18 December 2022

Product Lifecycle Management Portal – Human Variations eAF

Guide to registration

Version 1.4

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

EUROPEAN MEDICINES AGENCY
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Acronym key and glossary terms

EMA European Medicines Agency

PLM Product Lifecycle Management

eAF Electronic Application Form

SPOR Management Services for Substances, Products, Organisations and Referentials

OMS Organisation Management Service (part of SPOR)

NCA National Competent Authority

IT Information Technology

FAQ Frequently Asked Questions

MAH Market Authorisation Holder

Revision History

Version	Date	Description
1.4	18/12/22	Added guiding principles, revoke guide, real-case examples for granting access and PLM Chatbot information
1.3	10/11/22	Added information on multi-factor authentication
1.2	19/10/22	Updated Portal name and eAF Applicant Contributor role details
1.1		
1.0		Initial publication of the Guide to registration

1. Purpose and Context

This guide aims to support the users of the PLM Portal - eAF in completing the registration steps before accessing the platform. Most of these steps are independent from the PLM Portal - eAF and correspond to those to obtain registration to use other European Medicines Agency (EMA) systems, such as Management Services for Substances, Products, Organisation and Referentials (SPOR).

2. Pre-requisites to access the PLM Portal - eAF

To sign into the PLM Portal - eAF you are required to have:

(1) an **active EMA user account**, and,

(2) **user access role(s)** assigned to that account.

The EMA Account Management is the online platform where you can request and manage access to EMA applications. Refer to this platform to seek guidance on how to:

- Look up whether you already have an EMA account
- Re-activate your EMA account
- Recover your credentials
- Retrieve your username
- Reset your password
- Create an EMA account
- Request a user access role
- Manage users' access for your organisation as an "User Admin"
- FAQs

Furthermore, please note that to request the necessary user access roles (point (2) above) and, subsequently, submit Application Forms via the PLM Portal - eAF, the **organisation** on whose behalf you will be acting must be **listed in the EMA's Organisation Management Service (OMS)**. Refer to section 4. to seek guidance on how to:

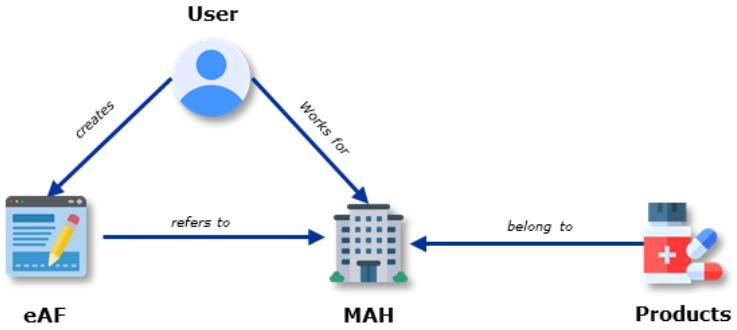
- Look up whether your Organisation is registered in OMS
- Request Organisation to be registered in OMS, or update its data

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

3.1. Guiding Principles

3.1.1. MAH - Products

- An eAF belongs to one MAH and is created by a user.
- Medicinal Products belong to an MAH (Location).



3.1.2. Users

- A PLM Portal – eAF user is either an applicant, part of an NCA or part of the EMA.
- A user has a role for each of the organisation on whose behalf s/he is acting.

3.2. Types of user access roles

The PLM Portal - eAF Identity Access Management consists mainly of two different layers – the **applicant**-related roles and the **admin**-related roles. A single user must have no more than two roles per organisation – one applicant-related role and, if applicable, one admin-related role.

3.2.1. Applicant-related roles

Within the applicant layer, there are four different roles, which allow performing different operations in the PLM Portal - eAF. The following table contains an overview of the **applicant**-related roles per user's place of origin and environment:

Table 1

User	Applicant-role name	
	in Production environment	in UAT environment
Industry user(s)	eAF Applicant Contributor	UAT_eAF Applicant Contributor
	eAF Applicant Manager	UAT_eAF Applicant Manager

User	Applicant-role name	
	in Production environment	in UAT environment
	eAF Applicant Coordinator	UAT_eAF Applicant Coordinator
NCA user(s)	eAF Competent Authority User	UAT_eAF Competent Authority User

The roles identified in the column above 'in UAT environment' are only for consideration in case you are/were involved in any testing activity of the PLM Portal - eAF. Please note that as from the go-live date of the PLM Portal - eAF, you must request an applicant-related role from the 'in Production environment' column, even if you were previously assigned with an applicant-related role 'in UAT environment'.

3.2.2. Admin-related roles

Within the admin layer, there are three different roles, which allow approving/rejecting roles requests. The following table contains an overview of the **admin**-related roles per user's place of origin and environment:

Table 2

Users	Admin-role name (in UAT/Production environment)
Industry user(s)	**IRIS - eAF Industry Admin** External Organisation Administrator *(optional)*
NCA user(s)	**IRIS - eAF Competent Authority Admin**

The **admin**-related roles aim exclusively to handle user's access management of a MAH. It does not provide access to the PLM Portal - eAF.

Please note that no differentiation is made on environment – whoever has an admin role can the approve/reject access roles requests in both Production and UAT environments.

Furthermore, the admin-related roles for the PLM Portal - eAF are shared with the IRIS Portal – if you are already an admin-user for IRIS, you will automatically be an admin-user for the PLM Portal - eAF. Similarly, if you become an admin-user for the PLM Portal - eAF, you will also become an admin-user of the IRIS Portal.

The **External Organisation Administrator** role, once validated by the EMA, can allow approving or rejecting access roles requests not only for eAF but also for other EMA-run systems within your organisation/country. More information about this role can be found on this webpage.

3.3. Grants provided by each user access role

3.3.1. Applicant-related roles

Different applicant-related roles grant different accesses when it comes to create / access / edit / manage Application Form(s) in the PLM Portal - eAF.

- A user originated from a National Competent Authority (NCA) can only request one applicant-related role – the (UAT) eAF Competent Authority User role;
- An Industry user can request three possible roles – the (UAT) eAF Applicant Contributor, the (UAT) eAF Applicant Manager or the (UAT) eAF Applicant Coordinator role.

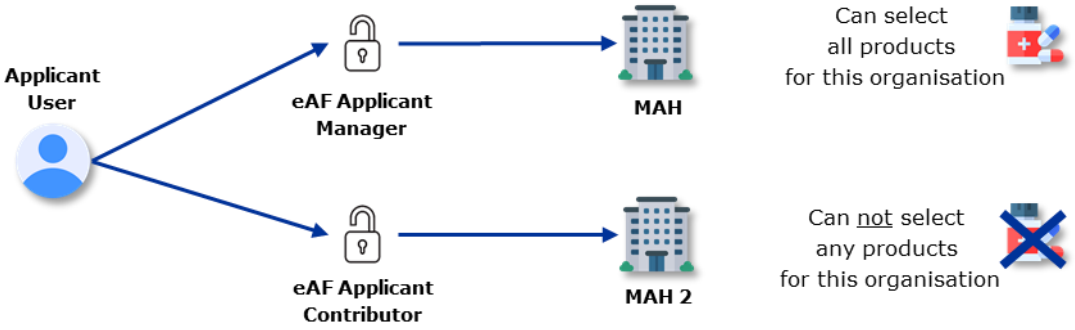
The table below summarises the operations that each role allows to perform in the PLM Portal - eAF, for each respective applicant-related role.

Table 3

User Role name / Grant	Industry user(s)			NCA user(s)
	(UAT) eAF Applicant Contributor	(UAT) eAF Applicant Manager	(UAT) eAF Applicant Coordinator	(UAT) eAF Competent Authority User
Create application(s)	✗	✓	✓	✓
Edit application(s)	✓	✓	✓	✓
Add co-author(s)	✗	✓	✓	✓
Be added as co-author	✓	✓	✓	✗
Select product(s)	✗	✓ of that organisation	✓ of that organisation	✓ of that country
Select classification(s)	✓	✓	✓	✓
Export and finalise application(s)	✗	✓	✓	✓
Delete application(s)	✗	✓	✓	✓
Manage application(s)	✗	✗	✓ of that organisation	✓ of that country

The roles are assigned to single users and are granted at organisation level – not at product level nor at scope/change level. For instance, a user should not be referred to as an 'Applicant Coordinator of product X' and 'Applicant Manager of product Y'. If a user holds the Applicant Coordinator role, s/he plays that role for the organisation on whose behalf s/he is acting – irrespective of which product(s) a given Application Form refers to. A user may be referred to as an 'Applicant Coordinator of organisation X' and 'Applicant Manager of organisation Y'.

