23 May 2025
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Data Analytics and Methods

EMA EudraVigilance Registration Manual

Note: Revision 16 contains the following:

- Sections 4.1 "Finalise organisation information in EV Human Production and XCOMP", 4.2 "EVPOST", 6.1 "EV restricted area and transmission mode for new organisation", 6.2.1.1 "Merge organisations (merge 2 HQs)" and 6.2.2.2 "Virtual affiliate users" were updated;
- Section 5.1.1 "Biannual review of the EV roles" was added
- Some editorial amendments were made to align the format with other EMA documents.

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1. Registration overview

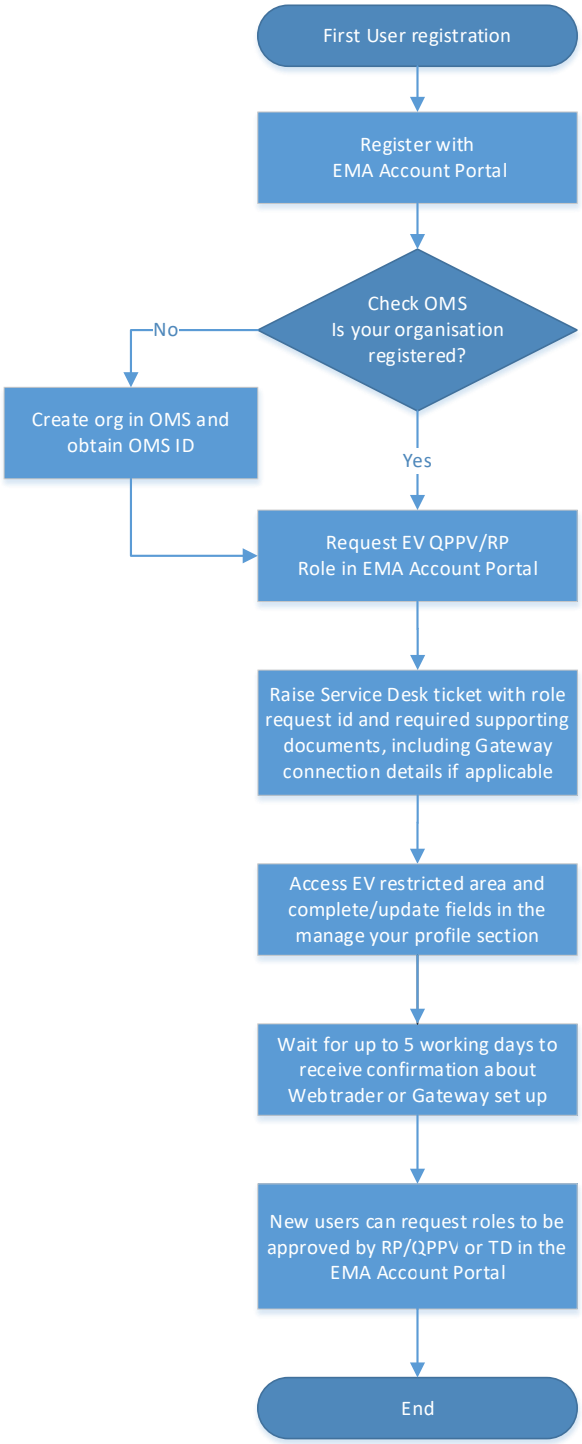
To set-up a new organisation in EudraVigilance (EV) Production or XCOMP (test) system, a series of steps need to be followed (also illustrated in **Figure 1**):

1. Register for an EMA user account in the EMA Account Management portal, if you do not already have one – see **section 2.**
2. 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.**
3. Submit a request to be registered as the Qualified Person for Pharmacovigilance (QPPV) or Responsible Person for EudraVigilance (RP) for the organisation – see **section 5.2.**
4. Complete organisation registration details in the EudraVigilance restricted area – see **section 4.1.**
5. Wait for confirmation from the EMA Gateway Team that the WebTrader or Gateway transmission mode has been set up for your organisation – see **section 6.1.1.**

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 and the QPPV/RP role is automatically assigned in the EV XCOMP (test system).

Note: If your organisation is a **non-commercial sponsor (NCS)** of clinical trials additional support is available for registration and User & Organisation management 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).

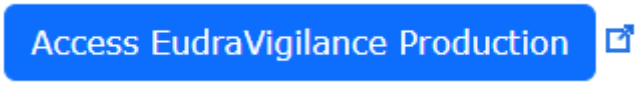
It is likely that you already have an EMA Account Management portal account if you have access to at least one of the following EMA systems: EudraLink, EudraCT Secure, IT Service Desk portal (ServiceNow), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR. 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 are not sure if you already have an EMA Account, please click on "account?" on the EMA Account Management portal page to review the EMA systems for which you could already have access to.

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. If you cannot remember your password or username, 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:

Figure 2 - EudraVigilance Human Production



If you are registering with EMA Account Management portal for the first time, please see **section 2.1.**

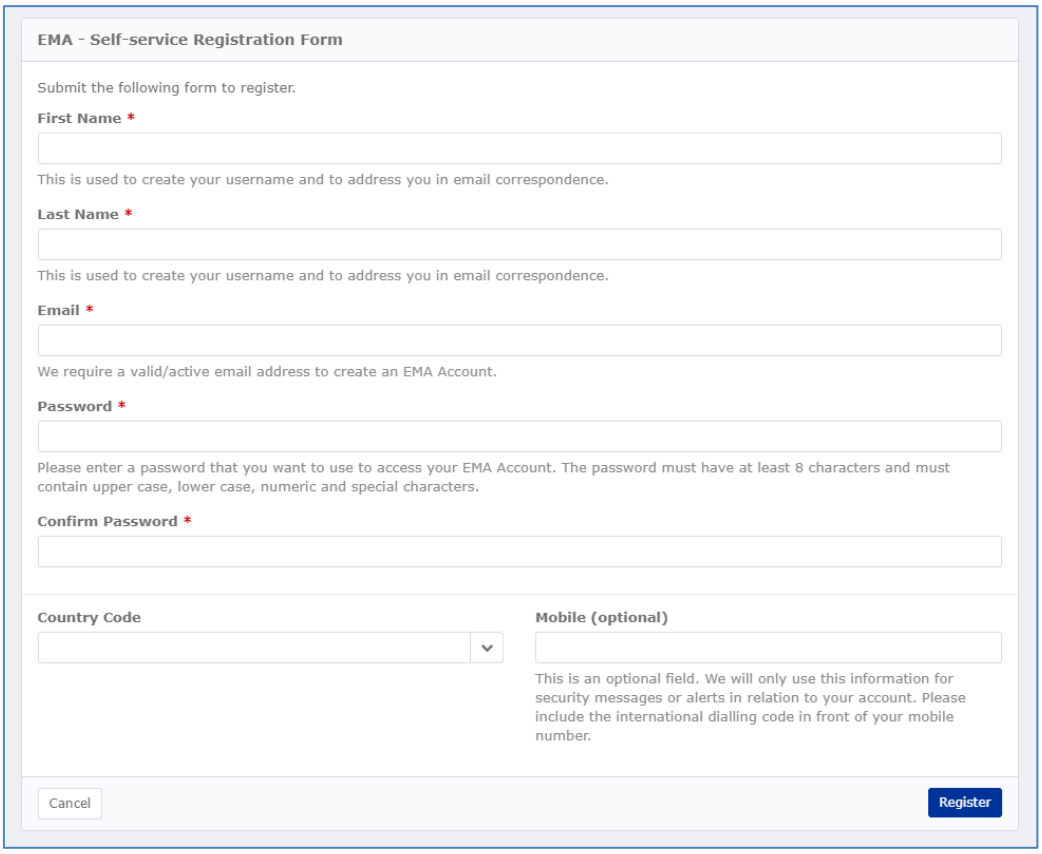
Important note: An individual can only have one EMA account. A user can, however, have more than one EudraVigilance account associated with their EMA account. In order to have access to more than one organisation in EudraVigilance, users need to submit separate EudraVigilance base role requests for those organisations by following the instructions detailed in **section 5.** The base roles and, therefore, levels of access, to each of these organisations can be different – see **Annex 1** for more information on EV Base roles and EV Supplementary roles.

