the organisation.
A future development will make it more intuitive to mark a deletion of the organisation.

6.9. The text I pasted in Present/Proposed free text field does not look well formatted in the exported PDF. What shall I do in this case?

When copying and afterwards pasting formatted text into the Present/Proposed free text fields, sometimes the formatting is not well interpreted by the portal, mainly because there are too many styling elements, sometimes not even visible in the text. The recommendation is to clear the formatting (in a simple text editor, for example), to paste to text again in the PLM Portal eAF, and apply the formatting which is available in the portal.

6.10. Can we place pictures in present and proposed? (Nov '25)

Yes, you can insert images in the present/proposed free text fields. Please make sure the size is small enough to not interfere with the size of a "normal" PDF.

6.11. For present/proposed section: is it acceptable to refer to a separate document (e.g. "variation overview") or we must add here this information in details? (Nov '25)

The PLM Portal eAF should be used the same way as the interactive PDF eAF. The practise of adding additional annexes is not recommended, but if the health authorities accept it and ask for it, please comply with the requirements.

6.12. How and by when will the eAF reflect if a submission is concerning an annual update? Previously you have mentioned that it should be reflected in the present/proposed as an interim solution. Will it be a drop down/tick box? (Nov '25)

The analysis of the implementation will take place next year and it will be made available for the annual update of 2026. For now, please use the method explained in the session (in the Background for change and in the Cover letter)

6.13. How can purely editorial changes be included in the present/proposed? In an own section or using some kind of colour code? (Nov '25)

The editorial text changes can be added the same way as before (like in the interactive eAF PDF): they can either be added in the "Background for change" or in one of the scopes in the free text fields "Present and Proposed", with a mention that they are just editorial changes.

6.14. How to provide the present proposed for manufacturing site addition? Should we add all the present sites in text area of present and proposed section and only add the proposed new sites in proposed site area from OMS? (Nov '25)

Some authorities ask for the full list of organisation in both present and proposed, and additionally the new ones in the "Proposed". For other authorities, only the changes are to be added in the Proposed organisation.

I suggest you contact the health authority before sending the eAF.

6.15. How would you suggest marking the changes in the present and proposed section using this eAF? Usually, we mark it in bold. (Nov '25)

Please use the same methods as you have been using in the interactive PDF eAF. In the free text fields of present and proposed you can use several formatting options, such as bold, italic, strikethrough, highlighter etc. It depends on the change you want to show.

6.16. In the present-proposed table, can we paste a text or image that we have copied from an external document? (Nov '25)

Yes, you can paste text from another source. However, make sure you do not paste elements which can be mis-interpreted by the portal. To verify that, after adding the text, Export the form and check how the present/proposed look like. If necessary, clean the formatting and re-apply in the PLM Portal.

6.17. Is copying of changes in track change mode possible into the present-proposed section? (Nov '25)

It is not possible to see the changes as you would o in a Word document, however there are HTML/styling elements that you can use to highlight the changes in "proposed" compared to "present" (for example highlighter, strike-through, different colours; the menu is above each free text field).

6.18. For non-CAP why can't we choose only some packages? Not all changes apply to all packages. (Nov '25)

The current setup, as decided together with Subject Matter Experts and CMDh, does not allow the de-selection of packages for non-CAPs. We are re-discussing the topic with the same groups, and potential changes will be made and announced on the PLM Portal.

6.19. Is it possible to do the present and proposed in a separate word document as done currently? (Nov '25)

The PLM Portal eAF should be used the same way as the interactive PDF eAF. The practise of adding additional annexes is not recommended, but if the health authorities accept it and ask for it, please comply with the requirements.

7. Integrity Stamp, signatures, finalisation and export

7.1. By using the Finalization process, isn't it necessary to validate section by section?

The 'Validation' button in each section checks that specific section for completeness and accuracy, also in relation to the other sections. The 'Finalisation' button triggers a validation of all sections.

Even though a manual validation section-by-section is not a prerequisite for the finalisation process, such manual validation before finalising is still good practice.

7.2. Will forms without the integrity stamp be rejected? What about forms generated via the interactive PDF eAF?

Forms created using the interactive PDF will not be rejected due to the absence of an integrity stamp. Those forms remain valid under current rules. The integrity stamp is only applicable to forms generated via the PLM Portal.

