eAF Portal – Guide to registration

Version 1

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Acronym key and glossary terms

EMA   European Medicines Agency

IT   Information Technology

eAF   Electronic Application Form

FAQ   Frequently Asked Questions

OMS   Organisation Management Service (part of SPOR)

SPOR   Management Services for Substances, Products, Organisations and Referentials

MAH   Market Authorisation Holder

1. Purpose and Context

This guide aims to support the users of the eAF Portal in completing the registration steps before accessing the platform. Most of these steps are independent from the eAF Portal 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 eAF Portal

To sign in to the eAF Portal 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 eAF Portal, 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 eAF Portal

3.1. Types of user access roles

The eAF Portal 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.

3.1.1. Applicant-related roles

Within the applicant layer, there are four different roles, which allow performing different operations in the eAF Portal. 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
	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 eAF Portal. Please note that as from the go-live date of the eAF Portal, 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'.

3.1.2. 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 eAF portal.

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 eAF Portal are shared with the IRIS Portal – if you are already an admin-user for IRIS, you will automatically be an admin-user for the eAF Portal. Similarly, if you become an admin-user for the eAF Portal, 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.

3.2. Grants provided by each user access role

3.2.1. Applicant-related roles

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

- 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 eAF Portal, 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)	✓	✓	✓	✓
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
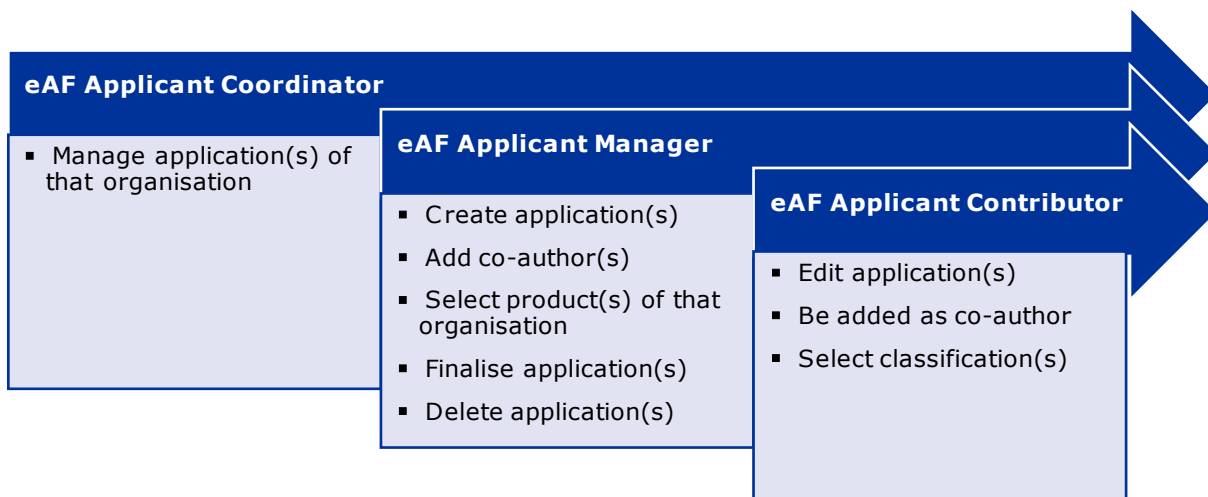
given Application Form refers to. A user may be referred to as an 'Applicant Coordinator of organisation X' and 'Applicant Manager of organisation Y'.

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.

eAF Applicant Coordinator

- Manage application(s) of that organisation

eAF Applicant Manager

- Create application(s)
- Add co-author(s)
- Select product(s) of that organisation
- Finalise application(s)
- Delete application(s)

eAF Applicant Contributor

- Edit application(s)
- Be added as co-author
- Select classification(s)

✓ 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.

3.2.2. 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 eAF portal. 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 eAF Portal, 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 eAF Portal, 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.