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

1. 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 **section 5.** of this manual. Go to EMA Account Management portal and click on "Create a new EMA account".
2. A Self-service Registration Form will be displayed – see **Figure 3.**

Figure 3 - Self-registration form on the EMA Account Management portal



3. Complete the form.

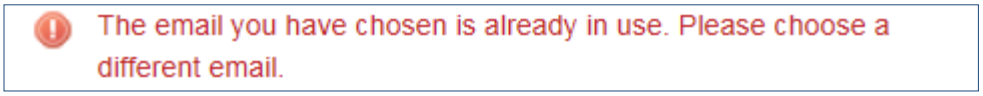
   Mandatory fields are marked by a red asterisk (*). Optional field – mobile phone (landline number can be provided too), strongly recommended for cases when e-mail does not work or changes.

4. Read the "EMA Privacy Statement" and "EMA systems security principles and responsibilities"

5. Click on "Register".

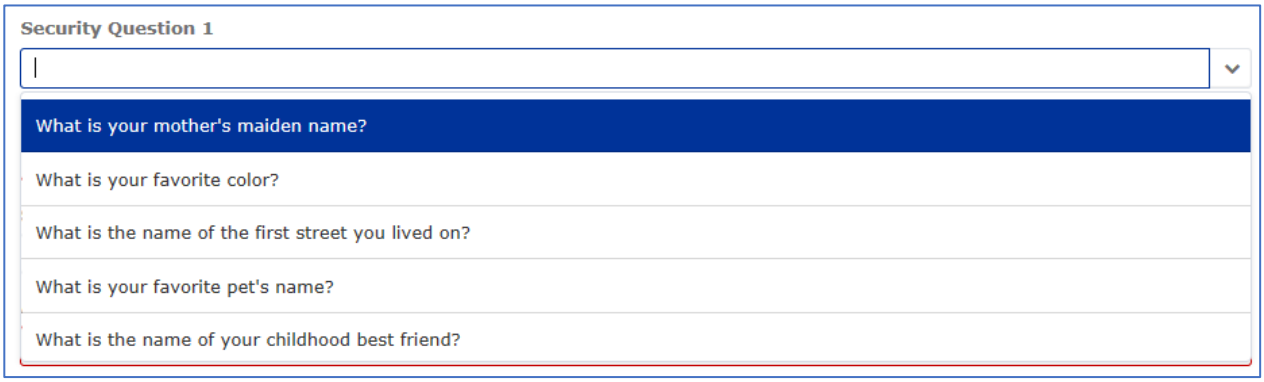
   The system can recognise already used e-mail addresses in order to prevent the creation of duplicate user entries. In case the e-mail address is already registered, the user is prompted to use a different e-mail address. In such a situation it is better to go back to the landing page and click the "Forgot password?" option – see **section 2.4.** for more details

Figure 4 - Error message



6. 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

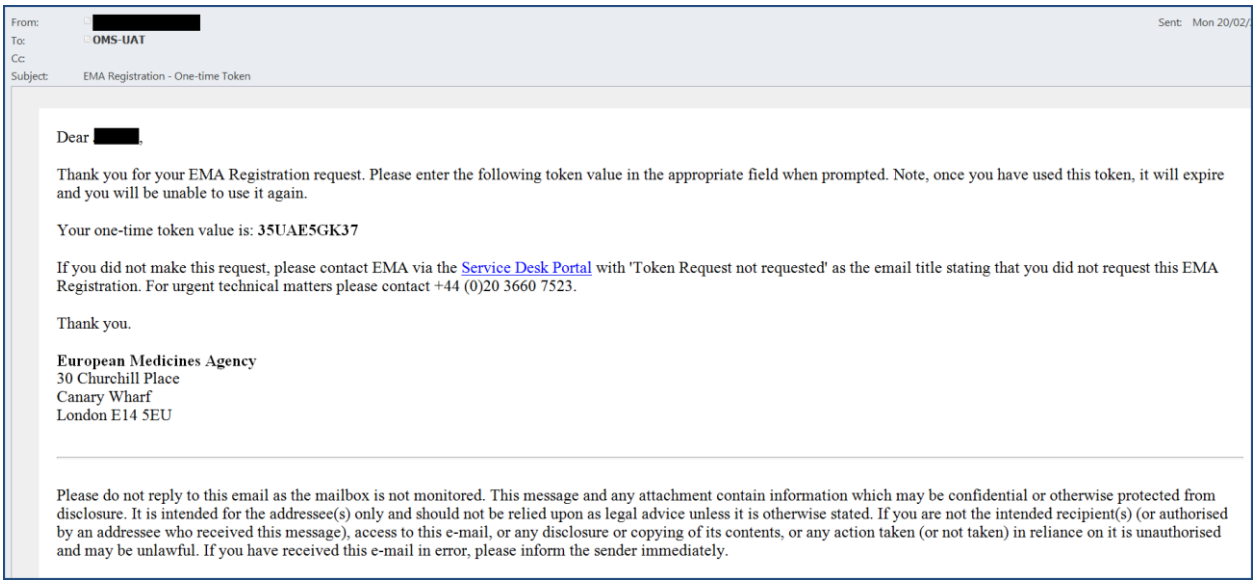


Answer the captcha question (an arithmetic calculation) and click "Next" to go to the registration confirmation page.

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 EMA 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

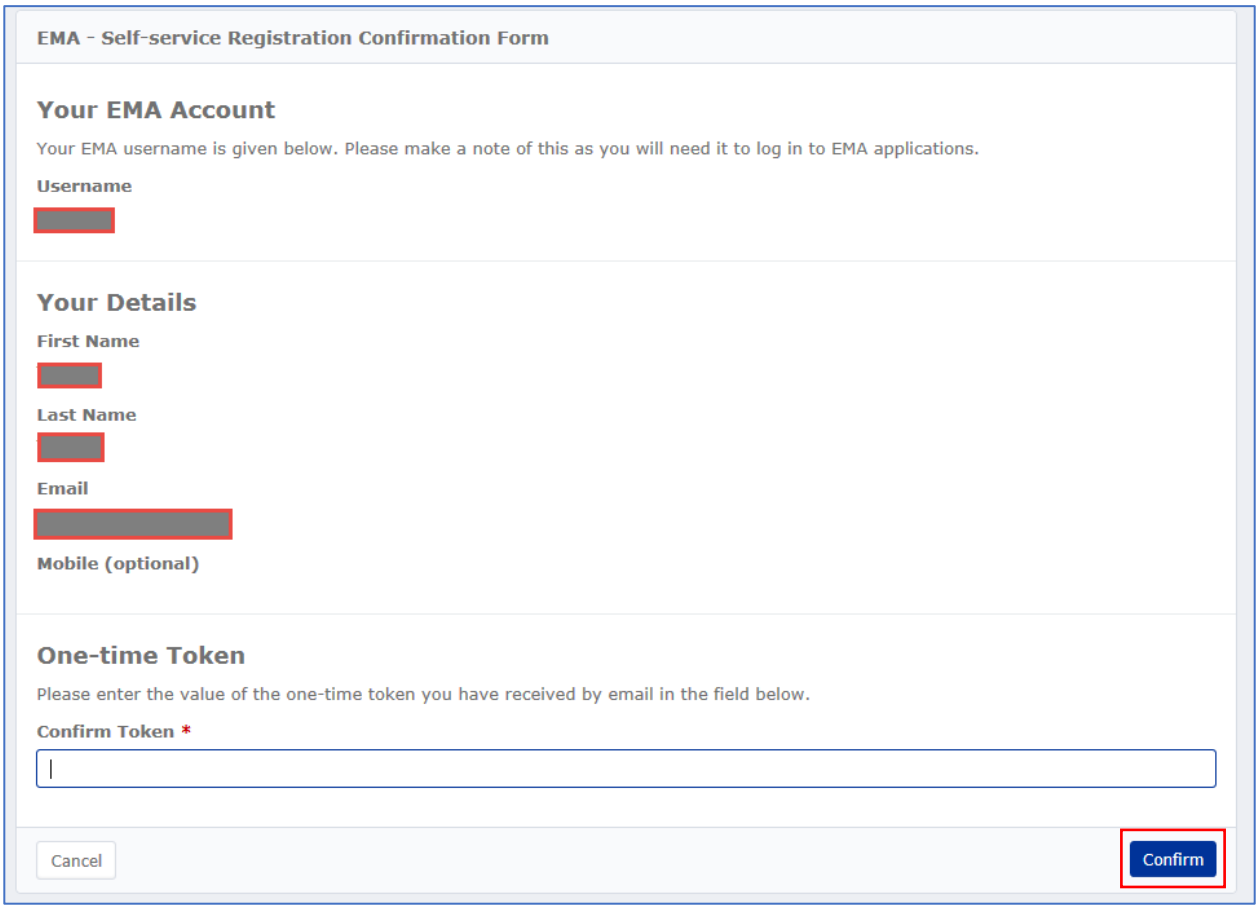
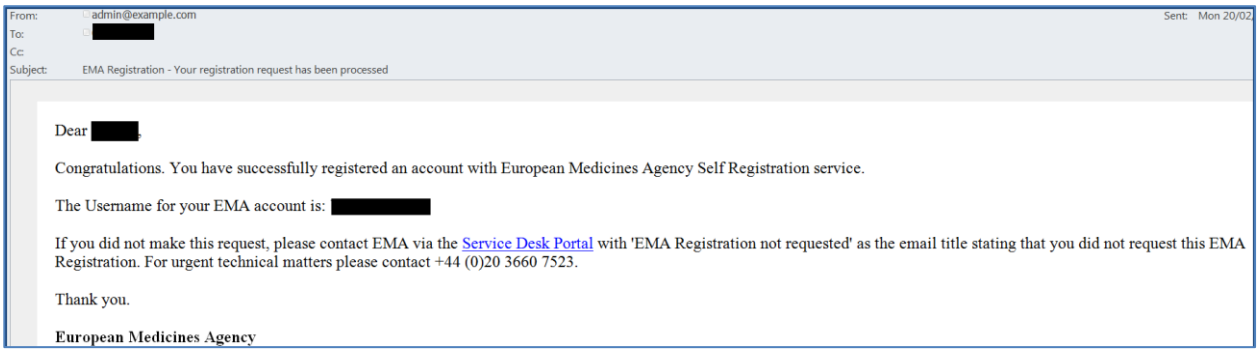