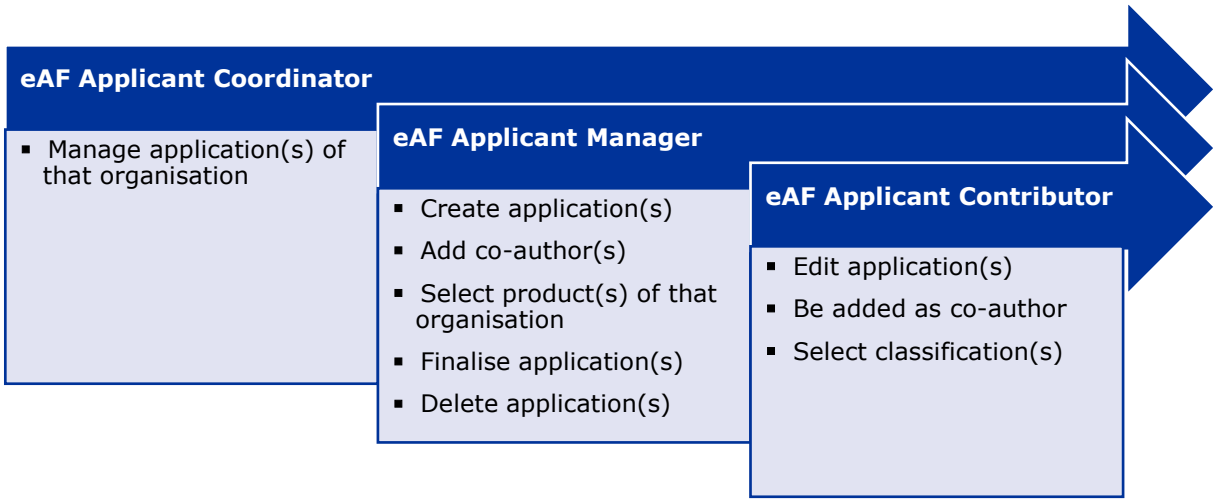
For every organisation you belong to, you can request a different role type. You can be contributor on ORG and, manager on ORG2 and ORG3, and coordinator on ORG4



For the Industry applicant-related roles, please note that higher levels roles inherit the grants of lower level roles. In concrete:

- the (UAT) eAF Applicant Manager role inherits the accesses granted to the (UAT) eAF Applicant Contributor role;
- the (UAT) eAF Applicant Coordinator role inherits the accesses granted to the (UAT) eAF Applicant Manager role, which inherits the roles of the (UAT) eAF Applicant Contributor role.

The diagram below displays the individual grants that each applicant-role applied for industry users includes.



- ✓ Each Industry organisation should have at least one user with the (UAT) eAF Applicant Coordinator role.
- ✓ Each National Competent Authority should have at least one user with the (UAT) eAF Competent Authority User role.

We recommend granting the role that allows the user to access only the resources necessary for its purpose. If someone operate with a contributor role, there is no need to extend its competence and assign the manager role. Unless the user is required to oversee all applications for a given organisation, do not assign a coordinator role.

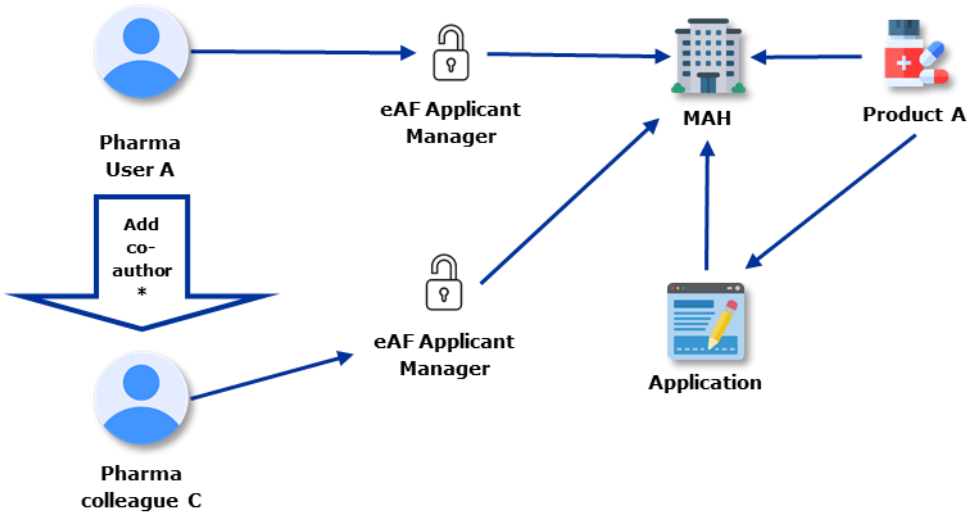
3.3.1.1. Real-case examples of granting access to the PLM Portal – eAF

The PLM Portal – eAF Access Management is designed in a flexible way so to cover each organisation's different working model. This is a decentralised method in which organisations can manage the access to the PLM Portal – eAF on their own, by their authorised Admin users. The following real-case examples reflect possible ways to manage the access on different working models.

3.3.1.1.1. Co-authoring with associated users

Applicable to:

- Colleagues within my organisation
- Consultancy who is allowed to see my products



***** *Add Co-author is only needed if the other participant does not already have a coordinator role*

Scenario:

Both Users A and C are associated to the same organisation
Both Users A and C have the eAF Applicant Manager role for the same organisation

User A creates a eAF

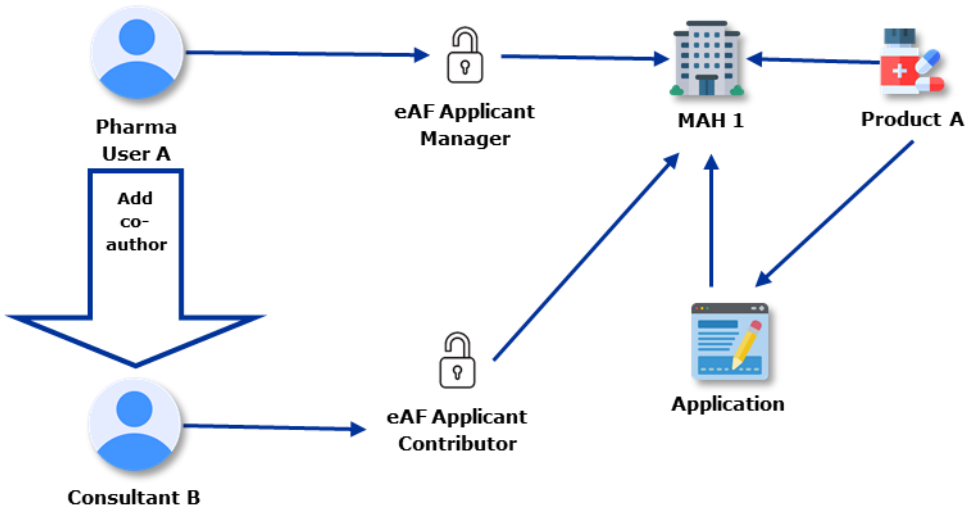
User A shares with the eAF with User C by adding User C as co-author (from the same organisation)

User C has the same rights as User A and can perform the same operations within the created eAF as User A

3.3.1.1.2. Co-authoring on an ad-hoc basis

Applicable to:

- Consultancy without access to products



Scenario:

User A works for MAH 1
User B works for a consultancy who should not see all MAH 1 products

User A has the eAF Applicant Manager role for MAH 1

User A creates an eAF

User A shares the created eAF with User B by adding User B as co-author (from a different organisation)

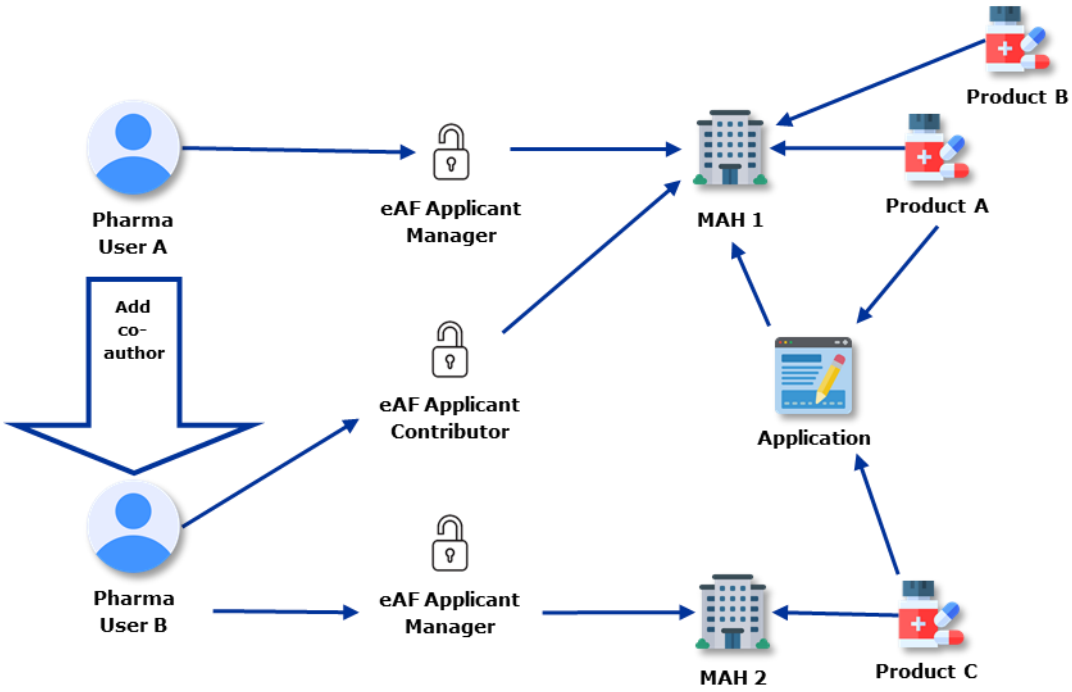
User B requests the eAF Applicant Contributor role for MAH 1

User B gets access to the eAF created by User A and, subsequently, to product A as soon as User B has the eAF Applicant Contributor role authorised for MAH 1

3.3.1.1.3. Worksharing

Applicable to:

- Worksharing with other companies



Scenario:

User A works for MAH 1
User B works for MAH 2

User A has the eAF Applicant Manager role for MAH 1
User B has the eAF Applicant Manager role for MAH 2

User A creates an eAF for Product A

User A shares the created eAF with User B by adding User B as co-author (from a different organisation)

User B requests the eAF Applicant Contributor role for MAH 1

User B gets access to the eAF created by User A and, subsequently, to product A (as soon as User B has the eAF Applicant Contributor role authorised for MAH 1)

User B can add product C (because User B is manager for MAH 2)

