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Data Analytics and Methods

EMA EudraVigilance Registration Manual

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1. Registration overview

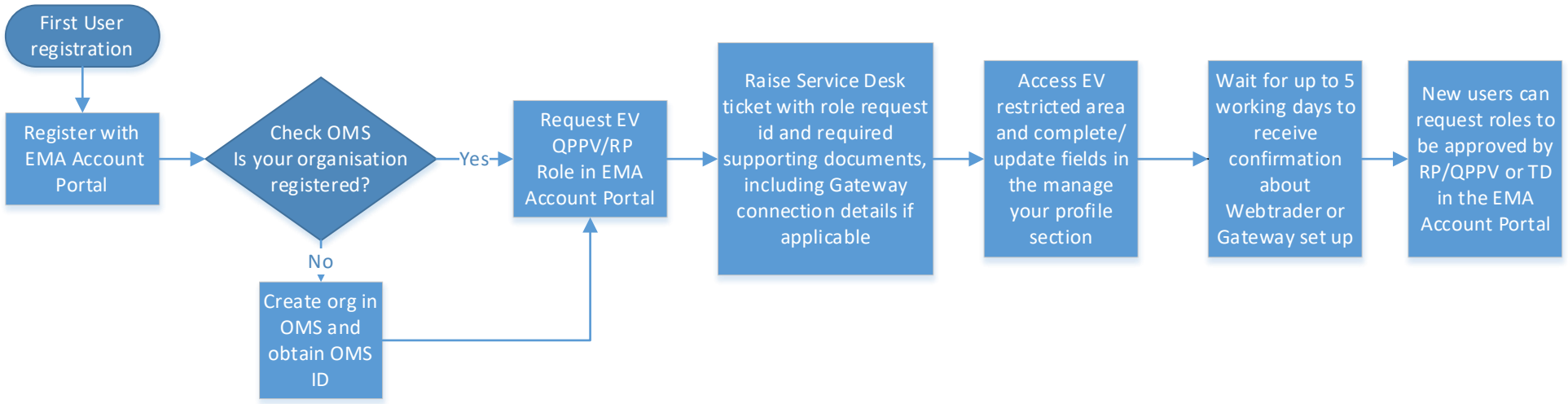
To set-up a new organisation in EudraVigilance (EV) Production or XCOMP (test) system, a series of steps need to be followed (also illustrated in **Figure 1**):

1. A person within the organisation needs to be chosen as being responsible for managing the organisation and its users in the EudraVigilance Production system. If the organisation is a marketing authorisation holder (MAH), the primary responsible person will be a **Qualified Person for Pharmacovigilance (QPPV)**; if the organisation is a commercial/non-commercial sponsor, it will be a **Responsible Person (RP)**.
2. Register for an EMA user account in the EMA Account Management portal, if you do not already have one – see **section 2.**
3. Search for your organisation in SPOR Organisation Management System (OMS). If your organisation is not present, it will need to be created – see **section 3.3.**
4. Submit a request to be registered as the QPPV/RP for the organisation – see **section 4.1.**
5. Complete organisation registration details in the EudraVigilance restricted area – see **section 4.2.**
6. Wait for EMA confirmation that WebTrader or Gateway transmission mode has been set up for your organisation – see **section 6.1.1.**

Once the QPPV or RP is registered for the Production EudraVigilance system they will automatically also be registered for an XCOMP test account for the same organisation.

NOTE: If your organisation is a **non-commercial sponsor (NCS)** of clinical trials additional support is available for registering and managing users within the organisation – see **section 8.**

Figure 1 - Overview of the Registration process with EudraVigilance Production system



2. EMA Account Management portal (IAM)

The first step to access EudraVigilance is to be registered with the EMA Account Management portal (IAM).

It is likely that you already have an EMA Account Management portal account if you have access to at least one of the following EMA systems: EudraLink, EudraCT Secure, IT Service Desk portal (JIRA), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR. Users who are already registered and have credentials for one or more of these systems do not need to re-register in the EMA Account Management portal.

If you cannot remember your password or user name please see **section 2.4.** and **section 2.5.** for details on how recover your account. The username and password are the same for all these systems.

Users registered with EudraVigilance can already log-in to EudraVigilance with their IAM username/password – you can find a shortcut to the EV Human Production restricted area on the EudraVigilance: how to register webpage. There is a validator on the e-mail address to prevent the creation of duplicate EMA IAM accounts during self-registration.

Important note: An individual can only have one IAM user account. A user can, however, have more than one EudraVigilance account associated with their EMA account. In order to have access to more than one organisation, users need to submit separate EudraVigilance base role requests for those organisations. The base roles and, therefore, levels of access to each of these organisations, can be different.

This document provides step-by-step instruction on how to register and how to apply for EV user roles. A list of base roles is provided in the **Annex 1** of this manual.

For more information about EMA Account Management portal please refer to Welcome to EMA Account Management | Self registration & access management.

2.1. Registration with the EMA Account Management portal

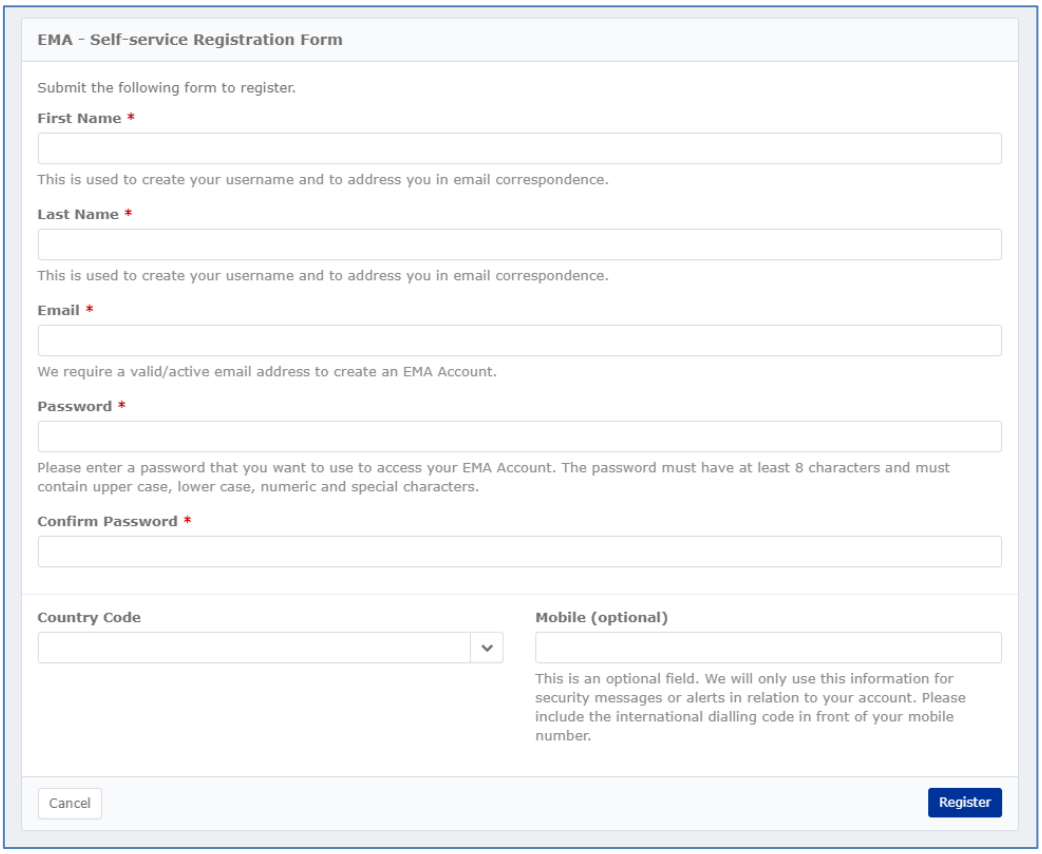
Users who do not have access to any of the Agency's systems should self-register following the steps described below. After registration, the user will be able to request EudraVigilance user roles as described in the EudraVigilance user access management section.

NOTE: before registering, click on "Not sure if you have an EMA account?" on the EMA Account Management portal page to review the EMA systems for which you could already have access to.

In addition, if you have access to IAM with different e-mail addresses, please raise an EMA Service Desk ticket to request the merge of your IAM accounts so that you have one unique EMA Account. Your current access to current systems will then be combined in this unique account. If you have duplicated IAM accounts, you will not be able to use one set of login credentials to access all the organisations you are registered with.

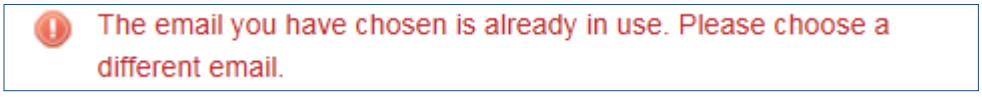
Please note that following registration to the EMA Account Management portal, it may take up to 24h for the systems to sync, please therefore allow 24h before trying to log in for the first time.

Figure 2 - Self-registration form on the EMA Account Management portal



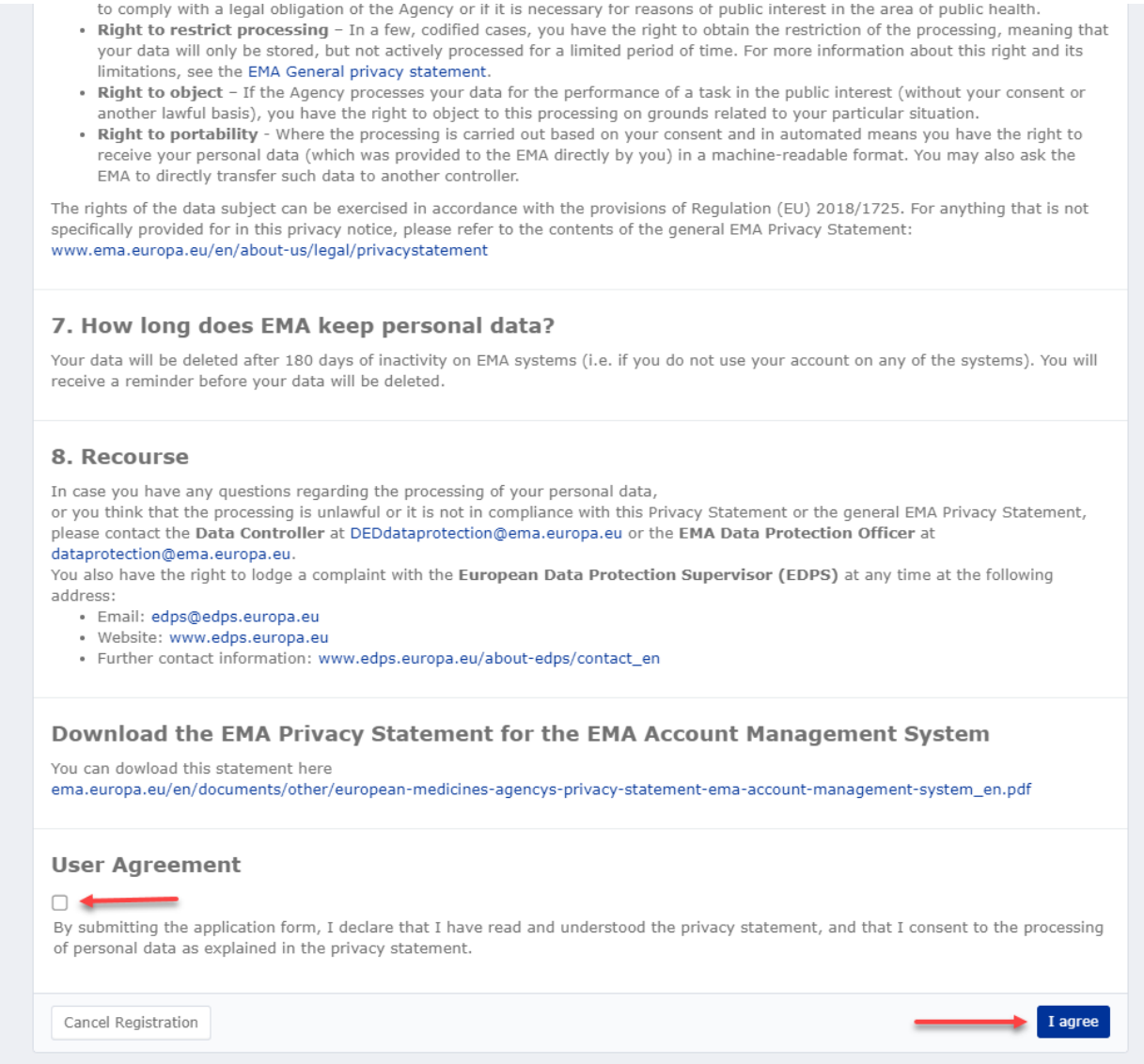
1. Mandatory fields are marked by a red asterisk (*).
2. Optional field – mobile phone (landline number can be provided too), strongly recommended for cases when e-mail does not work or changes.
3. Read the "Data protection policy agreement".
4. Click on "Register".

   The system can recognise already used e-mail addresses in order to prevent the creation of duplicate user entries. In case the e-mail address is already registered, the user is prompted to use a different e-mail address. In such a situation it is better to go back to the landing page and click the "Forgot password?" option.

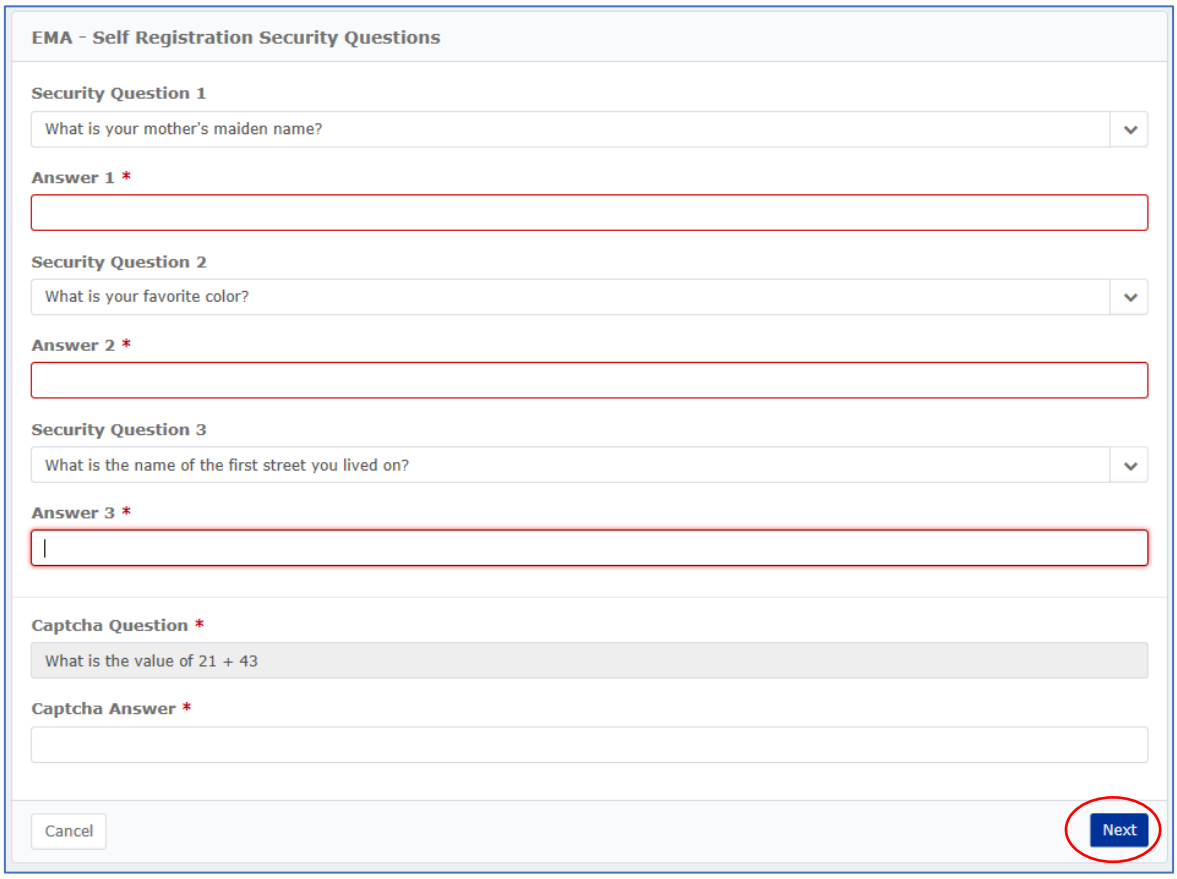
5. Once you have clicked on "Register", the system takes you to a page displaying the **EMA privacy statement**. Please read and agree by ticking the box in the "User Agreement" section at the end of the page and click "I agree" - see **Figure 3** below.

Figure 3 - EMA privacy statement



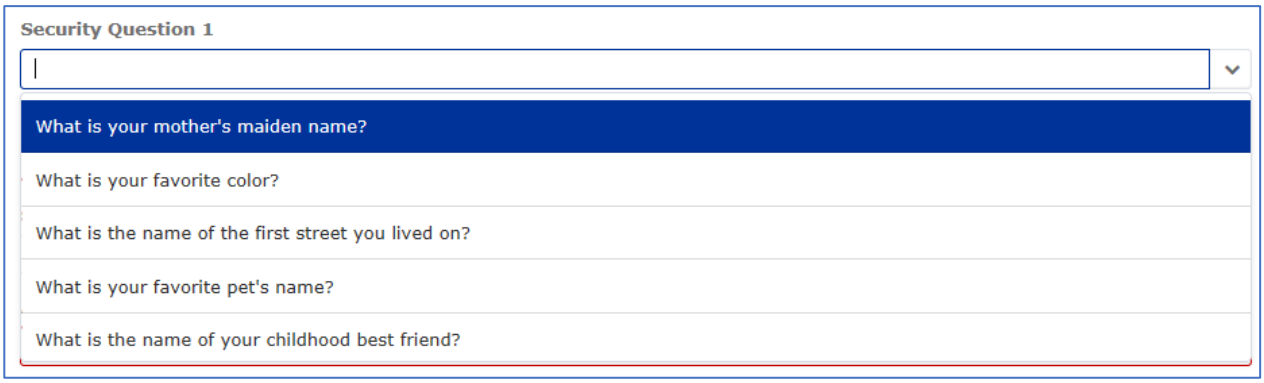
6. After agreeing to the statement, you are taken to a screen with **security questions** which will allow you to reset forgotten passwords - see **Figure 4** below.

Figure 4 - Security questions page



The same list of questions is provided for Q1, Q2 and Q3 – see **Figure 5**. The user must choose 3 different questions and click "Next".

Figure 5 - Security questions options – scroll-down list

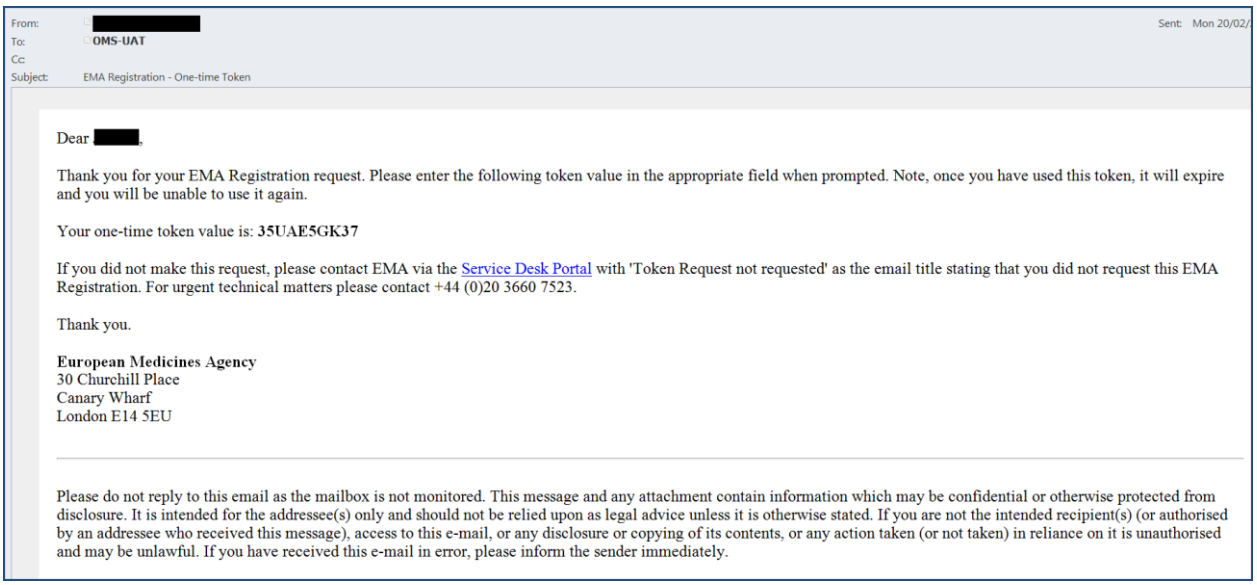


Answer the captcha question (an arithmetic calculation) and click 'Next' to go to the registration confirmation page.

Figure 6 - Captcha questions

7. An e-mail with an authorisation token is sent to the e-mail address provided.

Figure 7 - Authorisation token e-mail example



NOTE: if you have forgotten the answer to your security questions or your account is locked, please raise a Service Desk ticket.

8. Confirm the registration.

   The user needs to make sure that the data in the 'Your Details' section is correct.

   The code received in the email that was sent previously needs to be inserted in the field 'Confirm token' field found in the section 'One-time token' – see **Figure 7**.

   By clicking "Confirm" an EMA account is created. A confirmation e-mail of a successful registration is sent – see **Figure 8** & **Figure 9.**

Figure 8 - Confirmation of the user registration

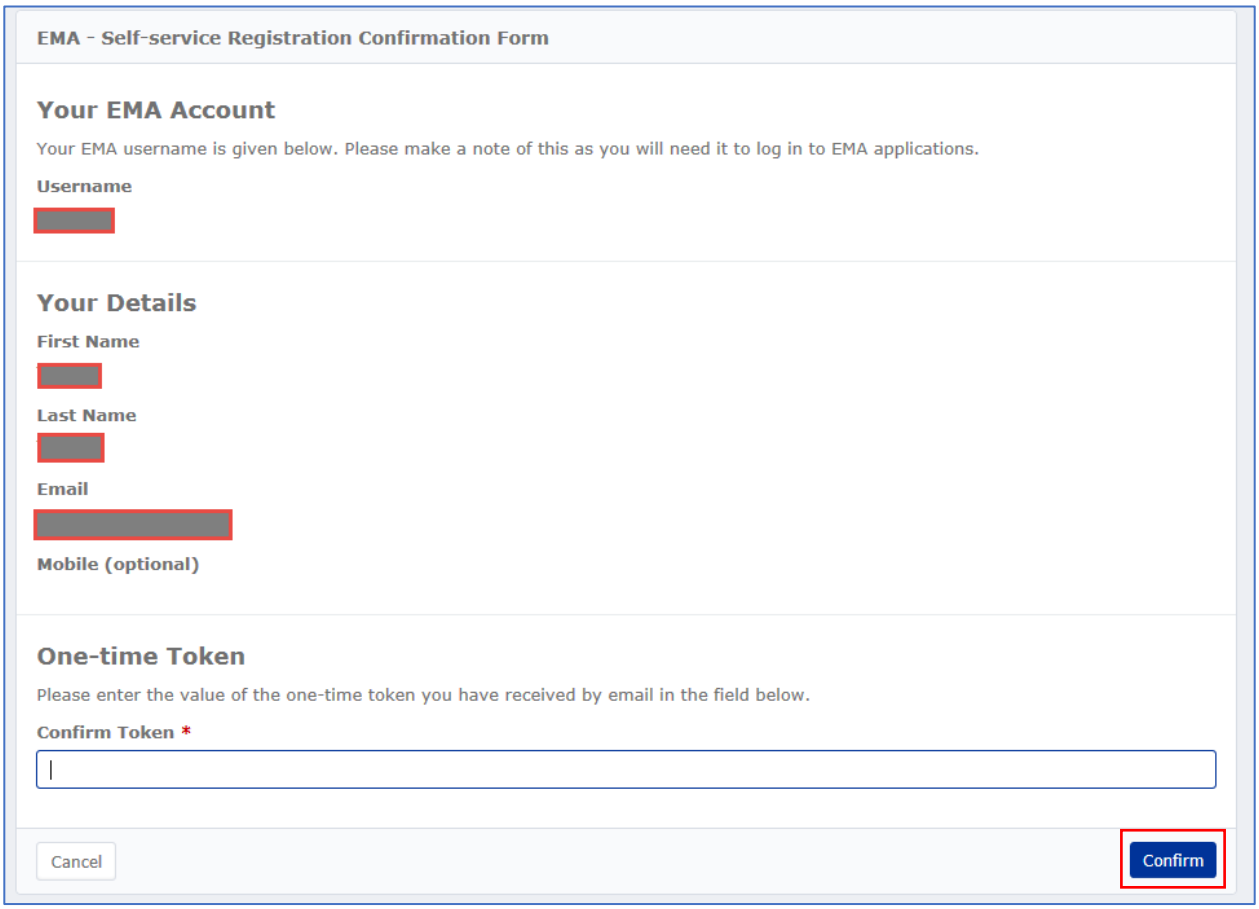
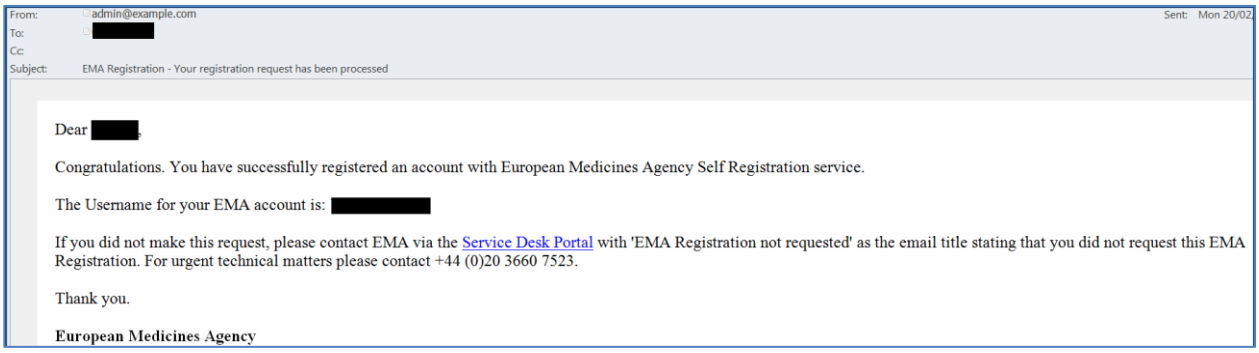


Figure 9 - Registration successful – confirmation e-mail example

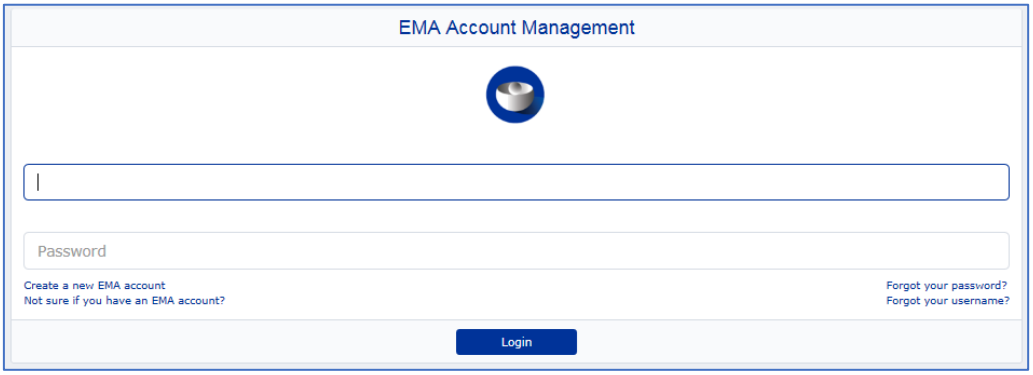


9. Once you have your credentials, log in via EMA Account Management portal.

2.2. Log into EMA Account Management portal

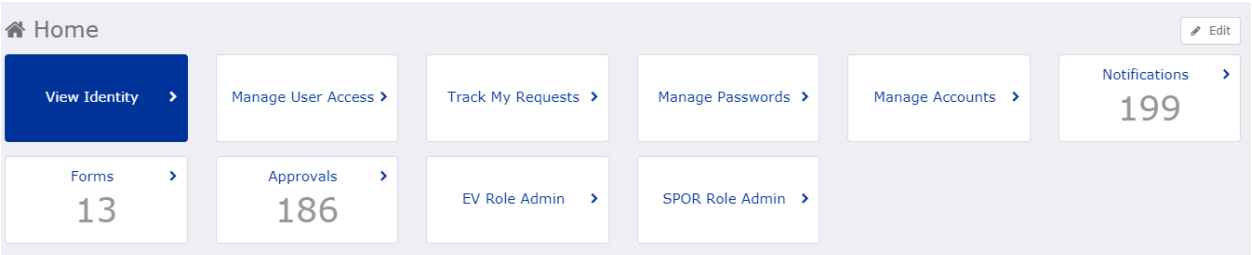
Using the username and password provided in the registration confirmation e-mail you can log into the EMA Account Management portal.

Figure 10 - Log-in page for registered users



Once you have logged in you will be presented with your user dashboard (tabs vary depending on the administrator or standard user access that the user has been granted).

Figure 11 - EMA Account Management portal dashboard



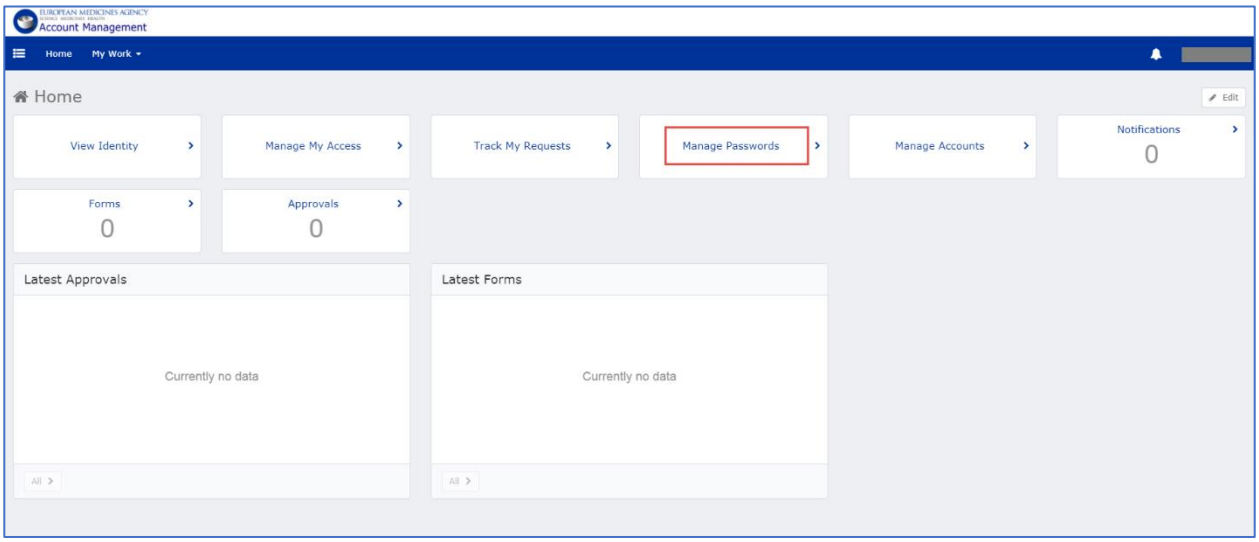
2.3. Change password in EMA Account Management portal

You can change the password used for the EMA Account Management portal either by using the "Forgot password" option on the main log in page or in the portal. Please note that changing the password here also changes the password for logging into all the systems managed by the portal.

In order to change your password follow the next steps:

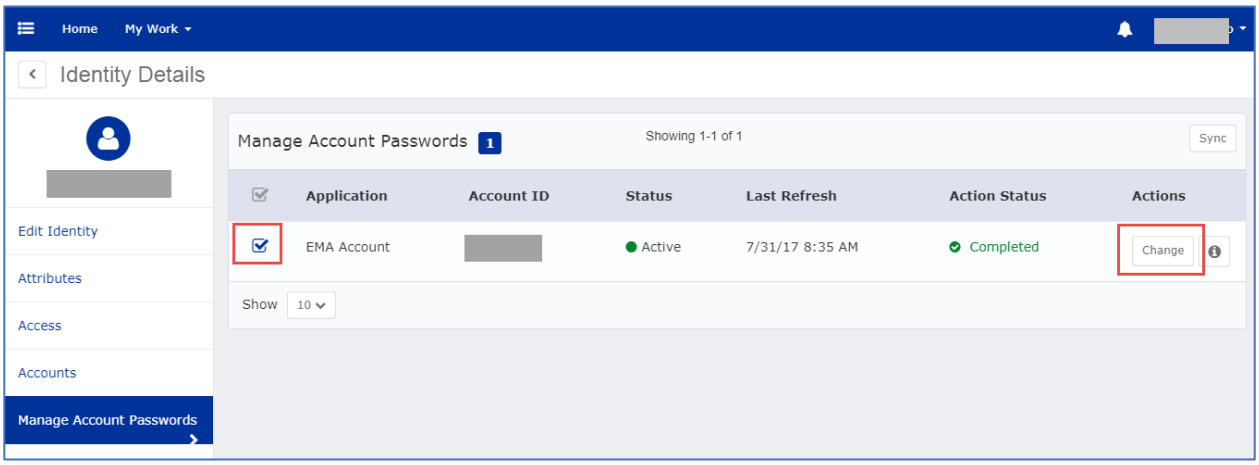
1. Log in to the EMA Account Management portal
2. Click on the 'Edit Identity' link on your Home page

Figure 12 - Change password in the EMA Account Management portal



3. Select your EMA Account by clicking on the checkbox in front of the account for the EMA Account Application, press 'Change'.