Figure 9 - Registration successful – confirmation e-mail example



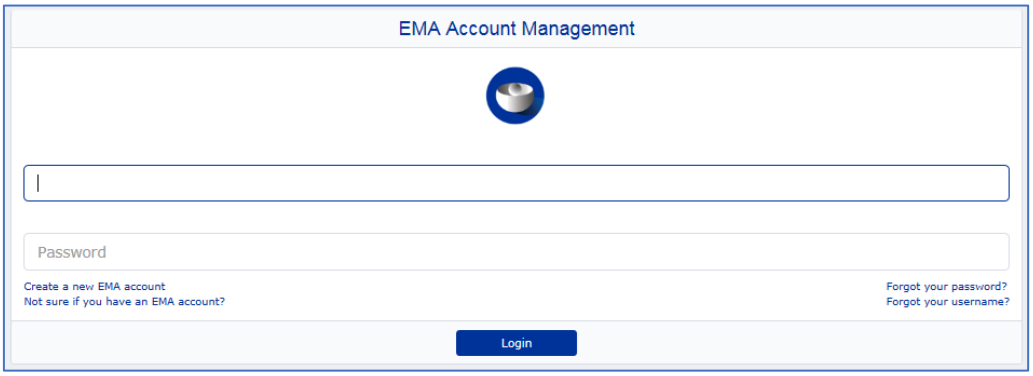
9. Once you have your credentials, you are ready to log in to EMA Account Management portal.

Please note that registration on the EMA Account Management portal, may take up to 24h for the systems to sync, therefore, you should wait 24h before trying to log in for the first time.

2.2. Log into EMA Account Management portal

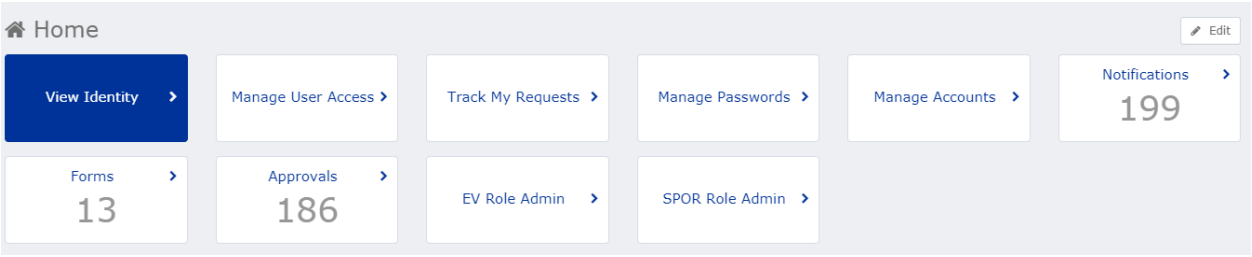
Using the username and password provided in the registration confirmation e-mail you can log into the EMA Account Management portal by completing the fields accordingly - see **Figure 10**.

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) – see **Figure 11.**

Figure 11 - EMA Account Management portal dashboard



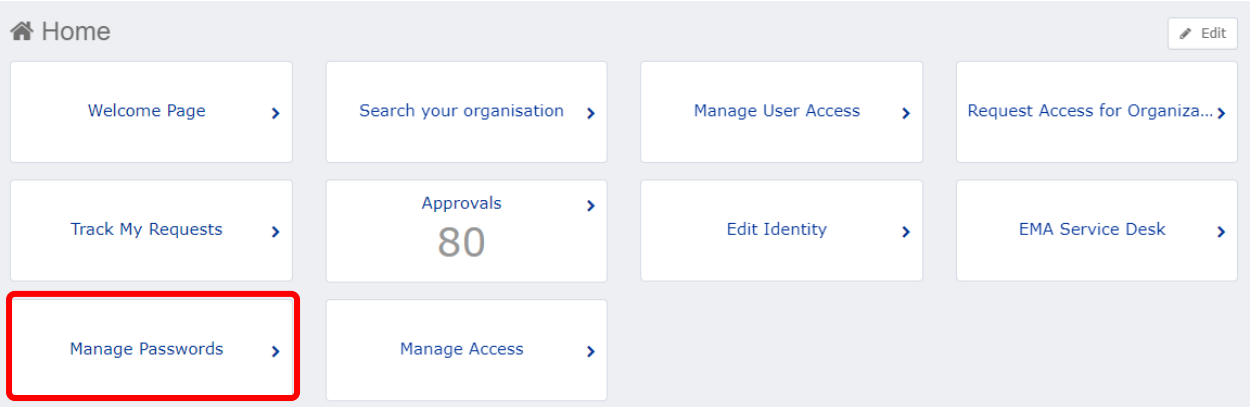
2.3. Change password in EMA Account Management portal

You can change the password used for the EMA Account Management portal either by using the "Forgot password" option – see **section 2.4.** - or via EMA Account Management portal by following the steps below.

Please note that changing the password here also changes the password for logging into all the systems managed by the portal.