3.3. 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.

3.4. Which access role(s) shall I 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 eAF Portal.

The following decision tree summarises the access role(s) you must request/ be granted with:
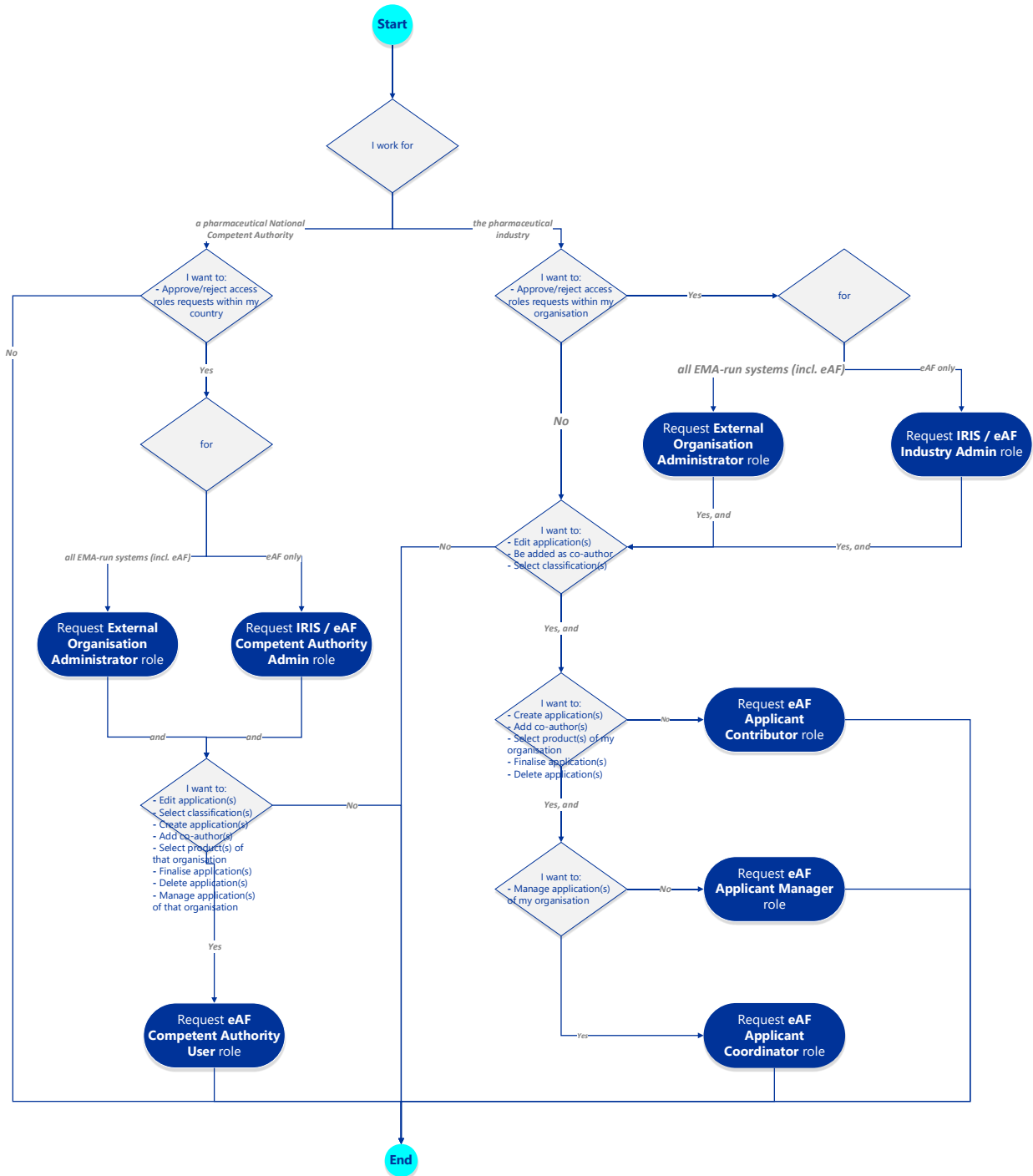
Please note that as a result of any path within the decision tree above, for every organisation a maximum of two roles are to be requested per each user (one admin-related role and one applicant-related role).