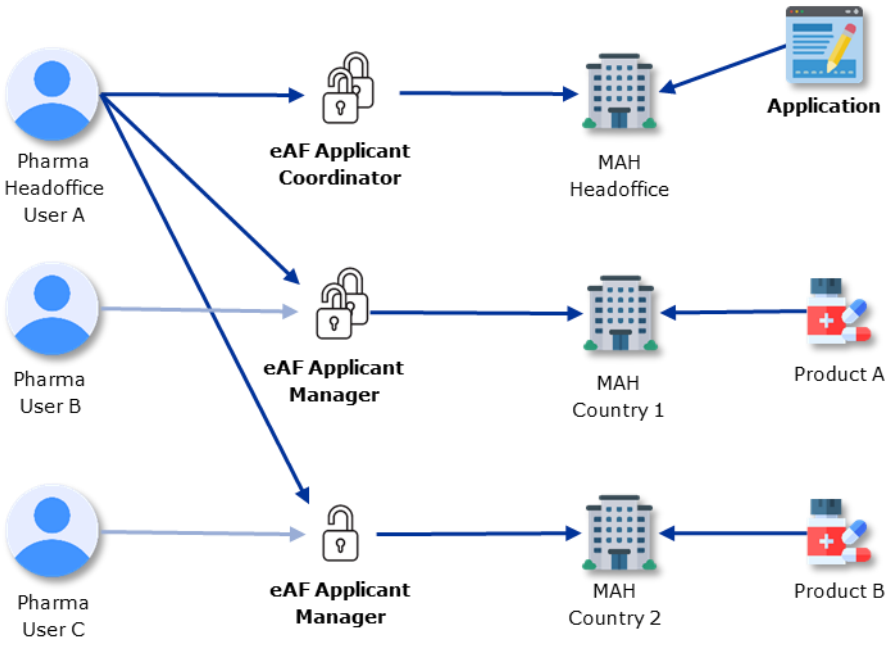
User B cannot finalise the eAF because User B is a contributor for MAH 1 (where the application sits); User A can finalise the eAF. User A can see commercially confidential information about product C in the FHIR xml export.

User B cannot see product B because User B is only a contributor for MAH 1

3.3.1.1.4. Head office does distributed applications

Applicable to:

- Head office setting up applications and adds details of members



Scenario:

User A works for MAH Head office
User B works for MAH Country 1
User C works for MAH Country 2

User A has the eAF Applicant Coordinator role for MAH Head office
User A has the eAF Applicant Manager role for MAH Country 1
User A has the eAF Applicant Manager role for MAH Country 2

(User B has the eAF Applicant Manager role for MAH Country 1)
(User C has the eAF Applicant Manager role for MAH Country 2)

User A creates an eAF

User A can add all necessary products (A and B) and data

User A can finalise the eAF

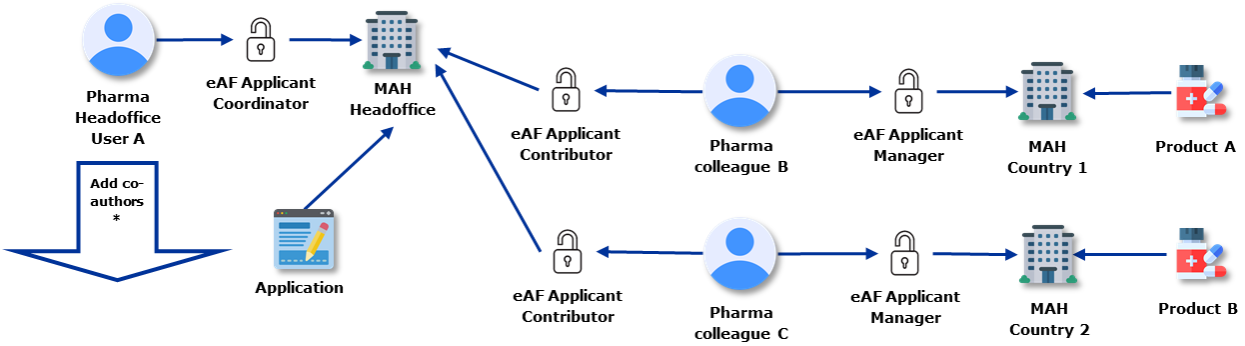
User B and User C cannot access/fill in the eAF created by User A because they are not assigned with any role for MAH Headoffice

User A cannot see other applications from Countries 1 or 2

3.3.1.1.5. Head office of a multinational company submits

Applicable to:

- Head office setting up applications
- Each member adds their details



** Add Co-author is only needed if the other participant does not already have a coordinator role*

Scenario:

User A works for MAH Head office
User B works for MAH Country 1
User C works for MAH Country 2

User A has the eAF Applicant Coordinator role for MAH Head office
User B has the eAF Applicant Manager role for MAH Country 1
User C has the eAF Applicant Manager role for MAH Country 2

User A creates an eAF

User A shares the created eAF with User B and User C by adding User B and User C as co-authors (from different organisations)

User B requests the eAF Applicant Contributor role for MAH Country 1
User C requests the eAF Applicant Contributor role for MAH Country 2

User B and User C get access to the eAF created by User A (as soon as User B and User C have the eAF Applicant Contributor role authorised for MAH Head office)

User B and User C add their products (A and B, respectively)

User A finalises and adds the application to the dossier

3.3.2. Admin-related roles

The **admin**-related roles exclusively allow approving/rejecting access roles requests. This means that if a user has (only) an admin-related role, s/he cannot access *per se* the PLM Portal - eAF. If users with an admin-related role also intend to manage Application Forms, they must request, in addition, an applicant-related role. The table below summarises the operations that each role allows to perform in the PLM Portal - eAF, for each respective admin-related role.

Table 4

Role name / Grant	Industry user(s)		NCA user(s)	
	IRIS / eAF Industry Admin	**External Organisation Administrator** *(optional)*		**IRIS / eAF Competent Authority Admin**
Approve / remove access roles request(s)	✓	✓	✓	✓
which roles:	- (UAT) eAF Applicant Contributor, - (UAT) eAF Applicant Manager, or - (UAT) eAF Applicant Coordinator	- (UAT) IRIS / eAF Industry Admin	- (UAT) IRIS / eAF Competent Authority Admin	- (UAT) eAF Competent Authority User

Refer to this webpage for more information on the *External Organisation Administrator* role.

If organisations intend to have more than a user accessing the PLM Portal - eAF, then it is required that some user performs the access management for that organisation. In that case:

- ✓ Each industry organisation (MAH) should have at least one user with the IRIS - eAF Industry Admin role;
- ✓ Each National Competent Authority should have at least one user with the IRIS / eAF Competent Authority Admin role.

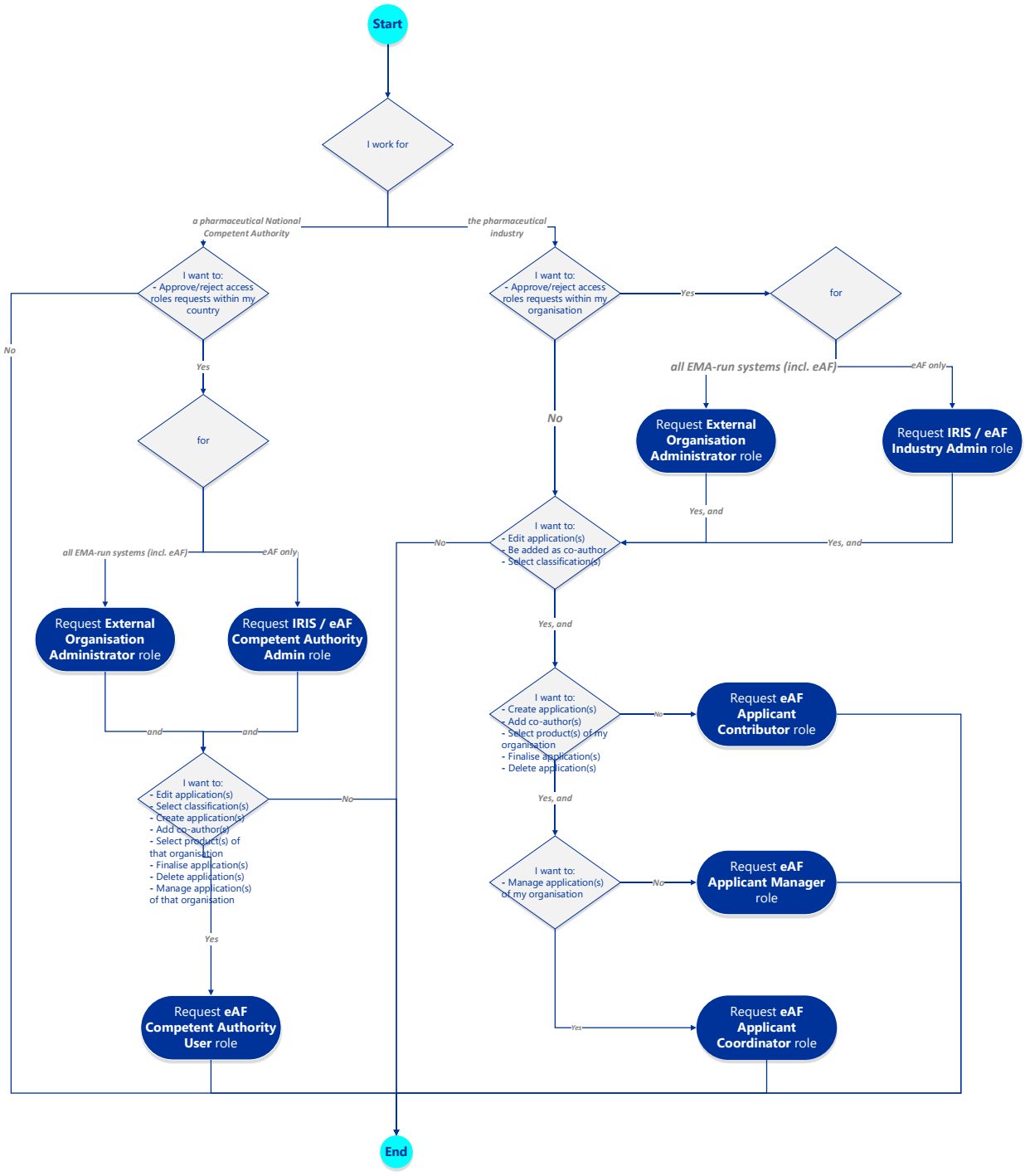
3.4. How to request a user access role

Follow the steps available in the *Request user access* webpage to request access on behalf of your organisation.
Please note that prior to the submission of access role(s) request(s), you must ensure that you have an active EMA account and that the organisation on whose behalf you will be acting is listed in the EMA's Organisation Management Service (OMS). Refer to sections 2. and 4. , respectively, for further information.