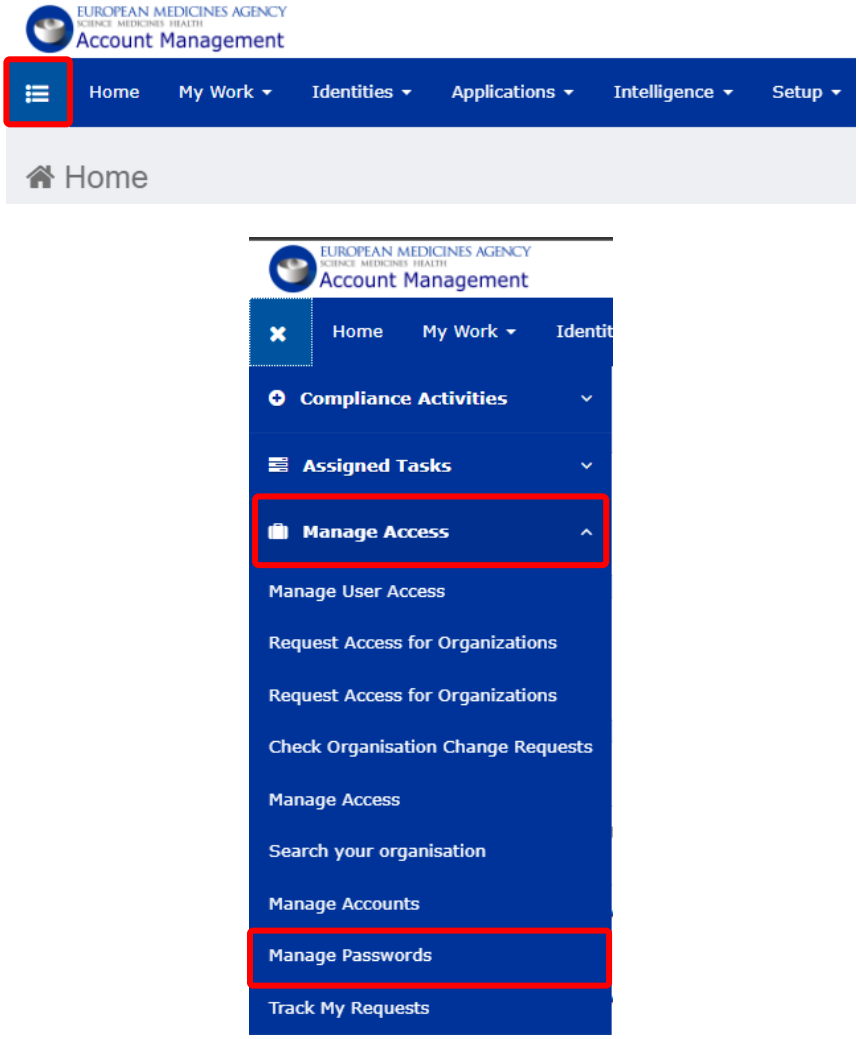
1. Log in to the EMA Account Management portal.
2. Click on the "Manage Passwords" tab on your Home page – see **Figure 12.**

Figure 12 - Change password in the EMA Account Management portal



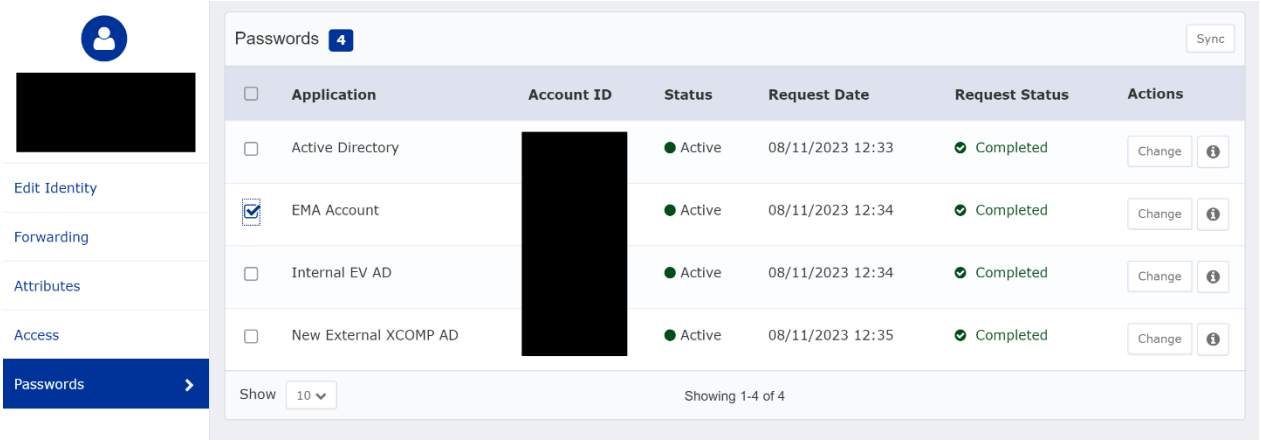
3. Alternatively, click on the left-hand side menu, then on "Manage Access" and finally on "Manage Passwords".

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



4. Select your EMA Account by clicking on the checkbox in front of the account for the EMA Account Application and press "Change".

Figure 14 - Manage passwords screen in the EMA Account Management portal

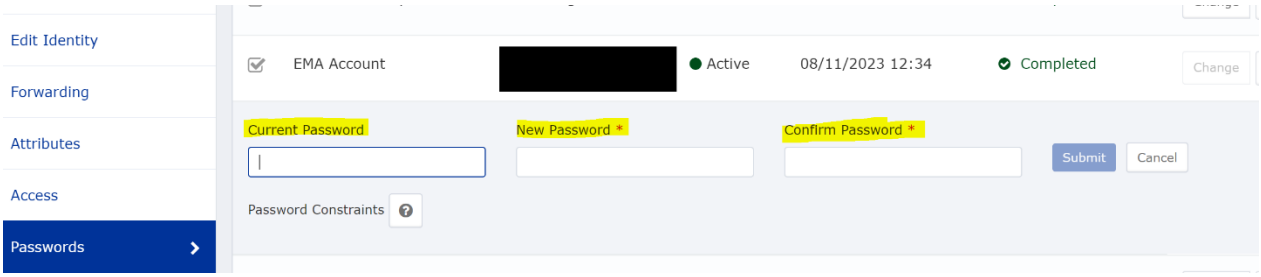


5. Type your current password in the "Current Password" field and the new password in the "New Password" and "Confirm Password" field.

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

6. Click the "Submit" button.

Figure 15 - New password and submit



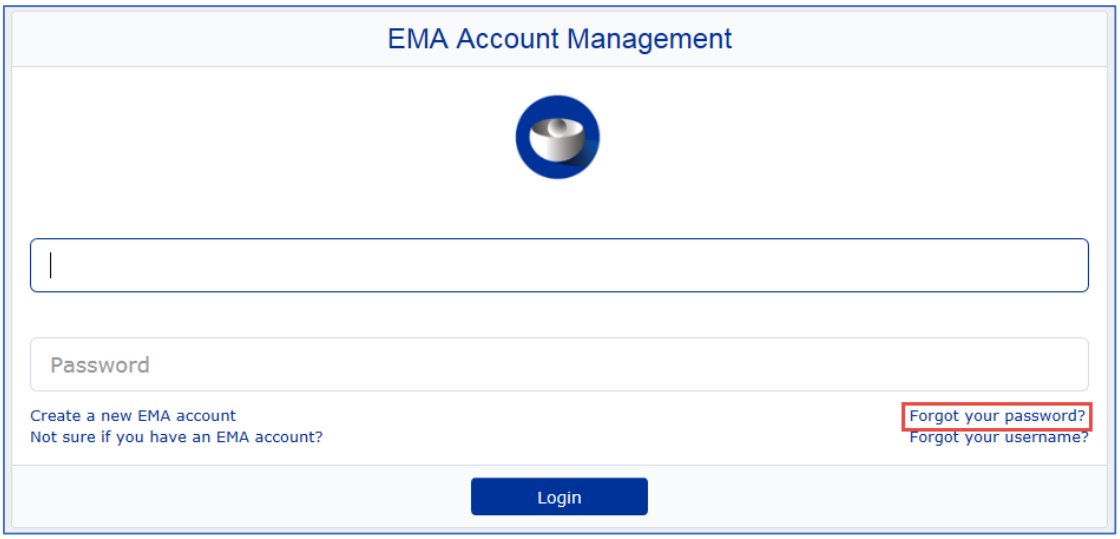
7. You can now log in to EMA Account Management portal with the new password

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. A forgotten password can be reset with the help of the security questions.