3.5. Other Frequently Asked Questions (FAQs)

3.5.1. 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, please contact the EMA Service Desk.

3.5.2. 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 contact directly the administrator of the organisation on whose behalf you will be acting for further information.

3.5.3. 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 3.1.1. and 3.2.1. for additional information on the applicant-related roles.

3.5.4. 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.

4. Organisation registration in OMS (SPOR)

To request the necessary user access roles and submit applications via the eAF Portal, 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.

4.1. Look up whether your Organisation is registered in OMS

4.1.1. From the EMA Account Management Portal

You can check whether your organisation is registered in OMS during the eAF Portal user access request process in the [EMA Account Management](#) Portal (see section 3.3. 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 4.2. Request Organisation to be registered in OMS, or update its data.

4.1.2. 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.

4.1.3. 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);
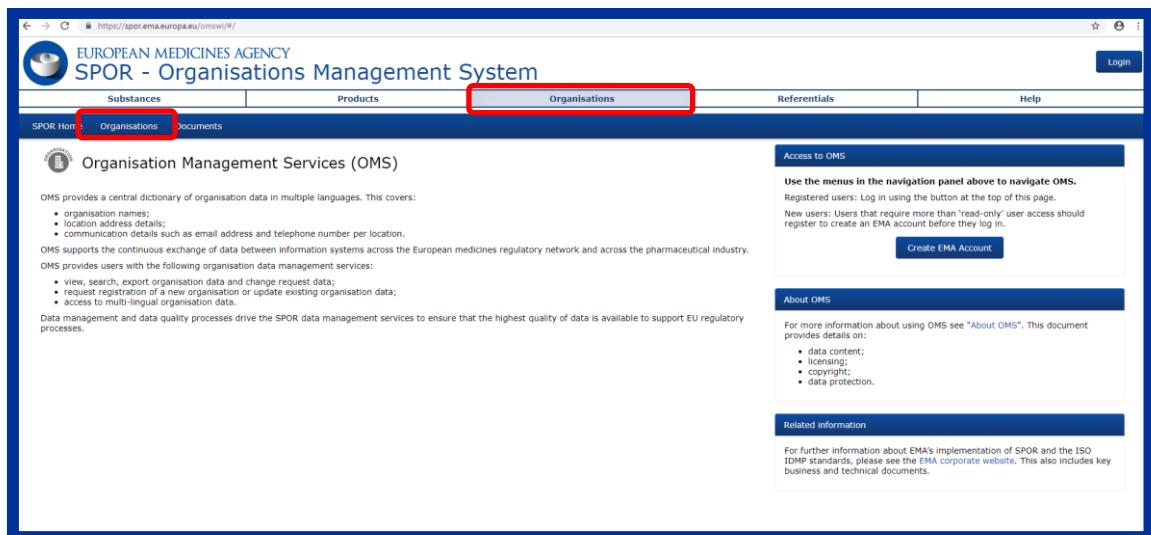
Figure 1