Figure 13 - Manage passwords screen in the EMA Account Management portal

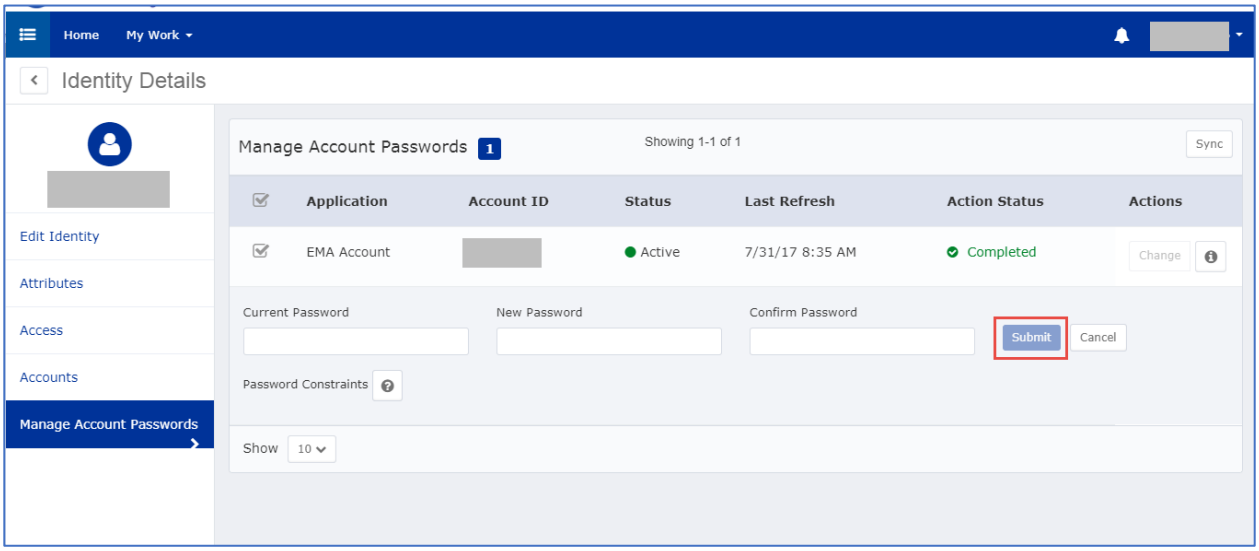


4. Type your current password in the 'Current Password' field and the new password in the 'New Password' and 'Confirm Password' fields.

   NOTE: Accented characters and the symbols '+' and '&' should be avoided as they will cause access issues to some EMA applications.

5. Click the ‘Submit’ button.

Figure 14 - New password and submit

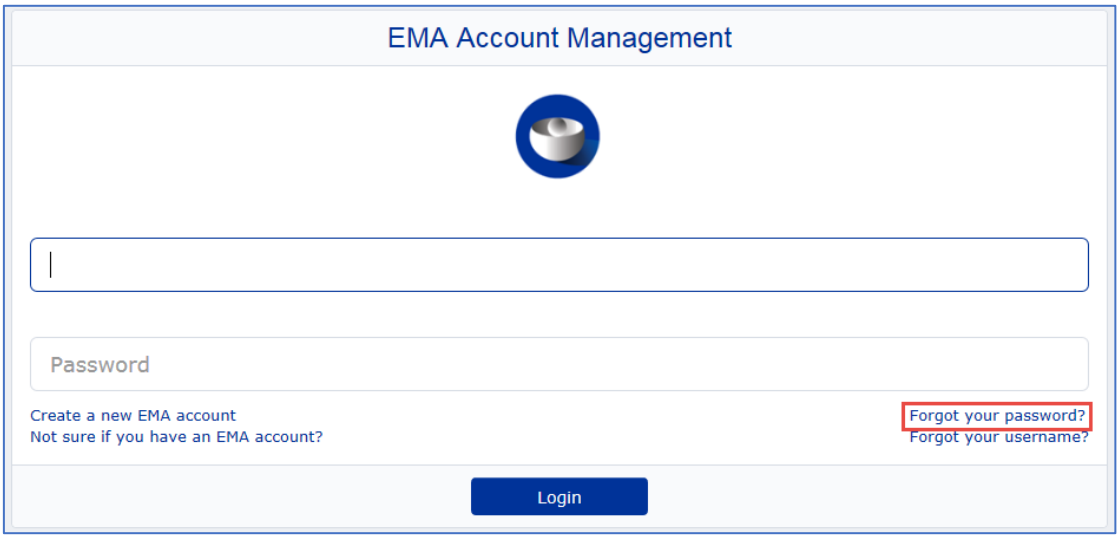


2.4. Reset forgotten password

If you forget your password for EMA Account Management portal & EudraVigilance you can reset it by following the next steps:

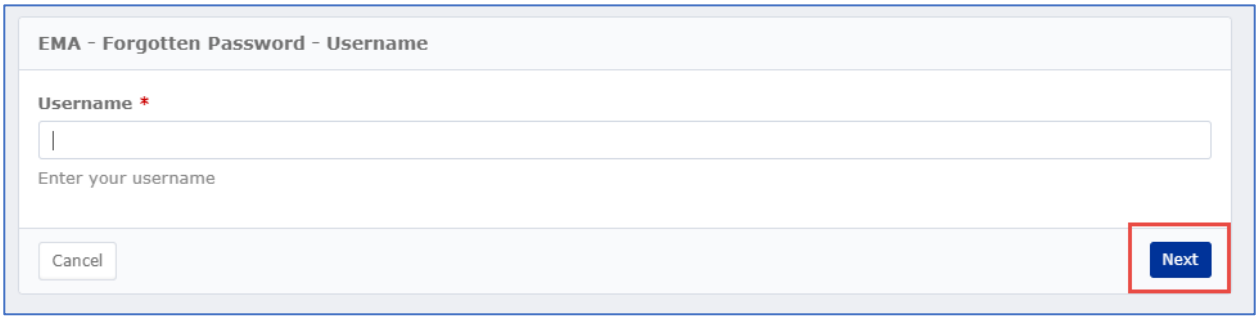
1. A forgotten password can be reset with the help of the security questions
2. Navigate to https://register.ema.europa.eu
3. Click the 'Forgot your password?' link.

Figure 15 - EMA Account Management Portal and forgotten password link



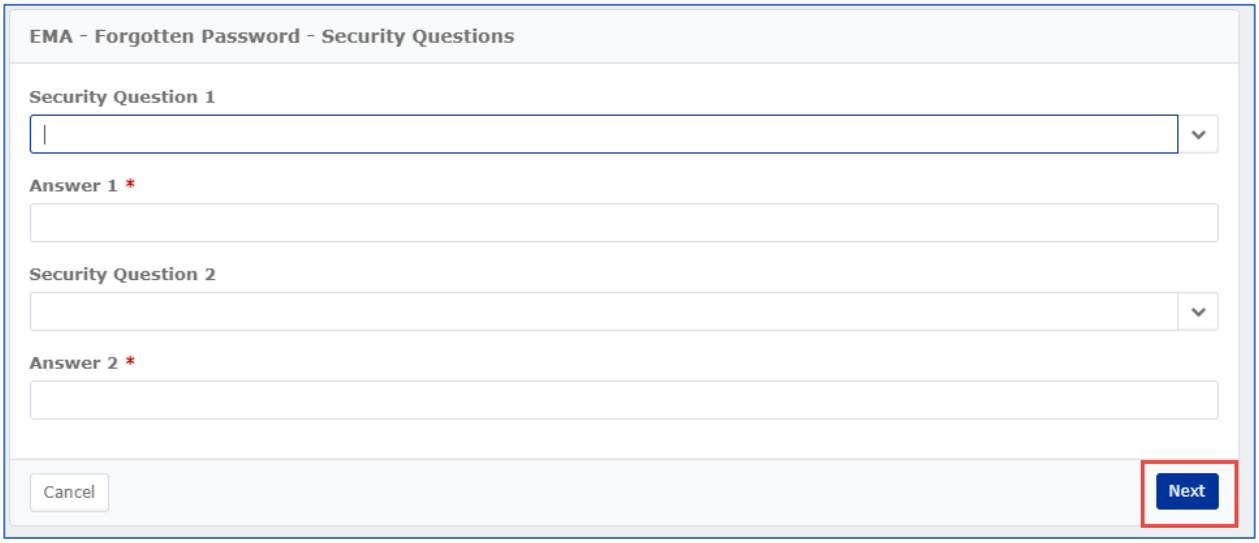
4. Input your username in the 'Username' field and click the 'Next' button.

Figure 16 - Input username to retrieve forgotten password



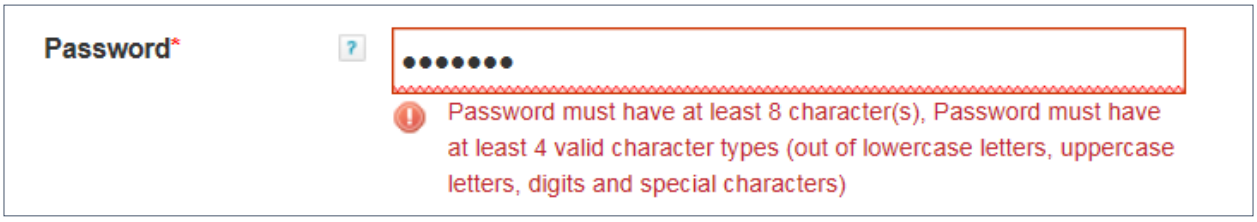
5. Select two of the security questions and enter the answers you have chosen during self-registration. Click on the 'Next' button to go to the next page.

Figure 17 - Answering the security questions



NOTE: Accented characters and the symbols '**+**' and '&' should be avoided as they will cause access issues to some EMA applications.

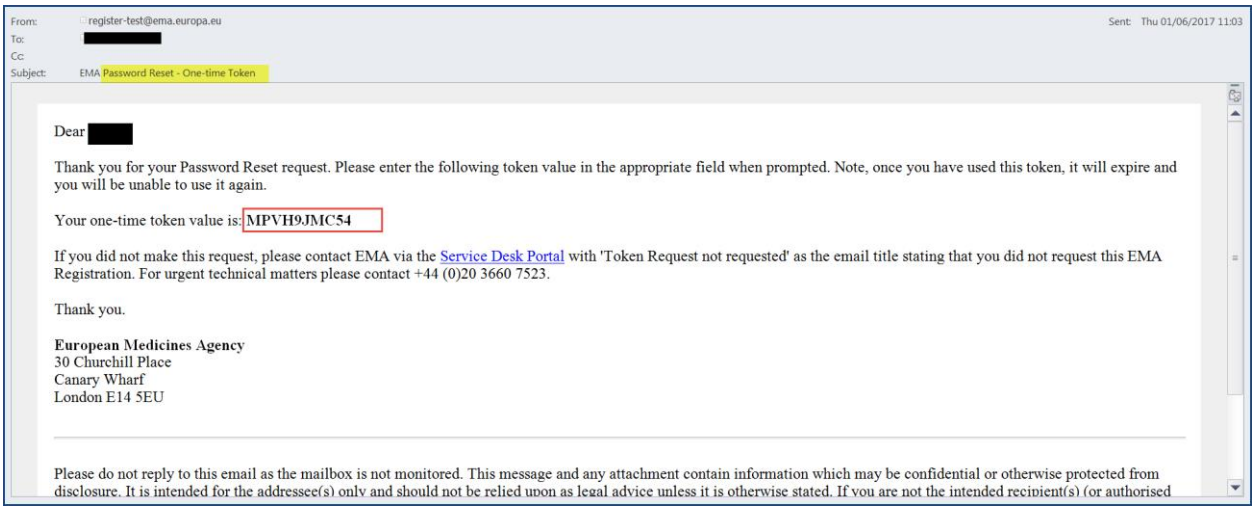
Figure 18 - Password requirements



If you receive a lock account message because you cannot answer correctly your security questions or you have never added these security questions information, please contact Service Desk via phone: +31(0)88 781 7523.

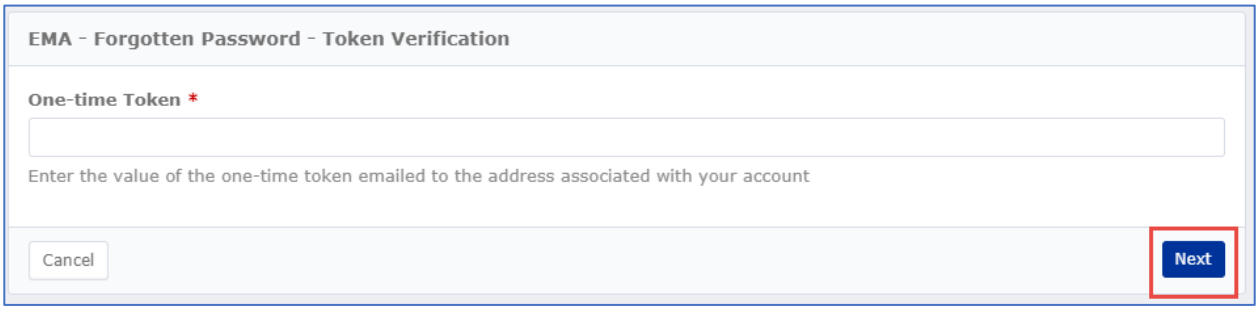
6. An e-mail with a registration token is sent to the registered e-mail address.

Figure 19 - E-mail containing one-time token



7. Input this token in the 'One-time Token' field and click 'Next'.

Figure 20 - Insert one-time token



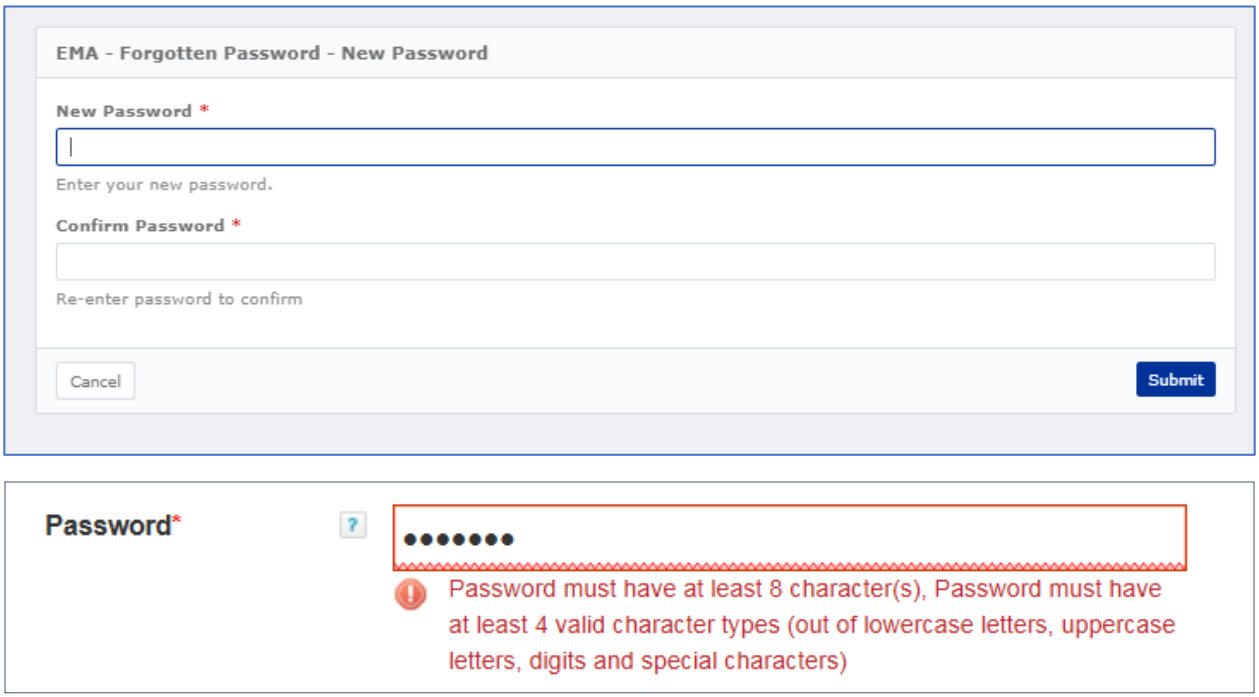
8. When choosing your new password, please choose a combination of lower case, upper case, numbers and symbols (hover your mouse over the red asterisk for guidance)

   NOTE: Accented characters and the symbols '+' and '&' should be avoided as they will cause access issues to some EMA applications.

9. Enter your new password in the 'New Password' and 'Confirm Password' boxes and click 'Submit'.

10. The password is reset.

Figure 21 - Enter new password



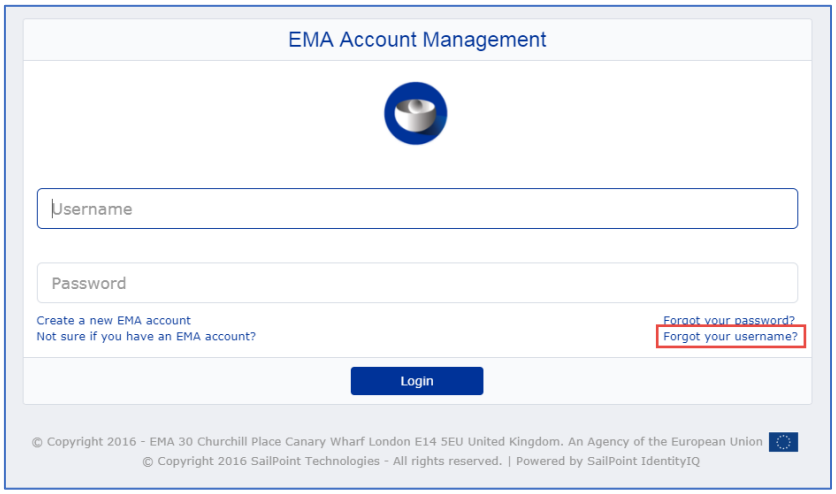
If your account is locked and you are unable to request a new password please contact Service Desk via phone: +31 (0)88 781 7523.

2.5. Retrieve forgotten username

If you no longer know the username assigned to your account you can retrieve it by following the steps below:

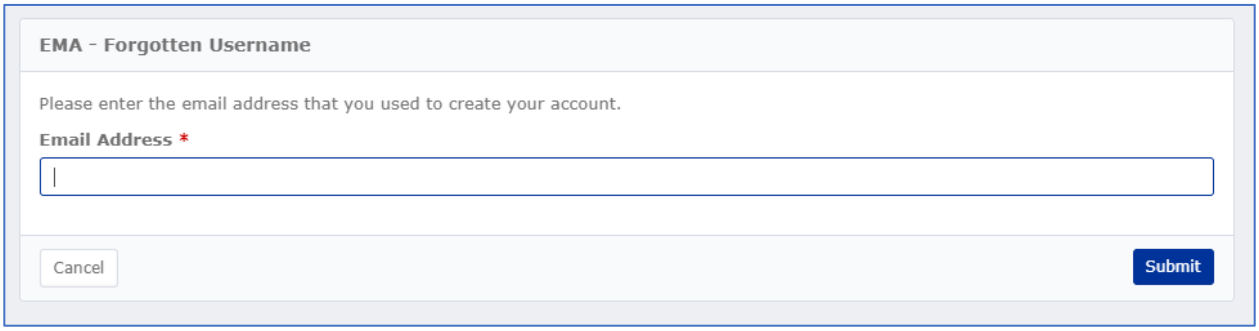
1. Navigate to https://register.ema.europa.eu/
2. Click the 'Forgot your Username?' link

Figure 22 - EMA Account Management portal and forgotten username link



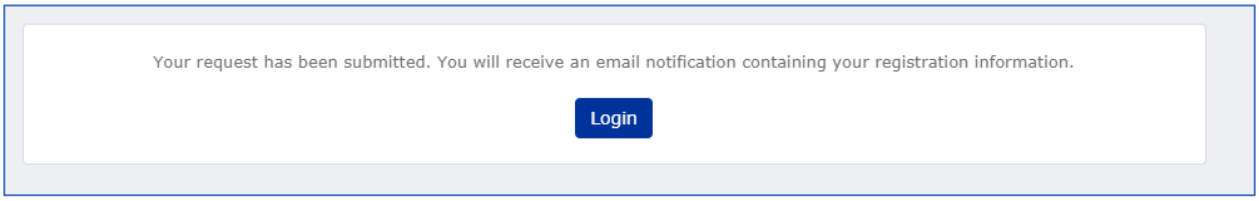
3. Enter the email address you used to register in the EMA Account Management portal and click 'Submit'

Figure 23 - Enter e-mail address to retrieve forgotten username



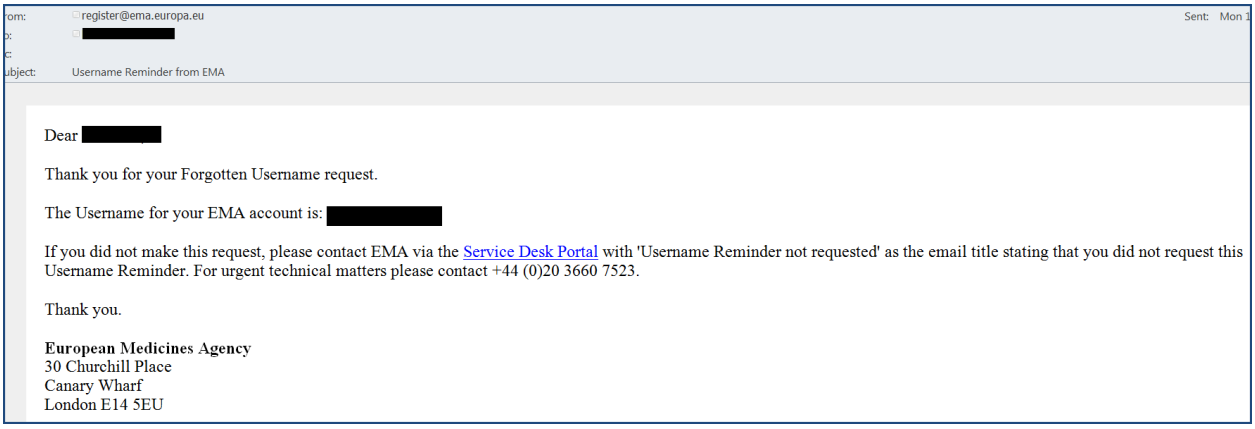
4. Confirmation of the request is displayed

Figure 24 - Confirmation of the forgotten username request



5. An e-mail with the username is sent to the registered e-mail address

Figure 25 - E-mail to the user containing a forgotten username



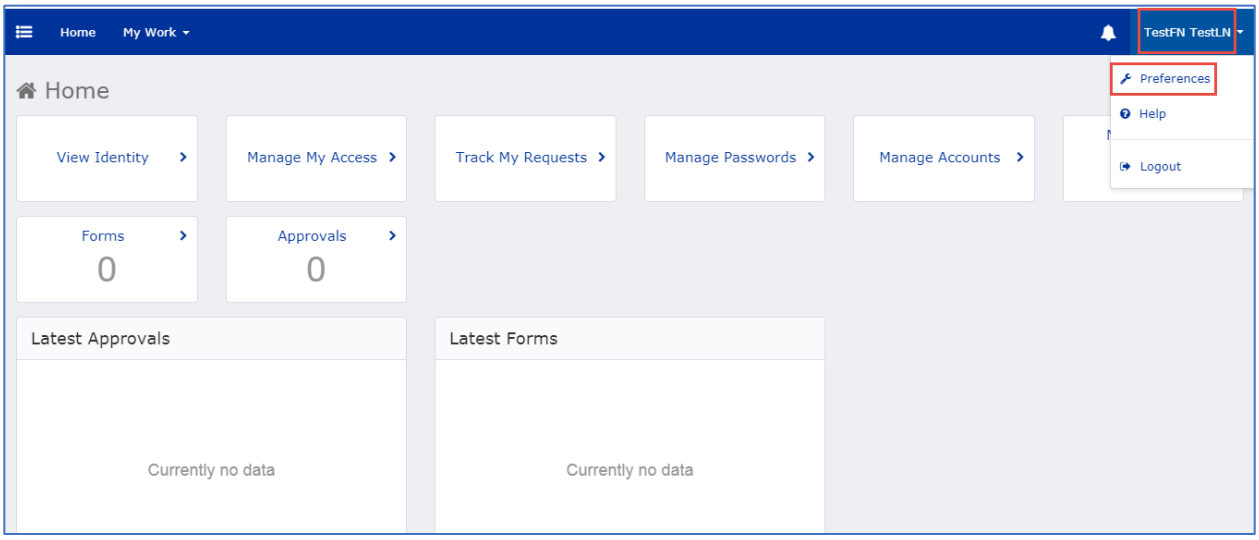
6. Log in with your username and password.

2.6. Update security (authentication) questions

In order for a user to be able to reset the password using the self-service functionality, they need to setup the challenge questions and answers in the EMA Account Management portal. The questions and answers are populated by the user input during self-registration. In case the user needs to update their challenge questions they should follow the steps below:

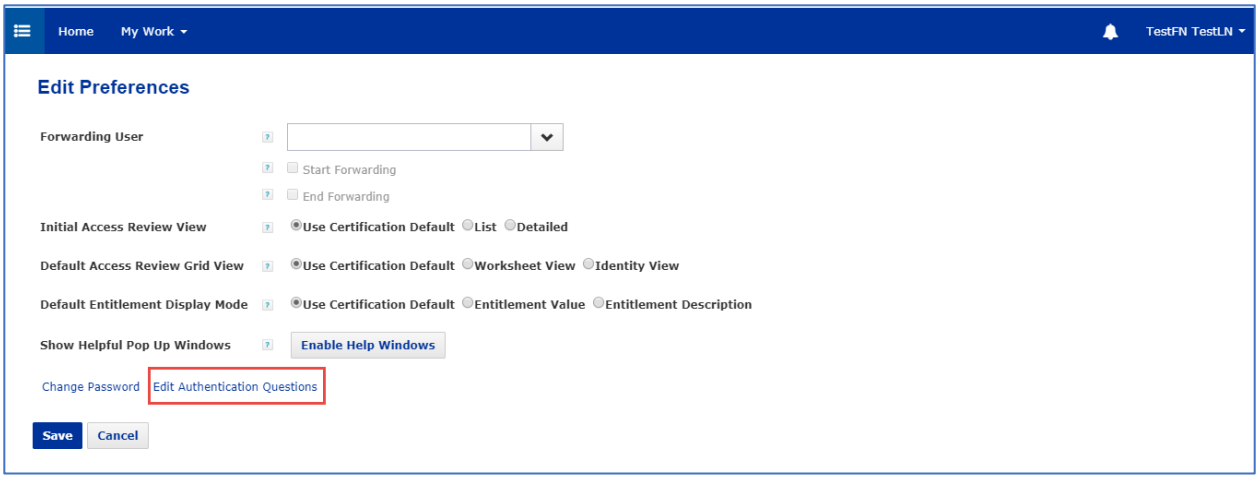
1. Login to the EMA Account Management portal.
2. Click on the username link on the top right corner of the homepage and click 'Preferences'.

Figure 26 - Access my preferences



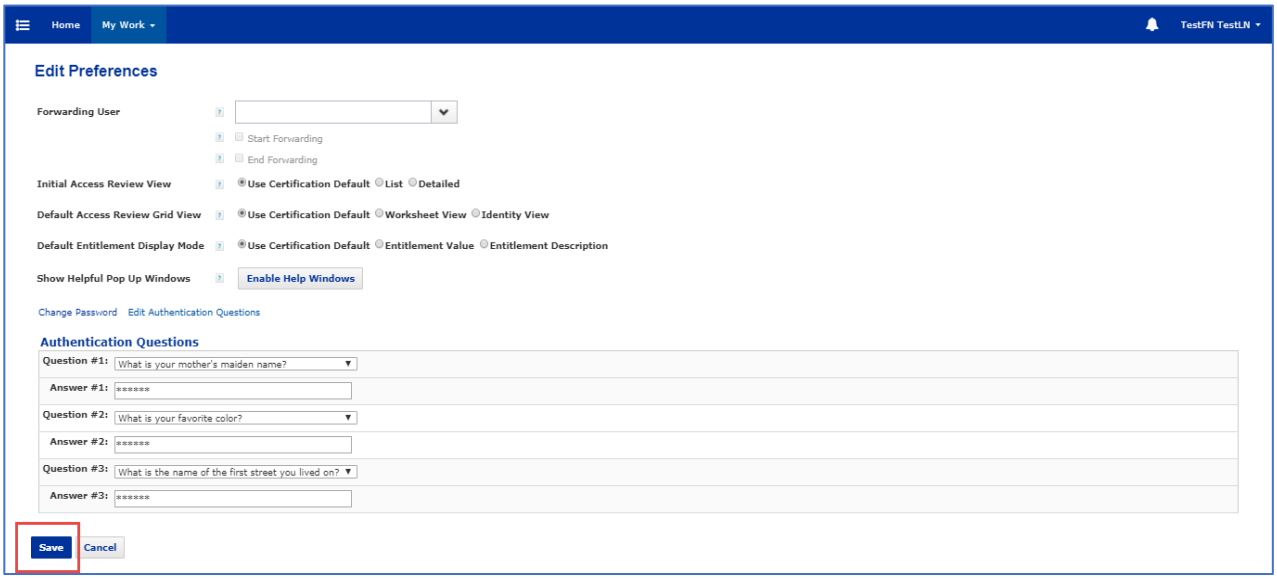
3. An option to edit preferences appears where the user can edit the security (authentication) questions.

Figure 27 - Edit preferences



4. Select the questions you would like to edit and input your answers.
5. Click on 'Save' at the end of the page to save your challenge questions and answers.

Figure 28 - Selecting security (authentication) questions

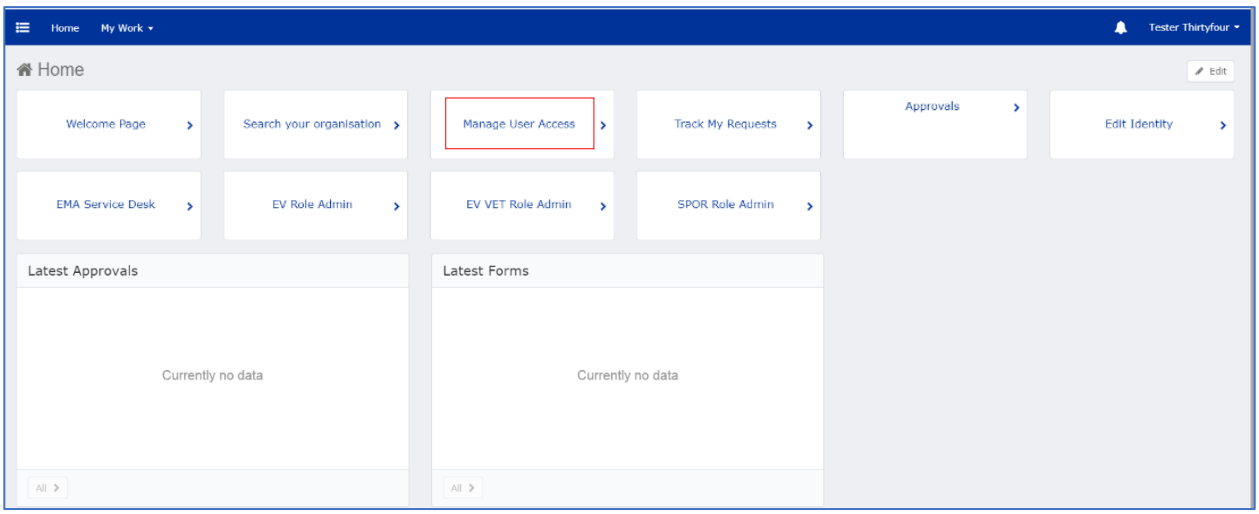


2.7. Request removal of your access to a system

A user can request their access to a system or organisation be removed at any time, a different process is followed for EU QPPV/RP users - see **section 5.5.1.** for details.