The forms created with the Interactive PDF will remain exactly the same and there will be no check for the integrity stamp, so they will not be rejected. The integrity stamp will be verified only for the forms created in the PLM Portal.

7.3. Will the Integrated stamp make the form technically valid?

Yes. The integrity stamp confirms that the PLM Portal eAF PDF was generated by the PLM Portal system and not manually altered. This serves as a technical validation. Note that one may try to tamper with this pdf, but the end-result will never be the same as this integrity stamped pdf.

Note that the certificate request for this EMA stamp is in progress. Nevertheless, the current version is technically valid and should be acceptable for the authorising NCA.

7.4. Will the integrity stamp replace the signature by the applicant?

The integrity stamp confirms the form was generated by the PLM Portal, which is sufficient for submission to most NCAs.

However, some NCAs or applicant company policies may still require a digital signature in addition to the integrity stamp. See relevant integrity stamp section of the web-based eAF user guide for more info on how to do this.

7.5. How is the web based eAF signed in the end before eCTD submission? Are eSignatures usable?

Upon finalizing the form and exporting it as a PDF, the form receives at the bottom a technical EMA signature, called the 'integrity stamp'. This is a technical insurance that the pdf has been generated from the PLM Portal eAF user interface and has not been manually edited afterwards. The only signatures that can be added as of now, are digital signatures i.e. 'certificates'. Adding an image or any signature that requires editing of the pdf, is no longer possible.

Note: such digital signature is optional, though some applicant company policies and/or NCAs may still request it.
Note: Tampering the integrity-stamped pdf (e.g. by exporting into MS Word then adding the manual signature, then converting back into pdf), will change the pdf. This tampered pdf is clearly distinguishable from the integrity-stamped pdf e.g. the embedded FHIR XML attachment.

7.6. How will the signature of the new form change?

The signature process remains flexible. While the integrity stamp confirms the form's origin from the PLM Portal, users may still apply a digital signature post-export. This is especially relevant for NCAs or companies that require an additional layer of authentication.

7.7. What about the digital signature? Can it be added after the export or not?

Yes, a digital signature can be added after exporting the form. However, care must be taken to ensure that the added digital signature, or the FHIR XML attachment embedded in the PDF, is not altered or removed during the signing process.

7.8. Does the person in charge of the eAF signature (different from the one filling in the eAF), need an eAF role?

No, the person signing the form does not need a specific PLM Portal eAF role. The responsibility lies with the signatory, not the preparer (the person who fills in the PLM Portal eAF form).

7.9. Will a MAH signature become mandatory with the web eAF?

The integrity stamp is considered sufficient for submission. Some NCAs or internal policies may still require a MAH signature.

7.10. What should be done if digital signature is required, but Adobe is not compliant? What are the options?

If your company does not have qualified digital signature tool, which is compatible with the integrity stamp which was implemented using a digital signature tool, it is possible to either save a separate copy of the form, without the xml and integrity stamp (export prior to finalisation) and sign this copy which should be provided as an annex to the application form. Alternatively, the exported pdf can be 'printed' and signed and scanned in and provided as an annex.

7.11. Can an eAF have 2 signatories?

Yes, up to two names can be added in the PLM Portal eAF user interface, under 'signatories' in the 'finalisation' section: one as main signatory, and one as additional signatory.

The 'finalised' PDF, generated by clicking the 'finalise' button existing in each UI (User Interface) section, can be signed by as many people as you wish, but only with a digital signature.

7.12. Will the manufacturing activities (as stated in IDMP IG chapter 3) be included as structured data in the variation PLM Portal eAF?

Structured data in the present/proposed section of the PLM Portal eAF is under analysis and development. The intention is to display the short name of the manufacturing activity from the corresponding RMS list. The granularity of the controlled vocabularies will be aligned between systems (eAF, PMS etc.). Details will follow at a later stage.

7.13. Are supporting documents to the application form (for example: comparative batch analysis, statements from the manufacturer, acceptance of letter of intent etc.) also to be included in the PLM portal?

No. The supporting documents are not to be uploaded in the PLM Portal. They need to be sent them together with the PLM Portal eAF PDF, through eCTD, to the regulatory authority for authorisation. The PLM Portal eAF has the same functionality as the interactive PDF eAF.

7.14. Will there be coming an import functionality to import FHIR message with data to fill/create eAF?

An API or import functionality was included in the scope of the PLM Portal eAF product roadmap. However, detailed timelines for its analysis, development and release are not yet available.