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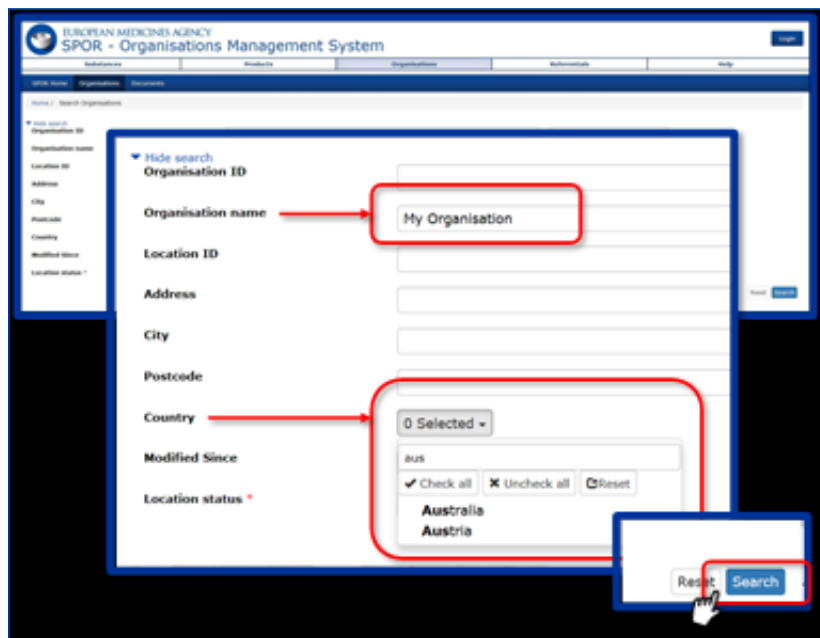

Figure 2

- 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 eAF Portal 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 eAF Portal 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".

4.2. 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.

4.2.1. 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);
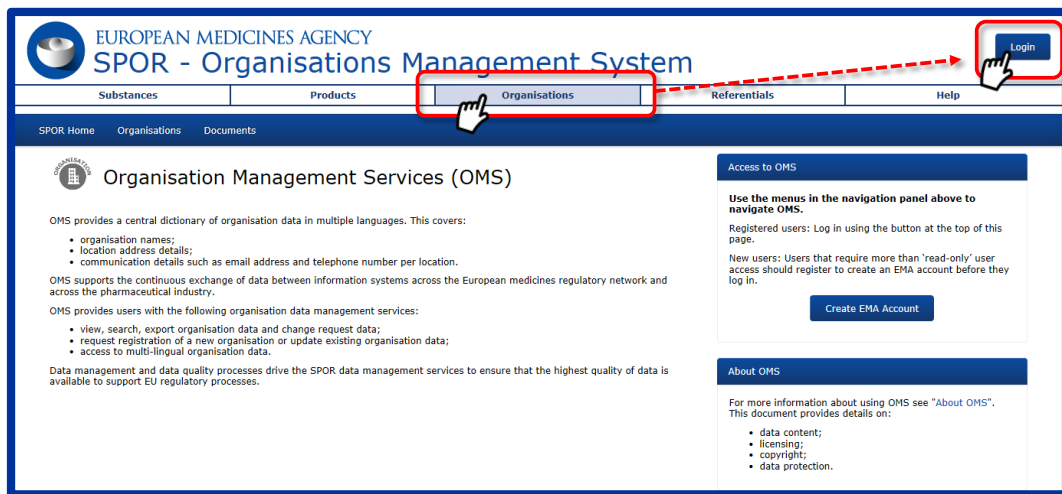
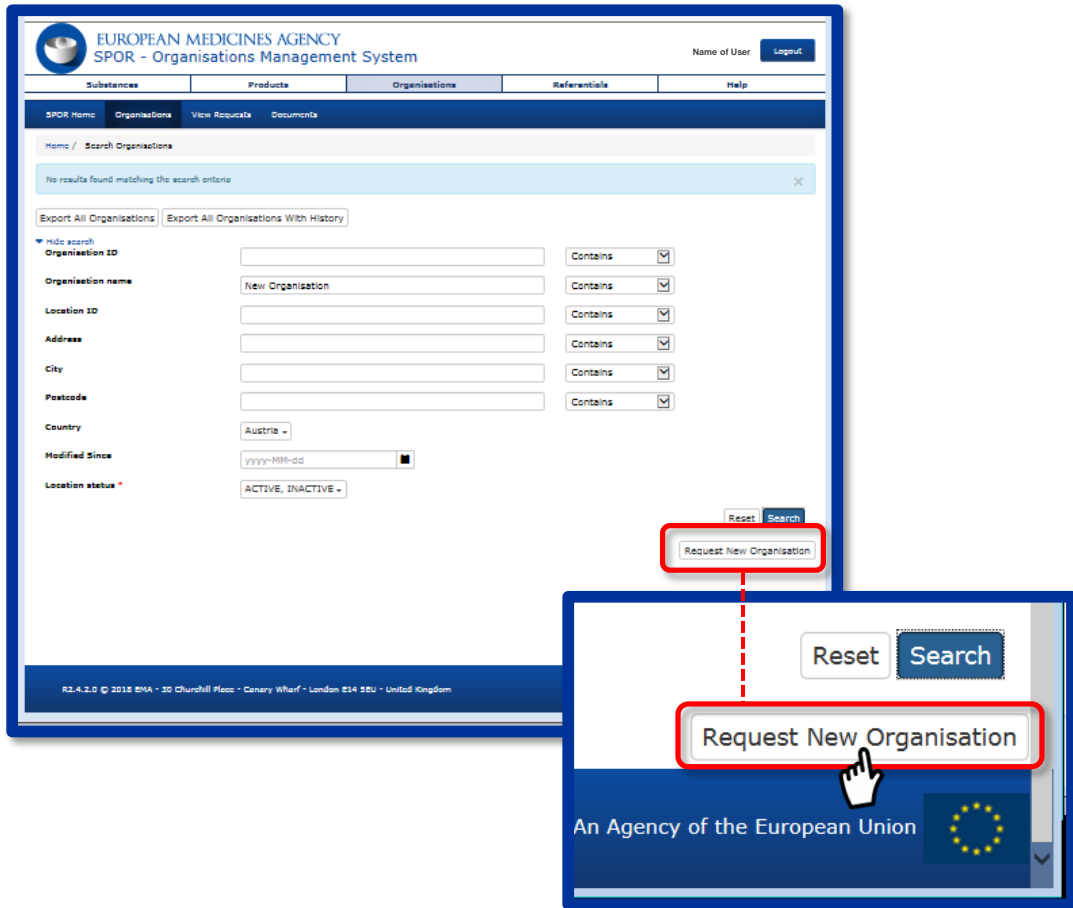3. Click on the "**Login**" button (Figure 4);