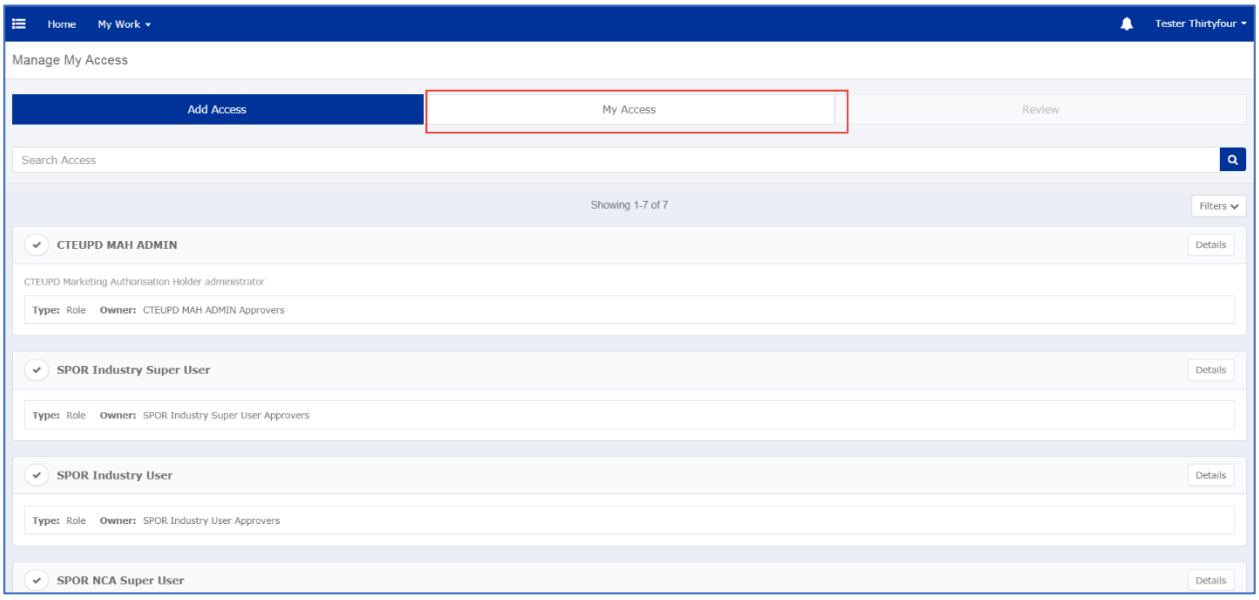
1. Go to the homepage
2. Click on "Manage my Access"

Figure 29 - Manage my access



3. Go to "My Access"

Figure 30 -My access

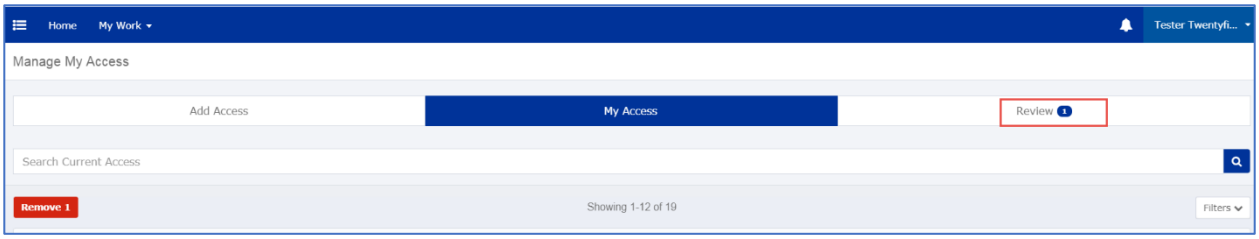


4. Select the role to be removed – click on  - it turns red.
5. Please note in this section the user will also find many entries called "entitlements". Do not pay attention to these, as they are triggered by the system and it is not relevant for role removal.

Figure 31 - Role to be removed

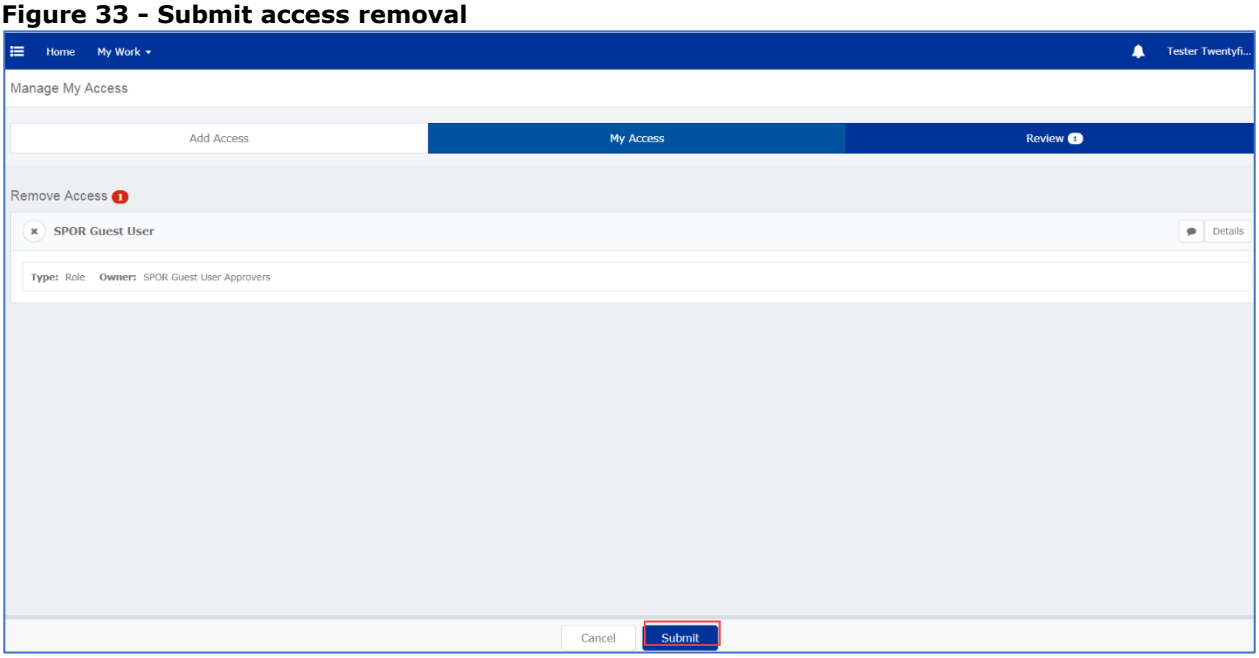
6. Scroll up the page and click "Review".

Figure 32 - Review access removal



7. Click “Submit”.

Figure 33 - Submit access removal



The system will automatically approve the removal of the role for all roles **except for EU QPPV/RP**, whose request will go to EMA for approval. For EU QPPV/RP the EMA should be notified of the role removal request by raising a ticket with EMA Service Desk, providing the removal request ID generated by EMA Account Management portal.

3. Organisation information in OMS system

In order to check data in the SPOR Organisation Management System (OMS) registration with IAM is sufficient – see **section 2.1.** above.

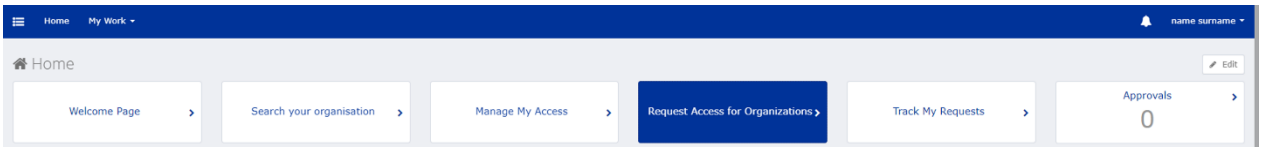
In order to change your organisation details in OMS, you need to have a "**SPOR Super User Industry role"**. This role must be requested via the EMA Account Management portal and will be sent to the EMA for approval – see **section 3.1.** below.

3.1. SPOR Super User Industry role request

In order to change your organisation details in OMS, you need to have a "**SPOR Super User Industry role"**. The steps are described below.

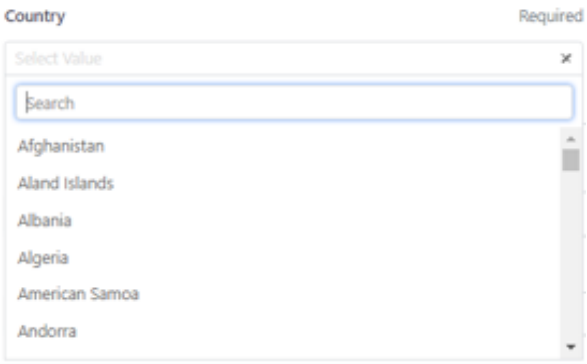
1. Ensure that you have completed the EMA Account Management portal registration process described in **section 2.** ;
2. Log into EMA Account Management portal
3. Please verify in EMA Account Management portal if you have the SPOR Super User Industry role assigned to your account. If yes, please proceed to **section 3.4.** ; if no, please proceed with this section.
4. On the home page click on "Request Access for Organisations" tab.

Figure 34 – Request Access for organisations



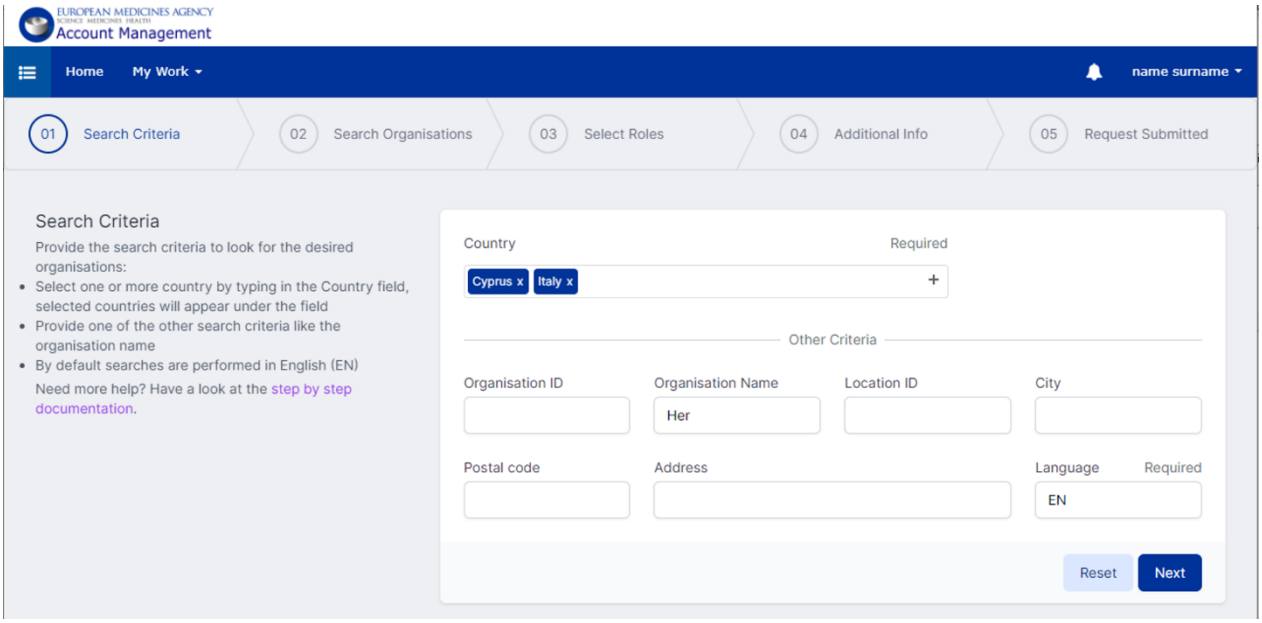
5. The first page to be displayed in the "Request Access for Organisations" page is the "Search Criteria" to look for an organisation. Under the word **Country** click into the dropdown box, and in the Search box type the country (in which the organisation is located). You can select or enter more than one country to search.

Figure 35 – Country search box



To add another country repeat the step above. When you have added all the required countries you wish to search, enter another search criteria in the boxes provided, for example organisation name, or city. Click **Next** button. The result of the search performed in this step will be viewed in the Organisations screen.

Figure 36 – Organisations screen

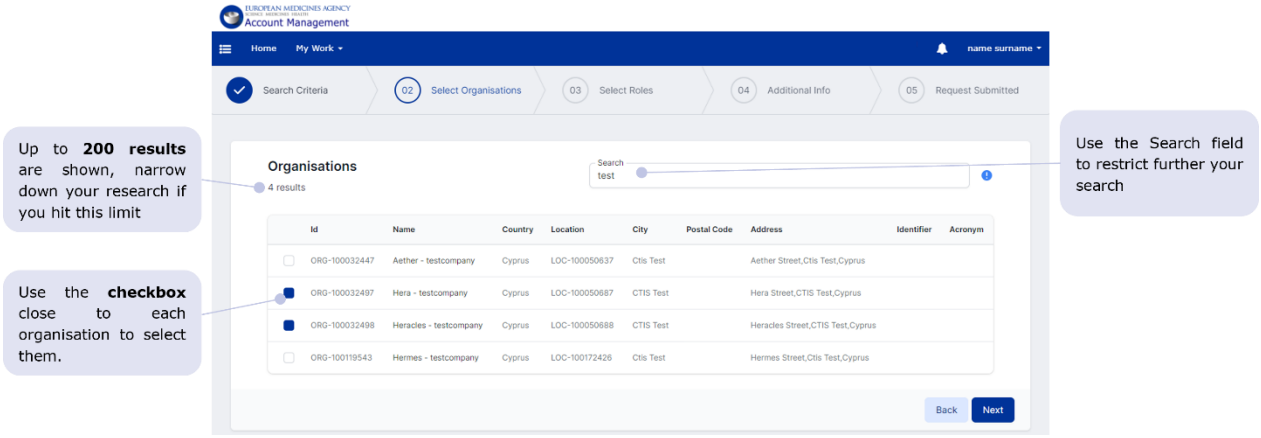


Note: all organisation names are stored in EMA Organisation Management Service (OMS) in English, if you wish to look for an organisation name in a different language you have to change the language to the related ISO code. Please note not all organisations have a local translation of their name in the local language.

6. Based on the search criteria the list of organisations is displayed, use the checkbox close to each organisation to select them. Even if location information is displayed, access is always requested on behalf of organisations and not by locations.

Up to 200 results are displayed, if the organisation you are looking for is not displayed and you are hitting 200 results, try to narrow down your search by going back to the previous step or looking for the organisation in [EMA Organisation Management Service](#).

Figure 37 – Search results window

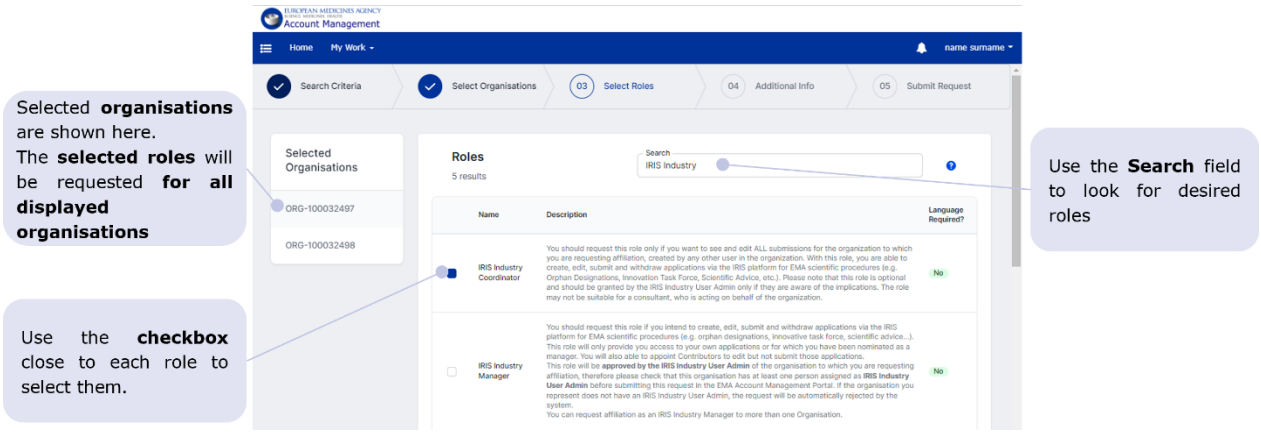


If the organisation you need to affiliate with is not listed in the results, it means that your organisation is not registered in the EMA Organisation Management Service, and therefore, your role request cannot be completed. Please see **section 3.3.** and **3.4.** for more information on how to create a new organisation or update your organisation details.

7. The roles listed on the Roles window (see below) can be selected by clicking the box next to a specific role title, to select another role use the scroll bar to the righthand side of the list.

   The list can be filtered using the search field on the top of the page.

Figure 38 – Role selection window



When you have selected the "**SPOR Super User Industry role**" you require access to, click **Next** button.

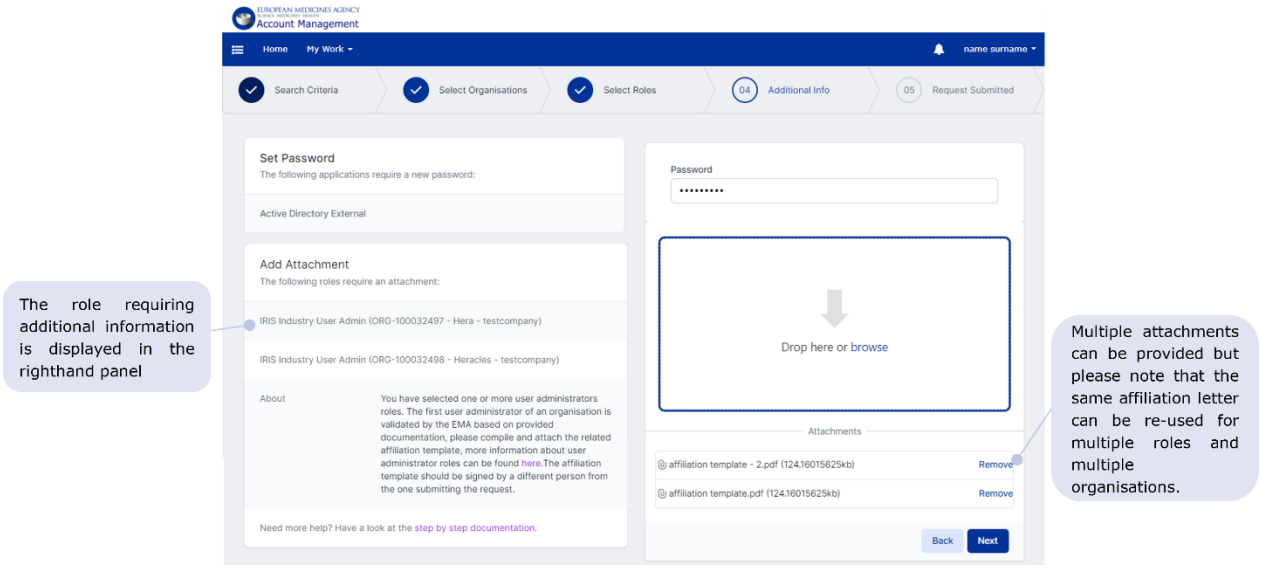
8. The **Additional Information** page is displayed only if the combination of selected organisations and roles requires it. If no additional information is required, your request will be submitted.

   To select the role of User Administrator (like IRIS User Admin or SPOR Super User) for your organisation, that organisation must first have at least one User Administrator allocated and validated by the EMA. This is done by completing the Affiliation Template and signed by an approved signatory (this person should be different from the person submitting the request) from your organisation, then the document can be downloaded or drag and dropped into the allocated box (see below).

   Upload a completed and signed copy of the Affiliation Template Letter, as proof of authority to represent the organisation. This must be on the official company letterhead and signed by someone currently employed by the organisation for which you will assume the User Administrator role (this person should be different from the person submitting the request). Please note if document attached for requesting the User Administrator Role is not compliant to above requirements, the request will be denied by the EMA administrators.

   In case a password is required the new password should have at least 8 characters(s) comprising: 4 valid character types (lowercase, uppercase letters, digits and special characters); at least 1 uppercase letter; 1 digit and 1 special character.

Figure 39 – Additional information window

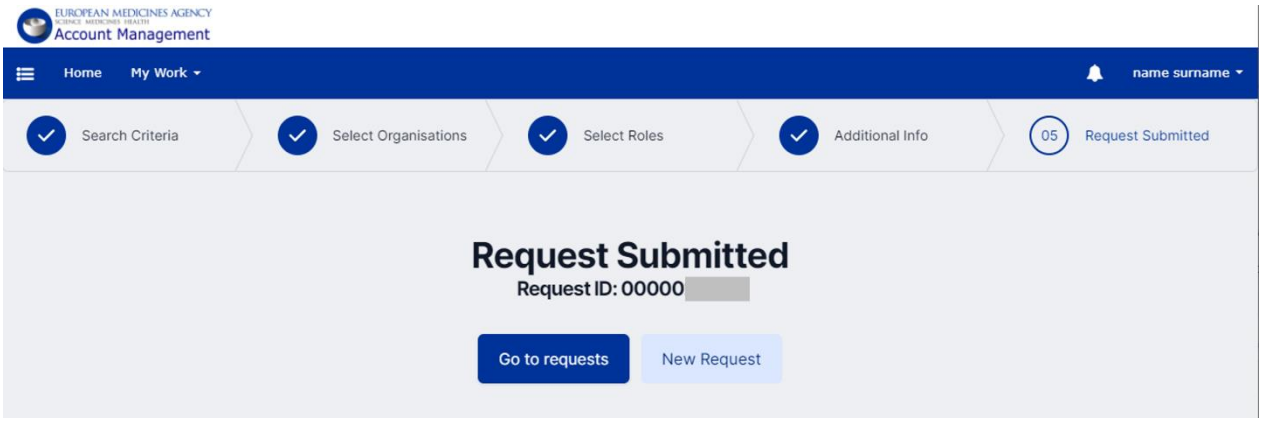


   Note: For the first User Administrator the requester's e-mail should preferably be a work e-mail from the same organisation on behalf of which the user is requesting the user access. The EMA will refuse requests coming from Gmail, Yahoo and similar private addresses.

   Click "Next".

9. The following window confirms the request has been submitted. You can reference the request ID if any problem arises.

Figure 40 – Request submitted window



Please note that the request must be sent to the EMA for approval. This SPOR Super User Industry role should not be confused with EU QPPV/RP which is the main user of an EV profile. The SPOR Super User Industry role only relates to maintaining data in SPOR OMS.

The SPOR Super User Industry role is not managed by the EV Registration team. Requests for this role are managed by the OMS/SPOR team; queries about such requests for this role need to be submitted to EMA Service Desk.

3.2. Search OMS information

In order to check that your organisation is correctly recorded in the SPOR OMS system you need to perform a search in the system. The steps below describe how to perform the search:

1. Log into SPOR Organisations
2. Search for your organisation. For further information on how to search, please check the "OMS Web User Manual" available on the SPOR Organisations web page (under the "Documents" tab).

Figure 41 - Organisation Search screen in OMS

3. If your organisation cannot be found, please follow the steps described in **section 3.3.** to create a new organisation in OMS. If you can find your organisation but some of the details are incorrect such as current address please refer to **section 3.4.**

3.3. Create a new Organisation in OMS

If your search of OMS returns no results a new tab called "Request New Organisation" appears. For full details of OMS organisation registration process please refer to the OMS user manuals that can be found in the Documents section of the SPOR Organisations website. For this process please refer to "Change request validation in OMS" and the "OMS Web User Manual" - Figure 42 and

Figure 43 show the screens used to request an new organisation and complete the information needed to register a new organisation in SPOR OMS

Figure 42 - Request the creation of a new organisation

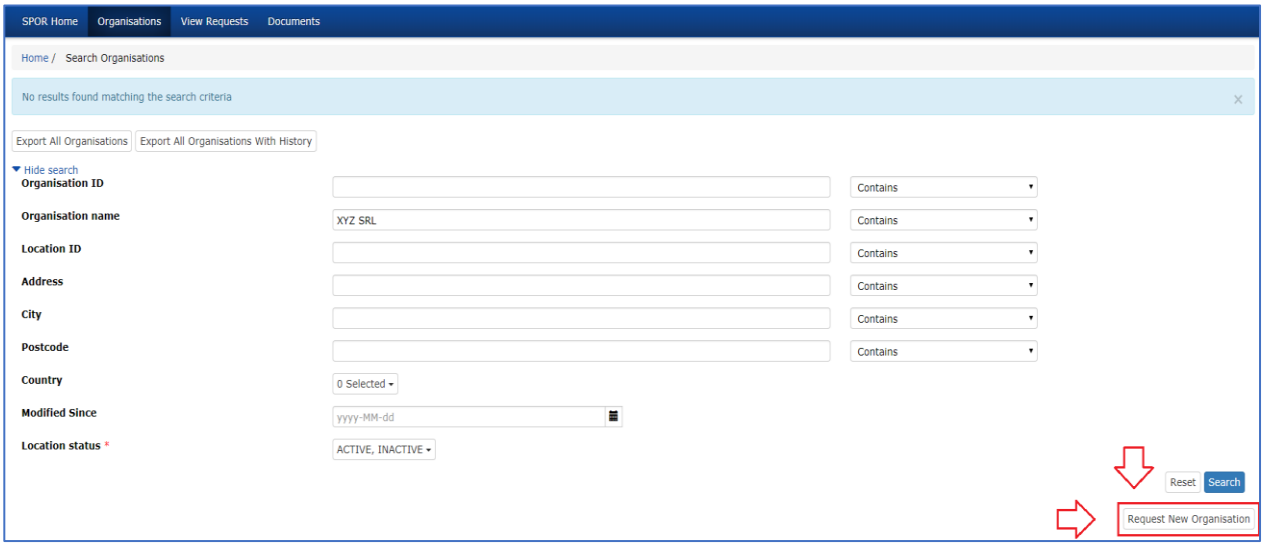
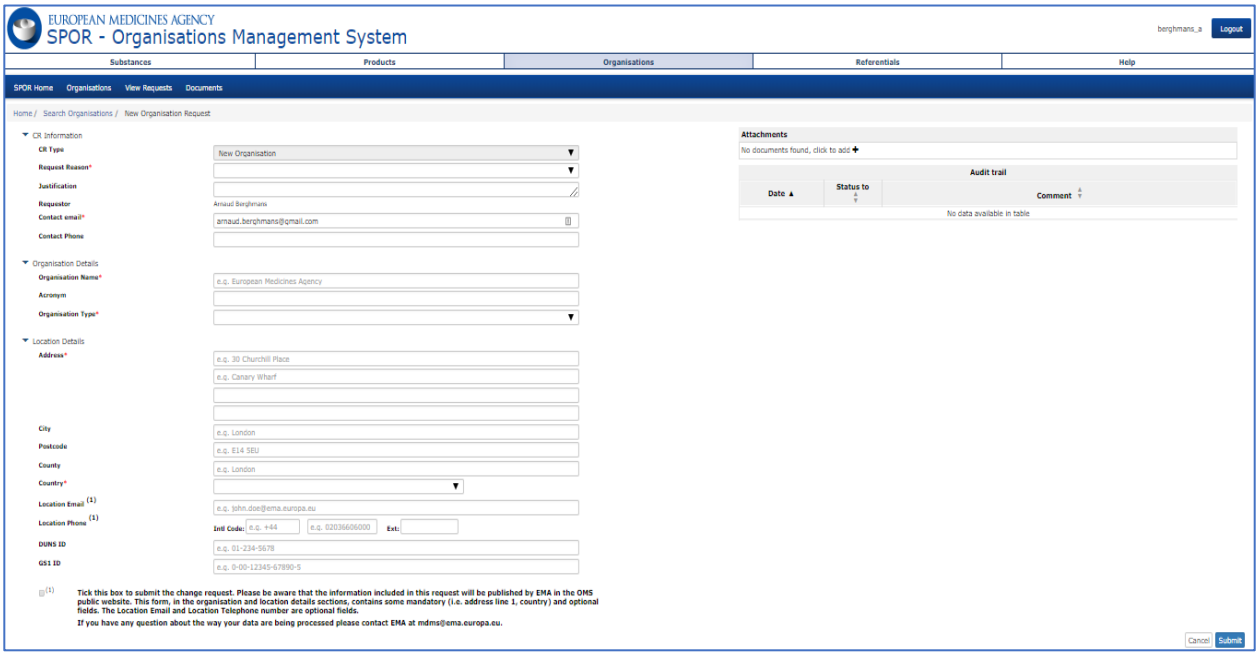


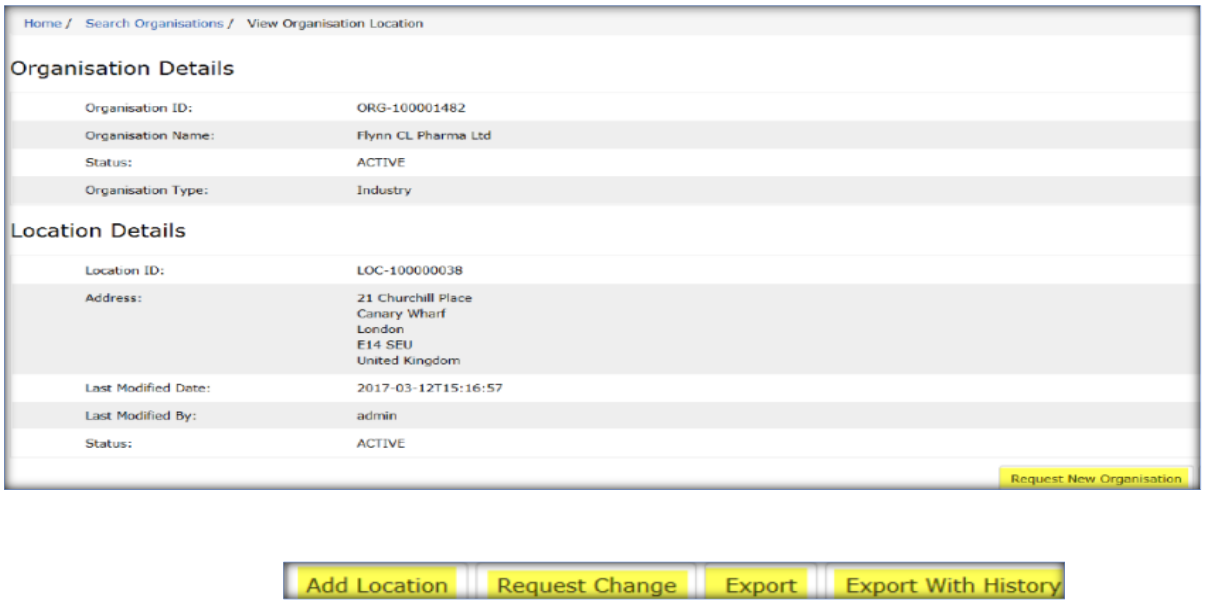
Figure 43 - Fill in the details and submit the new organisation



3.4. Update organisation details in OMS

To update data in the OMS Dictionary, you will need to create a change request through the SPOR Organisations website. Please refer to Guidance on how to create a change request (F - OMS Web User Manual) available in the documents section of the SPOR Organisations website.

Figure 44 - Change Request in OMS



Please be aware that, in order to change your organisation details in OMS, you need to have a "**SPOR Super User Industry role"** – see **section 3.1.** above.

In order for the address or organisation name information to be updated in the EudraVigilance system you will need to log into the EudraVigilance Restricted Area select the appropriate Location ID and click on "Update".

4. Registration of a new Organisation in EudraVigilance

In order for a new organisation to be registered in EudraVigilance it must first be registered in the SPOR OMS system – see **section 3.3.** above. Once the organisation is registered in OMS it can be registered in EudraVigilance through the registration of the QPPV/RP.

Once the registration of the QPPV/RP is complete the organisation will be registered in EudraVigilance and the profile accessible. However, additional steps are required in order to the profile to be active.

4.1. EU QPPV or Responsible Person access request

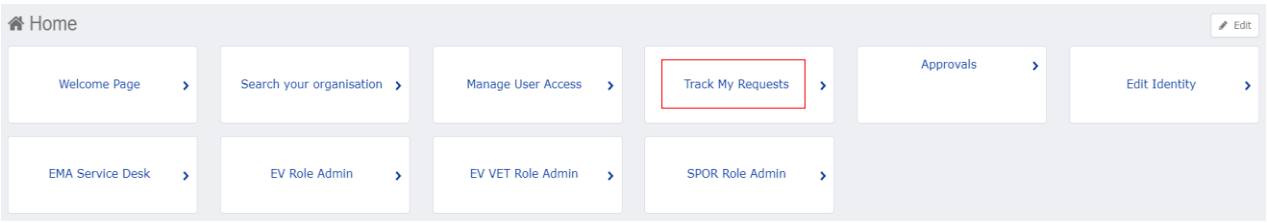
To request an EU QPPV/RP role, whether first user or change of QPPV/RP, the process detailed in the New Organisation First User QPPV/RP or Change of EU QPPV/RP guideline should be followed. **Please ensure you have no current base or supplementary role with the organisation before requesting the QPPV/RP role for that organisation and that the previous QPPV/RP role has been removed.** In case the previous QPPV/RP has already leaved the company, the role will be removed by the EV Registration team once all required documents have been provided. A QPPV/RP role request will be rejected by the system automatically if there is still a QPPV/RP registered for the organisation profile.