3.5. Which access role(s) shall a user request

The access roles(s) that you must request/obtain strongly depend on the type of operations you want to be able to perform related to the PLM Portal - eAF.

The following decision tree summarises the access role(s) you must request/ be granted with:



Please note that as a result of any path within the decision tree above, for every organisation a maximum of two roles are to be requested per each user (one admin-related role and one applicant-related role).

3.6. Other Frequently Asked Questions (FAQs)

3.6.1. How many roles can I have?

A single user must have no more than two roles per organisation - one applicant related role and, if applicable, one admin-related role.

3.6.2. Can EMA account requests be submitted on behalf of employees or must they be individually submitted?

You cannot submit EMA account requests on behalf of another employee. You will have to create the account separately. Same applies to the roles: you will have to access your EMA Account Management Portal and ask for your own roles.

3.6.3. Can I have multiple roles if I belong to more than one organisation?

Yes. For every organisation you belong to, you can request a different role type. For instance, you can be a contributor on ORG1, a manager on ORG2 and ORG3, and a coordinator on ORG4.

3.6.4. To what product is my role linked?

The roles are assigned to single users and are granted at organisation level – not at product level nor at scope/change level.

3.6.5. Are IRIS Admins automatically PLM – eAF Admins?

Yes, the *IRIS - eAF Industry Admin* role has been combined. If you are an IRIS administrator, you can also manage the PLM Portal - eAF access roles requests.

3.6.6. Where can I find the Affiliation Template letter which is used as a proof of authority to represent an organisation, which I need to attach in an admin-related request?

Please follow this link.

3.6.7. I requested an admin-related role however, I cannot yet approve/reject roles. What can I do?

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.

3.6.8. I requested an applicant-related role however, I cannot yet create/access/edit Application Forms? What can I do?

Applicant access role requests are forwarded to the administrator of your organisation for his/her approval. You should receive an e-mail notification as soon as you submit an access role request as well as when your request has been handled. You may want to directly contact the administrator of the organisation on whose behalf you will be acting for further information.

3.6.9. I have been assigned with an admin-related role however, I cannot create/access/edit Application Forms? What can I do?

A user with an admin-related role is only granted permission to approve/reject access role requests within the organisation on whose behalf s/he will be acting. If you want to also be granted access to create/access/edit Application Forms, you should request, in addition, one of the applicant-related roles. Refer to sections 3.2.1. and 3.3.1. for additional information on the applicant-related roles.

3.6.10. I have been assigned with an admin-related role for the organisation on whose behalf I will be acting. Can I also approve/reject access roles from its affiliates?

You may be responsible for the access management of as many organisations and/or affiliates as you wish. For each of those organisations and affiliates, you must ensure that you request/are granted with an admin-related role.

If you only have an admin-related role associated to the organisation on whose behalf you will be acting, you will only be able to approve/reject roles within that organisation. If you want to manage the access role requests of the affiliates of the organisation on whose behalf you will be acting, you must submit, in addition, an admin access role request for that affiliate separately.

3.6.11. What roles should be in place for an Industry organisation?

Each Industry organisation should have at least one user with the eAF Applicant Coordinator role.

3.6.12. Can access roles be revoked? If so, how?

Yes, 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.

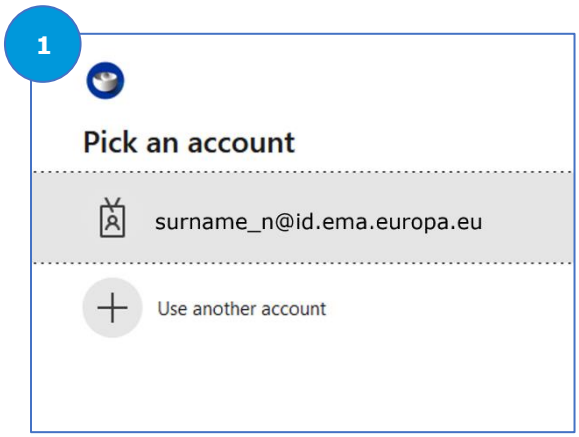
4. Multi-factor authentication (MFA)

Logging into the PLM Portal - eAF requires **multi-factor authentication** (MFA) i.e., you are granted access to the PLM Portal - eAF only after successfully presenting more than one authentication mechanism. In practical terms, this means that, in addition to the standard username and password, you are required to verify your identity with an additional authentication method. MFA adds a layer of security to access your account and it protects your data from being accessed by an unauthorised third party.

The additional authentication step can be using an app – the Microsoft Authenticator app – considered the most secure method. A SMS sent to a mobile phone number or calls to an office or a mobile phone number are other possible authentication methods. Please access My Account to manage/setup your MFA authentication methods.

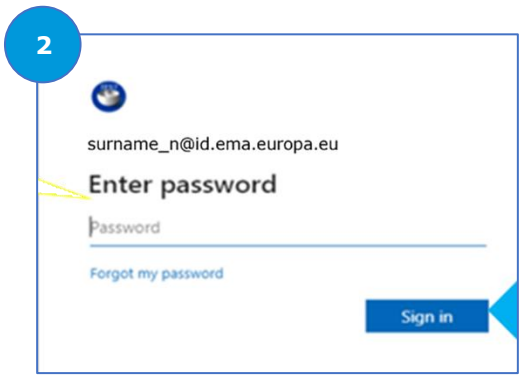
4.1. Authentication steps when signing into the PLM Portal – eAF

4.1.1. Pick an account



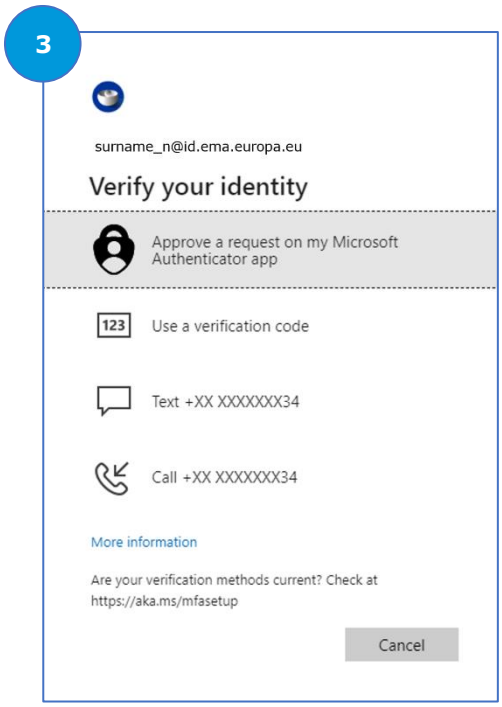
You must sign in with your username followed by @id.ema.europa.eu: *surname_n*@id.ema.europa.eu

4.1.2. Enter password



The password is the same as in the EMA Account Management Portal.

4.1.3. Verify your identity



Select one of the following authentication methods to verify your identity. Please see section 4.2. to know how to setup them.

- **Microsoft Authenticator app**

  The authenticator app is considered the most secure and convenient authentication method. Use the Microsoft Authenticator app in your registered mobile device to prove who you are either by:

  Approve a request on your Microsoft Authenticator app

  You receive a notification in your registered mobile device, which will direct you to the Microsoft Authenticator app. There, a pop-up will be displayed which you must Approve/Deny the sign in attempt.

  Use a verification code

  In the Microsoft Authenticator app, every 30 seconds a verification code is generated. Enter the code generated in the Microsoft Authenticator app.

- **SMS**

  You receive a verification SMS code in your registered mobile phone. Add that code to sign in.

- **Call**

  You receive a phone call in your registered mobile phone. In the call, approve/deny the sign in attempt.

4.2. Setup of Multi-Factor Authentication

Access My Account to manage/setup your MFA authentication methods. In this link, you can find guidance on how to do that setup.

- **Microsoft Authenticator app**

Follow the steps available in this link to setup the Microsoft Authenticator app.

NOTE: the mobile device in which you decide to download the Microsoft Authenticator app must have the capacity to scan QR Codes. You may need to download an app for a QR Code reader before downloading the Microsoft Authenticator app.

- **Other Authentication Methods – Mobile SMS or Phone Call**

Follow the steps available in this link to setup the phone number to which you would want to receive a SMS or Phone Call.

NOTE: receiving a SMS or a Phone Call are options that can be selected at any sign in attempt. These are available options in a sign in attempt if the phone number is set up.

- **Other Authentication Methods – Office Phone Call**

Follow the steps available in this link to setup your Office Phone to which you would want to receive an Office Phone Call.

5. Organisation registration in OMS (SPOR)

To request the necessary user access roles and submit applications via the PLM Portal - eAF, you will need to ensure that the organisation on whose behalf you will be acting is listed in the EMA's Organisation Management Service (OMS).