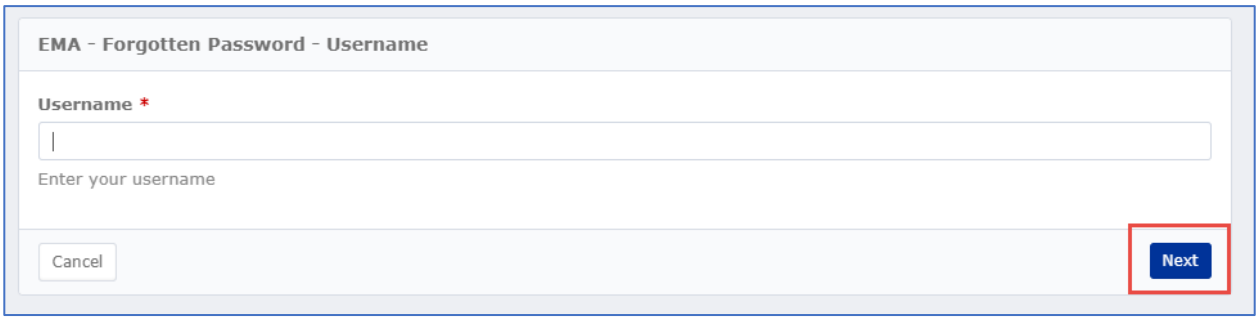
1. Navigate to https://register.ema.europa.eu/identityiq/login.jsf?prompt=true
2. Click the "Forgot your password?" link.

Figure 16 - EMA Account Management Portal and forgotten password link



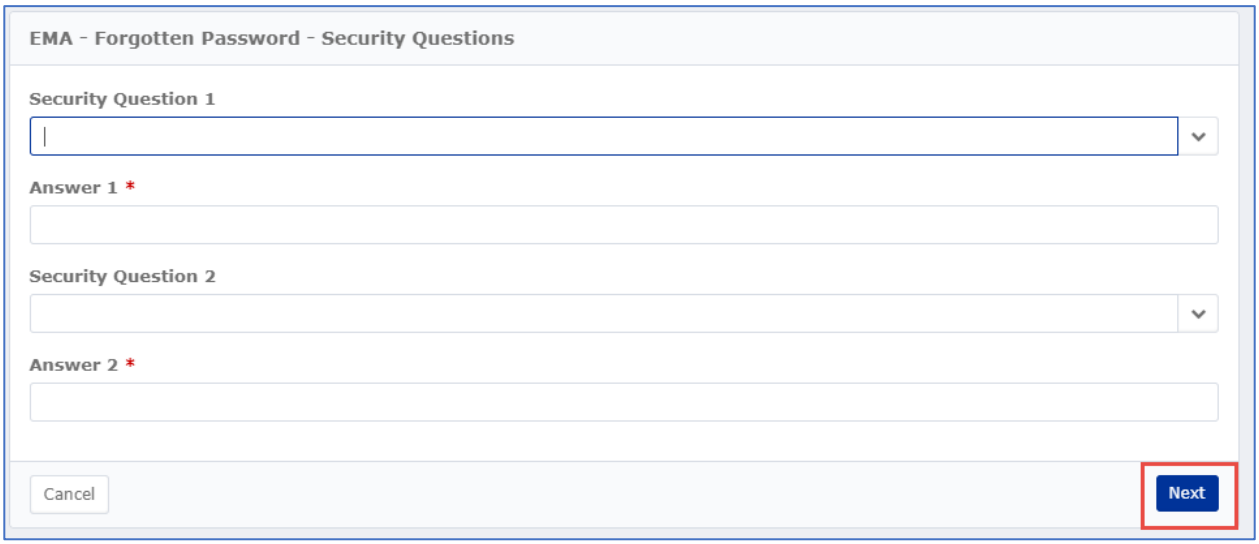
3. Input your username in the "Username" field and click the "Next" button.

Figure 17 - Input username to retrieve forgotten password



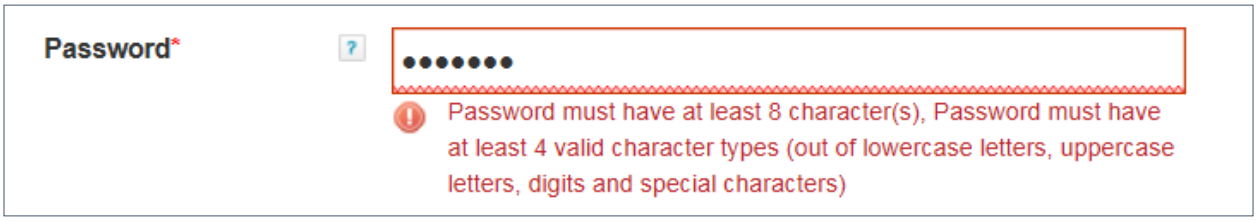
4. Select two of the security questions and enter the answers you have chosen during self-registration. Click on the "Next" button to go to the next page.

Figure 18 - Answering the security questions



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

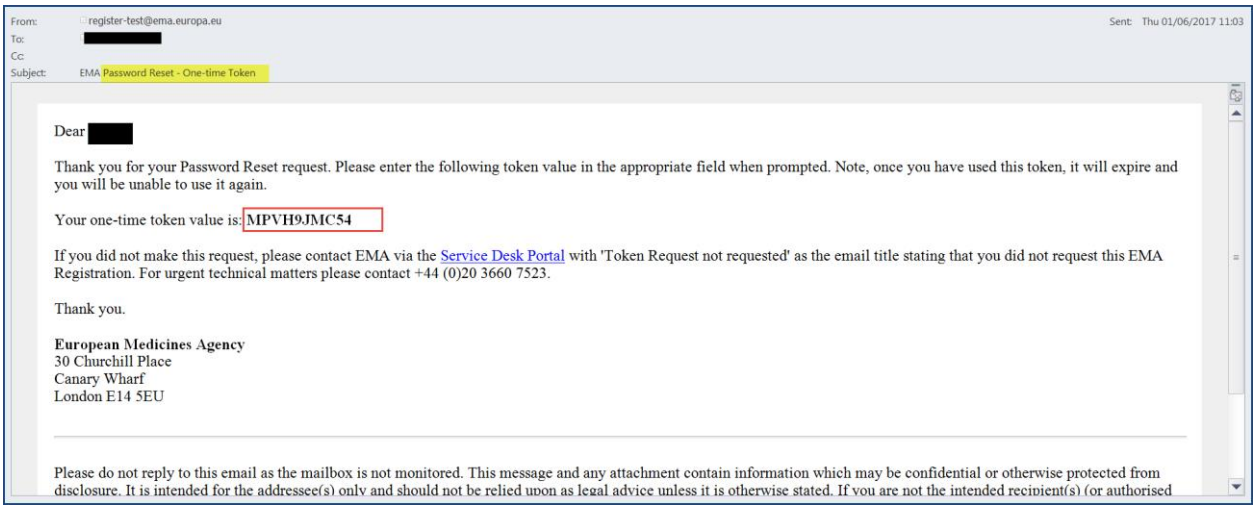
Figure 19 - Password requirements



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

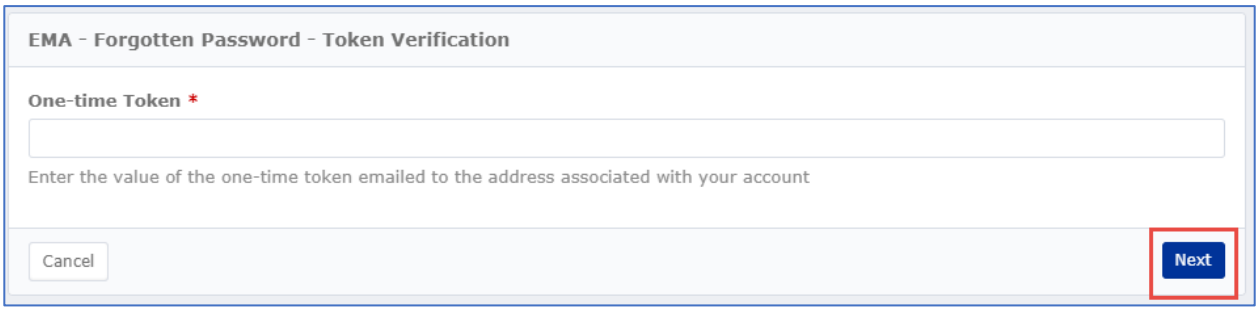
5. An e-mail with a registration token is sent to the registered e-mail address.