NOTE: an organisation profile is enabled in EudraVigilance when there is a registered QPPV/RP. During a change of QPPV/RP, the organisation profile will appear as disabled until the process has been completed. Active users linked to this profile will see a message stating "Your organisation is disabled".

- The registration process of Responsible Person for NCAs is the same as for QPPV/RP for Industry and sponsors of clinical trials.
- There can only be one EU MAH EU QPPV role or Responsible Person role (for Commercial Sponsor and Non-Commercial Sponsor or EV affiliate profiles) per organisation.
- The registration or change of QPPV/RP in the Production environment will be reflected automatically in XCOMP (and Virtual affiliates, if applicable).
- Documents for EU QPPV/RP authorisation must be submitted via a EMA Service Desk request (see **Figure 48**) quoting the Request ID number generated by the EMA Account Management portal**.**

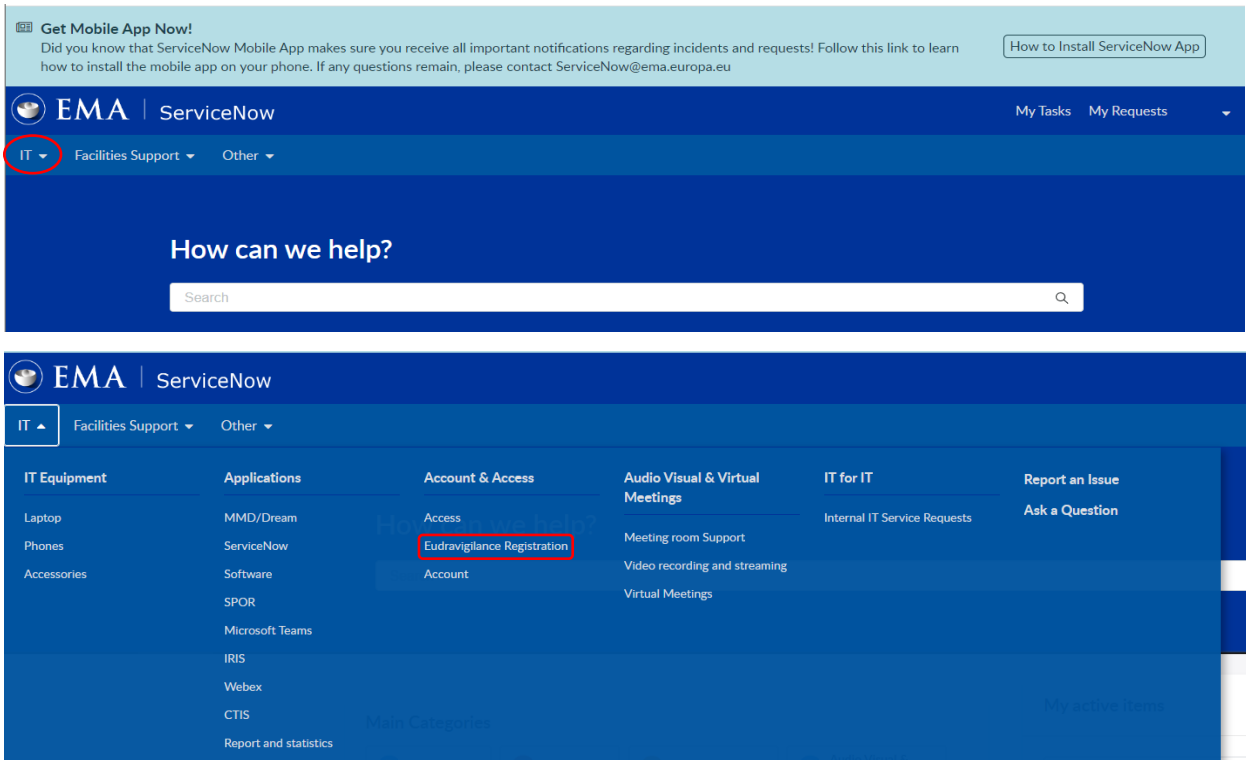
  The list of the required documents is available on New Organisation First User QPPV/RP or Change of EU QPPV/RP.

Figure 45 - Track My requests



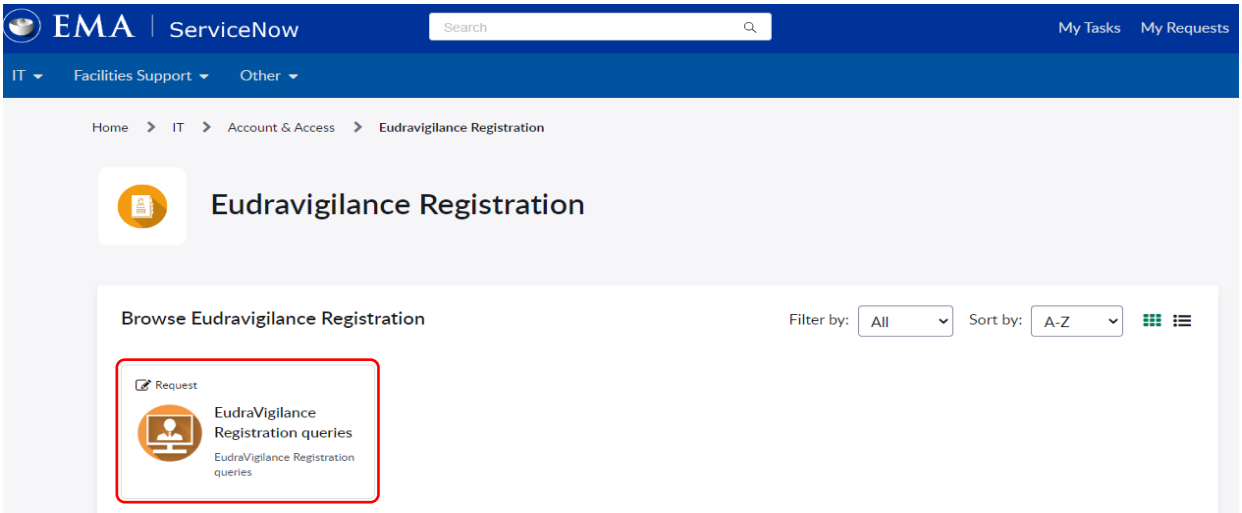
1. Navigate to the [EMA Service Desk] portal and do the log in.
2. In the Home screen, click on "IT", and then on "EudraVigilance Registration", under "Account & Access":

Figure 46 – Home screen



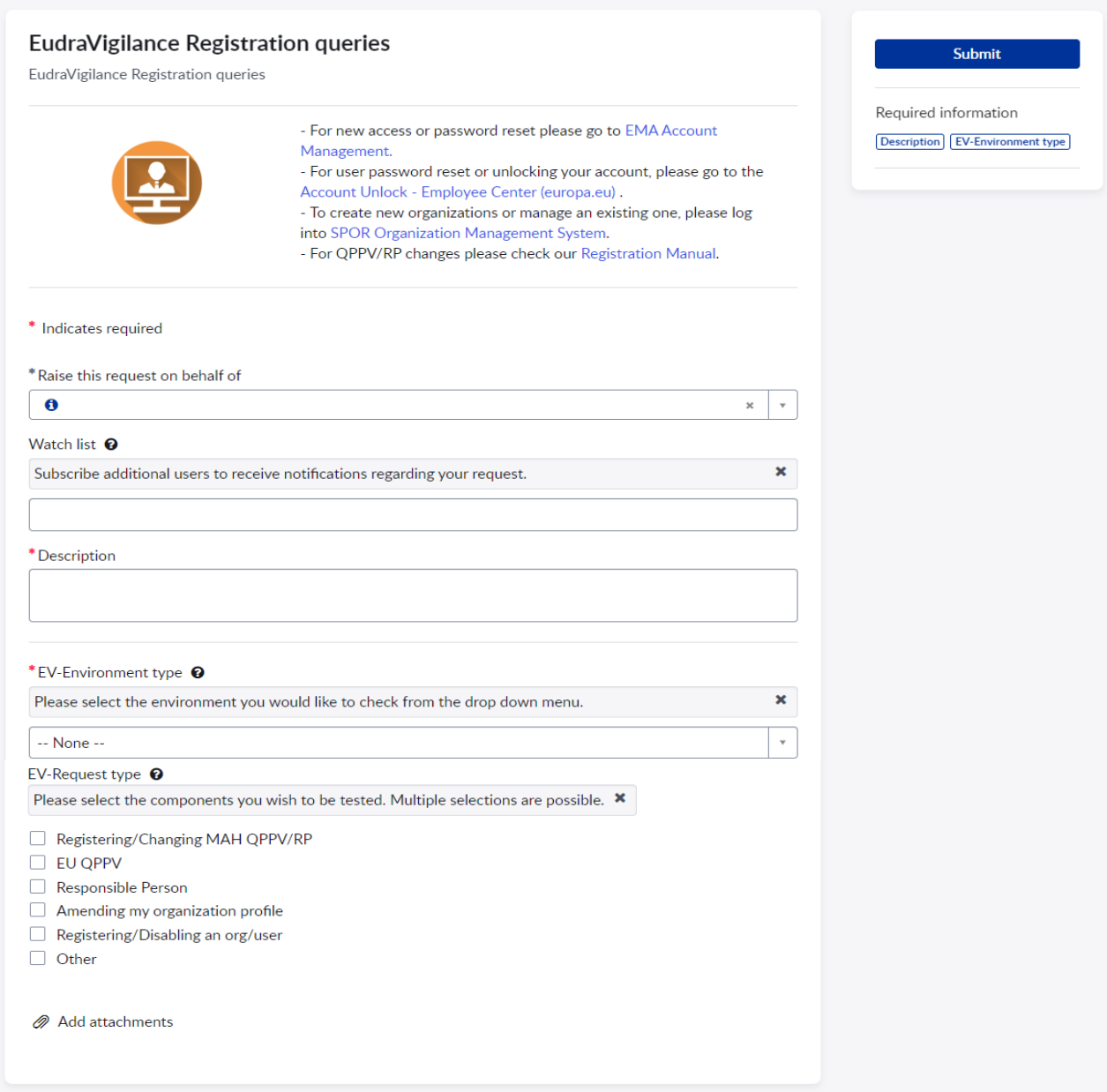
3. In the new screen click on "EudraVigilance Registration queries" and fill in the form.

Figure 47 – EudraVigilance Registration queries



4. In the description field, state your name, organisation ID and explain that you are requesting EU QPPV/RP role access.

Figure 48 – EudraVigilance Registration form



5. Upload the documents as stated in the document EudraVigilance registration documents, completed with all the necessary information. If a Gateway transmission mode is required, attach a completed Gateway connection form and an encryption security certificate in the Service Desk request.
6. Click on "Submit".
7. The EMA reviews the EU QPPV/RP request, approves or rejects it and notifies the requestor of the outcome.

8. The EMA confirms separately to the organisation that their WebTrader or Gateway transmission mode has been set up.
9. The QPPV/RP completes the organisation information in the EV Human Production and XCOMP restricted area, as per **section 4.2.**

4.2. Finalise organisation information in EV Human Production and XCOMP

Once the request for the EU QPPV/RP role for an organisation has been completed for a new organisation the EU QPPV/RP user will need to enter the EudraVigilance restricted area.

When the role approved, the QPPV/RP access the restricted area view for the Production or XCOMP (Test system) and selects "Manage your profile" on the left column.

Figure 49 – Menu available in the EudraVigilance restricted area

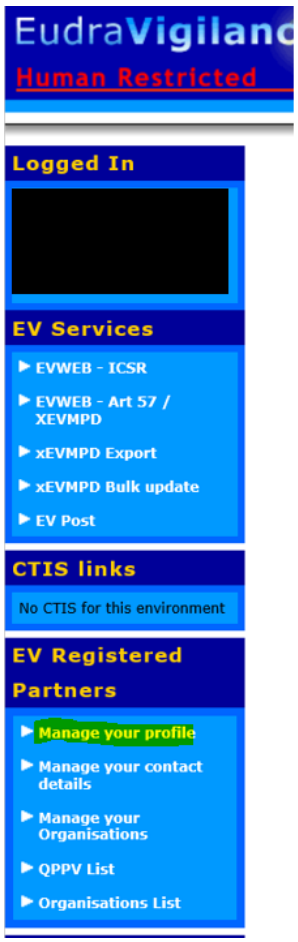
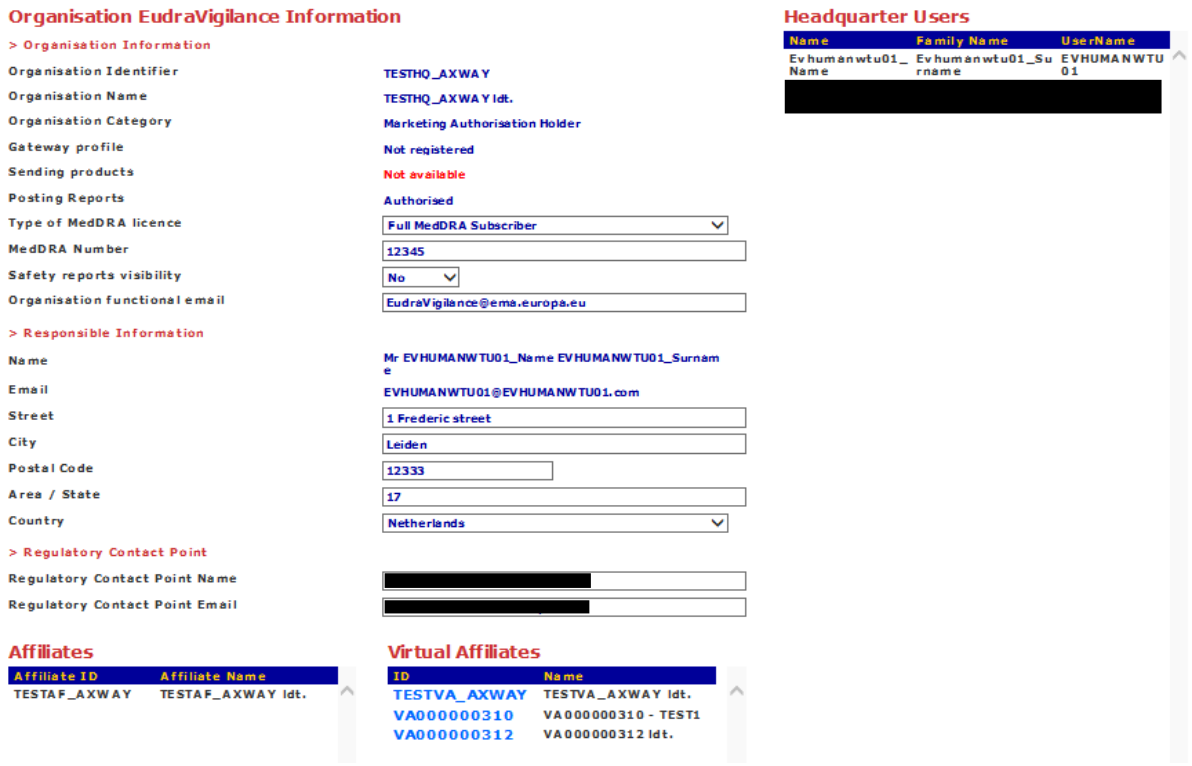


Figure 50 - View of EU QPPV/RP/TD Restricted Area



Complete and confirm the following fields:

- **Location** – Select the correct OMS Location ID this will update the organisation address information to match the records in the OMS system. The system will indicate if the current Location ID is marked as inactive in OMS and the user will need to select an available active location ID. If the address information needs correcting/updating this needs to be completed in the SPOR OMS system, see **section 3.4.** for further information
- **Organisation Category** – There is the option of MAH, NCA, Commercial or Non-Commercial Sponsor if the option to choose the category is not available you will need to submit an EMA Service Desk ticket for this information to be changed. Please note L2A/B downloads will not be available unless the organisation category is set as MAH.
- **Transmission mode - Gateway/Webtrader profile** – Organisations will show as "Not registered" by default. Sending ICSR reports and XEVMPD messages will not be possible until the Gateway/WebTrader registration step has been completed. Please note that the update to this field occurs overnight.

  If you wish to have Gateway transmission enabled, you will either need to enclose a Gateway connection form and an encryption security certificate with the initial registration request addressed to the EudraVigilance Registration team, or after your organisation has been registered and the main QPPV/RP role is assigned, raise a EMA Service Desk ticket, addressed to the Gateway Support team, in order to set-up a Gateway connection. Once the Gateway connection is completed this field will be updated, please note that the update to this field occurs overnight. Gateway organisation profiles cannot be used for sending products via the EVWEB tool, if you need to send products using EVWEB please register a virtual affiliate or legal affiliate with a WebTrader profile see **section 6.2.** for details.

Further information can be found on EMA's EudraVigilance: how to register webpage, in the "Transmission mode for reporting" sub-section, under "Required actions before EudraVigilance registration".

- **Sending products** – This field indicates if the selected organisation profile is set-up to be able to send XEVMPD products. The ability to send products is set to enabled if the organisation has a Gateway/WebTrader profile registered.
- **Posting reports** – This field indicates if the EVPOST function has been enabled for organisations using EVWEB. In order to have this functionality enabled organisations need to complete testing with the EMA - see EudraVigilance: Electronic Reporting for details of the process. Once this process has been completed successfully, please submit a Service Desk request in order for this field to be updated.
- **Type of MedDRA licence** – Select "Full MedDRA subscriber" if you have a MedDRA licence or MedDRA Fee waiver if your organisation qualifies for not requiring a licence. Please review the MedDRA MSSO website to confirm if you qualify for the special licence (https://www.meddra.org/subscription/special-licence) as a non-commercial organisation or as a micro, small and medium-sized enterprise (SME). If you believe your organisation should be considered as a SME company you will need to obtain an SME registration through the EMA.

  Non-commercial (non-profit) organisations should also consult the MedDRA MSSO website as full MedDRA licences may also be obtained for no subscription charge (at the time of writing) (https://www.meddra.org/subscription-rates).
- **MedDRA Number** – please add your MedDRA Number to comply with organisation access requirements. For further information on how to obtain it, go to the EudraVigilance: how to register webpage in the "Required actions before EudraVigilance registration" section.

  Important note: If you are accessing as an SME fee waiver organisation, please enter your SME registration number. If you in the process of registering with the SME office please enter "SME application sent". Once the SME registration is complete please return to this page in order to enter the SME number.
- **Safety Reports Visibility** – Only Select "Yes" if you wish to grant users of the associated affiliates and virtual affiliates to have access to the reports sent by the HQ or the other affiliates. The default of "No" will prevent users of the affiliates and virtual affiliates having access to data sent by the HQ or other affiliates, please note that users associate with the HQ will have full access to data submitted by the affiliates and virtual affiliates
- **Organisation Functional email** – Functional email that is available at all times, which does not change (e.g., pharmacovigilance@company.com) in case EMA needs to contact the organisation if the EU QPPV/RP or Trusted Deputy (TD) are not available.
- **Regulatory Contact Point** – It is mandatory for MAH organisations to have a regulatory contact point in case the EU QPPV is missing or for any legal enquiries.
- **Responsible Information** – Further Contact details for the EU QPPV/RP which are required legally.

Once these are added, please click on "Update". Please note that after the first update the "Organisation category" can only be changed subsequently through raising an EMA Service Desk request addressed to the EV Registration team.

Important note: the address of the organisation that appears in this section is stored in OMS and can only be amended via an OMS change request - see **section 3.4.** . In order to update the QPPV/RP contact details please refer to **section 6.4.1.**

4.3. EVPOST

The EVPOST function is an additional transmission mode that users who have organisation profiles set up with WebTrader transmission can use once they have completed quality assurance testing (QAT) with the EV XCOMP system.

In order to have this transmission enabled, the QPPP/RP or Trusted Deputy of the profile needs to:

1. Make sure that the EV XCOMP profile of the organisation is activated. For more detailed information on the EV XCOMP registration process please refer to **section 7.** of this manual.

4. Test the functionality with the QAT testing team. More information about the testing process can be found on the EudraVigilance: electronic reporting webpage.

5. Once this functionality is tested and validated, the QPPV/RP must request the activation of the EVPOST function in Production by raising a EMA Service Desk request addressed to the EV Registration team, providing proof of completed testing.

Note: In order to be able to access EVPOST, users must be working with a WebTrader profile and have MPR Browse and Send rights. These rights are contained within the QPPV/RP and Trusted Deputy roles. All other users must request these roles separately.

5. EudraVigilance user access management

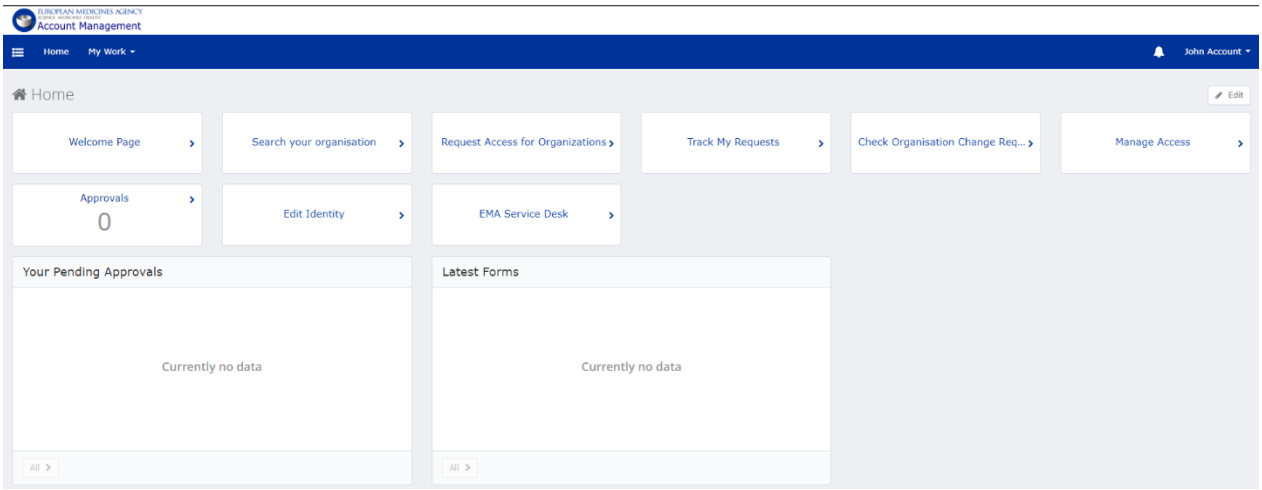
Users can manage their own EMA account via the EMA Account Management portal dashboard; this includes managing access to EudraVigilance Human Production, EudraVigilance XCOMP and to other EMA systems. The dashboard appears after successfully logging in.

Through this interface the user has the following functionalities:

- Welcome page
- Search your organisation
- Manage User access
- Request Access for Organizations
- Track my requests
- Approvals
- Edit Identity
- EMA Service Desk

All EV roles are organisation specific. In order to access EV Restricted Area, users need to have a base role approved for the organisation profile they need to access. If you are unsure of which role to request please consult the **Annex 1** of this manual as it provides descriptions of all the possible EV roles that can be requested.

Figure 51 - EMA Account Management portal dashboard



In order to obtain an EV user role, there must be an active QPPV/RP registered for the organisation that the user role is being requested. If there is none, the system will automatically reject the request and the user will need to liaise within their organisation in order to ensure a new QPPV/RP is registered.

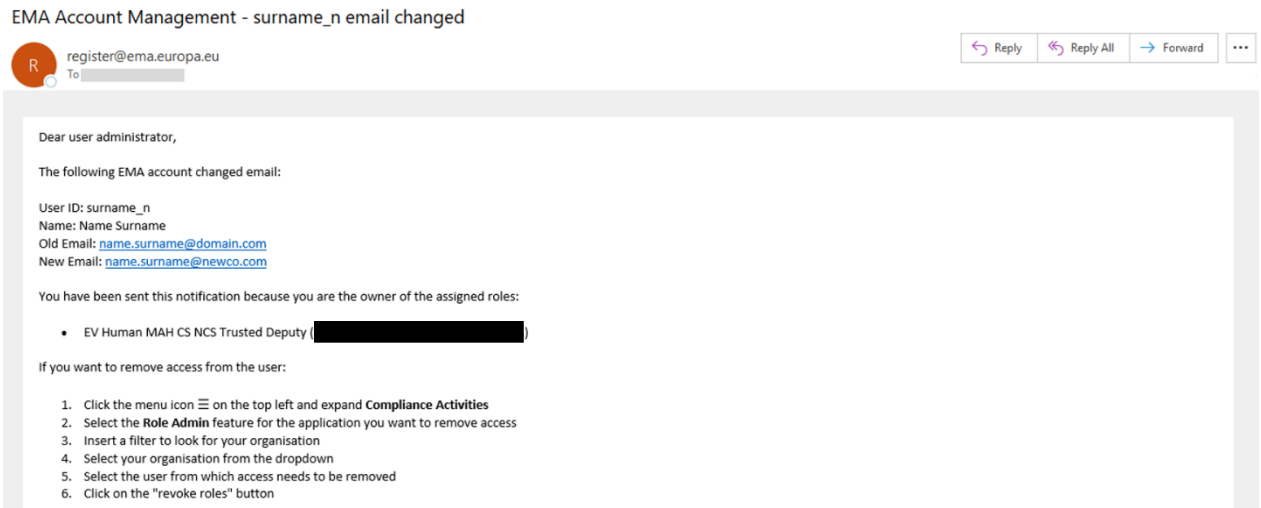
Moreover, if there is no active QPPV/RP registered for the organisation profile, the organisation will appear as disabled in EV and no user will be able to access it until the new QPPV/RP user is registered.

5.1. Responsibilities of the EU QPPV/RP and Trusted Deputy (TD) on the management of user access

The EU QPPV/RP and Trusted Deputy (TD) have the obligation to manage/maintain access to EV for the users in their organisation. Their responsibilities include:

1. To confirm that the users requesting access to EV indeed work for their organisation before granting them the requested access.
2. To ensure that only the users that truly require access to EV for their work are granted access. For most organisations we recommend at least 1 QPPV/RP, 1 Trusted Deputy and 1 standard user.
3. To approve and to remove access for the users of their organisation via EMA Account management portal and EudraVigilance restricted area for virtual affiliates.
4. To disable an user access to EV when that user leaves the organisation or when their work changes so that they no longer require EV access; the EU QPPV/RP/TD should disable their access in the EMA Account management portal by revoking their roles via EV Role Admin tab (see **section 5.5.1.**).
5. To review changes related to the users emails following the receipt of an email notification by the Account management portal. In the image below, the User Administrator (EU QPPV/RP/TD) received a notification for a user who had the email's domain changed.

Figure 52 – Update to the user's email



Important notes:

- Granting user access to the EV system on behalf of an organisation is the responsibility of the EU QPPV/RP/TD of that organisation and EMA will not perform this task on their behalf.

- For Access reviews and compliance forms, kindly refer to the EudraVigilance Registration FAQ document, available on the EMA's webpage EudraVigilance: how to register.

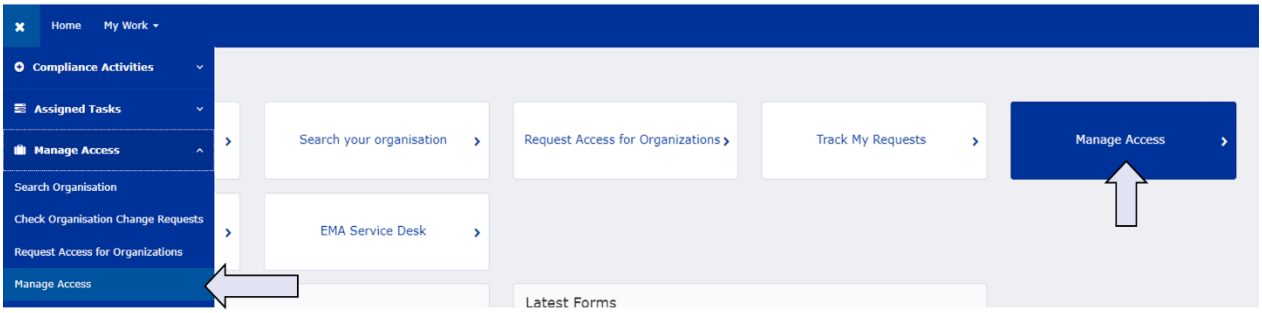
5.2. View the list of users for an organisation

The EU QPPV/RP or Trusted Deputy can view the list of all users assigned to the organisation they manage the access for, and they can revoke an approved access/affiliation.

To view a list of users in the organisation, the EU QPPV/RP or Trusted Deputy should access the EMA's Account Management portal and do the login.

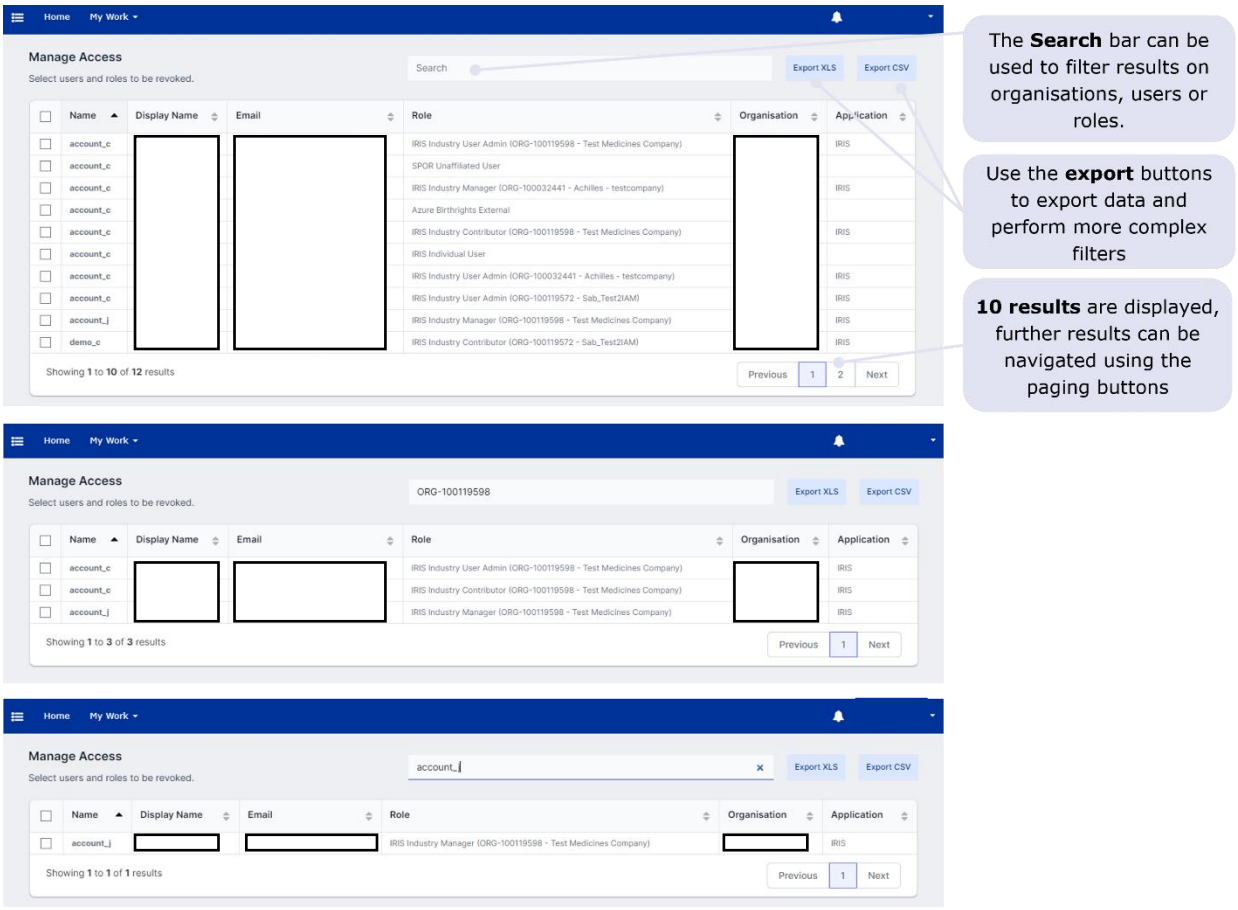
1. On the home page click on the "Manage Access" tab or, on the top left menu, select "Manage Access" and then "Manage Access".

Figure 53 – Manage Access



1. The list of all users and related roles will be displayed for all the organisations and applications for which the EU QPPV/RP or Trusted Deputy manage the access for.