There are a few ways for you to check this.

5.1. Look up whether your Organisation is registered in OMS

5.1.1. From the EMA Account Management Portal

You can check whether your organisation is registered in OMS during the PLM Portal - eAF user access request process in the EMA Account Management Portal (see section 3.4. How to request a user access role).

If you cannot find your organisation or the organisation data require an update, follow the instructions in section 5.2. Request Organisation to be registered in OMS, or update its data.

5.1.2. From IRIS *(alternative)*

1. Go to the Organisations and Locations List in the IRIS Home page (note: no login is required to search the list);
2. Type the name (or part of it, with an asterisk at the beginning) of the organisation you wish to find in the "**Organisation name**" box and hit "**Apply**". You can also add a country in the filters, if your company has multiple organisations with a similar name in different countries;
3. If the page displays all the locations (addresses) for the organisations found, this means that the organisation is already registered and will appear on the drop-down list when you are requesting your eAF user access role;
4. You may wish to take a note of your Organisation ID, which, in addition to the organisation name, can be used to search for an organisation you will need to affiliate with when you request your eAF user access role in the EMA Account Management Portal;
5. If you cannot find your organisation or the organisation data require an update, follow the instructions in the section Request Organisation to be registered in OMS, or update its data.

5.1.3. From SPOR (alternative)

1. Go to the SPOR portal;

   Note: No login is required to look up your organisation ID;
2. Click on "**Organisations**" in the top (white) menu bar (**Figure 1**);When the "**SPOR – Organisations Management Service**" web page opens, click on the "**Organisations**" button in the lower (dark blue) menu bar (**Figure 1**);

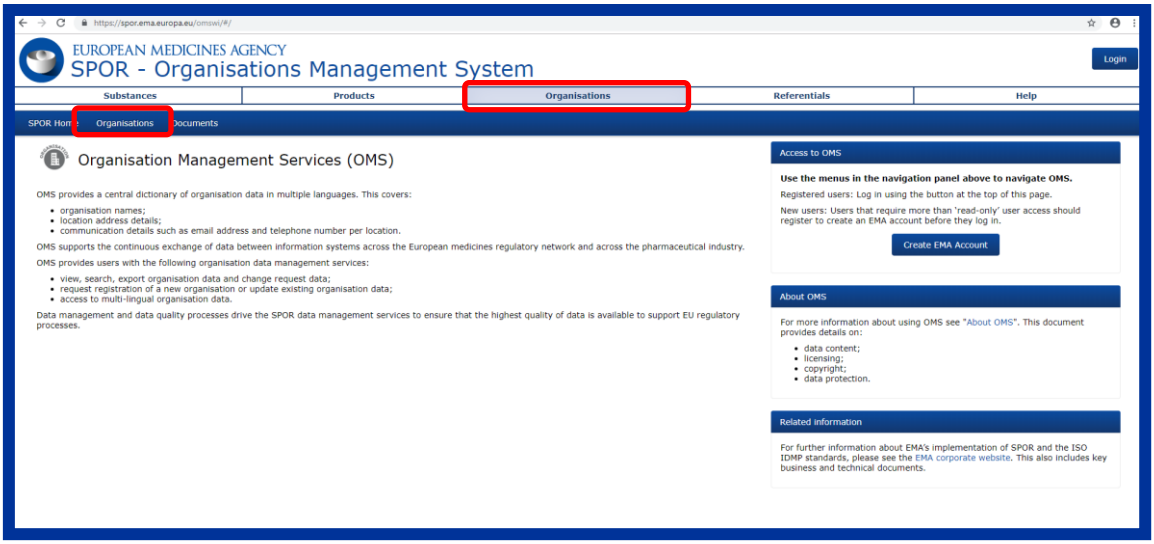


Figure 1

3. Type the name of the organisation you wish to find in the "**Organisation name**" box and hit "**Search**" (**Figure 2**);

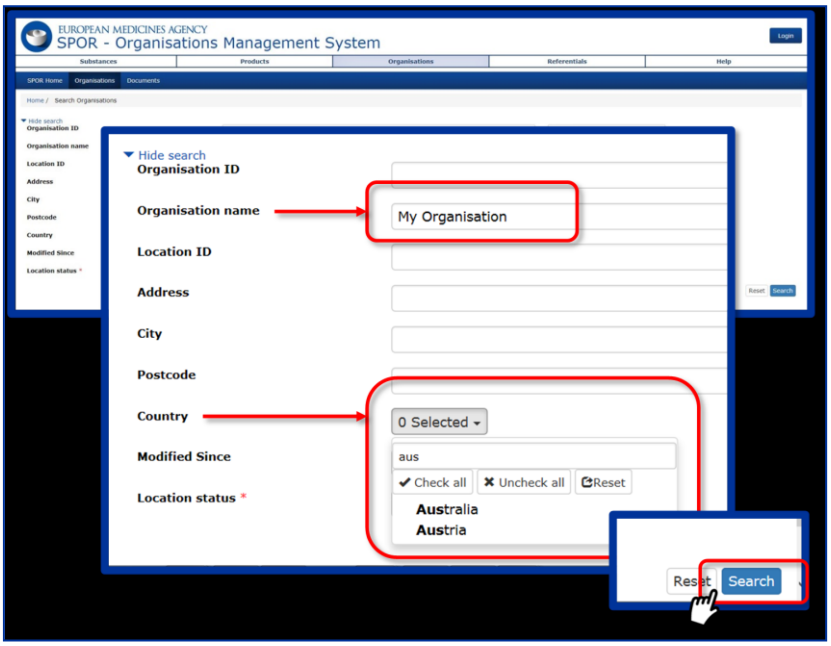


Figure 2

- If the organisation does not appear in the list after hitting search, then follow the instructions in the next section (see section "Raise a request to create a new organisation");
- If the organisation appears in the list, this means that it is already registered and will appear on the drop-down list when you are requesting your PLM Portal - eAF user access role via the EMA Account Management Portal;

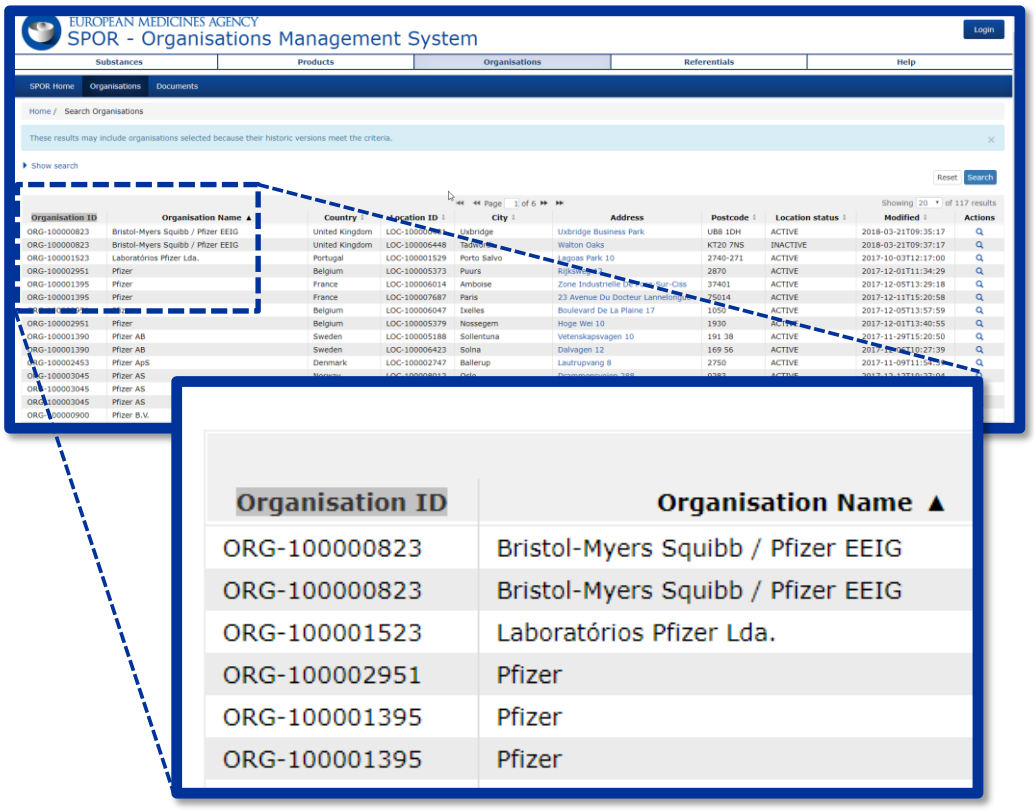


Figure 3

4. You may wish to take a note of your Organisation ID (left hand column, **Figure 3**) which, in addition to the organisation name, can be used to search for an organisation you will need to affiliate with when you request your PLM Portal - eAF user access role in the EMA Account Management Portal;

5. If the organisation data that appears require an update, follow the instructions in section "Raise a request to update organisation information**"**.

5.2. Request Organisation to be registered in OMS, or update its data

It is the responsibility of all external organisations to ensure that any data held in SPOR about their organisation is accurate and up to date. Creation of a new organisation or changes needed to organisation data in OMS must be requested using the change request functionality in the OMS interface.

All change requests must be accompanied by relevant **supporting documents or information** as described in the **"Change requests validation in OMS"** guidance document available on the OMS documents page.

Further information on OMS can be found on EMA's corporate website.

5.2.1. Raise a request to create a new organisation

During the self-registration process by the user, the **"SPOR unaffiliated user"** role is given by default so that they will be able to submit change requests for a new organisation, limited to one pending request at a time. Below steps describe this process in detail.