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;
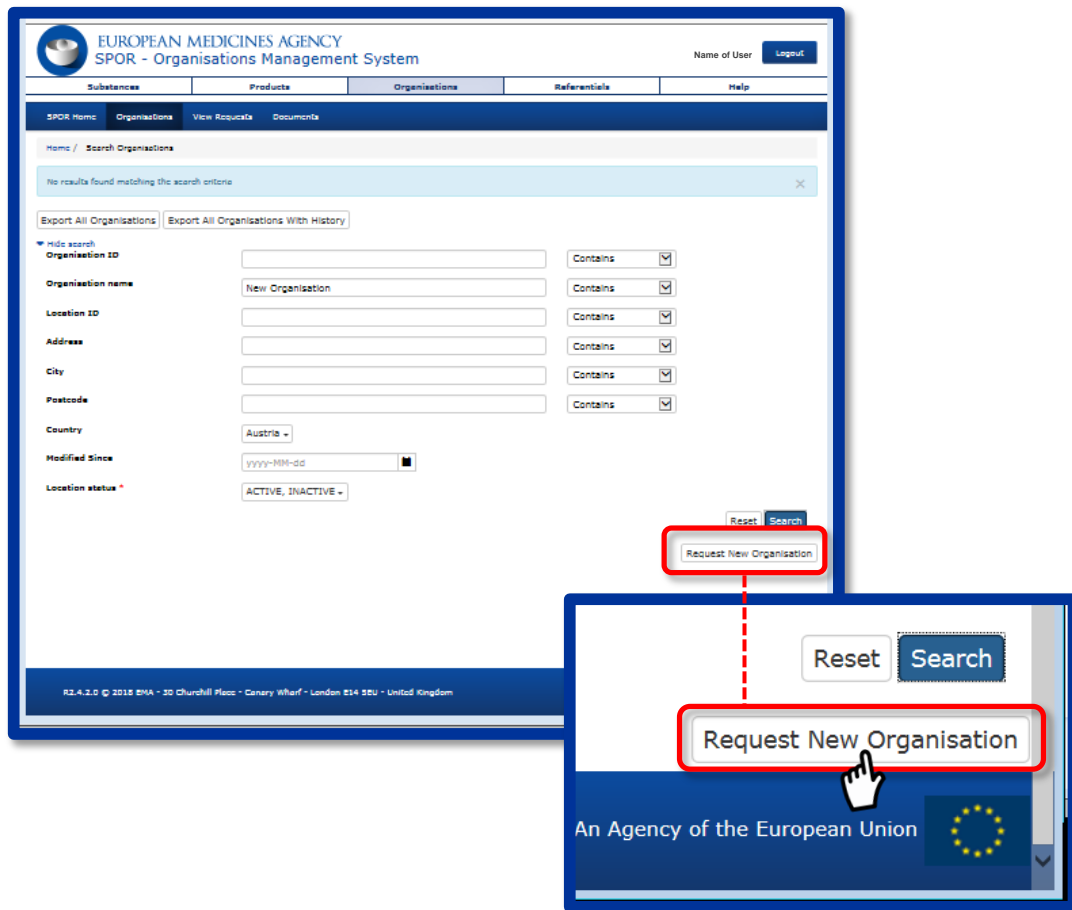
6. Search for the new organisation (Figure 5