Figure 54 – List of users

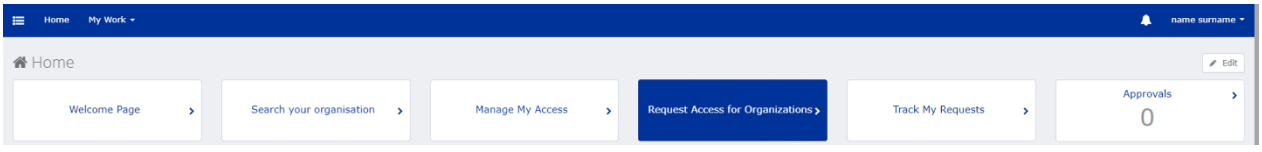


5.3. Request of EV user access for industry and NCA users

Individuals can request specific access roles to an organisation through the EMA Account Management portal. To make an access request please follow the steps shown below:

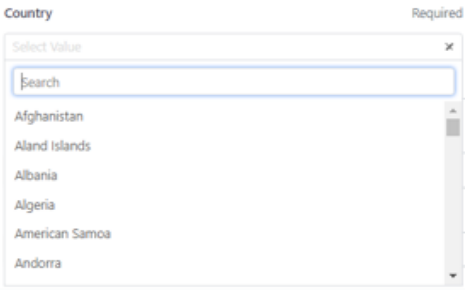
1. On the home page click on "Request Access for Organisations" tab.

Figure 55 – Request Access for organisations



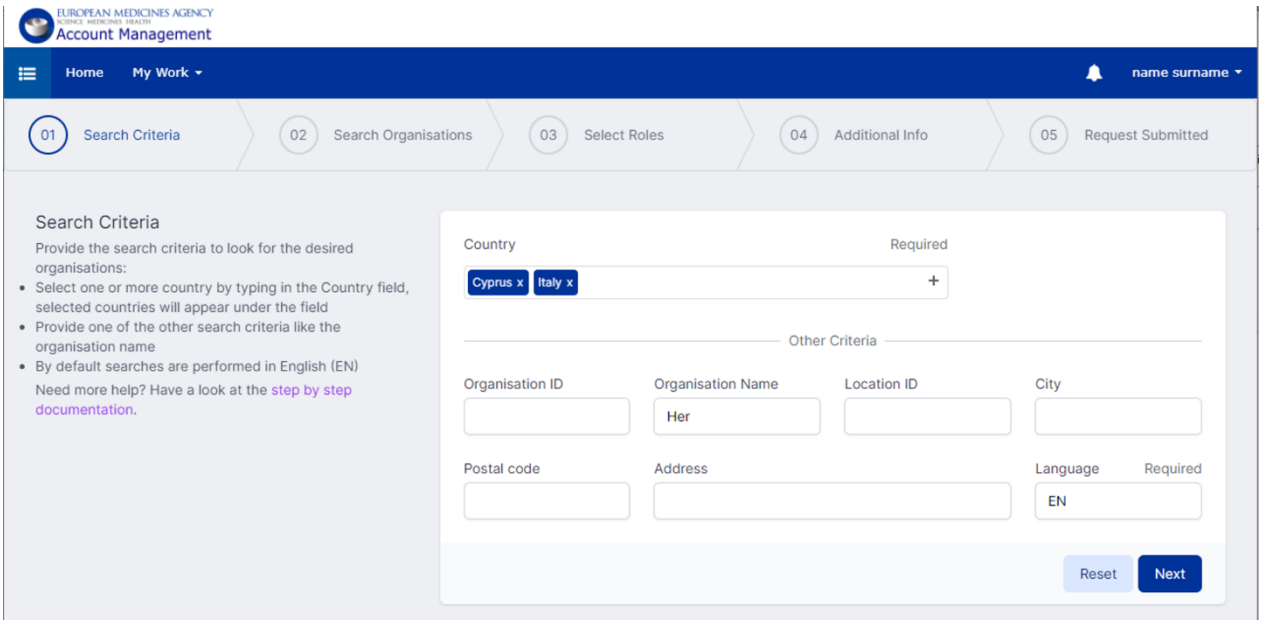
2. The first page to be displayed in the "Request Access for Organisations" page is the "Search Criteria" to look for an organisation. Under the word **Country** click into the dropdown box, and in the Search box type the country (in which the organisation is located). You can select or enter more than one country to search.

Figure 56 – Country search box



To add another country repeat the step above. When you have added all the required countries you wish to search, enter another search criteria in the boxes provided, for example organisation name, or city. Click **Next** button. The result of the search performed in this step will be viewed in the Organisations screen.

Figure 57 – Organisations screen

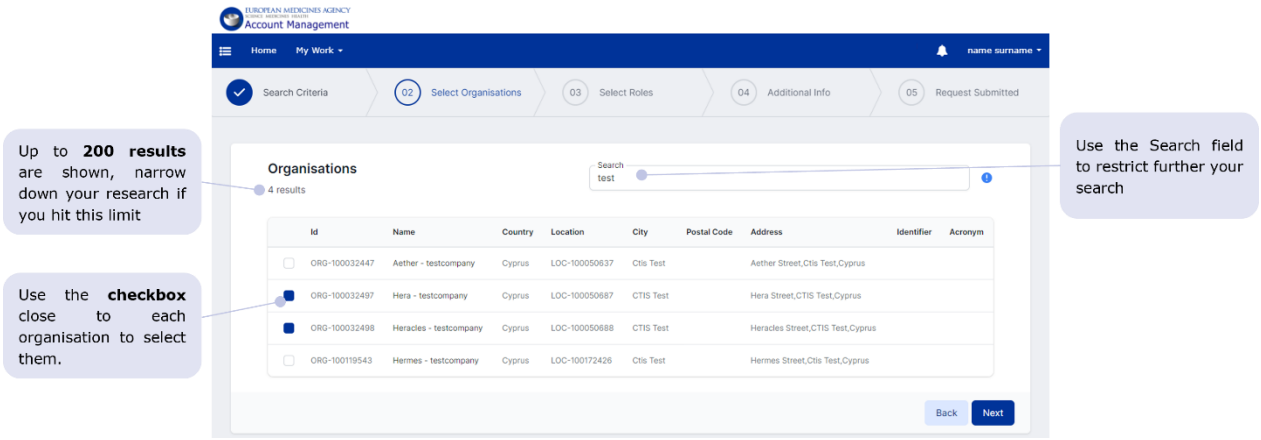


Note: all organisation names are stored in EMA Organisation Management Service (OMS) in English, if you wish to look for an organisation name in a different language you have to change the language to the related ISO code. Please note not all organisations have a local translation of their name in the local language.

3. Based on the search criteria the list of organisations is displayed, use the checkbox close to each organisation to select them. Even if location information is displayed, access is always requested on behalf of organisations and not by locations.

   Up to 200 results are displayed, if the organisation you are looking for is not displayed and you are hitting 200 results, try to narrow down your search by going back to the previous step or looking for the organisation in EMA Organisation Management Service.

Figure 58 – Search results window



   If the organisation you need to affiliate with is not listed in the results, it means that your organisation is not registered in the EMA Organisation Management Service, and therefore, your role request cannot be completed. To request the inclusion of your organisation or update your organisation data in OMS, follow the detailed in **section 3.** above.

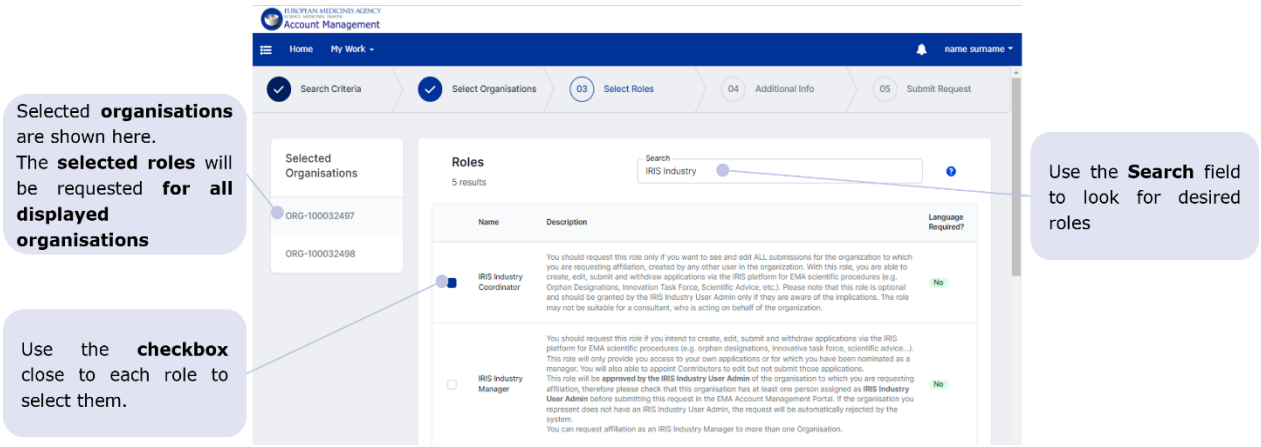
   Alternatively, it is possible to request the insertion/creation of an organisation directly in the EMA Account Management portal as the detailed in **section 5.3.1.** below.

   The request should be done in OMS or in the EMA Account Management portal but not in both.

4. The roles listed on the Roles window (see below) can be selected by clicking the box next to a specific role title, to select another role use the scroll bar to the righthand side of the list.

   The list can be filtered using the search field on the top of the page.

Figure 59 – Role selection window



When you have selected the role(s) you require access to, click **Next** button.

If you select a role for an organisation where a user administrator is missing the system will show the following message:

"There is no user administrator assigned to ORG-100000XXX. Your organisation must have one or more users who have been granted user admin role to approve such requests".

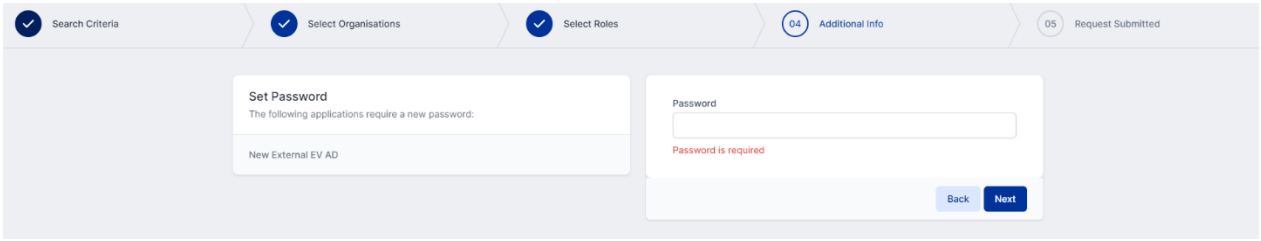
Make sure to select a User Administrator role first. A detailed explanation of the approval model can be found here.

5. The **Additional Information** page is displayed only if the combination of selected organisations and roles requires it. If no additional information is required, your request will be submitted.

   In case a password is required the new password should have at least 8 characters(s) comprising: 4 valid character types (lowercase, uppercase letters, digits and special characters); at least 1 uppercase letter; 1 digit and 1 special character.

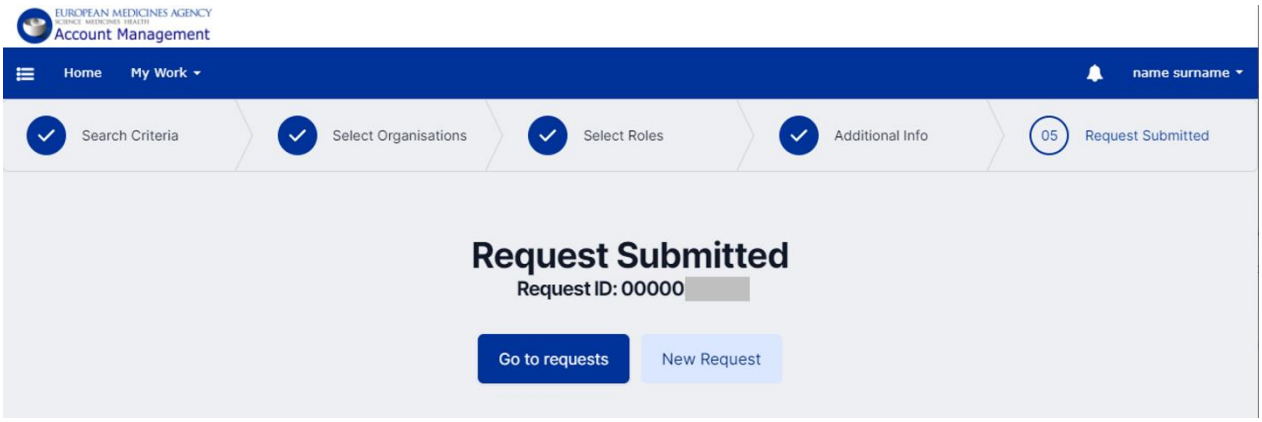
   Click "Next".

Figure 60 – Additional information window



6. The following window confirms the request has been submitted. You can reference the request ID if any problem arises.

Figure 61 – Request submitted window



Important notes:

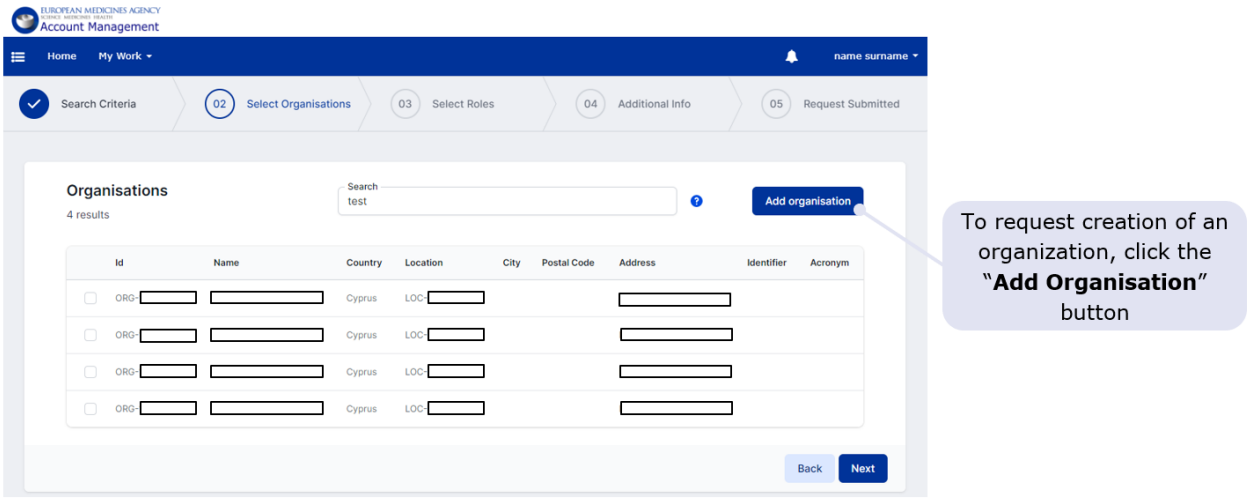
- All role requests are sent to the EU QPPV/RP and TD for internal approval, **except for EU QPPV/RP**, whose requests will go to EMA for approval – see **section 4.1.** above.
- The various EV roles are listed and described in the **Annex** 1**I** of this manual.
- A user can only have **one base role per organisation**.
- If a different base role is required, the user will first need to request the removal of access (see **section 2.7.**) of the base role that is no longer required prior to requesting the new base role. If the previous base role is not removed, the system will automatically reject the new role request. Please wait for e-mail confirmation that the base role has been successfully removed before requesting the new role.
- The role of Trusted Deputy (TD) is approved by the QPPV/RP of the organisation. Once a TD has been assigned, the TD can also approve role requests made by users within an organisation.

5.3.1. Request of a new Organisation in EMA's Account Management portal

If the organisation you need to affiliate with is not listed in the results, it means that your organisation is not registered in the EMA's SPOR Organisation Management System (OMS), and therefore, your role request cannot be completed. To request the inclusion of your organisation or update your organisation data in OMS, follow the guidance available in the Organisation Management Service on the EMA's corporate website and SPOR documents on the SPOR portal or use the "Add Organisation" button following the below steps:

1. Click on the "Add Organisation" button.

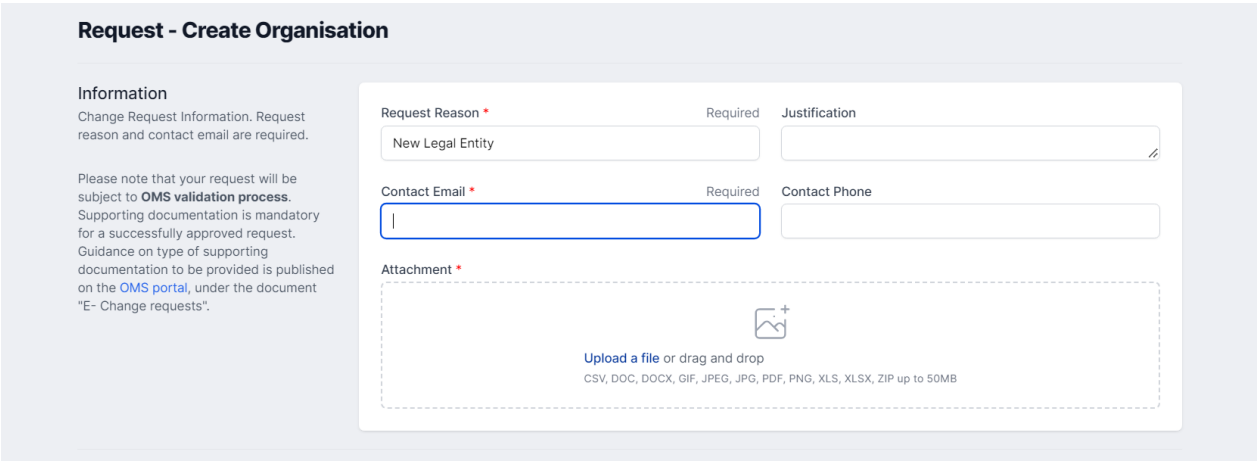
Figure 62 – "Add Organisation" button



2. The "Create organisation" form opens with three sections to be filled by the user.

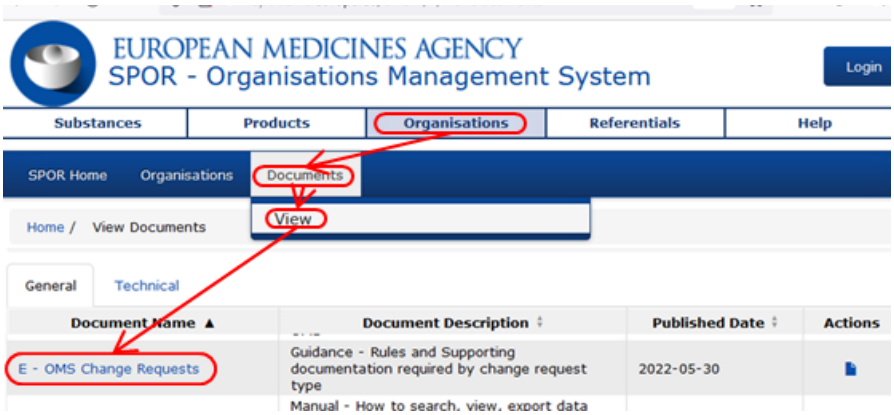
   Change Request Information: fill information like "Request Reason" and "contact email". Mandatory fields needs to be filled and relevant documentation attached in order for the request to proceed.

Figure 63 – "Create organisation" form



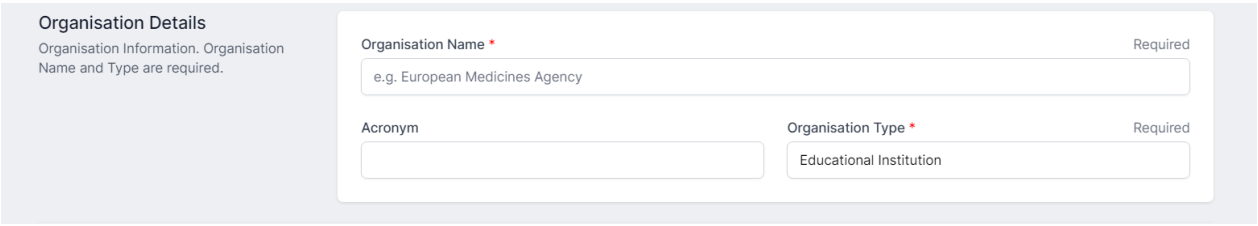
Note*:* Don't forget to provide mandatory supporting documentation for a successfully approved request. Guidance on type of supporting documentation is published on the Organisation Management Service portal, under the document "E- Change requests".

Figure 64 – Location of the documentation in OMS



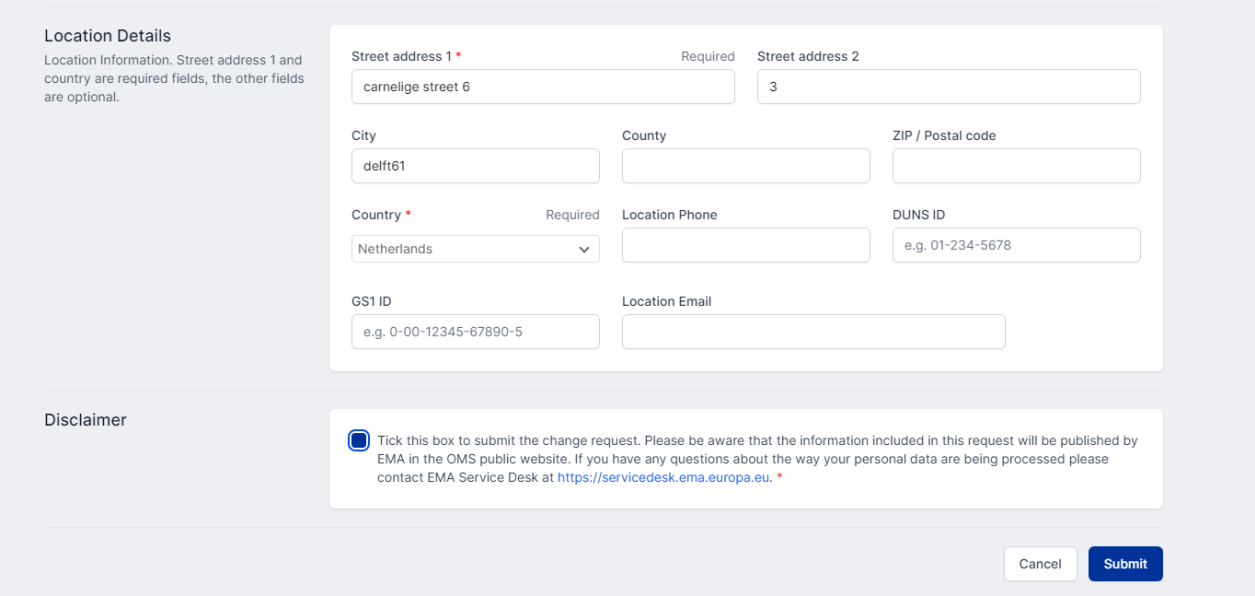
Organisation Details: Important information regarding organisation like name and Type needs to be filled in.

Figure 65 – Organisation details



Location Details: contains information about the location.

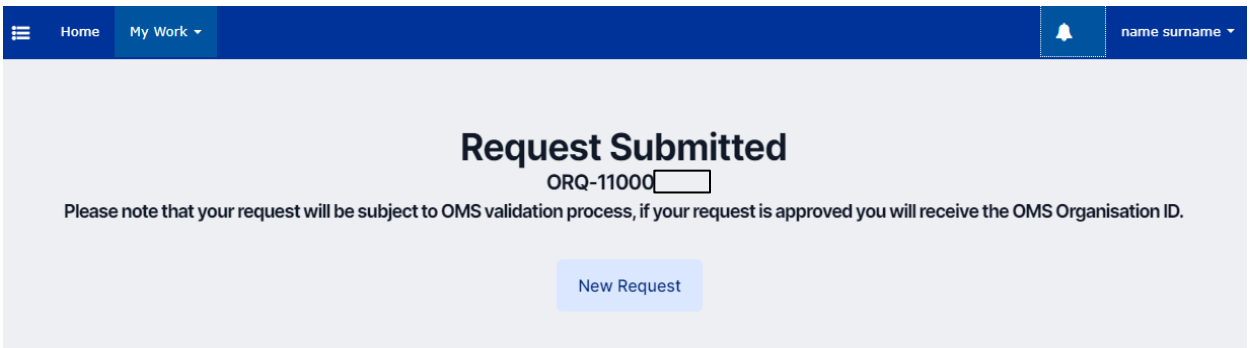
Figure 66 – Location details



3. Once all information has been filled, the user needs to mark the checkbox of the disclaimer message and click on the "Submit" button to send the request to OMS. The user will be provided with the generated request number starting with "ORQ".

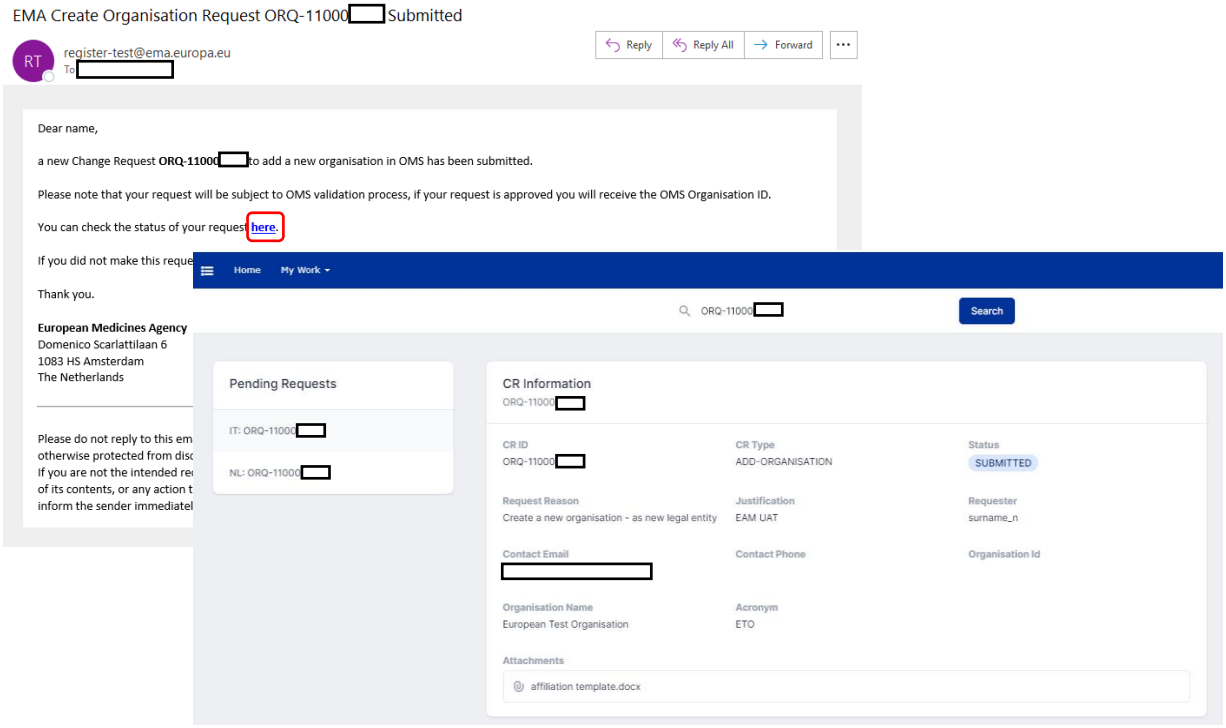
   Note: The ORQ Request number is not the OMS Organisation ID; this will be provided after the OMS Validation process.

Figure 67 – Request submitted message displaying the ORQ Request number



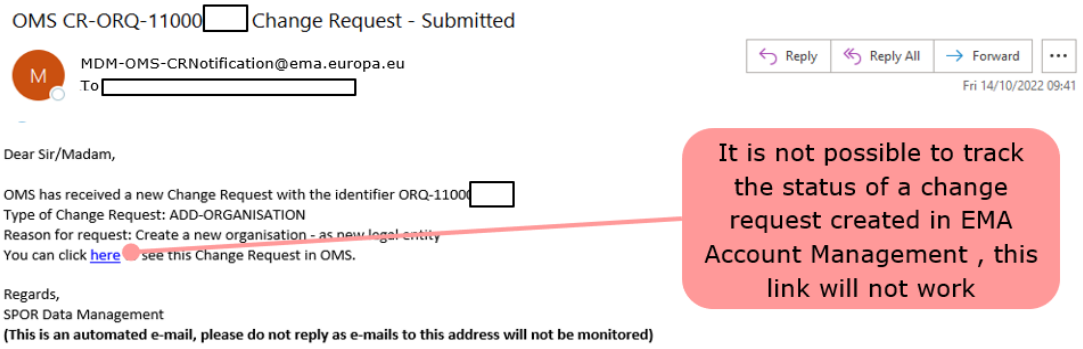
Users also receive a confirmation email coming from register@ema.europa.eu with a link to track the status of the submitted request(s).

Figure 68 – Confirmation email



Note: It is not possible to check the status of a change request submitted in EMA Account Management in OMS. The link provided in the email coming from the OMS system will not work.

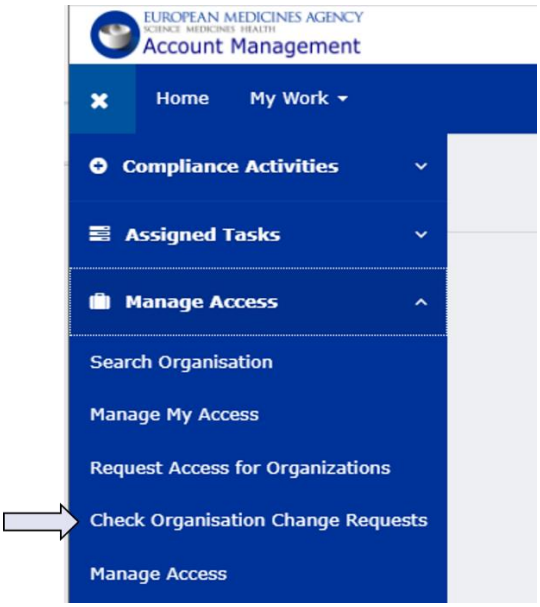
Figure 69 – Change request confirmation email



Tracking the Organisation Change Request

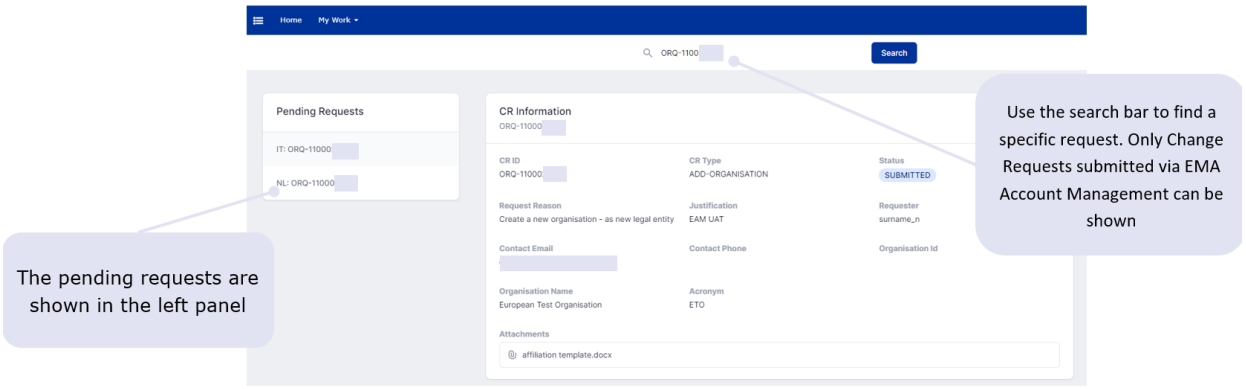
4. Click on "Check Organisation Change requests" under "Manage Access" as shown below.