7.15. Can the PLM Portal eAF PDF be renamed after export?

The PDF can and should be renamed so that is complies with the eCTD specification.

7.16. Can you explain how to sign eAF with Adobe scanned signature and submit it when required by EU Authorities? And what should be done for EMA if MAH wants to sign the form? (Nov '25)

This list contains all the national requirements for eAFs:
https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/eSubmissions/CMDh_006_2008_Rev_28_2025_06_clean_-_eSubmission_for_Variations_and_Renewals.pdf

For submissions to EMA, the integrity stamp generated by the PLM Portal is all that is required.

For national submissions, should a particular regulatory authority ask for an additional signature, the following options are available:

- you can finalise the form and add another (or more) certified signatures; the form will allow this.

- you can export the form before finalisation, and in that case you can add an un-certified signature (for example Adobe Signature); Adobe signatures are now allowed once the form was finalised and it has the EMA integrity stamp; this form should be added as an annex, alongside the form that you can finalise in a final step and will contain the EMA integrity stamp.

7.17. Could you please address the error message that appears in the signature panel of the PDF form? The error message states 'At least one signature has problems' - is this a known issue? (Nov '25)

That message signifies that the certificate is not final. We are in process of updating the certificate, but the form is valid even with that message.

7.18. Has the number of additional signatures changed? (Nov '25)

For the signatories, one signatory is mandatory, and a second one is optional.

7.19. I am a regulatory affairs specialist and I'm filling the eAF. On the finalization page, who should I include as contact? Is it myself, who filled out the eAF, or my manager, who until now has signed the eAF? (Nov '25)

The process hasn't changed compared to the interactive PDF eAF. If you were the one on the signatories part, you can continue to do so. If it used to be your manager, then you can add the manager's name.

7.20. If eAF is cloned in order to generate a national eAF, is it best to clone prior integrity stamp is included? (Nov '25)

The cloning in the PLM Portal can be done at any time. The cloned eAF can be then re-opened and then re-exported without the integrity stamp.

7.21. Can multiple signatures be added for each contact person at the end of the web-based form? (Nov '25)

Please note that in the signatory area 2 entries can be added.

For signing/certifying the form, this list: https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/eSubmissions/CMDh_006_2008_Rev_28_2025_06_clean_-_eSubmission_for_Variations_and_Renewals.pdf contains all the national requirements for eAFs.

For EMA forms, the integrity stamp generated by the PLM Portal is all that is required.

For national submissions, should a particular regulatory authority ask for an additional signature, the following options are available:

- you can finalise the form and add another (or more) certified signatures.

- you can export the form before finalisation and add an un-certified signature (like Adobe Signature); (Adobe signatures are not allowed once the form was finalised and it has the EMA integrity stamp); this form should be added as an annex, alongside the form that you can finalise in a final step and will contain the EMA integrity stamp.

7.22. Is the layout of the current and proposed sections displayed correctly in the exported PDF when the entire width is used on the web? (Nov '25)

The exported PDF was designed to display the content of present/proposed in an optimal way, to make the content readable and to fit as much as possible the size of a standard document. However, should the content have pre-formatted text, this could be rendered in an un-readable way.

Please check the present/proposed section before sending it to authorities, and should you notice any area that does reflect the intended structure, remove any additional formatting and re-export the form to re-check and re-adjust if needed.

7.23. Once exported to PDF, how should be updated? Could the exported pdf be edited? Or do we need to go back to the PLM portal? (Nov '25)

The PDFs exported from the PLM portal cannot be edited. The eAFs can be edited only in the web interface, in the PLM Portal, and exported as many times as needed.

Once an eAF is Finalised, it cannot be edited anymore. If you need to edit the form after finalisation, you can Re-open the form. Please consult the guidance to learn more on how to perform these steps.

7.24. Will the web based eAF be used by EMA during the review or only the exported PDF? (Nov '25)

The authorities will have access to the PDF (and the FHIR XML which is attached to the PDF). The authorities do not consult for the moment the web application. Nevertheless, the information is the same in the web interface and the exported PDF.