1. Go to the SPOR portal;
2. Click on the "**Organisations**" tab in the top menu (**Figure 4**);
3. Click on the "**Login**" button (**Figure 4**);

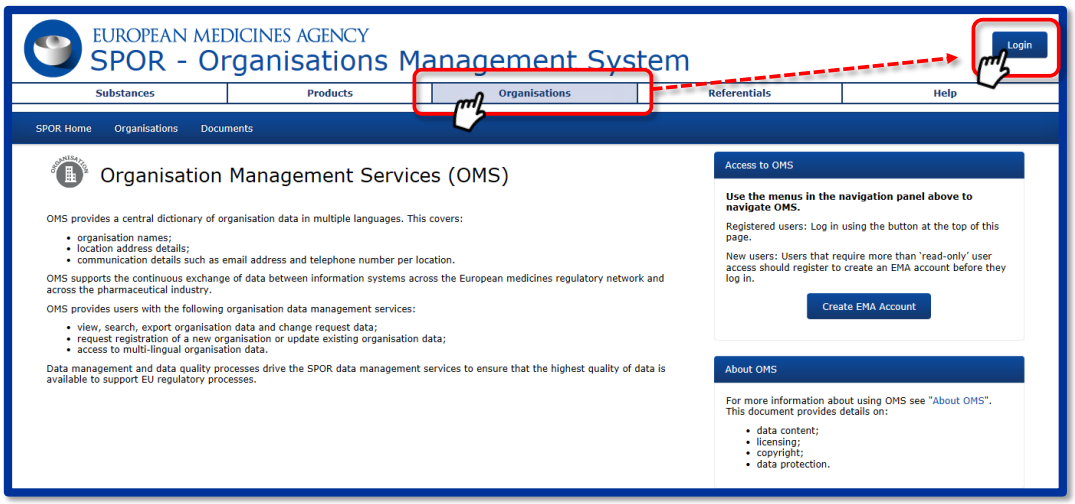
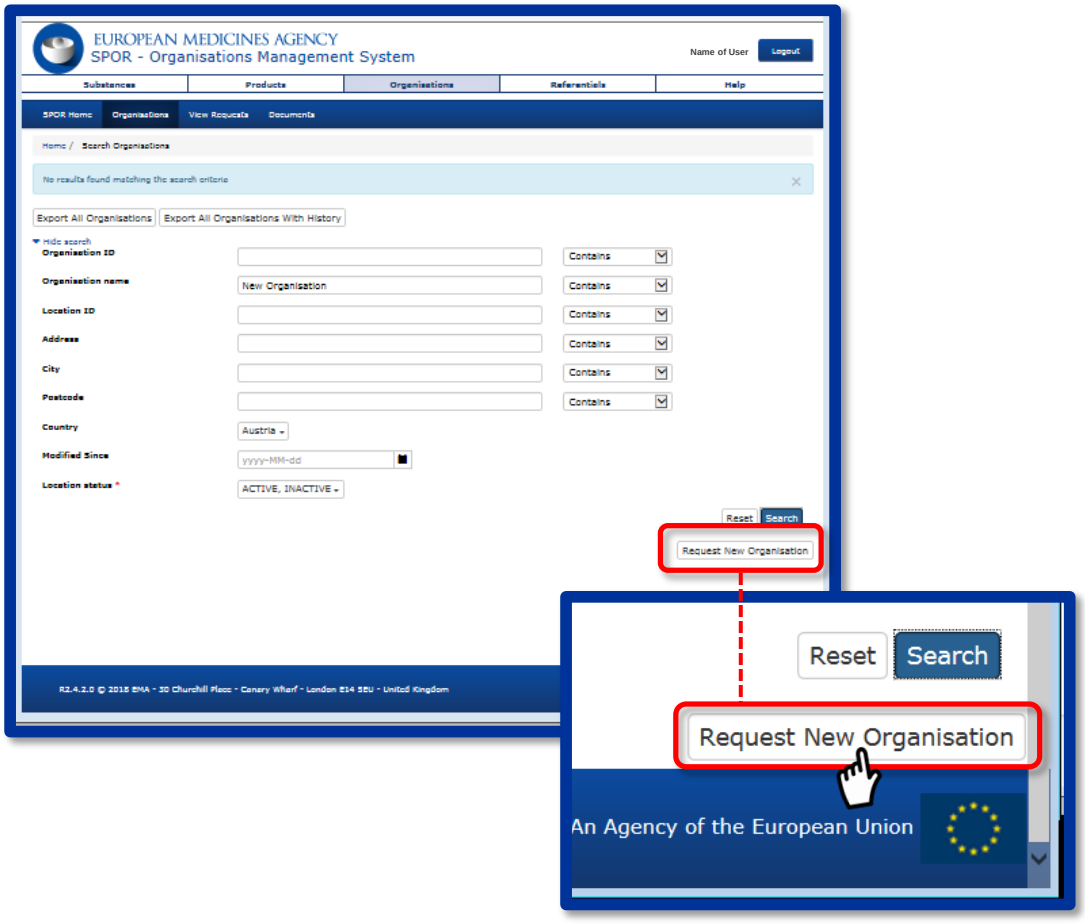


Figure 4

4. Enter your EMA Account username and password;
5. Once logged in, click on the "**Organisations**" button in the lower (dark blue) menu bar;

6. Search for the new organisation (Figure 5



);

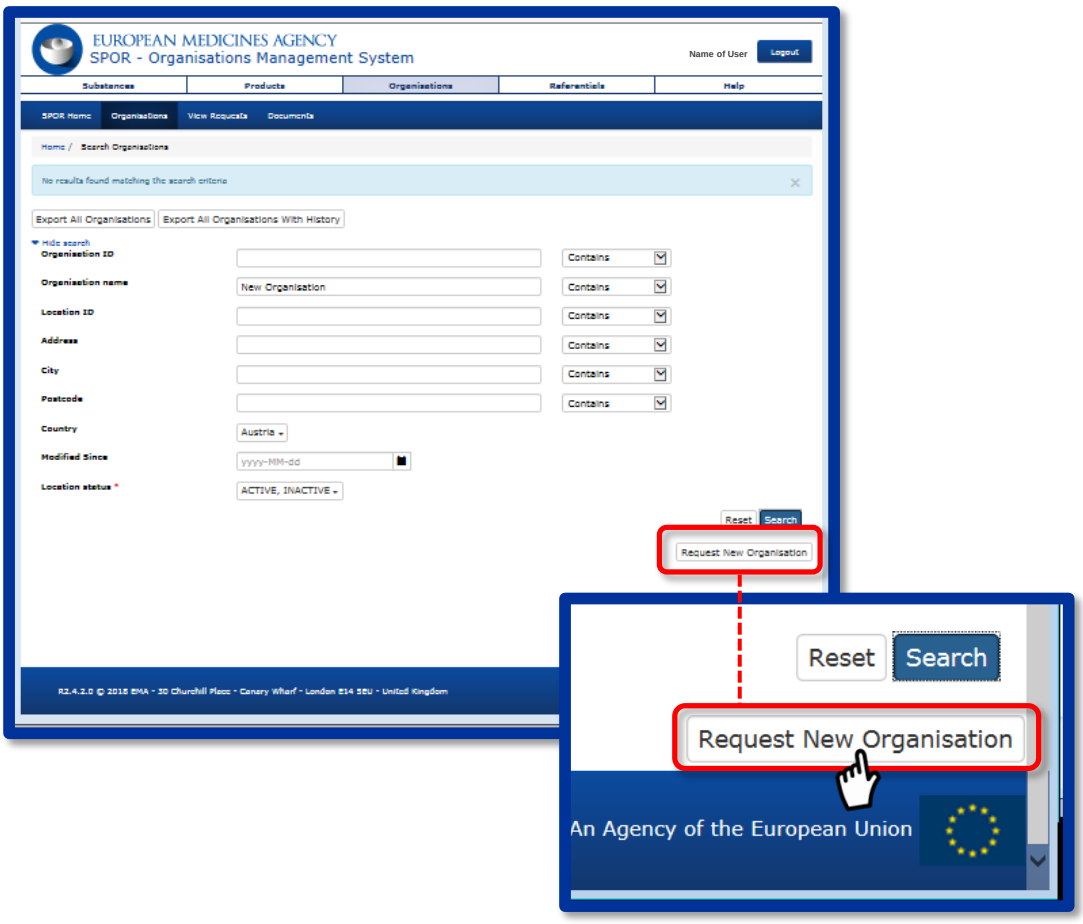


Figure 5

7. When the "*No results found…*" message comes up, click on the "**Request New Organisation**" button that appears in the bottom right of the screen (**Figure 5**). The option to request a new organisation is only made available after a search is performed;

8. Complete a change request form (**Figure 6**);

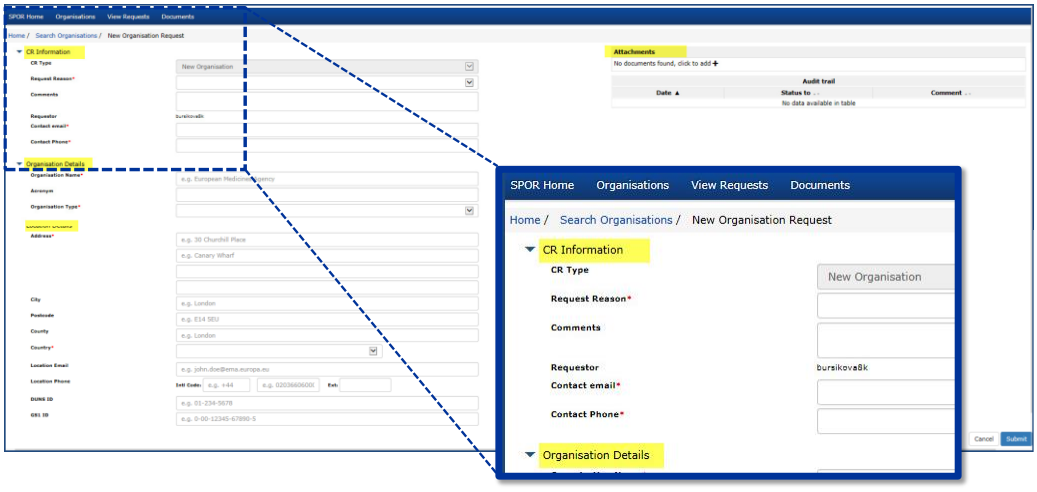


Figure 6

9. Attach the mandatory documents and submit. For guidance on which documentation should be attached to the change request to create a new organisation, refer to the "**Change requests validation in OMS**" document on the OMS documents page (**Figure 7**).

