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Human Variations eAF-PMS Frequently Asked Questions (FAQs) Document

Questions and Answers

Disclaimer

This Frequently Asked Questions (FAQs) document is for information only and is based on questions frequently asked during the Human Variations eAF Q&A Clinics (15 November 2022, 22 November 2022, 29 November 2022, 14 December 2022, 19 December 2022), Trainings (8 November 2022, 15 December 2022) or inquiries received from the product teams. 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
CMS	Concerned Member State
DADI	Digital Application Dataset Integration
DCP	Decentralised Procedures
eAF	Electronic Application Form
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
EU	European Union
FAQs	Frequently Asked Questions
FHIR	Fast Healthcare Interoperability Resources
IG	Implementation Guide
IRIS	EMA's Regulatory & Scientific Information Management Platform
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
MRP	Mutual Recognition Procedures
NAP	Nationally Authorised Product
OMS	Organisation Management Services
PLM	Product Lifecycle Management
PMS	Product Management Services
Q&A	Questions & Answers
RMS	Referentials Management Services
SIAMED	EMA database for Centrally Authorised Products
SMS	Substance Management Services
SPOR	Management Services for Substances, Products, Organisations and Referentials
UK	United Kingdom
xEVMPD	Extended EudraVigilance medicinal product dictionary

1. General information about the PLM Portal – eAF

1.1. When will the transition period to mandatory use of the Human Variations electronic application form (eAF) start?

The transition period to mandatory use of the Human Variations web-based eAF will start when all the necessary functionalities and features supported by the current PDF forms will be included in the web-based form. Before starting the transition period, it is essential that all the features required for mandatory use of the web-based form are available. Moreover, the transition to mandatory use of the web-based form should be aligned for both nationally and centrally authorised products.

The specific timeline for the transition period will be communicated to impacted stakeholders well in advance and publicly announced on the [Product Lifecycle Management \(PLM\) Portal Forum page](#) and on the [eSubmission website](#).

1.2. How and when will the split of specific Centrally Authorised Products (CAPs) and Nationally Authorised Products (NAPs) be released for use in the web-based eAFs?

In order to split specific CAPs and release NAPs products in the PLM portal for use in the web-based human variations eAF the following steps should be followed:

1. Load products into the test environment;
2. Load products into the UAT environment;
3. Test data quality and migration rules in the UAT environment;
4. Investigate issues, address them and repeat the previous steps;
5. Once ready, bring the migration of product data into the production environment.

The products will be gradually uploaded on the PLM Portal. Users are invited to check the [EU Implementation Guide Chapter 7 on migration rules](#), as well as the PLM Portal Forum and eSubmission website for information around the start and completion of the split CAPs and NAPs upload.

1.3. If applicants experience issues using the Human Variations eAF before the end of the transition period, will it be possible to revert to the PDF application form for individual submissions?

Yes, once the transition period starts, until its end, applicants are free to select whether they wish to use the PDF form or the new web-based form for their application. It is not mandatory to use the new form before the end of the transition period.

At the current stage of development, a validation issue could occur or there might be a limitation in the form that was not foreseen at the time of the submission. If applicants have already submitted an application using the web-form and have received a validation comment from EMA, in case they cannot fix the validation issue using that web-form, they can revert to the PDF following explicit agreement from EMA. However, the preference is not to change the form during an ongoing procedure.

1.4. Are web-based forms planned to be used for Marketing Authorisation Applications (MAAs) and Renewals?

For the moment, only the Human Variations web-based form is available through the [PLM Portal](#), while the PDF form should be used for MAAs and Renewals. As per the plan, other forms will be developed for MAAs and Renewals. The intent is to transition all the main application forms to web-forms.

1.5. Is the web-based eAF applicable for UK submissions as well?

No, it is not. The web-based eAF only applies to EU procedures.

1.6. What is the difference between the IRIS Portal and the PLM Portal?

The [IRIS Portal](#) is a secure online platform for handling product-related scientific and regulatory procedures with EMA, such as Orphan designation, Scientific Advice or Parallel Distribution procedures. Through IRIS, users can directly make submissions for certain procedures, however the regulatory application forms will not be included in this platform, as IRIS only covers EMA procedures.