8. Other systems (PMS/Product UI/xEVMPD)

For all PMS/Product UI/xEVMPD questions, please consult the relevant guides, most of which can be consulted under the PLM portal -> Product Management Service (PMS) -> PMS Guidance. For further guidance on documentation links, see chapter Support and Documentation

8.1. What PMS data is used in PLM Portal eAF and where can I find more information?

For a full list of the PLM Portal eAF fields, including those consumed from PMS, please consult the eAF FHIR XML - Release Notes. The page contains the latest FHIR Mapping and the columns AF ("PMS Business Review") from "Medicinal Product" tab and "T. Business rule " (with text "Populated from PMS") from the "Variation" Tab indicate the relationship with PMS data.

Note: Currently only some of the PMS fields are used in the PLM Portal eAF. More PMS fields will be integrated with eAF with the upcoming implementation of structured changes (e.g. ATC code).

For a full list of PMS fields, please check EU IG Chapter 2.

8.2. Is there a plan for a two-way integration between PLM Portal eAF and PMS: e.g. NCAs identify the variation(eAF) as approved and trigger an update of PMS data? Will the proposed changes from the PLM Portal eAF be pushed automatically to PMS upon approval?

The current process remains in place, and all the changes must be submitted through the known channels (e.g. xEVMPD).

A wide group of stakeholders are currently reviewing different options for a future target operating model (TOM) which will streamline the process.

8.3. What should I do if the selected products have missing or incorrect data?

First, review Chapters 7 and 9 of the EU IG. Also, review the PMS/ProductUI/xEVMPD guidance and Q&A documents. If the issue persists, please open an EMA ServiceDesk ticket, making sure you select the correct category.

8.4. How can I check my PMS product data?

Please consult the Dynamic product reports in the PLM Portal PMS User Interface.

For example, to see details about manufacturer operations, please use the specific "All manufacturing operations" report. For more information on how to use and update the product data, please consult the PMS guidance.

8.5. Is the PMS list of products updating automatically or should the MAH update the PMS list with NAPs?

The list of products is updated automatically in PMS, based on the data existing in xEVMPD. For more details on the xEVMPD-PMS synchronisation, please consult the PMS/ProductUI guidance.

8.6. The data in PMS is currently not reflecting the xEVMPD updates accurately. When is this expected to be resolved to support the strongly recommended use?

The PMS, IRIS and PLM Portal teams are collaborating and working on solving the existing integration issues. Please read the announcements and banners published on the PLM Portal to be aware of any existing issues, and proposed alternatives.

8.7. If my current and proposed ORG name is not available in SPOR, how can I proceed? (Nov '25)

First you need to submit a request to OMS for adding the organisation. After the new organisation is created, it will be accessible in the PLM Portal as well.

8.8. In case of duplicated MAs appears or missing MAs, which is the best way to proceed to fix it? (Nov '25)

Firstly, the products need to be verified in xEVMPD. If they are correct there, but incorrect in PMS and PLM Portal, then yes, a ticket must be raised for the PMS team.

8.9. We have noticed that not all Member States involved in the procedure are appearing in the eAF dropdown. This may be due to incomplete data enrichment in PMS. Could you please advise on how to resolve this issue? (Nov '25)

When creating a variation for MRP/DCP products, the member states which are available in the dropdown menu(s) in Procedural Information (Reference member state and Concerned Member state) will be the member states from the selected products in the variation. The RMS/CMS in this case are the member state responsible and concerned for the current procedure, not the RMS/CMS of the product(s). We understand the way the member states appear in the dropdown selection for RMS/CMS could create concerns and following discussions with subject member experts and national authorities, we will proceed to either expand the selection with more Member States or further explain the terms and their applicability.

8.10. Why differs a company name in the PMS selection menu from the name registered in SPOR? Which one is considered as correct? How/who shall align the information? (Nov '25)

The name in OMS (SPOR) is the correct one. The synchronisation between OMS and the PLM Portal goes through an intermediary EMA system (IRIS Dataverse), which is used for other applications as well (for example inspection, parallel distribution etc.). For this reason, the data in the PLM Portal is not always identical with the OMS information. Please raise a Service Desk request to flag inconsistencies.

8.11. You mentioned that some products are missing in the web based eAF and work is ongoing to add these. Can I proactively ask EMA to add some missing products? (Nov '25)

Please verify in the "Products of my organisation" menu the completion of the list. Or create an eAF and in the product selection browse through the products of your organisation.

There are other several menus for PMS (please consult the PMS guidance for more details), and should you identify any missing products (although they are in xEVMPD), please raise a ticket with the SPOR->PMS team.

Back to top

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000
An agency of the European Union