Figure 20 - E-mail containing one-time token



6. Input this token in the "One-time Token" field and click "Next".

Figure 21 - Insert one-time token



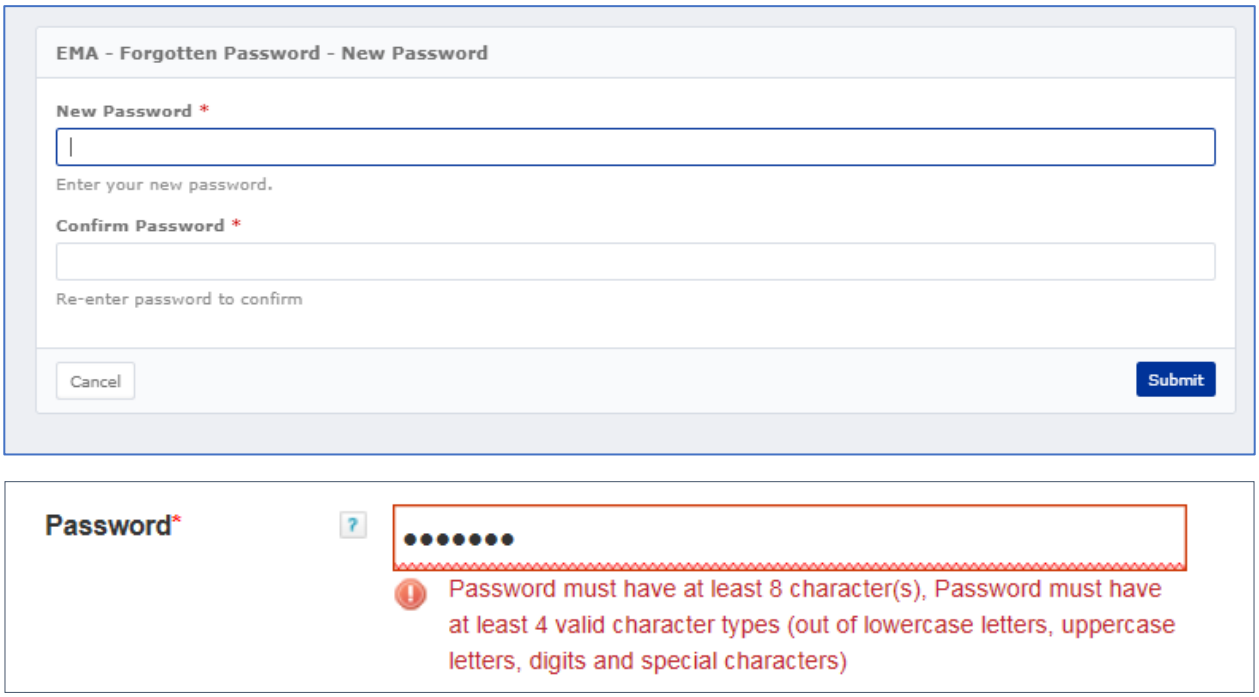
7. When choosing your new password, please choose a combination of lower case, upper case, numbers and symbols (hover your mouse over the red asterisk for guidance)

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

8. Enter your new password in the "New Password" and "Confirm Password" boxes and click "Submit".

9. The password is reset.

Figure 22 - Enter new password



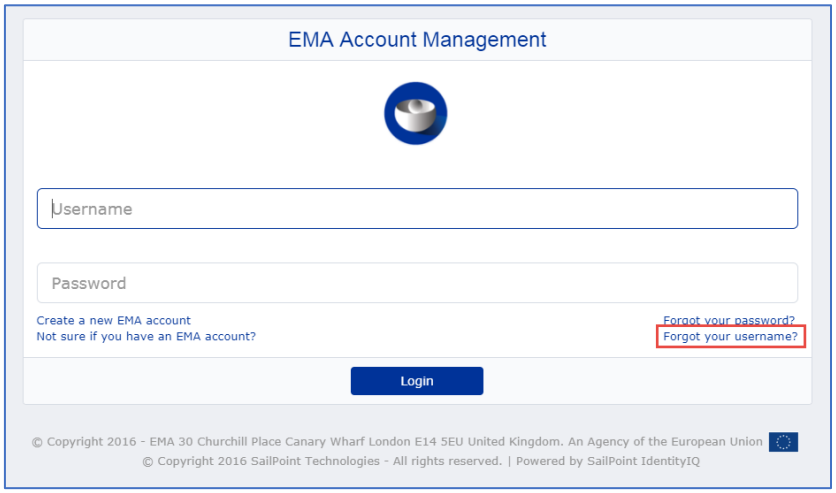
If your account is locked and you are unable to request a new password, please contact Service Desk via phone: +31 (0)88 781 7523.

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:

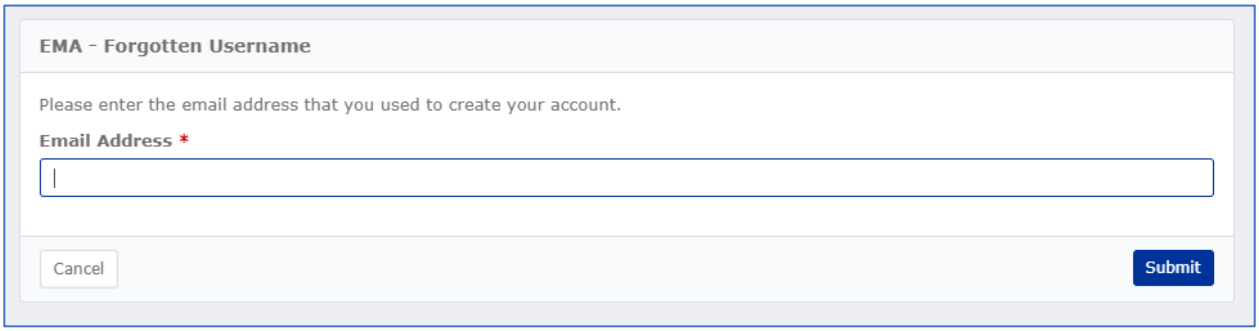
1. Navigate to EMA Account Management portal landing page.
2. Click the "Forgot Username?" link

Figure 23 - EMA Account Management portal and forgotten username link



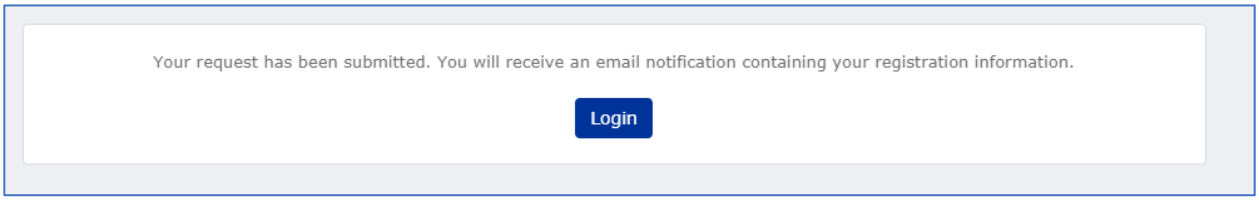
3. Enter the email address you used to register in the EMA Account Management portal and click "Submit".

Figure 24 - Enter e-mail address to retrieve forgotten username



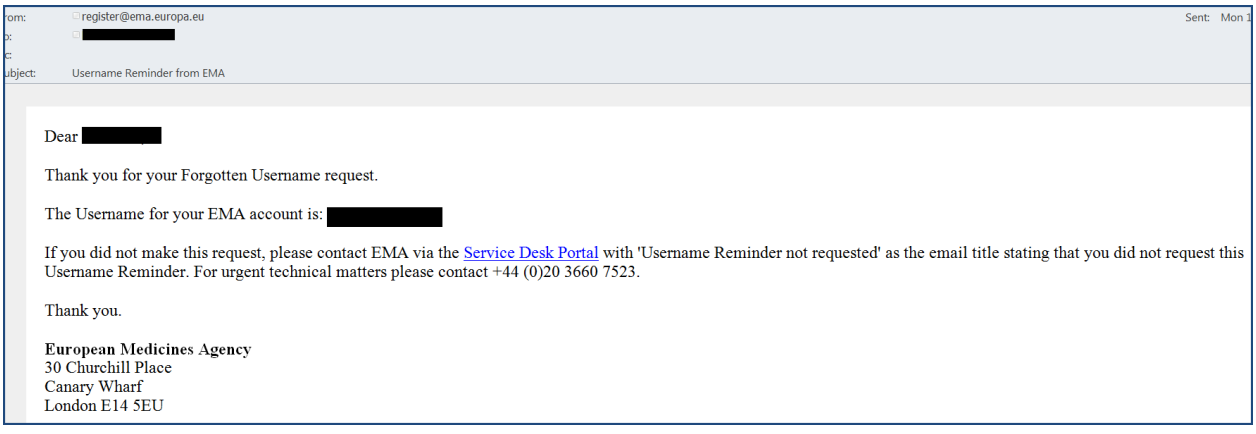
4. Confirmation of the request is displayed