The [PLM Portal](#) currently hosts the electronic application form for Human Variations. The web-based eAFs will in future support applications for both centrally as well as nationally authorised products and hence are not exclusively applicable to EMA procedures.

Another difference between IRIS and the PLM Portal is that while users can submit applications directly through IRIS, there are currently no plans to allow submission of the eAFs through the PLM Portal, as the PDF is exported and submitted as a part of the submission package through a different channel (eSubmission Gateway).

1.7. Is the PLM Portal supported by all common Internet browsers?

The PLM Portal can be accessed via Google Chrome (latest version) and Edge (including the new, Chromium-based Edge). No official testing has been done using other browsers, such as, for example, Safari 12 and above, Firefox (latest version), Vivaldi, etc.

1.8. How does SPOR interlink with eAF at present?

SPOR services support the data entry of product information in the web-based application form. The following SPOR services apply:

- The Substance Management Services (SMS) provide standardised master data terms aimed to identify the ingredients and materials that constitute a medicinal product.
- The Organisation Management Services (OMS) provide data comprising organisation name and location address, for organisations such as marketing authorisation holders, regulatory authorities and manufacturers.
- The Referentials Management Services (RMS) provide lists of terms (controlled vocabularies) containing attributes of products available for selection (e.g., lists of dosage forms, units of measurement and routes of administration). Of note, certain fields, which in the interactive PDF form used to be hardcoded tick boxes, are now RMS lists containing control vocabularies to select.
- The Product Management Services (PMS) provide product data which uniquely identify an authorised medicinal product based on regulated information (e.g., marketing authorisation, packaging and medicinal information).

Of note, it is important to specify that the web-based application form relies on the authorised product data available from PMS. Through the interactive PDF form, applicants used to type their product name and details and select the pharmaceutical form, strength and unit from RMS. When using the web-based application form, product data, such as pharmaceutical form, strength and unit, can be directly retrieved from PMS as part of the PMS product dataset.

1.9. How quickly do changes in OMS, like inactivation, take to synchronise with the PLM Portal?

The refresh time between the PLM Portal and OMS is in most cases two hours. Occasionally there may be some integration routine related issues. In case organisational details in the PLM Portal are not correct, users should raise a ticket via the [EMA Service Desk](#).

1.10. Where can users find online information on upcoming training sessions, Q&A sessions and webinars?

Information on these events is published on:

- the [event section](#) on the EMA Corporate website;
- the [PLM Portal Forum page](#);
- the [e-Submission website](#).

The [PLM Portal Forum](#) will become the main channel of communication, where users will be able to find the latest news and ask questions.

1.11. Is any newsletter active to receive all the updates published on the eSubmission website?

Yes, the eAF newsletter is released on a quarterly basis on the [EMA corporate website](#) and is also advertised on the [PLM Portal Forum](#) and [eSubmission website](#). To be updated more often on latest news, users are invited to check the section "[What is new in PLM](#)" in the Forum area of the PLM portal.

1.12. Is there a list of open/closed bugs and issues?

Yes, there is. A list of open/closed bugs and issues is included in the document titled "PLM portal eAF release notes" available from the [PLM Portal Forum page](#) and the [eSubmission website](#). The document is regularly updated to reflect details on the latest improvements and bug fixes, open bugs and known limitations.

1.13. What is the turnaround time for addressing PLM Portal related issues in EMA ServiceNow?

As both the EMA ServiceNow and the PLM Portal were recently introduced, the process for addressing issues raised through the portal is still under refinement.

There have been some delays in addressing issues raised through the portal but solving them is a priority and will be done as quickly as possible. There is no specified turnaround time indication for each type of issue at the moment.



1.14. How soon will the new presentations (new EU number) be linked to the PLM portal?

New presentations (EU numbers) are included in the PMS as soon as they are approved in SIAMED (EMA's internal database), while non-CAP products are still not available because there are bugs identified prior to the initial migration into production that still need to be fixed.

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

2.1 Is an organisation automatically registered in PLM or should applicants ask for registration?

In order to access the PLM Portal, applicants are required to have an active EMA user account and an applicant-related role assigned to that account. Both EMA user account creation and role(s) request can be performed via the [EMA Account Management Portal](#). To request the necessary roles and, subsequently, submit application forms via the PLM Portal, the organisation on whose behalf the applicant will be acting must be listed in the SPOR [Organisation Management Service \(OMS\)](#) database.