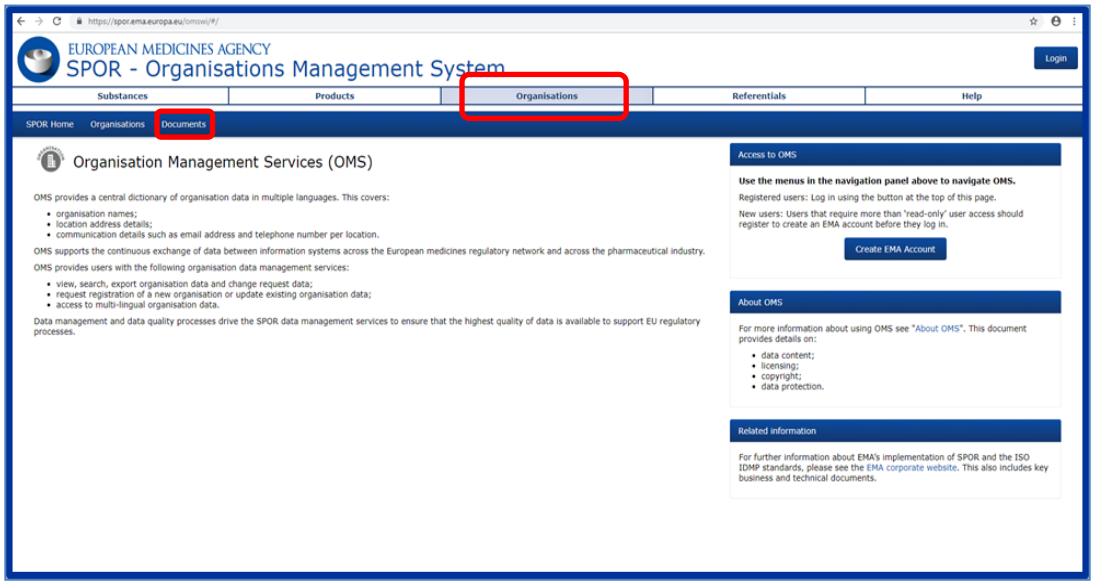


Figure 7

When your organisation has been successfully registered, you will receive an email with an Organisation ID code, confirming the successful inclusion of your organisation in the OMS dictionary.

The standard change request to register a new organisation can take **five to ten working days** to be processed.

5.2.2. Raise a request to update organisation information

Users can make changes to their organisation data in OMS using the already described **change request** functionality in the OMS interface (see section "Raise a request to create a new organisation").

The first step is to search for and view the full details of an organisation and its locations in OMS. If the users:

- find the organisation but not its location, they can ask to add a new location to the organisation;
- find both the organisation and its location, but either of these are not up to date, they can ask to update the organisation and/or location data;
- find the organisation with an active status but the location with an inactive status, they can ask to update the organisation data or add new locations.

In order to perform these changes you need to have "**SPOR Industry User**" access to the SPOR portal. Prior to that, you need to make sure that the "**SPOR Industry Super User**" role which manages access requests for your organisation has already been set up. For detailed instructions on the SPOR user registration, refer to the "SPOR User Registration Manual" found on the OMS documents page.

Note: The first "**SPOR Super User"** for each organisation will be approved by EMA. Therefore, factor in time to submit the request with the required documentation and allow up to **two working days** for EMA to approve it.

Once your request for the **"SPOR Industry User"** role has been approved, follow the steps below to request an update to your organisation data. Steps 1-6 are identical as in section "Raise a request to create a new organisation".

1. Go to the SPOR portal;
2. Click on the **"Organisations"** tab in the top menu;
3. Click on the **"Login"** button (top right of your screen);
4. Enter your EMA Account username and password;
5. Once logged in, click on the blue **"Organisations**" button in the lower (dark blue) menu bar;
6. Search for your organisation;
7. When your organisation data appears, click on the appropriate symbol under the "**Actions**" button on the right side of the screen to request a change (**Figure 8**). The option to request a change is only made available after a search is performed;

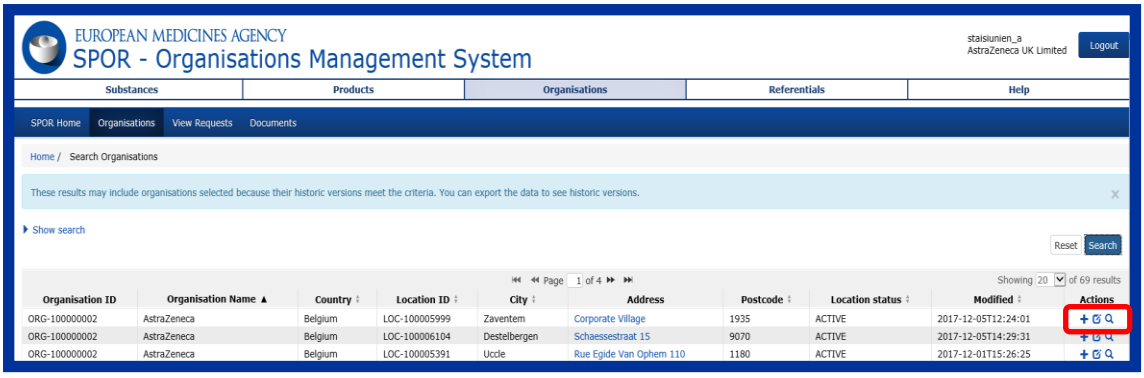


Figure 8

8. Complete a change request form;
9. Attach the mandatory documents and click "**Submit**".

For guidance on which documentation should be attached to the change request to update organisation data, refer to the "Change requests validation in OMS" document on the OMS documents page.

For more detailed instructions on how to request a new organisation, new location, request a change in organisation or location including the use of the Change Request form, please refer to section 8. ("**Request new organisation, new location or request a change in organisation or location**") on pp. 26-39 of the "**OMS web user manual**". This can be found on the OMS documents page.

If you prefer instructions in video format, you can watch the "SPOR Learning Module: OMS03 - Working with OMS Change Requests" video on the EMA YouTube channel. The section on requesting a new organisation starts about 6 minutes into this 25-minute video (06:15 –> 09:30) and shows an on-screen run through of the process with voiceover commentary in English.

6. Support

6.1. The PLM Forum

The **PLM Forum** is a public platform where users (primarily applicants) can stay up to date on the latest PLM news (e.g., new PLM features, release information), ask each other questions, provide suggestions, and discuss best practices. While posts are visible to everyone, users need to be logged in to create a new thread or reply to an existing one.

EMA staff may intervene in the forums, but replies to individual questions cannot be guaranteed, as the forum does not replace the established EMA communication channels:

- EMA Service Desk for access and registration requests and for reporting faults;
- EMA Account Management for access and registration requests
- Ask EMA for general questions not related to a specific submission/procedure;

Direct replies to eAF e-mails (without changing the subject), when responding to issues relating to a specific procedure.

Please note any text contained in the threads of the forum is publicly available, therefore please do not post any type of confidential information.

6.2. The Service Desk

For **technical support** with the PLM Portal, please use directly the PLM Portal-eAF section of the EMA Service Desk portal. This includes issues related to creation of new accounts, access to existing accounts, uploading data and performance of databases.

If you have a user account for a system hosted by EMA, you should use the same username and password for this service. Otherwise, please Sign up for a new account or reset your login credentials.

The Service Desk portal is optimised for use with Chrome, Edge, Firefox or Safari web browsers. If you encounter problems, please use one of these browsers instead.

Report an issue with the PLM Portal - eAF, to create a ticket for the issue you are experiencing, or,
Request information about the PLM Portal - eAF, to create a ticket for the question you have.

Depending on the issue or question, you can select from different problem areas:

- PLM portal – eAF FHIR XML (issues and questions on the FHIR xml)
- PLM portal – eAF General (topics covering multiple aspects and/or general nature)
- PLM portal – eAF PDF export (issues/discrepancies/errors in the generated pdf)
- PLM portal – eAF Web-form User Interface (issues/questions/improvements relating to the web UI)

Please provide a clear description of the issue and provide screenshots or the generated pdf as attachment as these can help to solve the query a lot faster.