Figure 25 - Confirmation of the forgotten username request



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

Figure 26 - E-mail to the user containing a forgotten username



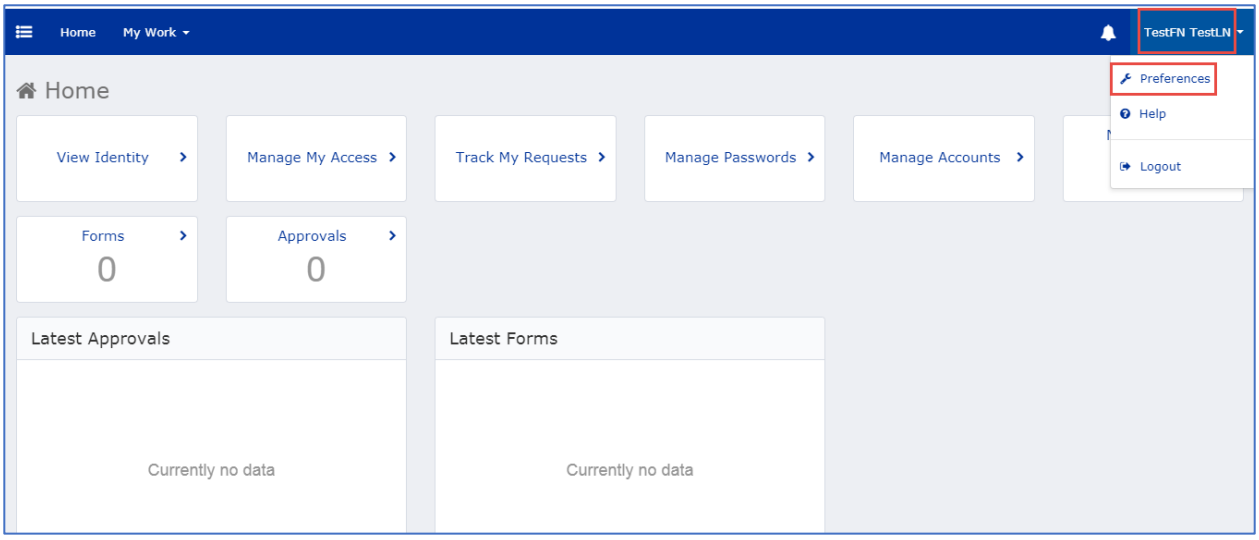
6. Log in with your username and password.

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:

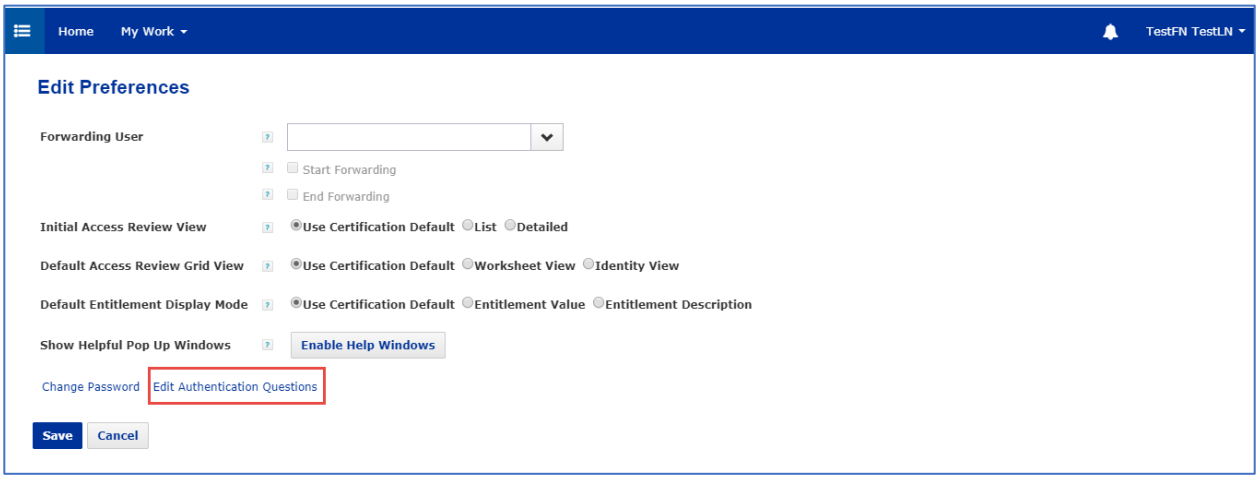
1. Login to the EMA Account Management portal.
2. Click on the username link on the top right corner of the homepage and click "Preferences".

Figure 27 - Access my preferences



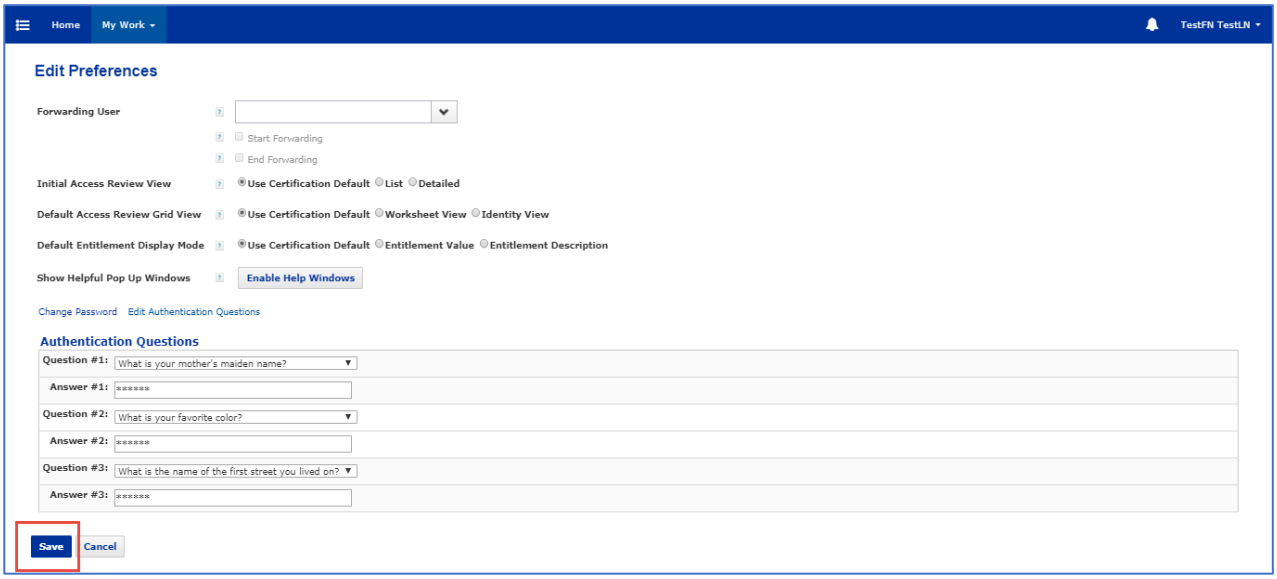
3. An option to edit preferences appears where the user can edit the security (authentication) questions.

Figure 28 - 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 29 - Selecting security (authentication) questions



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.

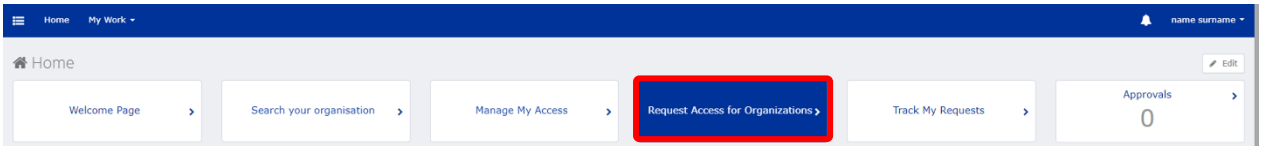
In order to change your organisation details in OMS, you need to have a "**SPOR Super User Industry role**". This role must be requested via the EMA Account Management portal and will be sent to the EMA for approval – see **section 3.1.** below.