Therefore, prior to requesting an applicant-related role or initiating an application form, users must check whether their organisation is registered in the OMS Database. If not, users must register their organisation in OMS. Please consult chapter 5 of the [User Guide to Registration](#) for step-by-step instructions on how to check whether an organisation is registered in OMS or how to register an organisation.

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

EMA aims to approve requests for role assignments as soon as possible. Once approved, users will be notified via e-mail. From the moment the request is approved by the Organisation Administrator, it takes approximately 45 minutes for the role to become effective on the PLM Portal. Users may want to directly contact the Administrator user within their organisation to speed up the approval process.

2.3 Can a user have both the eAF Applicant Manager and eAF Applicant Coordinator role?

For a given organisation, a user should only have one applicant-related role. Please note that the eAF Applicant Coordinator role inherits the privileges given to the eAF Applicant Manager role, which in turn inherits the privileges of the eAF Applicant browser Contributor.

Please note that a user can have the eAF Applicant Coordinator role for an organisation and the eAF Applicant Manager role for a different organisation.

2.4 Is the eAF Applicant Manager role denied for Admins?

No, it is not. Admin users can request the eAF Applicant Manager role to have access to the PLM Portal. As they are Admins, they need to submit the request and approve it by themselves.

2.5 If users have admin rights for the IRIS Portal, do they need additional admin rights for eAF (PLM Portal)?

No, they do not. The User Admin role is valid for both IRIS and the PLM Portal.

2.6 Can all members within the same team have the Coordinator role?

Yes, they can. EMA does not limit the number of users for each type of role. Each organisation is allowed to decide which type of role to assign to their users.

2.7 For consultancy users, does each user need to have an individual EMA account so that the marketing authorisation holder (MAH) can assign them relevant access level on the PLM Portal or could the MAH EMA account also be used by consultants?

It is recommended for each consultancy user to have an individual EMA account. It is not possible to create an EMA account on behalf of someone else. Consultancy users can be affiliated to the MAHs that they will be working for. Users can have distinct roles for different MAHs, so it is important that each consultant has their own individual account. This is also important for log-in, considering the multifactor authentication.

2.8 Do consultancies need to affiliate themselves for each organisation they work for through the EMA Account Management Portal?

Each user (including consultants) must individually submit access role request(s) for the organisations they work for through the [EMA Account Management Portal](#). The PLM Access Management is set up so that each Organisation's Administrator decides who is assigned which role in accessing the PLM Portal.

2.9 If the co-authors belong to different organisations (e.g., in the case of large pharmaceutical companies) can they be selected to contribute to the same eAF?

Yes, this is possible. Applicants should use the 'Add co-author' feature to add a user from 'Another organisation'. They will need to search for the specific users by using their e-mail address. The selected users from other organisation(s) will need to request affiliation to the organisation of the applicant and will then be able to edit the forms and add the products from their organisation(s). Please note that these co-authors will be able to see Commercially Confidential Data related to the applicants' product(s) in the FHIR (Fast Healthcare Interoperability Resources) XML which is part of the PDF rendition exported from the PLM Portal.

2.10 How many users can edit an eAF and have access to product information at the same time?

There is no limitation on how many users from one organisation can operate in the system. However, there is a known limitation regarding parallel editing. Currently, there is no warning in the system if more colleagues are editing the same application form simultaneously, which could lead to an accidental overwrite of each other's changes. A feature to indicate when another colleague is editing the application form is under development. However, for the moment, users are invited to try to coordinate and not work in the same application form at the same time to avoid any accidental overwrite.



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

Access roles can be revoked either by the Applicant users themselves or by the Administrator user(s) of the Organisation. Revoking access can be done in the “Manage Access” section of the [EMA Account Management Portal](#).

2.12 Should MAHs grant access to individual external users through the EMA portal?

The MAH who owns the product is responsible for granting access to the correct level of information for consultants or other external parties (e.g. worksharing). It is possible to grant access to all products or at the individual application level. The Contributor role is used for specific applications (containing the products you wish to share). For more information, please consult the [User Guide to registration](#).