);

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;

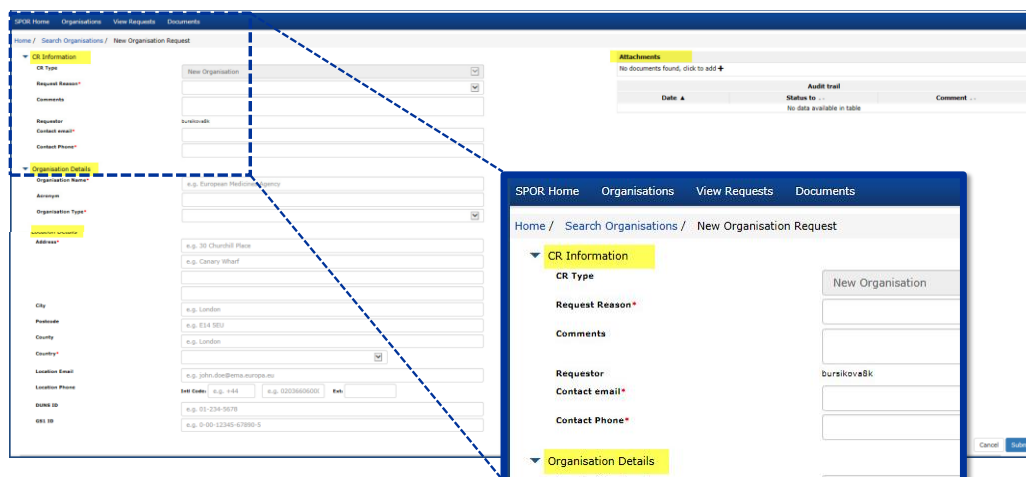**8.** Complete a change request form (Figure 6);