Figure 70 – "Check Organisation Change Request"



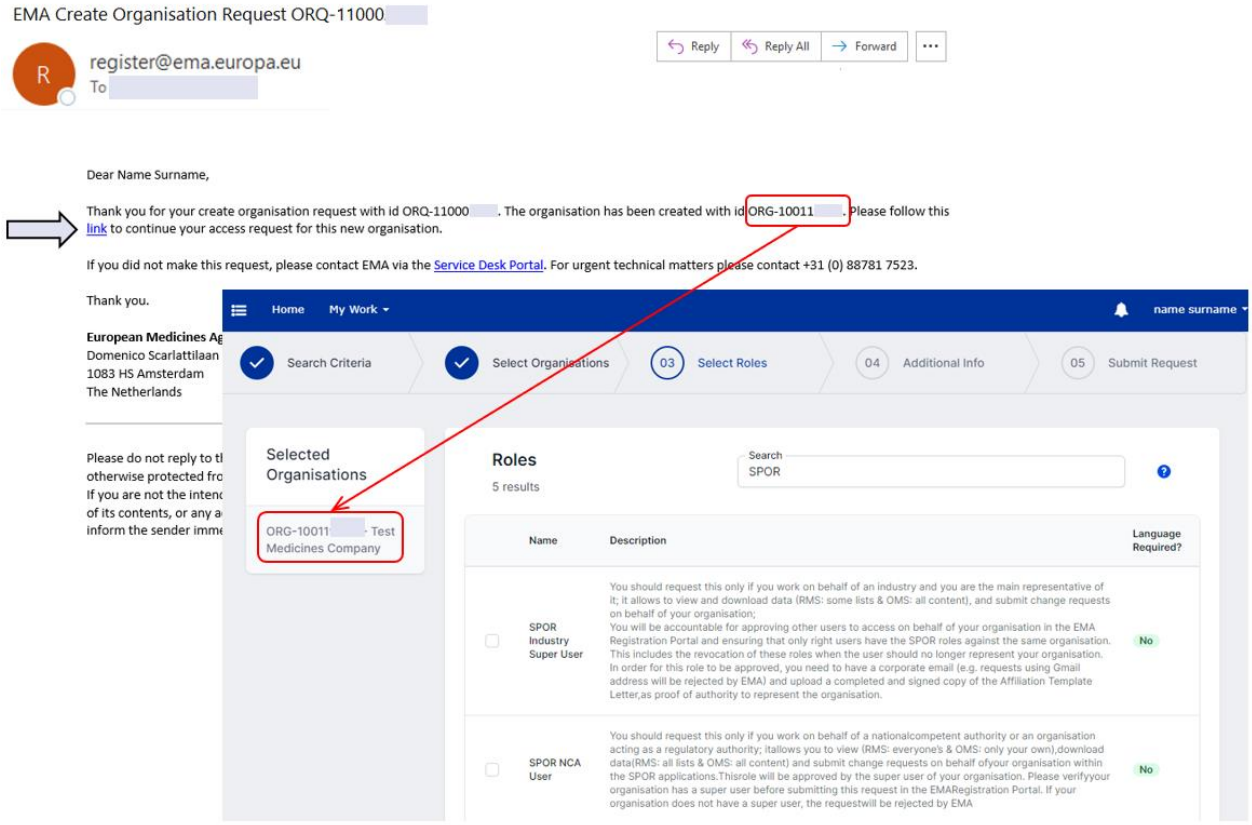
5. Enter the Change Request number starting with "ORQ" or select the change request from the left panel: the corresponding status (Submitted/Rejected/Approved) of the request will be presented.

Figure 71 – Status of the Change Request



6. The user will receive an email following the approval or rejection of the request by the OMS Data Stewards. If approved, the email sent by the EMA Account Management portal will contain a link so that user can directly procced with the next step and request the required roles based on organisation recently approved.

Figure 72 – Notification email following the creation of the organisation

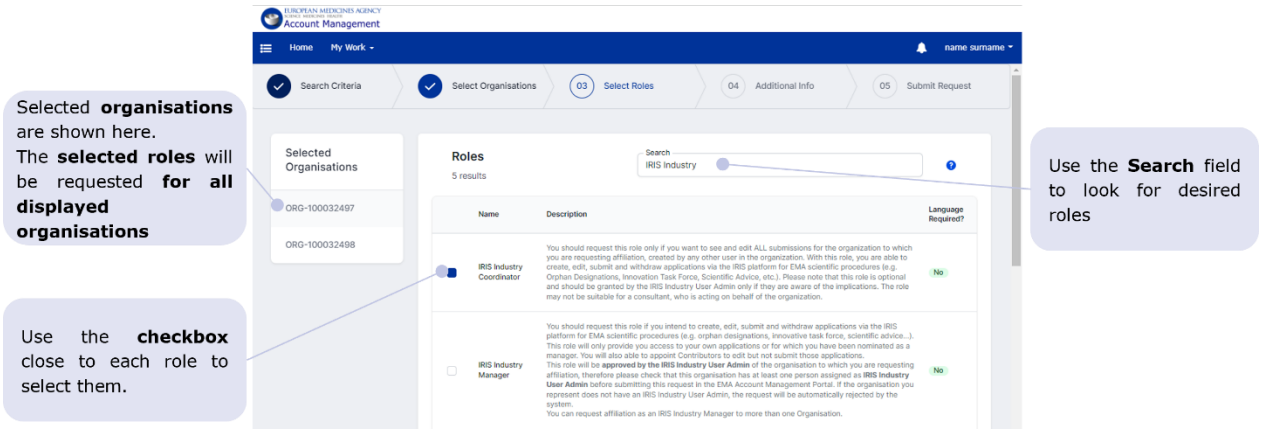


Note: After an organisation becomes available in OMS it could take up to half an hour for the organisation to be also available in EMA Account Management. The organisation becomes available in EMA Account Management when the above email is sent.

7. The roles listed on the Roles window (see below) can be selected by clicking the checkbox next to a specific role title; to select another role, use the scroll bar on the righthand side of the list.

   The list can be filtered using the search field on the top of the page.

Figure 73 – Role selection



When you have selected the role(s) you require access to, click on the "Next" button.

If you select a role for an organisation where a user administrator is missing the system will show the following message:

There is no user administrator assigned to ORG-100000XXX. Your organisation must have one or more users who have been granted user admin role to approve such requests.

Make sure to select a User Administrator role first. A detailed explanation of the approval model can be found here.

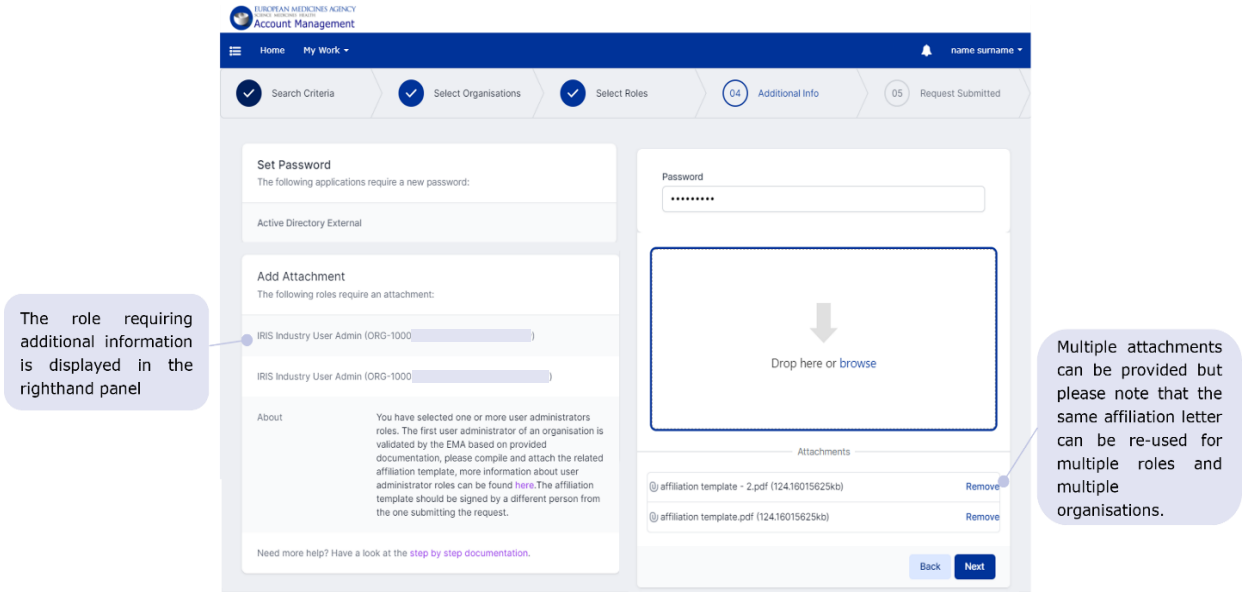
8. The **Additional Information** page is displayed only if the combination of selected organisations and roles requires it. If no additional information is required, your request will be submitted.

   To select the role of User Administrator (like IRIS User Admin or SPOR Super User) for your organisation, that organisation must first have at least one User Administrator allocated and validated by the EMA. This is done by completing the affiliation template and signed by an approved signatory (this person should be different from the person submitting the request) from your organisation, then the document can be downloaded or drag and dropped into the allocated box (see below).

   Upload a completed and signed copy of the affiliation template letter, as proof of authority to represent the organisation. This must be on the official company letterhead and signed by someone currently employed by the organisation for which you will assume the User Administrator role (this person should be different from the person submitting the request). Please note if document attached for requesting the User Administrator Role is not compliant to above requirements, the request will be denied by the EMA administrators.

   In case a password is required the new password should have at least 8 characters(s) comprising: 4 valid character types (lowercase, uppercase letters, digits and special characters); at least 1 uppercase letter; 1 digit and 1 special character.

Figure 74 – Role selection

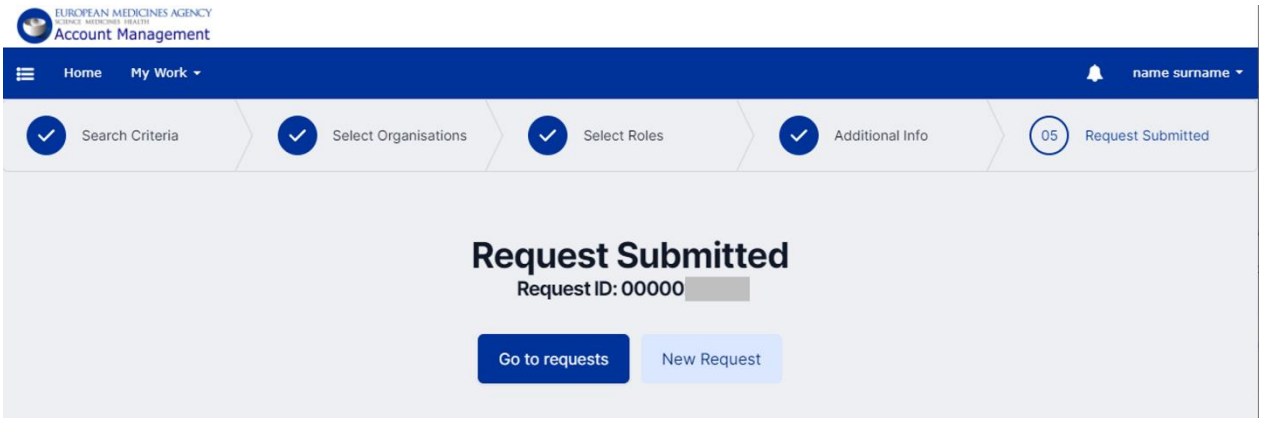


Note: For the first User Administrator the requester's e-mail should preferably be a work email from the same organisation on behalf of which the user is requesting the user access. The EMA will refuse requests coming from Gmail, Yahoo and similar private addresses.

EudraVigilance: When requesting access as a Responsible Person (RP) or EU QPPV/Additional QPPV/Trusted Deputy (TD) please follow the steps described in **section 4.1.** of the registration manual.

9. The following window confirms the request has been submitted. You can reference the request ID if any problem arises.

Figure 75 – Confirmation message of role request



5.3.2. Multiple EV roles

Industry users can have multiple roles assigned in the EMA Account Management portal, each of these base roles must belong to a different organisation, e.g. there cannot be 2 base roles requested for the same organisation. This enables users to work on behalf of several organisations.

- Each user role will be linked to a unique organisation
- Managing multiple organisations as an EU QPPV/RP/TD requires multiple EV MAH EU QPPV/RP/TD user roles with the associated organisations
- The users will need to submit individual access requests for each of the roles

Each of the user access requests will be approved by the respective EU QPPV/RP of the organisation for which the role is requested unless it is a first EU QPPV/RP for this organisation, in which case EMA would approve.

Each organisation should have at least one registered EU QPPV/RP (EMA recommends two administrators - that is the required QPPV/RP and at least one Trusted Deputy).

An organisation can also have multiple users with different levels of access and multiple trusted deputies.

An organisation may have different subsidiary organisations, each with their own organisation ID

Organisation structures and hierarchies are not defined in OMS so there is no recognition of HQ or affiliates in OMS.

The QPPV/RP/TD of the HQ does not automatically have access to the affiliates; the QPPV/RP/TD role will need to be requested for the concerned affiliates (not applicable to Virtual Affiliates).

The list of possible EV roles is provided in the **Annex 1** of this manual.

5.4. Role approval for EudraVigilance

The EU QPPV/RP for each organisation will be approved by EMA after they select the MAH/NCA/CS/NCS EU QPPV/RP role through the request access tab in the EMA Account Management portal and submit the required documents via EMA Service Desk access request, as described in **section 4.1.**

When their access is granted, the user will receive a confirmation e-mail and the role will appear in the EMA Account Management portal "Identity" tab ("Access" section).

The EU QPPV/RP/TD user can then approve EV access requests for other users within their organisation.

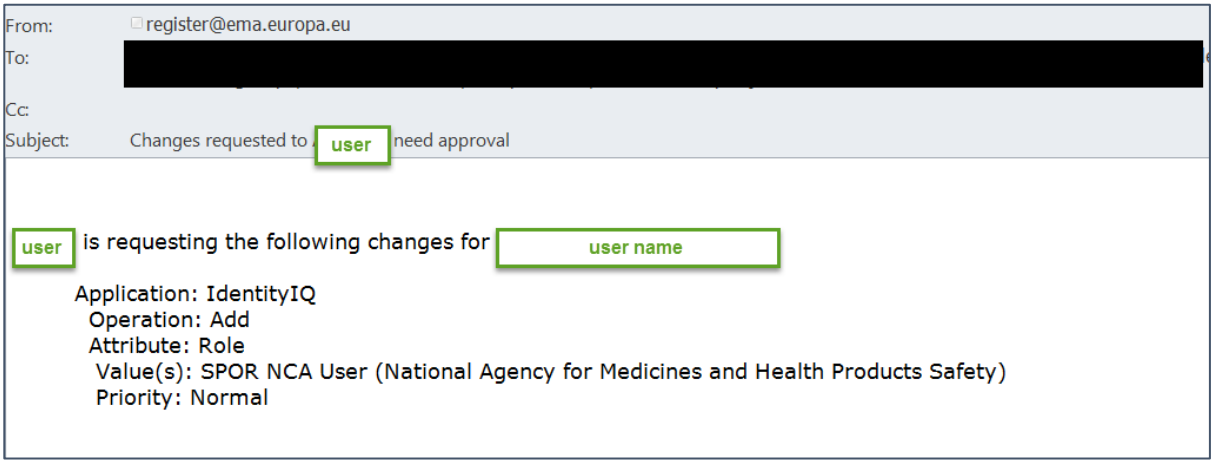
A role will be rejected if the system finds a clash (another role for the same organisation profile is already present). It is important to first revoke all the existing active roles for a single user profile before requesting a new base role for that user.

NOTE: An organisation can have multiple users with the same role, but a user needs to ensure they only have one base role per organisation profile. It is very important that for the new EU QPPV/RP to ensure that the previous EU QPPV/RP has removed their role and that this request has been approved. For TD and standard users, please ensure all base and supplementary roles for your organisation are removed before you request a new one.

5.4.1. Approval process managed by EU QPPV/RP and Trusted Deputy

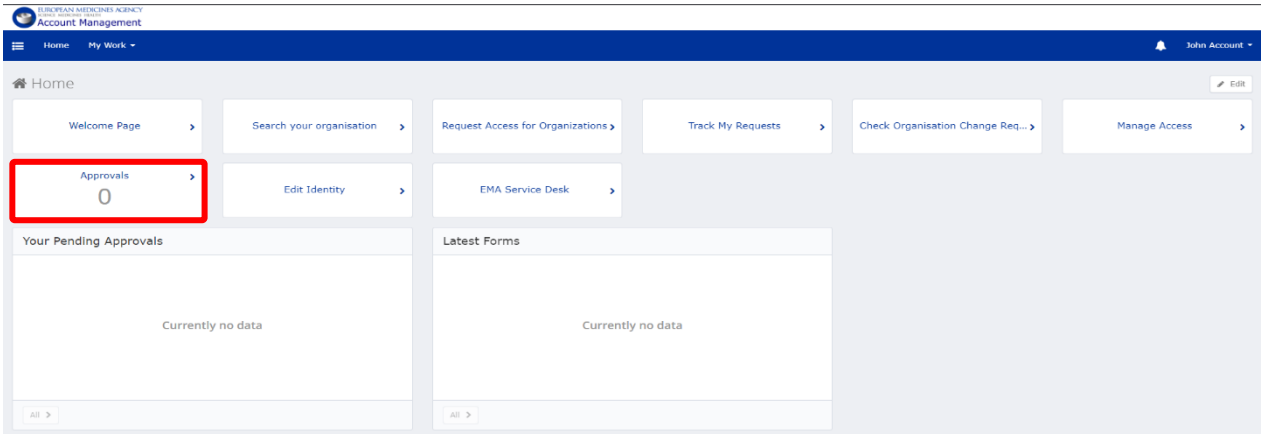
Once a request is sent for a user role, the EU QPPV/RP/TD receives an e-mail stating the name of the user, the role requested and the organisation affiliation.

Figure 76 - E-mail alert for a new EV role request



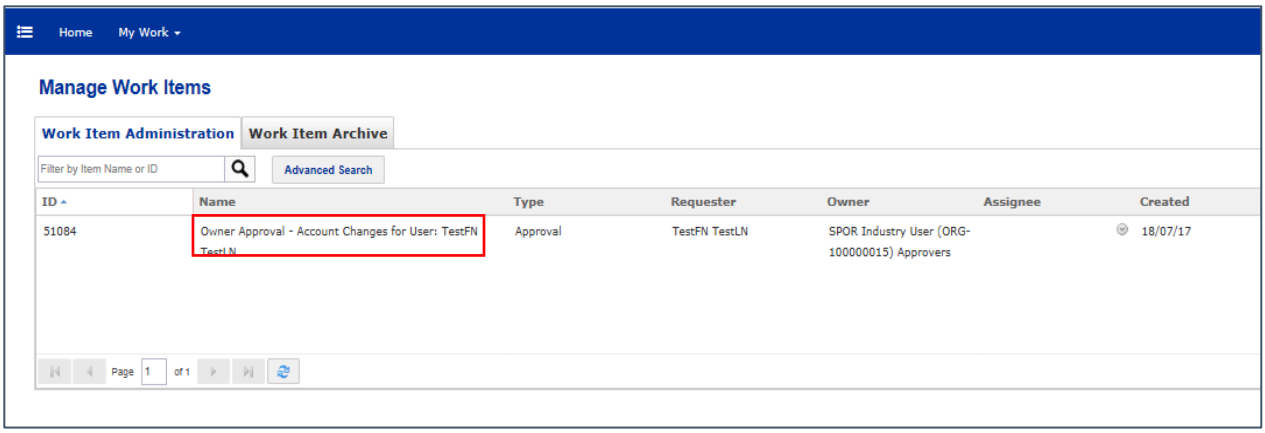
1. The EU QPPV/TD/RP needs to log in to the EMA Account Management portal.
2. The request appears in the "Approvals" tab and "Your Pending Approvals" field.

Figure 77 - EU QPPV/RP's homepage with a new access request in the inbox



3. Click on Approvals – overview of the request appears.

Figure 78 - Request overview



4. Click on the request itself (in red box) – the approval page is displayed.

Figure 79 - Request approval page – approval details

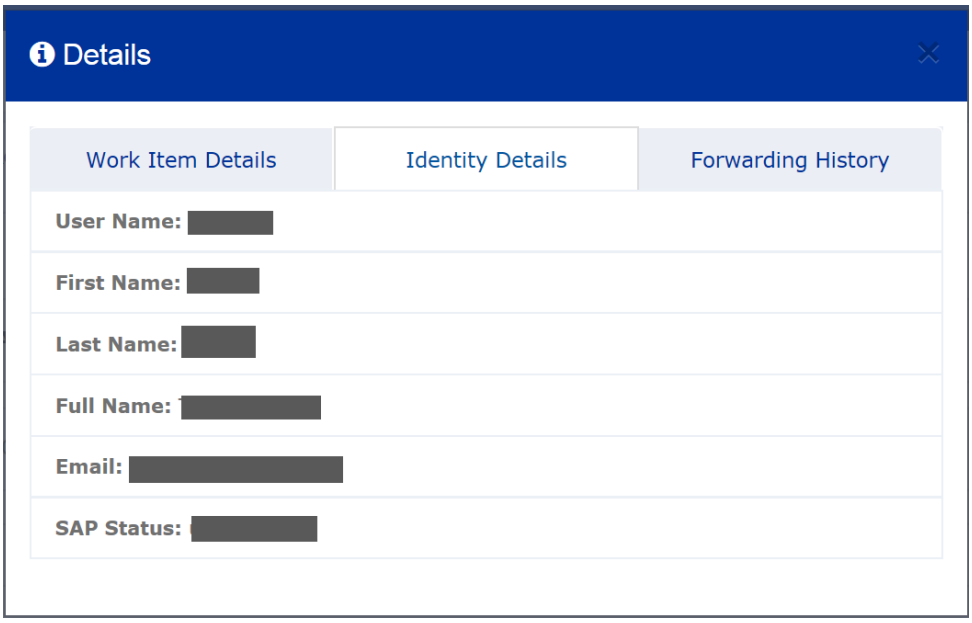
5. Click on "Approval details" – the options include:

   Work Item details (request ID, requester name, creation date, etc.)

   Identity details (username, first name, last name, email of the person requesting the access)

   Forwarding History (information on whether the request has been forwarded by another approver)

Figure 80 - View requestor's identity details

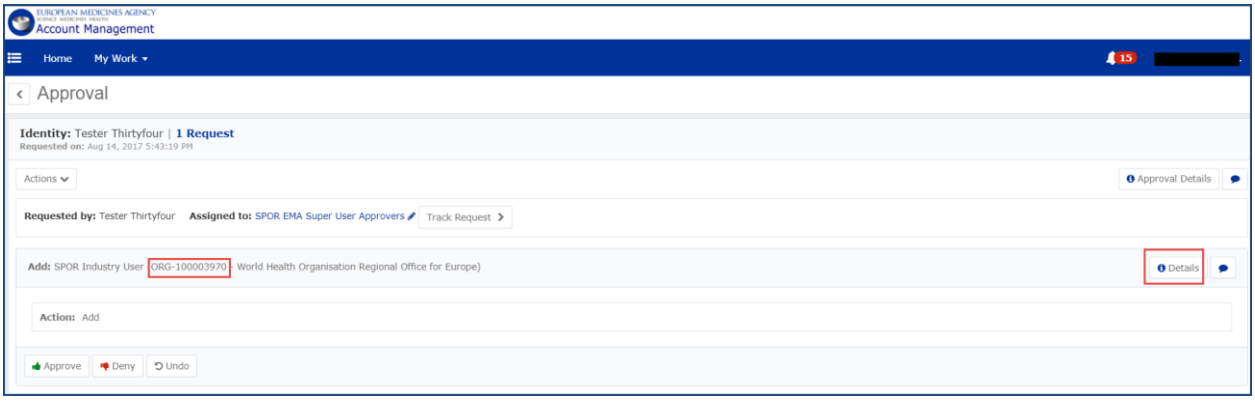


The requester's e-mail should normally be a work e-mail from the same organisation the user is requesting the EV access.

Requests with private e-mail addresses should normally be rejected or at least further checks should be made about the authenticity of the request.

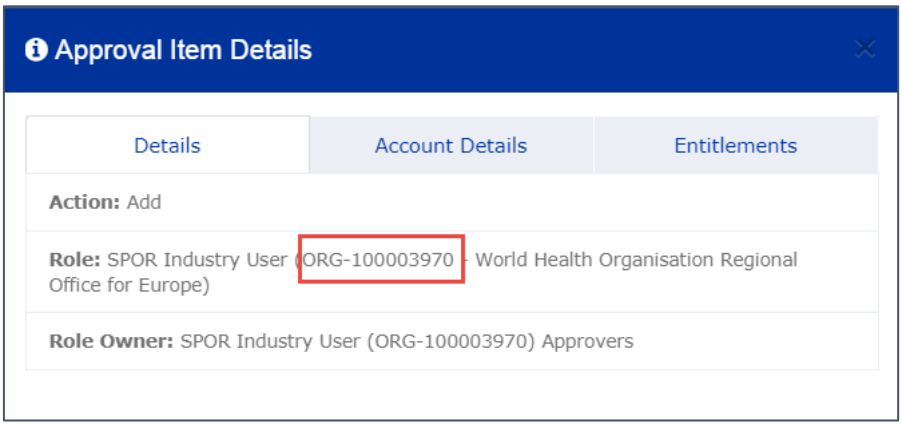
6. After checking the approval details, close the window and proceed with checking the approval item details back on the approval page.

Figure 81 - Request approval page with approval item details and organisation ID

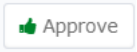


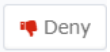
7. Approval item details also include the affiliated organisation ID. The organisation must be the same as the organisation of the Role Owner User.

Figure 82 - Approval item details



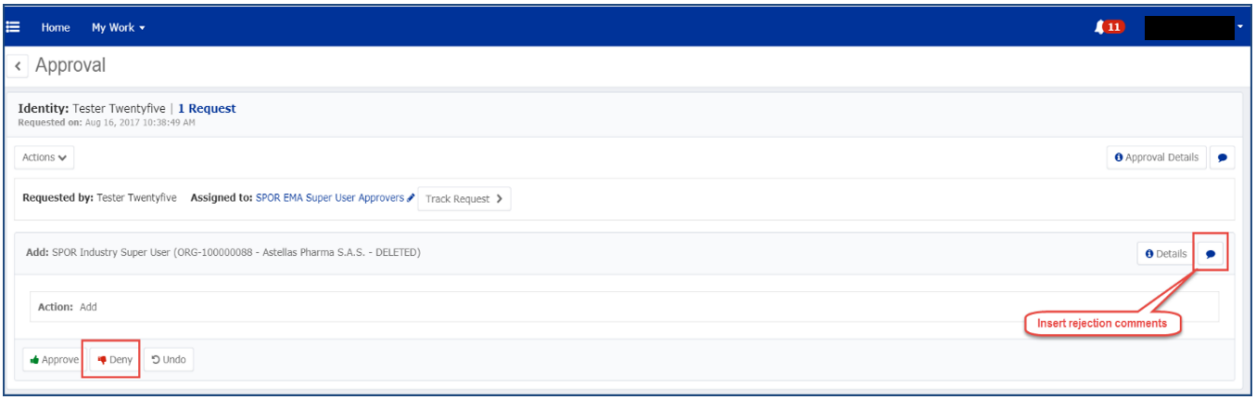
8. Go back to the approval page.

9. Select the approve 

or deny 

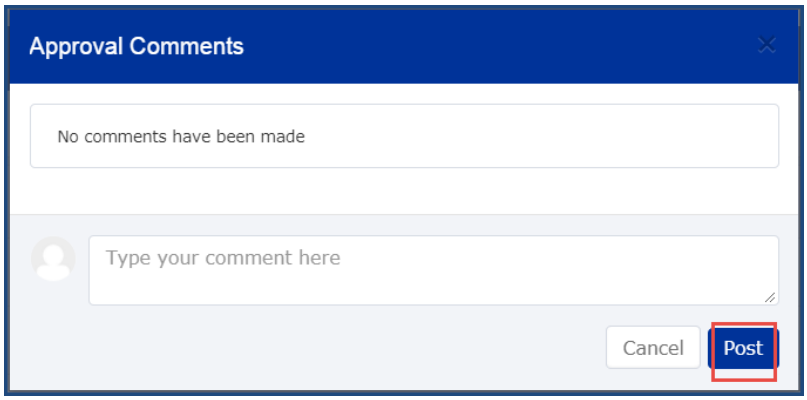
icon as appropriate. We recommend the QPPV/RP/TD inserts a comment before rejecting a role so that the user can be informed as to what the issue was and can make a modified new request if needed. You can also add a comment before approving them. Comments should be inserted BEFORE approving or rejecting a role.

Figure 83 - Approval item details



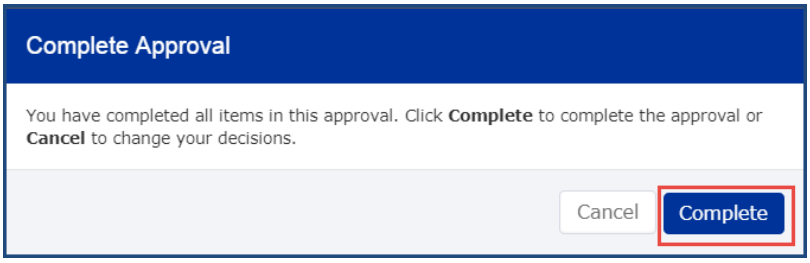
10. A pop-up window appears – enter your comments and click "post"

Figure 84 - Insert rejection comments – pop-up window



11. Click "Complete" (both for approve and deny).

Figure 85 - Complete approval



12. For approved access – the access is now active, and the requestor is notified via e-mail (including any comments added).
13. For rejected access – the access is not granted, and the requestor is notified via e-mail (including any comments added).

5.5. Remove (revoke) user access

The EU QPPV/RP/TD user can also revoke the access for approved users. The possibility to revoke access is available the day after an access request is approved.

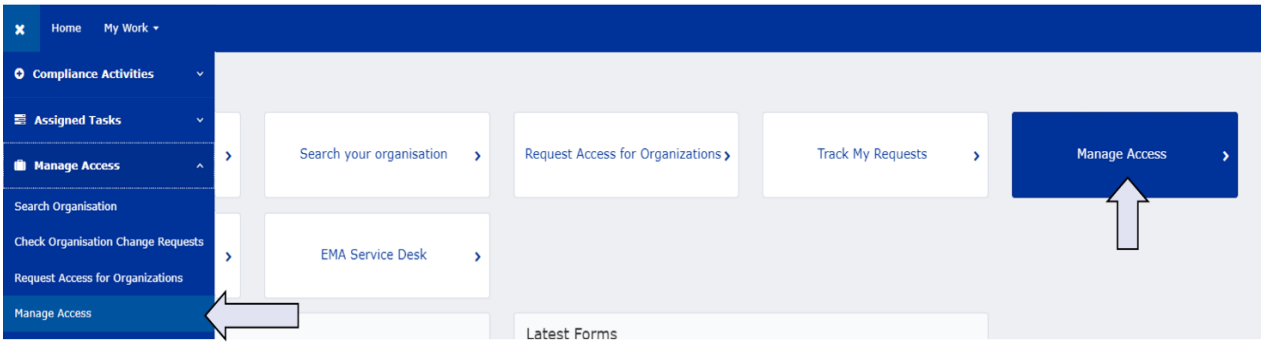
5.5.1. Revoke an EV user role by the EU QPPV/RP or Trusted Deputy

When a person leaves an organisation or no longer has need to access a system, their access should be revoked by either the user itself by following **section 2.7.** or this can be done by the EU QPPV/RP or TD of the organisation. The EU QPPV/RP or TD should follow the steps below to remove access for a user within their organisation:

1. The EU QPPV/RP or Trusted Deputy accesses the EMA's Account Management portal and does the login.

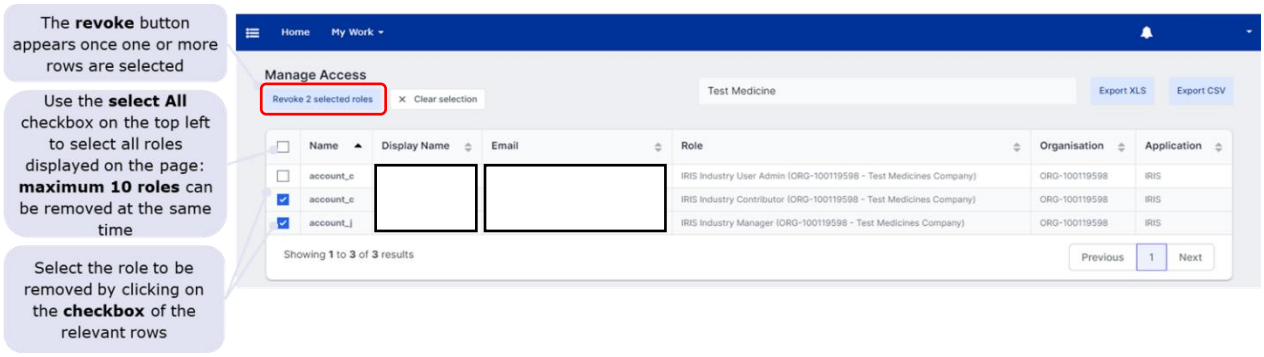
2. On the home page, clicks on the "Manage Access" tab or, on the top left menu, selects "Manage Access" and "Manage Access".

Figure 86 – Manage Access



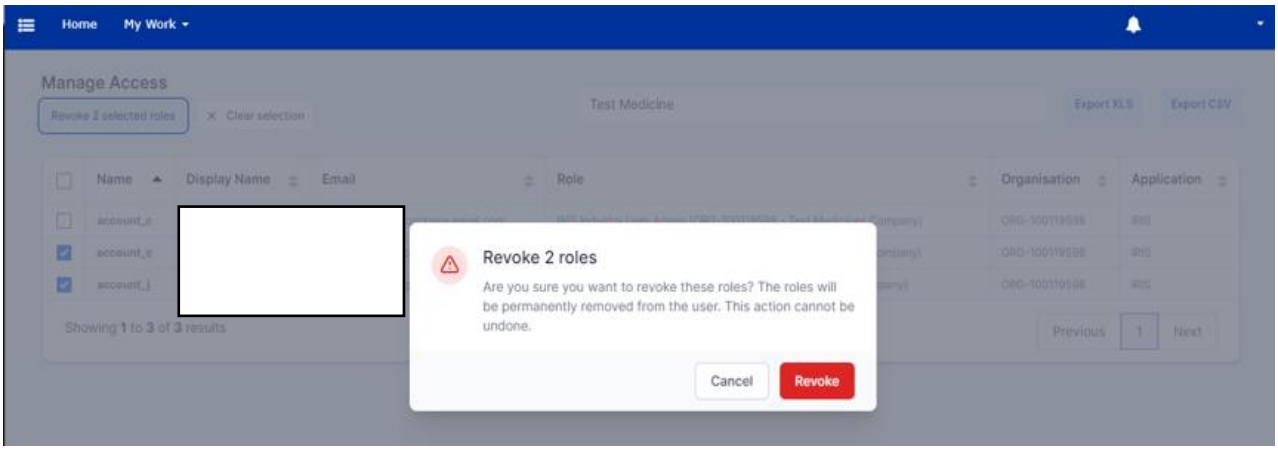
3. Selects the roles to be removed by clicking on the checkbox of the relevant row(s); once selected, the "revoke selected roles" button appears as per image below.

