Information Management

November 2022

Human Variations eAF go-live Q&A session (8 November 2022)

Questions and Answers

Disclaimer

This Question and Answer (Q&A) document is for information only and is based on insights available at the time of the Human Variations eAF go-live Q&A session held on 8 November 2022. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the eAF (DADI) and PMS product teams.

For convenience, many technical terms are explained in the table of abbreviations at the beginning of this document.

For general inquiries, please contact the eAF (DADI) team via esubprogofficer@ema.europa.eu or the PMS team via the EMA Service Desk. For questions or comments around the content of this Q&A document, please raise a ticket via the EMA Service Desk.

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Acronym key and glossary terms

CAP	Centrally Authorised Product
DADI	Digital Application Dataset Integration
DCP	Decentralised Procedure
eAF	Electronic Application Form
EMA	European Medicines Agency
ePI	Electronic product Information
IRIS	EMA's Regulatory & Scientific Information Management Platform
MAH	Marketing Authorisation Holder
MRP	Mutually Recognised Procedure
NAP	Nationally Authorised Product
PMS	Product Management Services
Q&A	Questions & Answers
UAT	User Acceptance Testing
xEVMPD	Extended EudraVigilance medicinal product dictionary

1. General information about the PLM Portal – eAF

1.1. When will the PLM portal go live?

The PLM portal is already available via this link: https://plm-portal.ema.europa.eu/

1.2. The correct name for DADI is "PLM portal eAF"?

The Product Lifecycle Management (PLM) Portal is a Portal that applicants can fill in to generate electronic Application Forms for European Regulatory Procedures and to update Product Data (PMS and ePI will be in the same portal in the future). DADI refers to the name of the project, even though we are trying to rename it as we have moved to an Agile Project Management approach.

1.3. When does web-based eAF become mandatory for NAPs?

Please refer to the following link:
https://esubmission.ema.europa.eu/gateway/DADI_newtimeline.pdf

We have not yet started the transition period towards the mandatory use. The team is currently working on the release that contains the Nationally Authorised Products. Once we have provided a version that covers all necessary scenarios i.e., the functionality covered by the interactive PDF eAFs, we will trigger the transitional period which will last 6 months leading to the mandatory use. The timings will be confirmed at a later stage.

1.4. When will eAF become mandatory for centrally authorised products?

Please refer to the following link:
https://esubmission.ema.europa.eu/gateway/DADI_newtimeline.pdf

1.5. Are the new forms planned to be used for MAAs and Renewals, and what is the timeline?

For the moment, only variation form is available. For MAAs and Renewals, the PDF form should be used.

1.6. When will the current PDF be refused in order to use this new eAF (variation form)?

The existing interactive PDF form can be used for new procedures until the end of the transitional period. If your procedure has started before the end of the transitional period, it is recommended not to change the form in the middle of the procedure. Timelines will be announced well in advance to give users sufficient time to prepare.

1.7. Is there any test system for eAF?

Yes, there is a test environment. The ALPHA UAT colleagues and colleagues that were involved in the BETA UAT, the larger external user acceptance testing, still have access to the test system and can execute it. As soon as new features and functionalities will be released, we foresee a larger external UAT testing. More details on the timing and approach will be announced timely for the participants and stakeholders to have sufficient time to prepare.

1.8. How long will the drafts, deactivated or completed forms be retained in PLM?

The retention period for drafts and completed forms is 2 years, while for deactivated forms it is 1 year. Before anything is automatically deleted, you will be notified. Please note that if you make any changes in a draft or in a form, the 2 years period will be restarted respectively.

1.9. How will the products be available in the PLM portal? Will they be retrieved from xEVMPD? After my login to the PLM portal can I see our products?

For the moment only Centrally Authorised Products are available in the portal coming from PMS. By the end of Q1 2023, non-CAP products coming from xEVMPD will be available.

2. Identity and Access Management in the PLM Portal – eAF

2.1. How much time does it take to have an admin role approved by the EMA?

Admin access role requests are managed (approved/rejected) by the EMA. The EMA aims to process all admin access role requests as soon as possible. You should receive an e-mail notification as soon as you successfully submit an access role request as well as when your request has been handled by the EMA. In case your request takes an unreasonable amount of time to be processed, please contact the EMA Service Desk.

2.2. What was the background for creating three different roles in preparing eAF? Could you please give some examples of working flow to get the best from the new platform?

For a given Organisation: Coordinators have full access to all created application forms and are able to create/edit/manage their own application forms; Managers can create/edit/manage their own application form(s); Contributors have limited permissions, they can just edit an existing application and select a classification. The Contributor role is useful when someone needs help in filling in an application form.

Different roles were created to ensure data confidentiality and integrity so that users who should not have access to commercially confidential data cannot see it.

2.3. How long does it take from approval of a role in EMA Account Management to the role becoming effective in PLM?

We try to approve requests in EMA as soon as possible. Once approved, you will be notified with an e-mail. From the moment your request is approved by your Organisation Administrator, it takes approximately 45 minutes for the role to become effective in PLM portal. You may want to directly contact the administrator user within your Organisation to speed up the approval process.

2.4. Can the eAF Applicant Manager select classifications?

Yes, the applicant manager, as well as all other roles can select classifications.

2.5. When it comes to revoking your PLM access role, should the users do this by themselves through the EMA Account Management Portal?

Access roles can be revoked either by the Applicant user himself/herself or by the Administrator user(s) of the Organisation to which that role pertains to. It can be done in the "Manage Access" section of the EMA Account Management portal.