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).
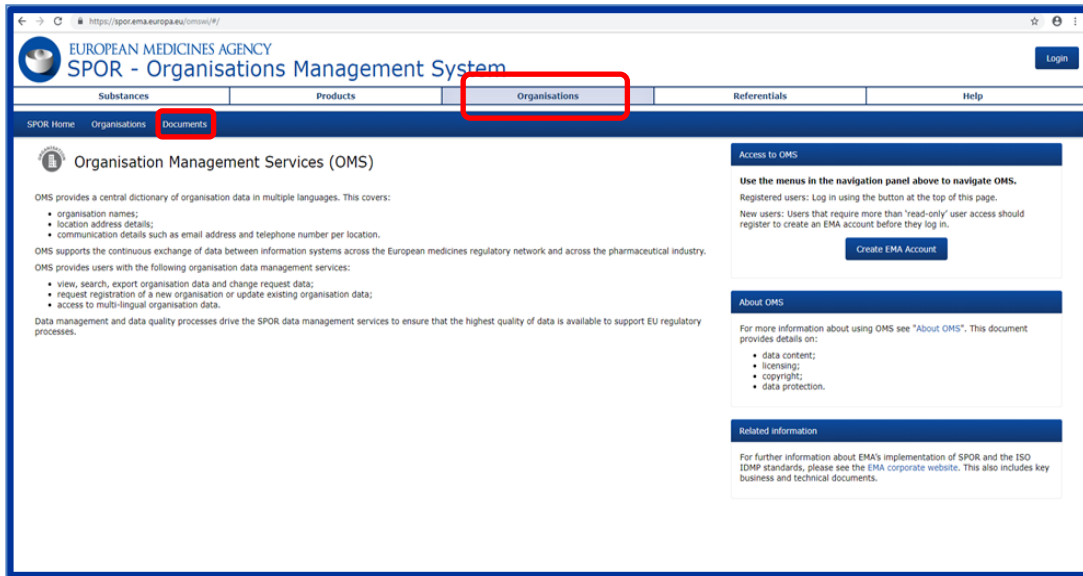

Figure 7

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.

4.2.2. 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:
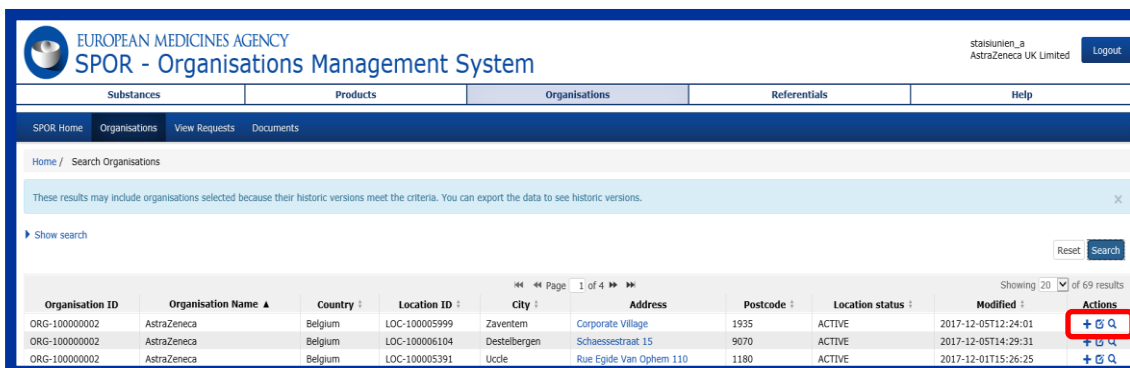
▪ find the organisation but not its location, they can ask to add a new location to the organisation;

▪ 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.

![European Medicines Agency logo - EUROPEAN MEDICINES AGENCY - SCIENCE MEDICINES HEALTH]

<u>Note:</u> 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.

5. Support

The **eAF Forum** is a public platform where users (primarily applicants) can stay up-to-date on the latest eAF news (e.g., new eAF 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;
- [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.

For **technical support** with EMA's IT systems, please use the [EMA Service Desk](#) portal. This includes 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 use Internet Explorer and encounter problems, please use one of these browsers instead.