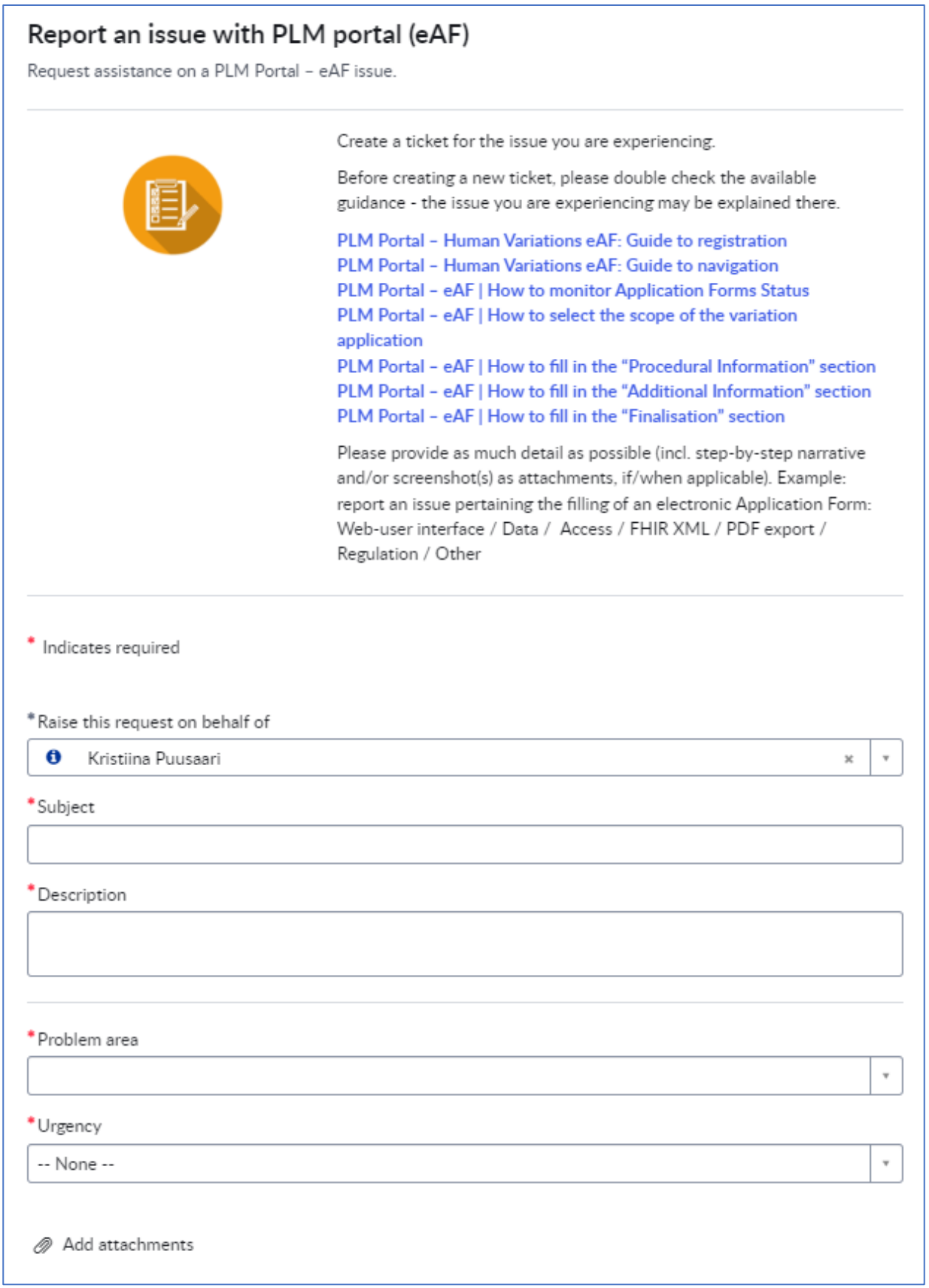


Figure 9 – Report an issue with PLM Portal (eAF) form

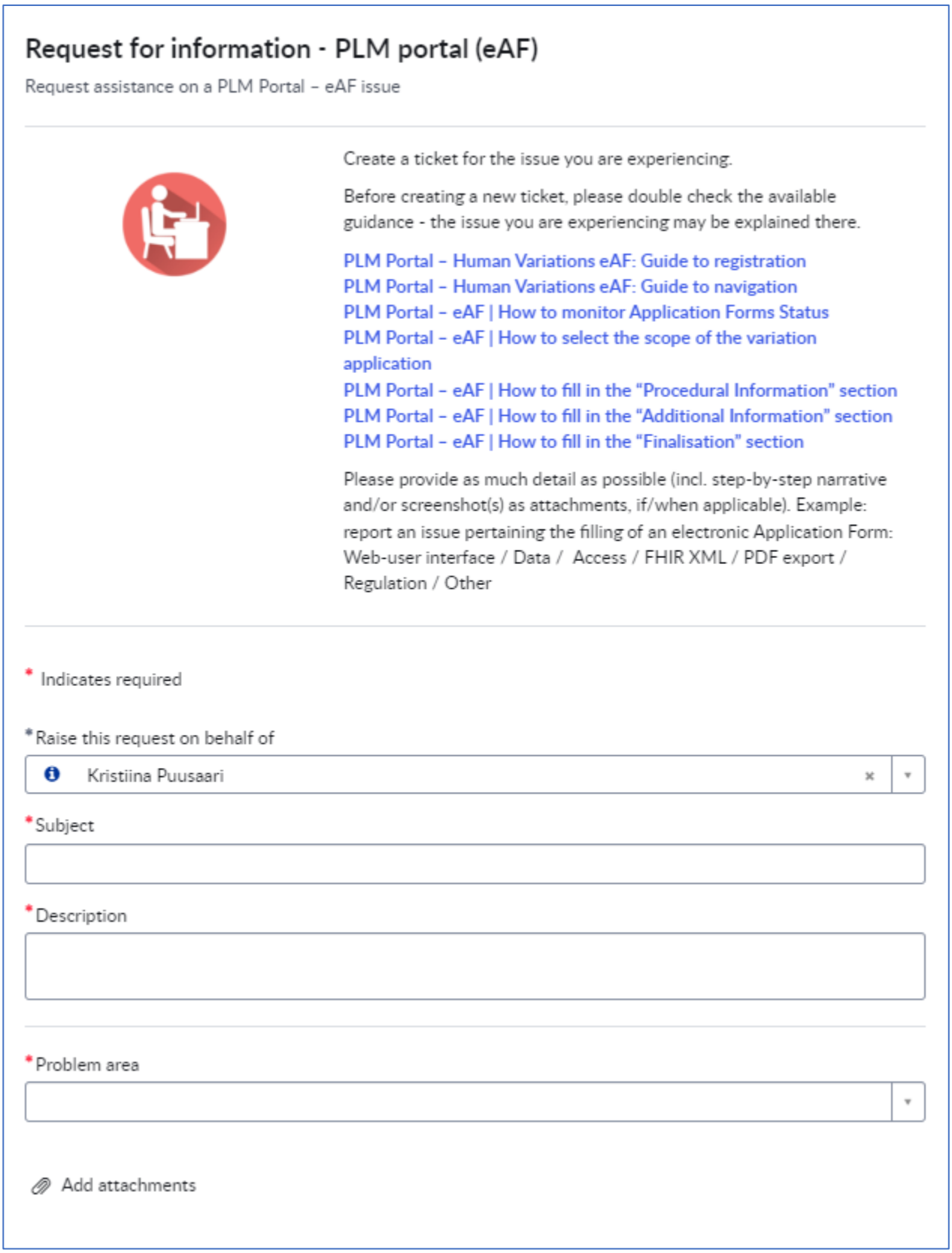


Figure 10 – Request for Information - PLM Portal (eAF) form

6.3. The PLM Chatbot

The **PLM Chatbot** is an artificial intelligence tool where users are offered with digital assistance for commonly asked questions in an interactive mode. You are encouraged to use the buttons to navigate through the information or to type your question directly into the chat.

To access and engage with the PLM Chatbot, click on the icon, available on the right hand side of the PLM Portal.

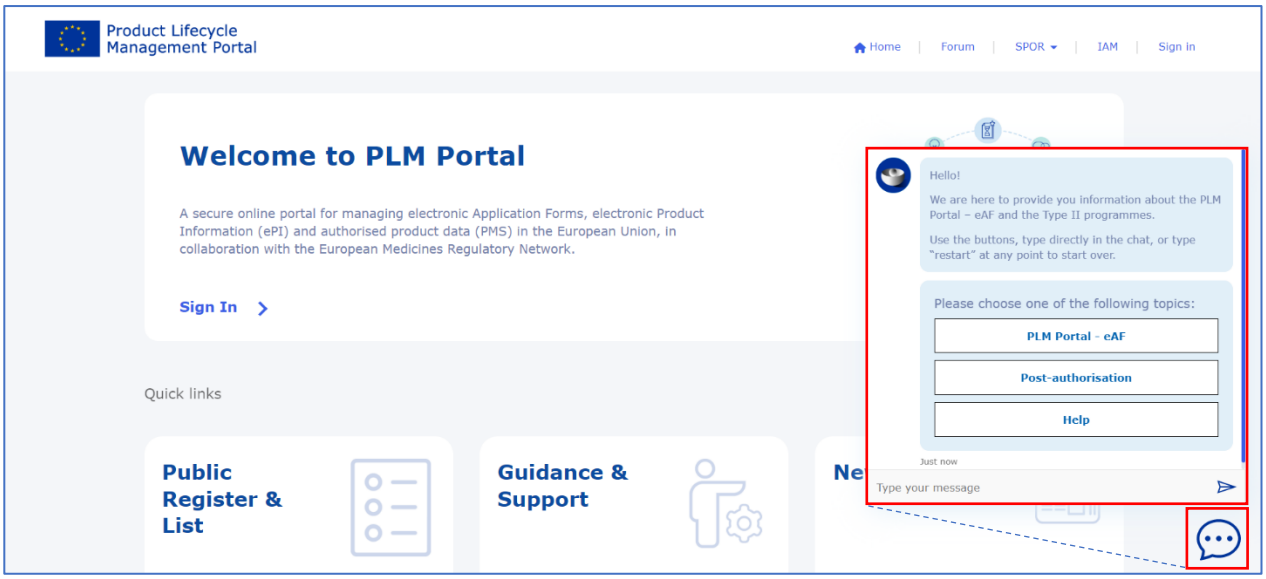


Figure 11 – PLM Chatbot