Figure 87 – Selection of users having their access revoked



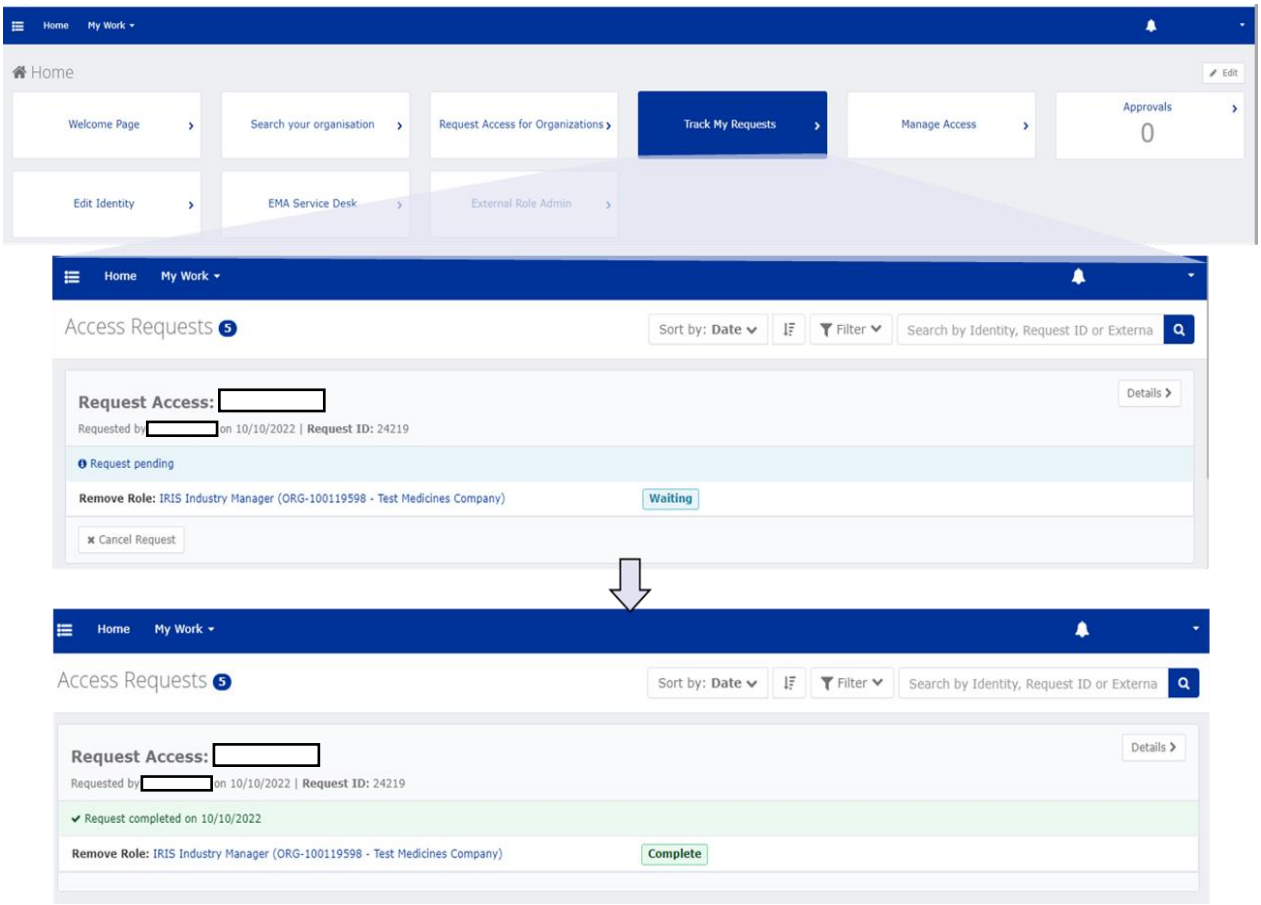
4. Once the EU QPPV/RP or Trusted Deputy clicks on the "revoke selected roles" button, a confirmation pop-up message is displayed.

Figure 88 – Revocation of user access



5. After clicking on "Revoke" in the pop-up message, the system will start processing the request. The roles are not removed immediately as the process takes about 15 minutes to be completed. In the meantime, the EU QPPV/RP or Trusted Deputy can track the status of the removal request with the "Track My Request" tab.

Figure 89 – Tracking of the request



6. Once the request has been processed by the system, the user administration who requested the revocation of the user(s) access (i.e., the EU QPPV/RP or Trusted Deputy) and the impacted user(s) will receive an email confirmation when roles are removed/revoked.

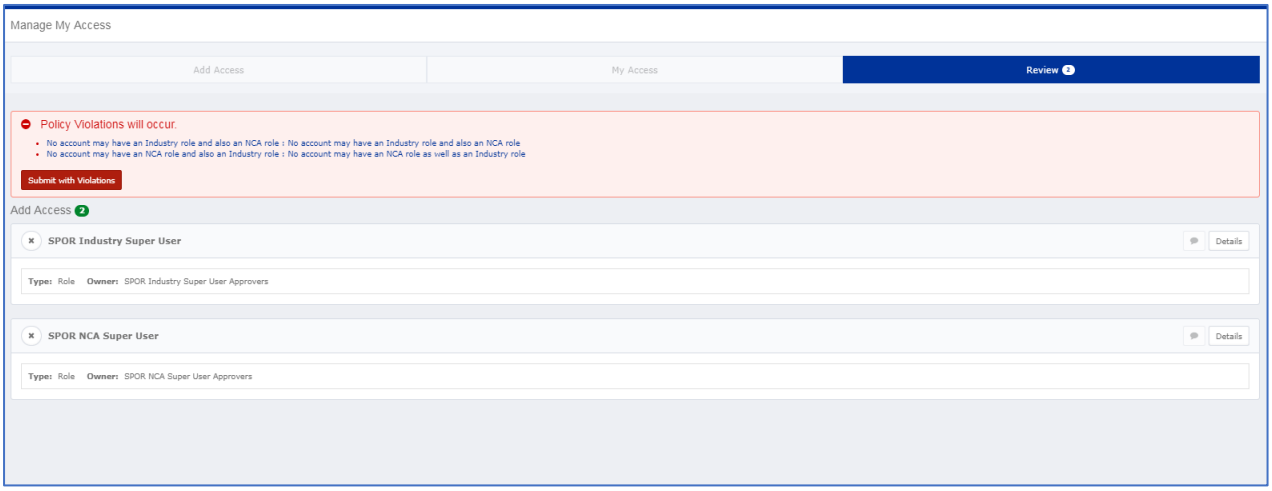
   The EU QPPV/RP and Trusted Deputy role will receive an email notification when any user from their organisation is re-activated after a period of inactivity.

5.6. Policy violation

There are policy rules about what types of access can be held by a user; e.g. a user cannot have an account for an MAH if they have an account for an NCA and *vice versa*.

If the policy is breached, a warning appears as Figure 90 shown below.

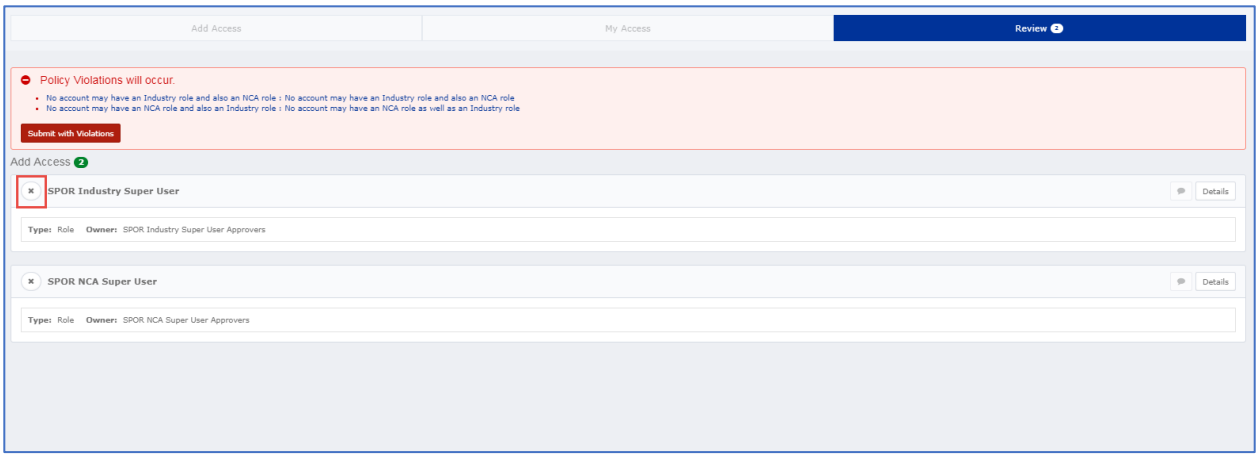
Figure 90 - Policy violation examples



To solve a policy violation and submit the request, one the following should be done:

- Remove a role to proceed by pressing 
- Or submit the request with violation
- Or cancel request

Figure 91 - Policy violation solution – remove a role



6. EudraVigilance Organisation Management

The first time an organisation profile is created in EV Human Production, the EU QPPV/RP needs to fill in all the blank fields in the EV Restricted Area – see **section 4.2.** Once done, the QPPV/RP must select "update" for the information to be registered and saved in the system.

The transmission mode will not be activated until a confirmation by the EMA has been received that the transmission registration has been completed – see **section 6.1.1.** for more details.

6.1. EV restricted area and transmission mode for new organisation

After the first user QPPV/RP role has been approved by the EV Registration team, organisations will receive confirmation of the role approval. If a Gateway connection form and an encryption security certificate, applicable to EV XCOMP (Test system), were provided with the initial organisation registration request, the organisation will also receive a separate confirmation from the EMA that the Gateway set up has been completed.

When creating a profile with Gateway transmission, it is recommended to create a virtual affiliate with WebTrader transmission in order to ensure that XEVMPD data can be submitted.

6.1.1. WebTrader and Gateway transmission mode set up

WebTrader transmission mode for submission of ICSRs and XEVPRM reports via EVWEB will be activated once the organisation receives confirmation from the EMA that the transmission registration has been completed. All new organisations are registered with Webtrader transmission mode by default.

Gateway transmission mode will be activated after confirmation is received from the EMA that the Gateway set up has been completed. For this, an encryption certificate and a completed Gateway connection form should be provided either in the initial registration request for an organisation or as a subsequent Service Desk request addressed for the attention of the Gateway Support team. More information can be found in the section "Required action before EudraVigilance Registration" – "Transmission mode for reporting" on the EudraVigilance: how to register webpage.

6.1.2. Change of transmission mode from WebTrader to Gateway

If an organisation operating as webtrader (i.e., that uses EVWEB or EVPOST to send ICSRs to EMA) wishes to change their transmission mode to gateway trader (i.e., to submit the cases to EMA directly via their pharmacovigilance database), they should follow the steps below:

1. Create a Service Desk request addressed to the Gateway team and attach a completed Gateway connection form and encryption certificate for transmission mode change. This change needs to be done in XCOMP first. In the form please make sure that you have included the XCOMP Organisation ID as it is displayed in the EV XCOMP Restricted Area. The EV XCOMP IDs follow format ORX#########.
2. When confirmation from the Gateway team is received, a separate Service Desk request should be raised addressed to the QAT team in order to complete quality assurance testing.

3. Once testing is completed successfully in XCOMP, activation of the Gateway profile in Production can be requested, again by raising a call to Service Desk for the attention of the Gateway support team, attaching a confirmation email with successful completion of testing, as well as a completed Gateway connection form and encryption security certificate for Production. In the Gateway connection form please make sure you have included the Production organisation ID as it is displayed in the EV Production restricted area.

6.2. Manage organisation hierarchy in the Production system

Only EU QPPV/RP/TDs have access to the Affiliate and Virtual Affiliate view. Affiliates and virtual affiliates should only be used when there is a need to submit data using these profiles.

Important note: we recommend keeping profiles as clean as possible. If you can work with just a HQ profiles instead of adding multiple affiliates, then this is recommended. You can also disable affiliates if they are no longer being used for the submission of data.

6.2.1. Affiliates

Affiliates are legal entities (national organisations part of a global or holding company, which have different VAT and legal requirements, or acquired companies).

The affiliate's profiles will not be accessible by the EU QPPV/RP or TD of the HQ without having a role in the affiliate. The management of affiliates is only performed in the production EudraVigilance system, in the XCOMP system only virtual affiliates can be created.

6.2.1.1. Merge organisations (create or move an affiliate)

In order to merge a HQ profile for it to become an affiliate under another HQ profile, or for an affiliate that is already registered under one HQ profile to become an affiliate under another HQ profile, please follow the steps below.

1. Make sure that the merging organisations are fully registered, including having a QPPV/RP user. An organisation without a QPPV/RP has a disabled status and cannot be merged through this process, service desk request will need to be raised.
2. The QPPV/RP of the merging organisations must log in to the Restricted Area and update the organisation details if needed.
    a. Both organisations must have the same QPPV/RP user, this is to prevent organisations being accidently merged. The requester of the Merge must be the QPPV/RP or Trusted Deputy in both organisations – go to step 3.
    b. Only if the QPPV/RP user or Trusted Deputy cannot be the same (or if the request is being done on their behalf), then the user creates a cover letter on official company headed paper, dated and signed. The letter must be signed by the QPPV/RPs of all involved organisations. Add the following information clearly explained:
        i. EV ORG ID of the HQ profile,
        ii. Organisation category of the HQ profile, and

iii. EV Org ID, organisation category and name of the new affiliate to be added to the HQ.

The user raises an EMA Service Desk ticket to request the merge attaching the signed letter. Go to step 7.

Important notes:

- The QPPV/RP must make sure that their HQ organisation category displays correctly within the EudraVigilance Restricted Area. When a merge is completed, the category of the merged affiliate(s) profile(s) is aligned with the category of the HQ profile.
- All registered virtual affiliates of the merging HQ profile will be re-linked to the new HQ. Users with EV Contributor role to the virtual affiliates associated with the previous HQ will need to re-request the contributor role for the new HQ organisation.

3. The QPPV/RP or Trusted Deputy accesses the Restricted Area and under 'EV Registered Partners', clicks on 'Manage your Organisations' and then on 'Merge'.

Figure 92 – EudraVigilance restricted area: Manage your organisations – Merge

4. If no merge was yet requested, a new screen appears: the two organisations to be merged (one as HQ and the other as Affiliate) should be selected accordingly in the corresponding fields; the user then clicks on 'Accept', followed by 'Ok'. If, on the other hand, previous merges

were already requested, and in order to insert a new merge, the QPPV/RP or Trusted Deputy clicks on 'Insert Merge' and then selects the two organisations to be merged.

Figure 93 – Merge request of two organisations

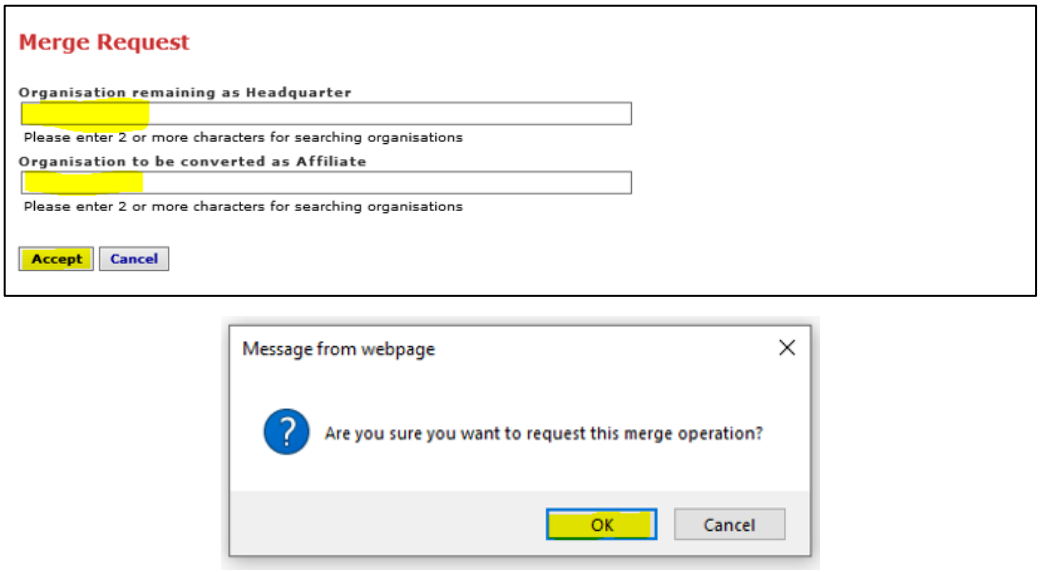


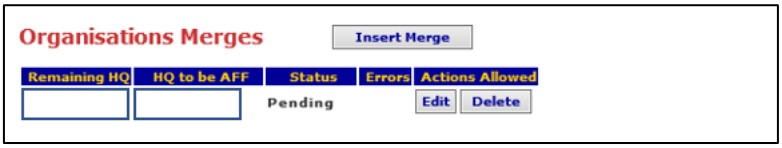
Figure 94 – Insert Merge request of two organisations

Important notes:

- It is only possible to merge an organisation involved in another ongoing merge process if that organisation remains as the HQ in both the merge requests. Conversely, it is not possible to merge an organisation involved in another ongoing merge process where it does not remain as the HQ in both the merge requests.
- It is not possible to merge two organisations whilst one of them is being swapped (**section 6.2.1.2.**).

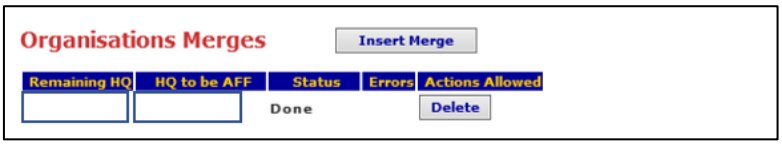
5. The pending merge request appears with status 'Pending' in the Merge area. Please note that the merge operations are executed on a weekly basis, every Friday night. While the merge request is pending, it is possible to make changes to it by clicking on 'Edit', or to delete the request by clicking on 'Delete'.

Figure 95 - The Merge request appears with status 'Pending'.



6. After being processed by the system, the status of the merge request will change to 'Done'.

Figure 96 - The Merge request appears with status 'Done'.



Important notes:

- After a merge request has been processed, clicking on 'Delete' will only hide the record of that merge, meaning that the merge itself won't be reverted; the record will be marked as 'disabled' and it will be filtered from the merge log history.
- Please note that product (eXtended EudraVigilance Medicinal Product Report Message – XEVPRM) and ICSR messages are not transferred to the new HQ during and after the merge process. In other words, the new HQ won't get a copy in its inbox of the ICSRs and product messages sent by the new affiliate.

7. End of process.

6.2.1.2. Swap organisations (make an affiliate as the new HQ)

In order to change a HQ profile to become an affiliate, while an existing affiliate of the same HQ profile becomes the new HQ profile, please follow the steps below.

1. Make sure that the swapping organisations are fully registered, including having a QPPV/RP user. An organisation without a QPPV/RP has a disabled status and cannot be swapped.
2. The QPPV/RP of the each swapping organisation must log in to the Restricted Area and update the organisation details if needed.
    a. Both organisations must have the same QPPV/RP user, this is to prevent organisations being accidently swapped. The requester of the Swap must be the QPPV/RP or Trusted Deputy in both organisations – go to step 3.
    b. Only if the QPPV/RP user or Trusted Deputy cannot be the same (or if the request is being done on their behalf), then the user creates a cover letter on official company headed paper, dated and signed. The letter must be signed by the QPPV/RPs of all involved organisations. Add the following information clearly explained:
        i. HQ Org ID to be turned into an Affiliate Org ID which is to be changed to become the new HQ profile.

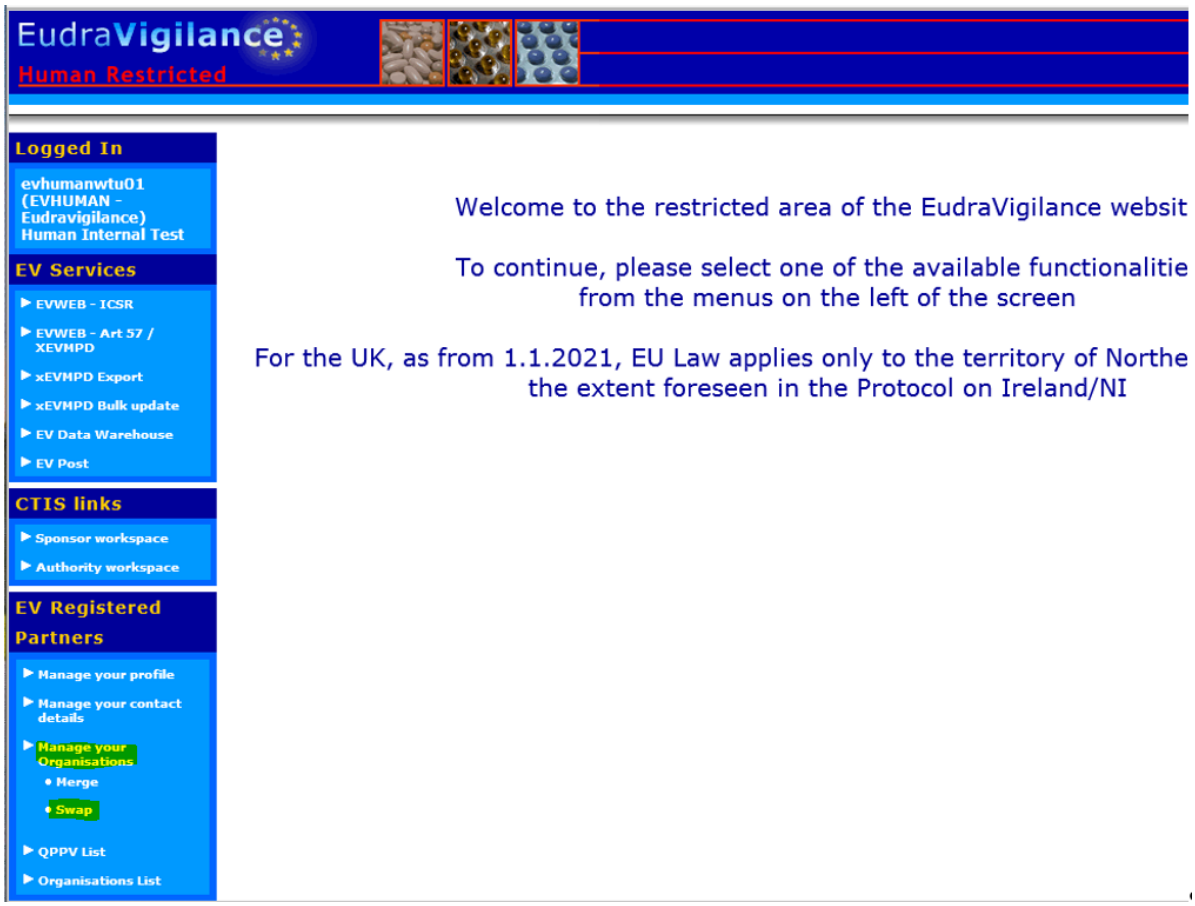
    The user raises an EMA Service Desk ticket to request the merge attaching the signed letter. Go to step 7.

Important notes:

- The QPPV/RP must make sure that their HQ organisation category displays correctly within the EudraVigilance Restricted Area. When a swap is completed, the category of the swapped affiliate(s) profile(s) is aligned with the category of the (new) HQ profile.
- All registered virtual affiliates of the swapped HQ profile will be re-linked to the new HQ. Users with EV Contributor role to the virtual affiliates associated with the previous HQ will need to re-request the contributor role for the new HQ organisation.

3. The QPPV/RP or Trusted Deputy of the HQ organisation accesses the Restricted Area and under ‘EV Registered Partners’, clicks on ‘Manage your Organisations’ and then on ‘Swap’.

Figure 97 - EudraVigilance restricted area: Manage your organisations – Swap



4. If no swap was yet requested, a new screen appears: the two organisations to be swapped (one as HQ and the other as Affiliate) should be selected accordingly in the corresponding fields; the user then clicks on 'Accept', followed by 'Ok'. If, on the other hand, previous swaps were already requested, and in order to insert a new swap, the QPPV/RP or Trusted Deputy clicks on 'Insert swap' and then selects the two organisations to be swapped.

Figure 98 - Swap request of two organisations

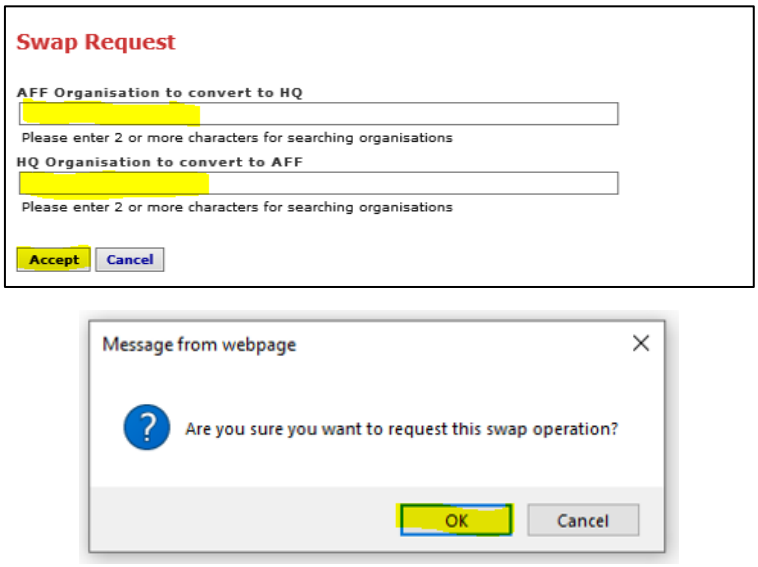


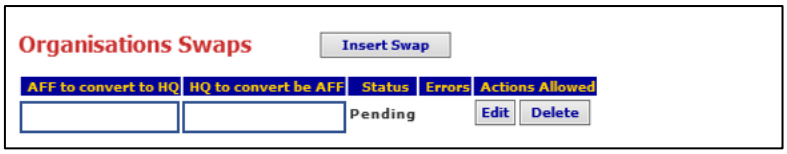
Figure 99 - Insert a swap request of two organisations

Important notes:

- It is not possible to swap two organisations whilst one of them is being merged (see **section 6.2.1.1.** above).
- It is not possible to swap two organisations whilst one of them is being swapped.
- It is not possible to swap two unrelated organisations.

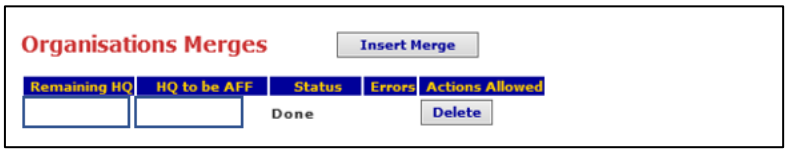
5. The pending swap request appears with status 'Pending' in the Swap area. Please note that the swap operations are executed on a weekly basis, every Friday night. While the swap request is pending, it is possible to make changes to it by clicking on 'Edit', or to delete the request by clicking on 'Delete'.

Figure 100 - The Swap request appears with status 'Pending'.



6. After being processed by the system, the status of the merge request will change to 'Done'.

Figure 101 - The Merge request appears with status 'Done'.



Important notes:

- After a swap request has been processed, clicking on 'Delete' will only hide the record of that swap, meaning that the swap itself won't be reverted; the record will be marked as 'disabled' and it will be filtered from the swap log history.
- Please note that product (eXtended EudraVigilance Medicinal Product Report Message – XEVPRM) and ICSR messages are not transferred to the new HQ during and after the swap process. In other words, the new HQ won't get a copy in its inbox of the ICSRs and product messages sent by the new affiliate.

7. End of process.

6.2.1.3. Split (demerge) organisations

In order to move an affiliate that is already registered under a HQ profile to sit separately as a HQ profile, please follow the steps below.

Create a cover letter on official company headed paper, dated and signed. The letter must be signed by the QPPV/RPs of all involved organisations. Add the following information clearly explained:

1. Org ID and name of the affiliate profile which is to be changed to become a HQ profile
2. Raise a EMA Service Desk ticket to request the split attaching the signed letter.

6.2.2. Virtual Affiliates

Virtual affiliates should be created only for administrative purposes such as:

a. A gateway organisation needs to use EVWEB to send XEVMPD art57 data.

b. A gateway organisation wants to use EVWEB as a back-up system in case of system failure with their own system.

c. A CRO or MAH is sending data on behalf of another organisation.

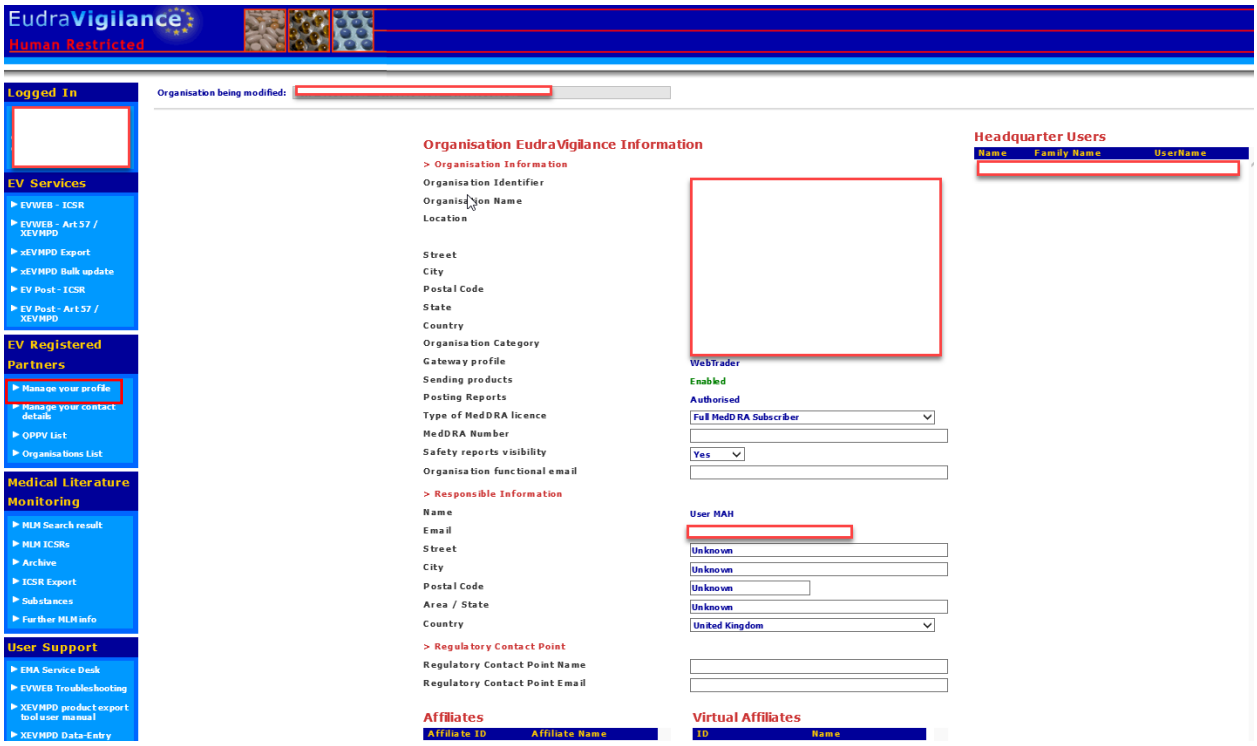
d. A MAH has more than one PV system and needs them to be manged by different users/profiles

e. A non-commercial organisation is running multiple trials which need user access to be kept separate.

Please note that Virtual Affiliates can only be created under HQ profiles. Users with EU QPPV/RP/TD role can create virtual affiliates by following the steps described below.