2.6. What role should you have when you are managing dossier from other MAH?

It is very hard to give a generic answer. The role depends on the type of affiliation that you have for the other organisation. Each organisation may have very different

rules and procedures related to the access given to users coming from other organisations. It is good to bear in mind that some roles give access to commercially confidential information and that may impact the decision on the role given.

2.7. Can all members within the same team have the coordinator role?

Yes, the EMA does not limit the number of each type of role. Each organisation decides which type of role to give to their users.

2.8. Does it mean that the Applicant Manager must create /initiate the eAF and not the consultant in charge of filling the eAF?

Ideally the consultant has a role that allows them to fully manage the form filling procedure from start to end, but this of course depends on the relationship between the MAH and the consultancy. A consultant can have an Applicant Manager role or Coordinator role for a MAH.

2.9. Where is the link to the template for "Proof of Authority" for the administrator role?

Please follow this link: https://register.ema.europa.eu/identityiq/help/affiliation template.docx

2.10. Once the role is granted to a person can it be changed in the future for the same person?

Yes. Granted roles can be revoked and a new role request can be then submitted. Please make sure that at any point in time, you have only one applicant related role and one Administrator role (if applicable) per each Organisation you belong to or act on behalf of.

2.11. If I am a coordinator and I am creating an eAF including another colleague as co-author and he/she has a contributor role, can I upgrade this person to e.g. a manager role for this specific application?

Yes. The Administrator user or the user himself/herself should first revoke the contributor role. Then, the Manager role request can be submitted. Please make sure that at any point in time, you have only one applicant related role and one Administrator role (if applicable) per each Organisation you belong to or act on behalf of.

2.12. You just mentioned 4 options for the MFA. However, only 3 of them are explained (SMS, call, or Microsoft app). What about the verification code?

Within the Microsoft Authenticator app, you have two MFA methods: you may confirm your identity by approving/denying a pop-up question, or by inserting the code that is automatically generated in the app. Other than that, you can opt for SMS or call.

2.13. If I have admin rights for IRIS portal, do I need additional admin rights for eAF (PLM portal)?

No. The User Admin role is shared with IRIS and the PLM Portal – eAF.

2.14. How many industry administrator roles are allowed per company?

The EMA recommends having at least two User Admins per each Organisation. There is no limit on the number of User Admins per Organisation.

2.15. Is it possible for the same person to have administrator role and eAF applicant coordinator?

Yes.

3. Navigation through the PLM Portal – eAF

3.1. Could you please share the link where the training can be found afterwards?

It will be posted in the EMA YouTube channel:
https://www.youtube.com/user/emainfo/videos

3.2. Is it possible at any stage of filling out the eAF to save and export the Form, even if it is not completely filled in and validated?

Yes, it is possible to save the form at any stage. It is also possible to export the form at any point to view how it will look in PDF format and then return to the web form to continue filling it in. This can be done as often as necessary.

3.3. How does it work for a MRP if you have different MAHs in the involved MS?

Currently, the forms are serving only for centrally authorised products. We will address this question when the nationally authorised products, including DCP/MRP, are available in the form.

3.4. Why this form is not applicable for DCP/MRP? What will happen once it is superseded?

Non-CAP data has not been migrated to PMS and, therefore, those products are not available yet in the DADI form. The plan is to have those products by the end of Q1 2023.

3.5. Is it possible to "re-use"/ "clone" a form for another procedure and then adjust it?

The "clone" or "copy" feature is not yet available as it is something technically very complex to provide and it is not a mandatory feature. It is strongly recommended to create a fresh form instead of re-using a previous submission to avoid unintended changes.

We are working to implement a "clone" or "copy" feature.

3.6. Can you please tell me if currently the products contain prefilled pens and syringes needed to follow the old eAF but not new web-forms?

For those products it is recommended to use the old PDF eAF. These products are not split based on the Name of the medicinal product (they don't follow IDMP). They will be updated soon, so we recommend not to start variations for these types of products using the web-based form at this point of time.

However, the products are available in the form and it is of course possible to test and fill in the forms for also these types of products to gain experience on the use of the form. Applications received using the new web form will not be rejected, however, it is strongly recommended not to use the web eAF for longer procedures such as

Type II variations at this point of time in case the procedure is still ongoing at the time of the data update in the system.

3.7. What is the recommended way to check the migrated product data?

PMS contains all the data migrated, but for the moment in the DADI portal only some fields are displayed. Therefore, only those fields can be checked. You can find this information in your list of products.

3.8. What happens, if two colleagues are working on the same eAF in parallel?

There is no feature that indicates that two people are working simultaneously on the same form. We advise you to coordinate with the other colleagues who have to edit the form to avoid overwriting. We have in the backlog a feature which could at least highlight the presence of other people working in the form at the same time to prevent the loss of other's changes.

3.9. Is transfer considered to be a variation or should the PDF form still be used for MA transfers? Will it be possible in the future to use PLM for MA transfers?

Transfers of MA are not considered variations. The existing PDF form can continue to be used for Transfers for now. We are already discussing with the regulators how this procedure might be covered in future.

3.10. Will you explain again how to fill in the eAF?

You will be able to watch again the recording of this session on the EMA YouTube channel.

3.11. Does this application also support MRP/DCP licenses?

Not for the moment as these products are not available in the PLM portal. They are supposed to be included by the end of Q1 2023.