3. Navigation through the PLM Portal – eAF

3.1 Is the submission process of the new web-based eAF the same as it is for PDF forms?

Yes, it is. The main difference between the PDF and web-based eAF is in the filling of the form. Instead of working with an interactive PDF form, users will fill in the form through the PLM Portal. After filling it in, users will need to export the form and include it in their eCTD package, in the same way they are including the interactive PDF form today. Finally, they will have to submit the form. There is no change in how to submit the form.

3.2 Is there any training environment available to create test eAFs and to prepare training for eAF users within an organisation?

There is no need to create a separate training environment since it is possible to use the production environment for training purposes. In fact, the production environment always has the latest available features and functionalities. The products available for use in the production environment are those of production PMS and these are currently coming directly from EMA's internal product and procedure database, SIAMED.

As the PLM Portal is designed in a way which does not enable the user to submit anything from the Portal itself, there is absolutely no harm in using the production environment as a "sandbox" or a "training area". Users can create as many forms as needed and edit them for purely training purposes. If the forms used for training purposes are not needed afterwards, it is possible to deactivate them, and they will be moved under the "deactivated" tab. A functionality which could permanently delete the deactivated forms is under development, but, for now, they can simply be moved under the "deactivated" tab.

3.3 Will it be possible to include products from more than one MAH in a web-based Variations form?

Yes, it is. Currently, it is possible to use the form for worksharing procedures that contain only CAPs. If two MAHs work together, the colleagues editing the forms need to be affiliated, with relevant access level, to add their products and co-edit the form.

In future, once the NAPs become available in the system, it will also be possible to use the form for mixed CAP/NAP worksharing procedures.

3.4 What is the recommended way to check the migrated product data?

PMS contains all the product data migrated from SIAMED (currently) and from xEVMPD (in future), but only some fields are displayed in the PLM Portal for the moment. Therefore, only those fields can be checked. Applicants can find this information in their list of products. For further information related to the data migration of authorised products in PMS, please refer to EU IG (Implementation Guide) Chapter 7 and Question 40 of the [eAF \(DADI\) and PMS joint Q&A document](#).

3.5 Is it possible at any stage to save and export the eAF, even if it is not completely filled in and validated?

Yes, it is always possible to save the form at any stage by clicking the available 'Save' button in the web user interface. It is also possible to export the form at any point to check

how it will look in PDF format and then return to the web-form to continue filling it in. The export to PDF can be done as many times as necessary simply by clicking the 'Export' button.

3.6 How long will the draft, deactivated or completed forms be retained on the PLM Portal?

The retention period for drafts and completed forms is two years, while for deactivated forms it is one year. Before anything is automatically deleted, applicants will be notified via e-mail. Please note that making any changes in a form, regardless of its status, will restart the clock for the retention period.

3.7 What are the options for signing the form? Is it mandatory? Will there be the option to add more than one additional signature in the future?

It is recommended to sign the form using a digital signature. However, EMA is currently not reinforcing the signature requirement and applications without signature are being accepted. The mandatory requirement for a signature for application forms for Centralised Procedure is still under discussion.

It is foreseen that there will be no signature requirements imposed for non-CAP application forms created in the PLM Portal in future.

The limitation of allowing only two signatories for the eAF has been discussed at the eAF Maintenance Group and it has been confirmed by the SMEs that there will be no need to include more than 2 signatories in the future. For the time being, if applicants need to include more than two signatories, they can continue using the interactive PDF form.

3.8 Is it possible to import an eAF regenerated by another user in the PLM Portal?

It is possible to "invite" other users to edit application forms by adding co-authors to the forms created. Depending on their access rights, the "invited" user will see different levels of information in the forms. Details on what different user roles are able to see in the form are explained in the [User Guide to registration](#).

3.9 Regarding MRP/DCP, will the RMS and CMS be populated automatically by the system once the procedure number is entered?

When the user starts to fill in the form, the first step is the selection of the MAH. In the case of MRP/DCP, this is the selection of the 'lead' MAH. The authorisation countries of the products are known by the system and the user only has to select RMS and the rest of the countries will be listed as Concerned Member State (CMS).