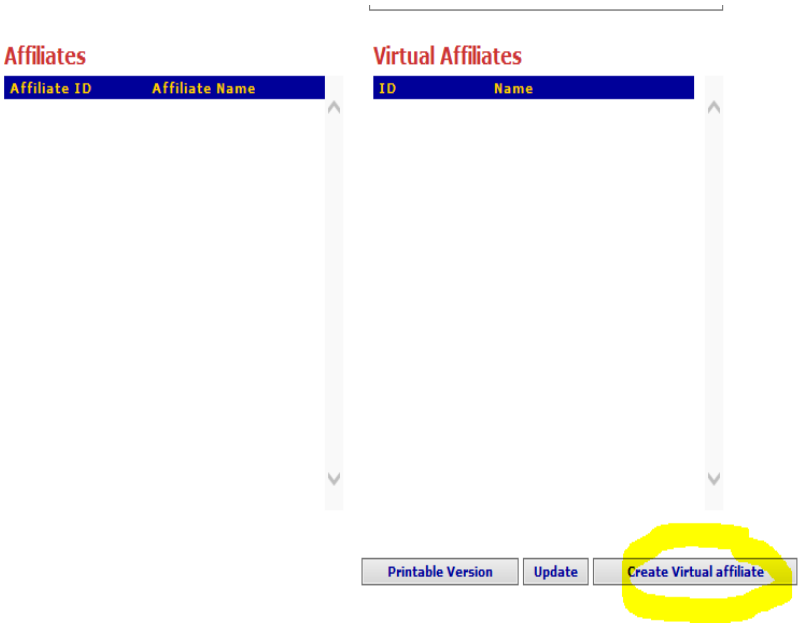
1. EU QPPV/RP/TD logs into EV Human Production and selects "Manage my Profile" from the left-hand side column.

Figure 102 - Access your Restricted area view



2. Click on the "Create Virtual Affiliate" button from the bottom menu.

Figure 103 - Creation of Virtual Affiliate

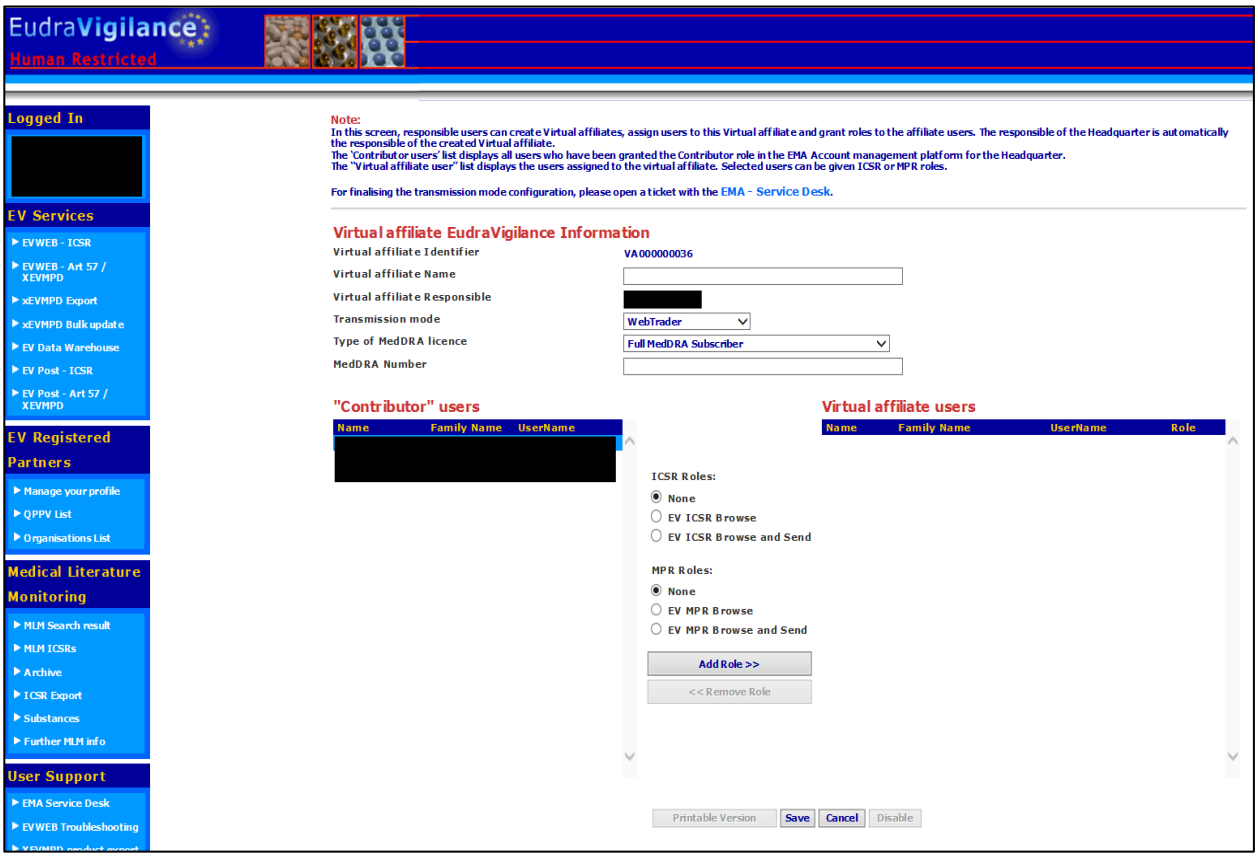


3. Fill in all the details of the organisation.
4. Ensure that any user to be added to the Virtual affiliate has an account created in EMA Account Management portal and has requested the EV Contributor role for the HQ profile.
5. Add users by selecting a user from the Contributor role column. Once selected, click the access rights and then select "Add Role". The new Virtual affiliate user will appear on the right column "Virtual Affiliate users"
6. Set up the transmission mode/gateway profile – organisations will show as "Not registered" by default. ICSR reports and XEVMPD messages cannot be sent using EVWEB until a Gateway profile has been registered. A Service Desk request should be raised addressed to EMA Gateway support team, quoting the Virtual Affiliate routing ID number as well as the HQ name and routing ID. This helps to identify the location of the Virtual Affiliate. Access to EVWEB will not be active until confirmation from the EMA has been received confirming WebTrader registration. Once the WebTrader profile is created this field will be updated; please note that the update to this field occurs overnight.

   Similarly, if you wish to have Gateway transmission enabled, you will need to raise a Service Desk ticket. Once the Gateway connection is completed this field will be updated, please note that the update to this field occurs overnight. Gateway organisation profiles cannot be used for sending products via the EVWEB tool, if you need to send products using EVWEB please register a virtual affiliate or legal affiliate with a WebTrader profile.

   For documentation to set up a Gateway transmission mode, kindly refer to the EudraVigilance: how to register webpage Section "Transmission Mode for reporting".
7. Once all information is added, click "Save".

Figure 104 – Virtual Affiliate view and action buttons



6.2.2.1. Management of Virtual Affiliates

In the Virtual Affiliate page, the QPPV/RP/TD of the HQ profile can:

1. Remove a user by selecting the "Remove Role" (below "Add Role") in between Contributor User and Virtual Affiliate user columns.
2. Disable a Virtual Affiliate selecting the "Disable" button (in the menu on the bottom part of the page). Revoke Contributor role in EMA Account Management portal if required (see section 5.5.1.) and Raise an EMA Service Desk request to our Gateway team with your ORG ID and Name to request the disabling of the transmission mode.
3. Change User rights by selecting user and changing the access rights in the middle, then click "Update".
4. Update information in the Virtual Affiliate Information fields.

6.2.2.2. Virtual affiliate users

The EU QPPV/RP or TD will automatically be able to access all the virtual affiliates (VA) of the HQ profile. The EU QPPV/RP from the HQ is automatically reflected in all VAs profiles.

In order to be part of the virtual affiliate profile, please note the following scenarios:

1. You are a user in the HQ profile – you do not need to request any further role. The QPPV/RP of the HQ profile will have you in the list of potential EV contributor users for them to manually add a role for you directly in the virtual affiliate profile
2. You are a new user – please log into EMA Account Management portal and request the "EV Contributor" role to the HQ profile. Once this role is approved by the QPPV/RP/TD of the HQ profile, you will be added in the list of users that the QPPV/RP/TD can add to this virtual affiliate profile.

6.3. Disable organisation profiles: HQ, Affiliates and Virtual Affiliates

When an organisation no longer has a requirement to submit data to EudraVigilance or the XEVMPD the EU QPPV/RP/TD for a HQ profile can request for the organisation to be set as disabled.

6.3.1. Disable HQ and Affiliate profiles

The process is the same for both HQ and affiliate profiles (not virtual affiliates).

If an organisation no longer exists as a legal entity the data in OMS should be updated, the deactivation of an organisation in OMS automatically disables the organisation in EudraVigilance. To do this the steps below should be followed:

1. If an affiliate remains as a legal entity, before disabling the HQ profile please ensure that the affiliate is separated from the HQ profile (see **section 6.2.1.3.**).
2. Raise an EMA Service Desk ticket to request that the organisation is disconnected on the EMA Gateway. Please provide the organisation ID for each profile to be disconnected (HQ and/or affiliates). The organisation ID is the routing ID that needs to be disabled.
3. The QPPV/RP user should log in to the SPOR OMS platform and create a change request to deactivate the organisation in OMS.

If the organisation is to remain as a legal entity but no longer has reporting obligations to EudraVigilance the following steps should be taken to disable the organisation in EudraVigilance:

1. If an affiliate is to remain enabled, i.e., as a legal entity with reporting obligations, before disabling the HQ profile in EudraVigilance please ensure that the affiliate is separated from the HQ profile (see **section 6.2.1.3.**).
2. The QPPV/RP user should log into the EMA Account Management portal, revoke all user roles for the organisation and request the removal of their own QPPV/RP role (5.5.1.). The QPPV/RP role removal request ID should be communicated to the EMA via a Service Desk ticket in order to approve the removal of their role.
3. Raise an EMA Service Desk ticket to request that the organisation is disabled in the EudraVigilance system and that it is disconnected from the EMA Gateway. Please provide the EudraVigilance organisation ID for each profile to be disconnected (HQ and affiliates).

6.3.2. Disable a Virtual affiliate

If the virtual affiliate is set up as gateway organisation an EMA Service Desk ticket to request that the organisation is disconnected on the EMA Gateway. Please provide the EudraVigilance organisation ID for each profile to be disconnected.

The QPPV/RP/TD should log into the EudraVigilance Restricted Area for the HQ profile concerned,

1. Open the virtual affiliate concerned from the list at the bottom of the manage organisation profile page;
2. Remove access for all the users from the virtual affiliate and press the save button to update the system;
3. Re-open the virtual affiliate concerned from the list at the bottom of the manage organisation profile page;
4. Select the "Disable" button.

NOTE: Once a virtual affiliate is disabled the QPPV/RP/TD users will not be able to re-enable it. In case of mistake please raise an EMA Service Desk ticket for support.

6.4. Manage Art 57 QPPV and any other user contact details

The EudraVigilance restricted area includes a function for users to be able to manage their EudraVigilance contact details that are used in EVWEB and the XEVMPD. These details are maintained separately to those found in the EMA Management Account portal.

The contact details are kept separately for each organisation a user is registered under. This is important to note for people who are the QPPV for more than one organisation as they will need to login to each HQ and affiliate profile separately in order to update their contact details.

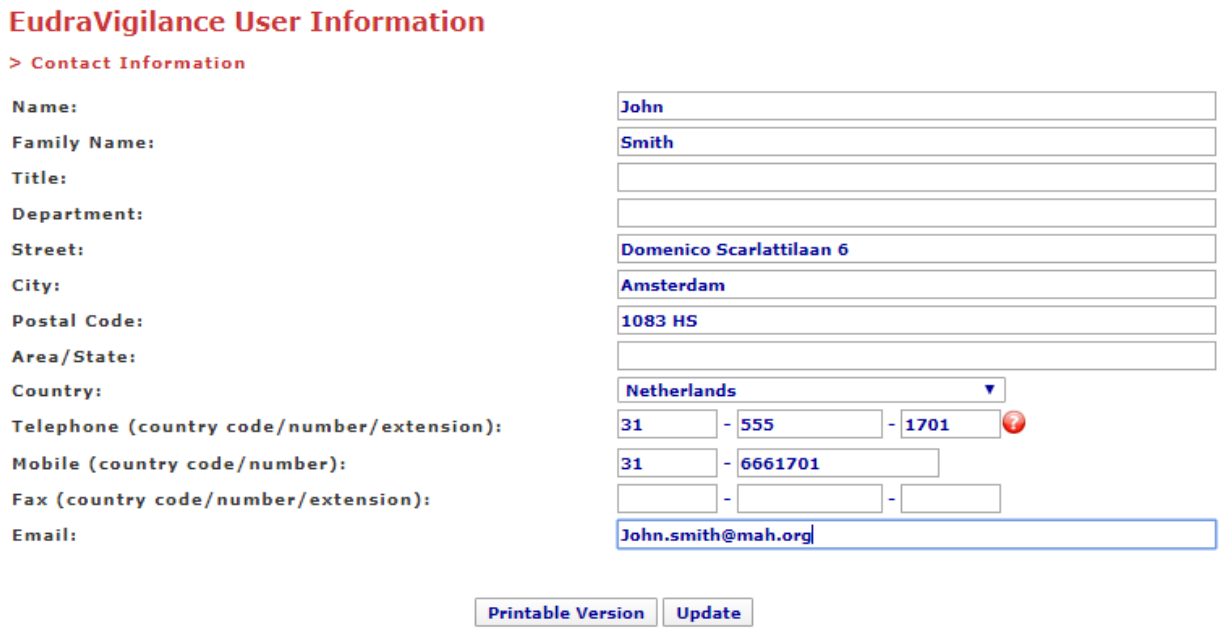
For QPPV users the update of this contact information will immediately affect all the associated authorised medicinal products linked to their organisation profile (QPPV code).

6.4.1. Manage your contact details

In order to update your contact details, you will need to log in to the EudraVigilance restricted area and select the organisation for which you wish the details to be updated. Please note you may need to repeat these steps if you have access to more than one organisation by logging into each organisation separately.

Figure 105 - Manage your contact details

Figure 106 - Review of contact details



After reviewing and updating your details press the update button to save the changes in EudraVigilance.

7. XCOMP registration process

The EudraVigilance XCOMP registration process has been integrated with the EMA Identity and Access Management (IAM) system. This means that the same self-service process MAHs, NCAs and sponsors currently use to manage user access and maintain accurate data on their organisation is now available for the XCOMP test environment.

Legacy XCOMP Gateway profiles (i.e. those that already have a XCOMP organisation ID that does not have the format ORXnnnnnn and are registered as Gateway partners) can continue to be used to send test ICSRs and XEVMPD messages and receive back automatic acknowledgements. However, please note that these legacy organisations are no longer visible and are not managed in the EudraVigilance XCOMP Restricted Area. These legacy EV XCOMP Gateway IDs simply continue to exist on the EMA Gateway portal. If access to the XCOMP Restricted Area is required for Gateway profiles, a Gateway connection will need to be set up under a newly created XCOMP organisation ID, which is generated automatically for each Production HQ organisation profile.

Legacy WebTrader XCOMP organisations, including those that use the EV POST function, can no longer be used and re-registration will be needed. Users registered legacy profiles, will no longer be able to access the EVWEB ICSR, XEVMPD applications and the XCOMP restricted area. They will need to be re-registered under a new XCOMP organisation registration, which is generated automatically for each Production HQ organisation profile. To be able to use XCOMP again, users need to re-register for XCOMP.

Pharmacovigilance IT system vendors are not permitted to register in the Production EudraVigilance system, however they may register for an XCOMP account that limits them to sending and receiving ICSRs via a Gateway connection. The process for IT system vendor registration is described in section 7.3.

The newly created XCOMP EudraVigilance Organisation ID now follows a similar format to the Production system by using the same numerical digits of the OMS organisation ID and the Pre-fix **ORX** rather than **ORG** that is used in the Production system.

7.1. XCOMP registration for organisations with a Production profile

When the main QPPV/RP has completed their registration of an organisation in the EudraVigilance Production system (i.e. when a QPPV/RP role has been approved) an XCOMP organisation profile is created automatically for that organisation. The QPPV/RP role is automatically assigned in the XCOMP test system. This also applies to organisations that have existing registrations in the EudraVigilance Production system as of 26th March 2020.

Important note for existing organisations: to continue to have access to the XCOMP restricted area, you must change your password via the EMA Account Management portal. This can be done either via the "Forgot Password?" option on the initial log on screen or once logged in via the "Change Password" functionality in the Preferences section of your profile.

The registered QPPV/RP must then access the XCOMP restricted area using the same login details that they use for Production, in order to complete the organisation registration information. This will then activate the new XCOMP profile within the registration system. Please see section 4.1. on how to complete this step.

Note: If a WebTrader XCOMP profile is required, the EVWEB applications will not be accessible initially. A request must be raised via the Service Desk portal notifying the EV Registration team that a new

XCOMP WebTrader needs to be created. The EVWEB applications will not work until a confirmation has been received by the EMA Gateway Support Team that the transmission registration has been completed.

If a Gateway XCOMP profile is required, when submitting the initial organisation registration documents via the Service Desk, please attach a completed Gateway connection form and encryption certificates. The Gateway XCOMP profile will be activated upon resolution of the Service Desk request.

If a user has a trusted deputy role in the EudraVigilance Production system, they will automatically be given the same role in the XCOMP system.

If additional users need access to XCOMP EVWEB applications, users need to specifically request a XCOMP specific role:

"EV Human XCOMP User"

1. This role can be requested through the EMA Account Management portal, following the steps outlined in section 5.3. . A user needs to be registered on the portal in order to request XCOMP access (see section 2.1. for details). Users do not need to have roles associated with the Production profiles of their organisations in order to have access to XCOMP EVWEB applications (i.e. a user can request a "EV XCOMP User" role without having access to Production).
2. Please note: When requesting a XCOMP role via the EMA Account Management portal, users should use the same OMS Organisation ID for the EudraVigilance Production system (i.e. ORG-####). The above mentioned XCOMP specific ORX#### EudraVigilance IDs will not show within the portal.

Once the XCOMP access request is submitted, the registered QPPV/RP or trusted deputy for the organisation will be notified and they will be able to approve the request following the steps outlined in section 5.4.1.

7.2. Managing a XCOMP organisation profile

When the main QPPV/RP role for an organisation is removed via the EMA Account Management portal for Production, this automatically removes the same role in the XCOMP system. The removal of this role deactivates the organisation in both the Production and XCOMP test systems. Disabling of an XCOMP organisation profile only, while the corresponding Production profile remains active, is not possible.

The addition of legal affiliates to XCOMP HQ organisations through a merge request is not supported. Please add Virtual Affiliates if you need secondary test profiles.

7.3. IT system Vendors registration with XCOMP

The process for registering IT system Vendors in XCOMP follows the same process as for other organisations for the Production EudraVigilance system. The main difference is that the Responsible person for EudraVigilance nominated by the system Vendor will choose the Vendor specific base role.

The nominated person from the Vendor will need to perform the following steps in order to successfully complete their registration in XCOMP:

1. Register in the EMA Account Management portal;

2. Request "SPOR unaffiliated role" via the portal;
3. Register the Vendor organisation in the Organisation Management System (OMS) – for more information see Section 4. of the EudraVigilance registration manual;
4. Request the base role "**EV Human XCOMP Vendor Responsible person**" via the EMA Account Management portal;
5. Raise a Service Desk call via the EV Registration section including the role request ID generated by the EMA Account Management portal. The ticket should be addressed to the EV Registration team who will approve the "EV XCOMP Vendor Responsible person" role.
6. When the Vendor role has been approved, a separate Service Desk ticket should be raised, addressed to the Gateway support team, attaching a completed Gateway connection form and the Vendor's encryption certificate. The relevant EV XCOMP vendor organisation ID should be included in the form. In their request Vendors are required to clearly indicate that they wish to set up a Gateway testing profile for a Vendor organisation. The Gateway support team will then send the Vendor the EMA connectivity details.

When the gateway set-up is complete, the Vendor is notified and can commence testing.

NOTE: Vendors do not receive access to the EVWEB application in EV XCOMP.

Vendors can perform testing for a specific version and build of their database and have the completion of this testing confirmed by the EMA by contacting the Quality Assurance Testing team via the Service Desk platform.

The EMA will confirm if this precise version and configuration of the database has completed testing. Significant changes to the database will require re-testing with the EMA.

7.3.1. Removal of a Vendor's access from EudraVigilance

To disable a Vendor organisation profile in XCOMP, the registered Responsible person for the Vendor should request the deactivation of their role via the EMA Account Management portal. A Service Desk request should then be raised, providing the removal request ID which will be generated by the EMA Account Management system. The request should be addressed to the EV Registration team. Changing connection details

If a Vendor needs to change their Gateway connection details, they should log a request via the Service Desk portal addressed to the Gateway support team. The request should include the Vendor name and EV organization ID (Routing ID), as well as the Vendor's new connection details.

More information about Vendor registration in XCOMP can be found on the EudraVigilance: how to register webpage in the "IT Vendors and third party service providers" section.

8. Non-Commercial Sponsors Additional Organisation & User management support

Some organisations such as universities and hospitals can have complex independent internal structures that make user management difficult to manage. In order to assist such organisations the EudraVigilance Registration Team can provide some additional help.

When registering the organisation for the first time the first user will need to be registered with the role of responsible person (RP) for EudraVigilance. Normally this first user will need to approve and manage all the subsequent users within their own organisation. This responsible person can also approve other users to have an Administrator role to help with this task.

In addition to the RP managing user registrations the EV Registration team can be given permission by the organisation to approve requests for additional administrators for the organisation and also for approving users requesting access to their organisation.

In order for the EV registration team to be able to approve additional user access to an organisation the user making the request must have an e-mail address associated with the organisation. When such a request is made the registered RP and other administrators will be sent the details of the request and if no objections are raised within one week the access request will be approved.

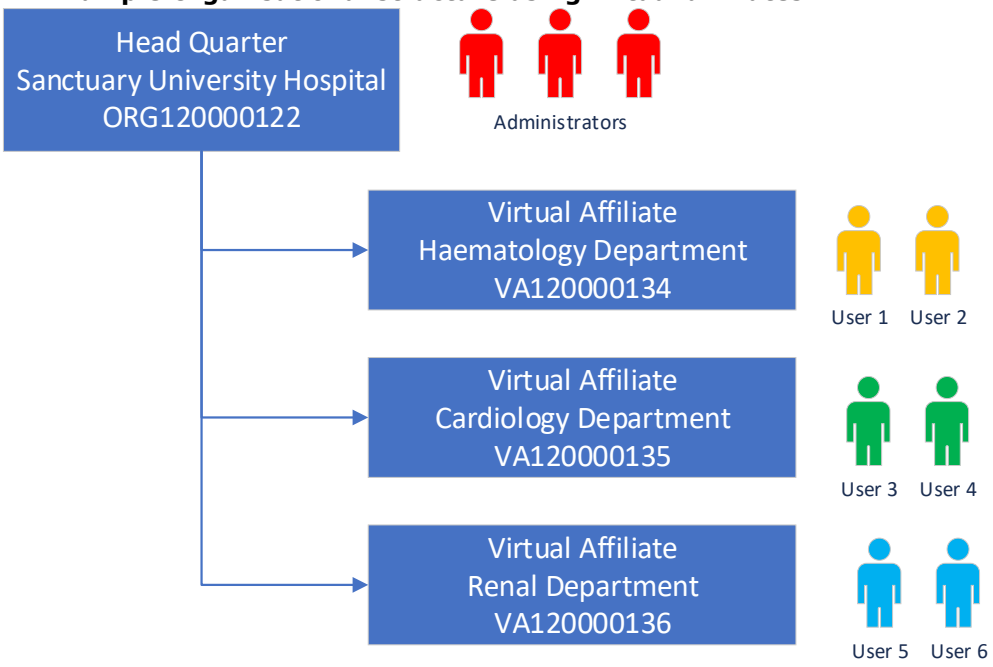
If a request is made using a different e-mail domain, the RP and registered administrators will be contacted to confirm the registration can be approved. The approval will not be made until positive confirmation has been received.

8.1. Non-commercial Sponsors managing user access to data

The next aspect to consider is if user access needs to be limited by organising users into groups so that the data submitted by one group is not accessible by a different group. It should be noted that users with the administrator role will however be able to access all the data submitted by the whole organisation.

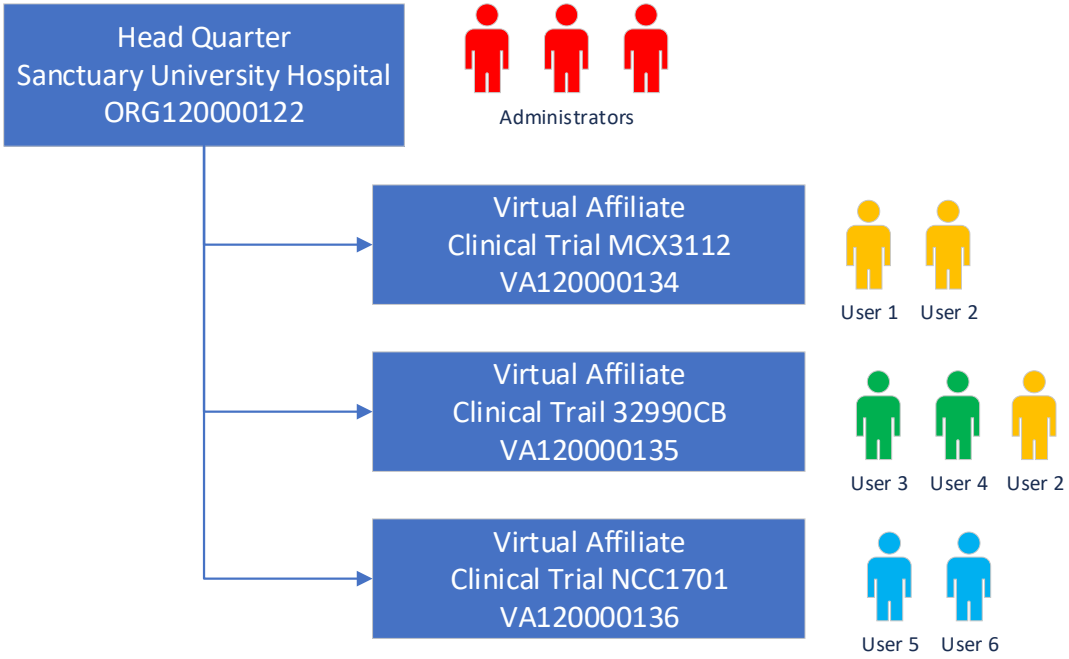
There are two main approaches that can be used for managing user access to data submitted by an organisation. The first option is to create virtual affiliates that are arranged by departments (or similar internal structures) so that users in the same department is able to access EudraVigilance and the data submitted by their department. These users will not have access to the data submitted by other departments, this set-up is shown in Figure 107 below.

Figure 107 - Example Organisational structure using virtual affiliates



The second option is to group the users based on trials (or research groups) being run by the organisation, it is also possible for a specific user to be assigned to more than one trial (or research group) if needed whilst restricting other users to a specific trial (or research group). This set-up is shown in Figure 108 below.

Figure 108 - Example Clinical Trial based structure



The administrators of the organisation are able to register virtual affiliates themselves directly in EudraVigilance and assign users to those virtual affiliates. The process on how to do this is described

above in **section 6.2.2.** However, non-commercial organisations can contact the EV registration team through the EMA service desk for assistance in registering Virtual affiliates and assigning users to the affiliates. The EV Registration team can also remove user access if a request is received from the organisation via the EMA service desk.

8.2. Non-Commercial sponsor registration steps

Before starting the registration process non-commercial sponsors can contact the EMA service desk for assistance in completing the process. The registration steps are summarised below and the EV Registration team can assist in these steps of first registration:

1. Check SPOR OMS system to see if the organisation is already registered and if not get the organisation registered.
2. The person registering the organisation requests the "EV Human CS/NCS Responsible" and submits an EMA service desk registration ticket.
3. EV Registration Team approves the registration request.
4. Responsible person logs on to the EV restricted area and accepts the terms and conditions of access to EudraVigilance and completes the organisation profile information.
5. EV registration Team will check the information and set-up the organisation as Webtrader or Gateway organisation as requested by the responsible person.
6. The Responsible person can now give permission to the EV registration team to approve additional administrators and users request from their own organisation on behalf of the responsible person.
7. Virtual affiliates can now be registered to reflect different departments, research groups or for specific trials. The EV registration team will need to ensure that these virtual affiliates are set up as Webtrader or Gateway organisations before these profiles can be used.
8. Non-administrator users can request "EV Human Contributor" role for the organisation and the access request can be approved by either the organisation's administrators or by the EV Registration team if permission was given. For the EV registration team to approve these requests the user must raise an EMA Service Desk ticket.
9. The EV Human Contributor users can then be added to the correct virtual affiliate(s) by either the organisation's administrators or EV registration team.

The organisation's administrators can remove, change and add users to virtual affiliates directly in the system or raise a EMA Service Desk ticket to request the EV registration team to make the changes as needed.

Annex 1 - EV "base" and "supplementary" roles

To change role in a profile, please remove all the roles you have (see **section 2.7.**) and then request the role again.

EV Production Base Roles	
EV Human NCA Responsible	Request this role, if you work for an NCA/Regulatory Agency and you are the main responsible for the Pharmacovigilance in your organisation profile. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human MAH EU QPPV	Request this role, if you work for a MAH and you are the main QPPV. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human CS/NCS Responsible	Request this role, if you work for a Commercial Sponsor or a Non-Commercial Sponsor and you are the main responsible for the Pharmacovigilance in your organisation profile. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human NCA Trusted Deputy	Request this role, if you work for an NCA/Regulatory Agency and you are supporting the main responsible for Pharmacovigilance in the administrative tasks. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access. Please note, this role will be rejected, if your organisation does not have an EV NCA Responsible.
EV Human MAH/CS/NCS Trusted Deputy	Request this role, if you work for an MAH, Commercial Sponsor or Non Commercial Sponsor and you are supporting the main responsible for Pharmacovigilance in the administrative tasks. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access. Please note, this role will be rejected, if your organisation does not have an EV MAH EU QPPV or an EV CS/NCS Responsible.
EV Human NCA/MAH/CS/NCS Browse ICSR	Request this role, if you need only access to ICSR messages. Please note, this role will be rejected, if your organisation does not have an EV Responsible or EV EU QPPV.
EV Human NCA/MAH/CS/NCS ICSR Browse & Send	Request this role if you need to perform queries, create and send ICSRs, receive safety messages, store the safety messages locally and generate acknowledgement messages.
EV Human NCA/MAH/CS/NCS Browse MPR	Request this role, if you need only access to browse Medicinal Products in the XEVMPD.

EV Human MAH/CS/NCS Browse & Send MPR	Request this role, if you work for an MAH, Commercial Sponsor or Non Commercial Sponsor and you need only functionalities related to the Medicinal Products: create queries, create and send extended Medicinal Products Reports or generate acknowledgement messages.
EV Human MAH/CS/NCS Browse and Send ICSR and MPR	Request this role, if you work for an MAH, Commercial Sponsor or Non Commercial Sponsor and you need full functionalities related to the Medicinal Products and ICSRs: perform queries, create and send extended Medicinal Products Reports, create and send ICSRs (including L2A access to ICSRs, applicable only to MAHs and based on the active substance for medicinal products for which the MAH holds a marketing authorisation).
EV Human NCA/MAH/CS/NCS Browse ICSR and MPR	Request this role, if you need basic functionalities related to the Medicinal Products and ICSRs (including L2A access to ICSRs, applicable only to MAHs and based on the active substance for medicinal products for which the MAH holds a marketing authorisation).
EV Human Contributor	Request this role only, if you need access to EV on behalf of a Virtual Affiliate. You will only be able to access EV, after a Responsible or Trusted Deputy has assigned you adequate access through the EV Restricted Area. Please note this role is limited to a Virtual Affiliate only and for this reason, you won't be able to access your organisation's HQ profile in EV; if you need access to it, you should liaise with your organisation's QPPV/RP or trusted deputy to change in your access permissions.
EV Production Supplementary Roles Note: EVDAS roles are only for NCA and MAH HQ profile users	
EV Human MAH Additional QPPV	Request this role only, if you are NOT the EU QPPV user for that profile, work for an MAH organisation and you need a QPPV Code. Please note that you can only request this after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR).
EV Human L2B Access	Request this role only, if you are authorised to visualize personal data of the patients by your QPPV. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS Human NCA Administrator	Request this role only, if you work for an NCA/Regulatory Authority and need browse access to EVDAS. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS Human NCA Scientific	Request this role only, if you work for an NCA/Regulatory Authority and need access to ICSR forms. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).

EVDAS Human NCA Art57	Request this role only, if you work for an NCA/Regulatory Authority and need access to Art57 data. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS MAH Scientific	Request this role only, if you work for an MAH and need access to EVDAS/ICSR forms. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).

EV XCOMP Base Roles	
EV Human XCOMP User	You should request this role if you want to access XCOMP environment. Before requesting this role a Responsible person for your organisation must be appointed.
EV Human XCOMP Vendor Responsible person	A responsible person from an IT Vendor of a Pharmacovigilance system should request this role in order to register their organisation in EV XCOMP. No user access permissions for XCOMP are given with this role.