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.

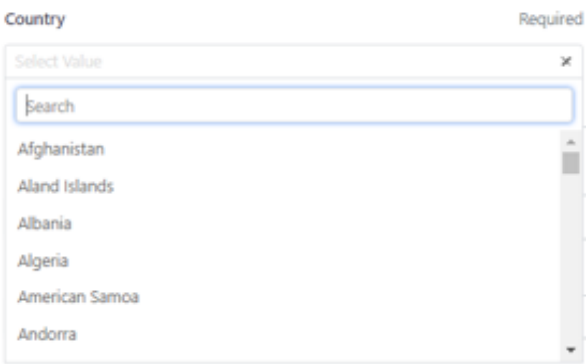
1. Ensure that you have completed the EMA Account Management portal registration process described in **section 2.**
2. Log into EMA Account Management portal.
3. Please verify in EMA Account Management portal if you have the SPOR Super User Industry role assigned to your account. If yes, please proceed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

Figure 30 - Request Access for organisations



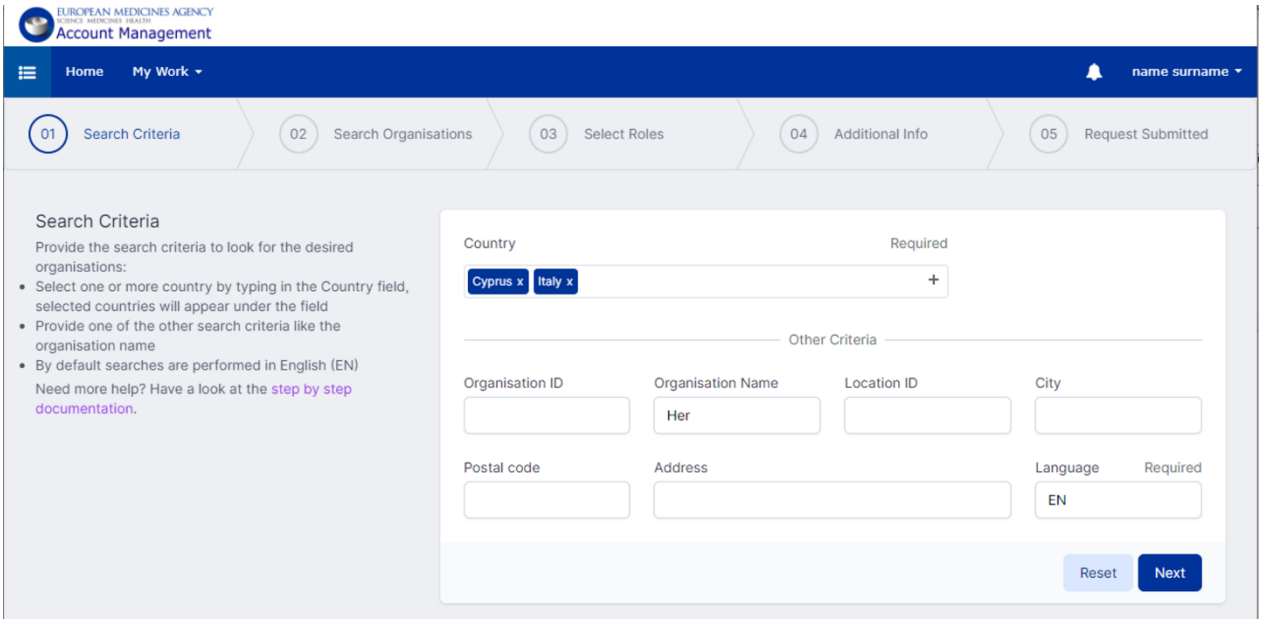
5. The first page to be displayed in the "Request Access for Organisations" page is the "Search Criteria" to look for an organisation. Under the word **Country** click into the dropdown box, and in the "Search" box type the country (in which the organisation is located). You can select or enter more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

Figure 31 - Country search box



6. 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 32 - Organisations screen

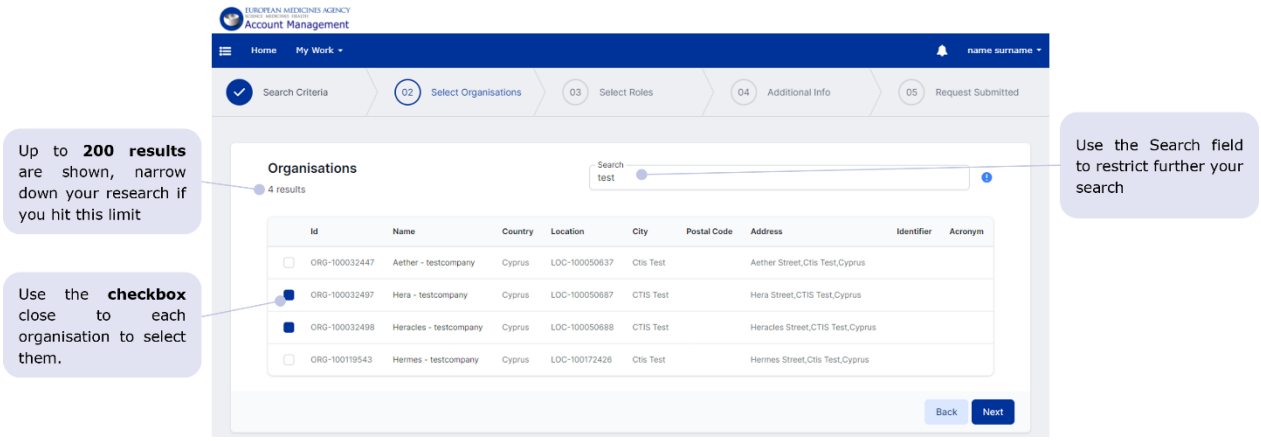


Note: all organisation names are stored in EMA Organisation Management Service (OMS) in English, if you wish to look for an organisation name in a different language you have to change the language to the related ISO code. Please note not all organisations have a local translation of their name in the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

7. 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 33 - Search results window

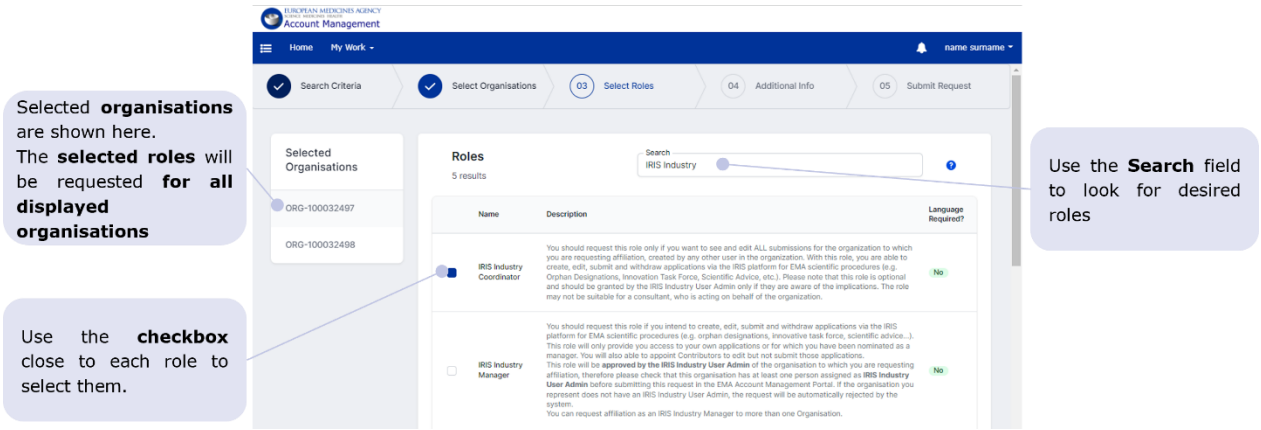


If the organisation you need to affiliate with is not listed in the results, it means that your organisation is not registered in the EMA Organisation Management Service, and therefore, your role request cannot be completed. Please see **section 3.3.** and **section 3.4.** for more information on how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

8. 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 34 - Role selection window



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

10. 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.

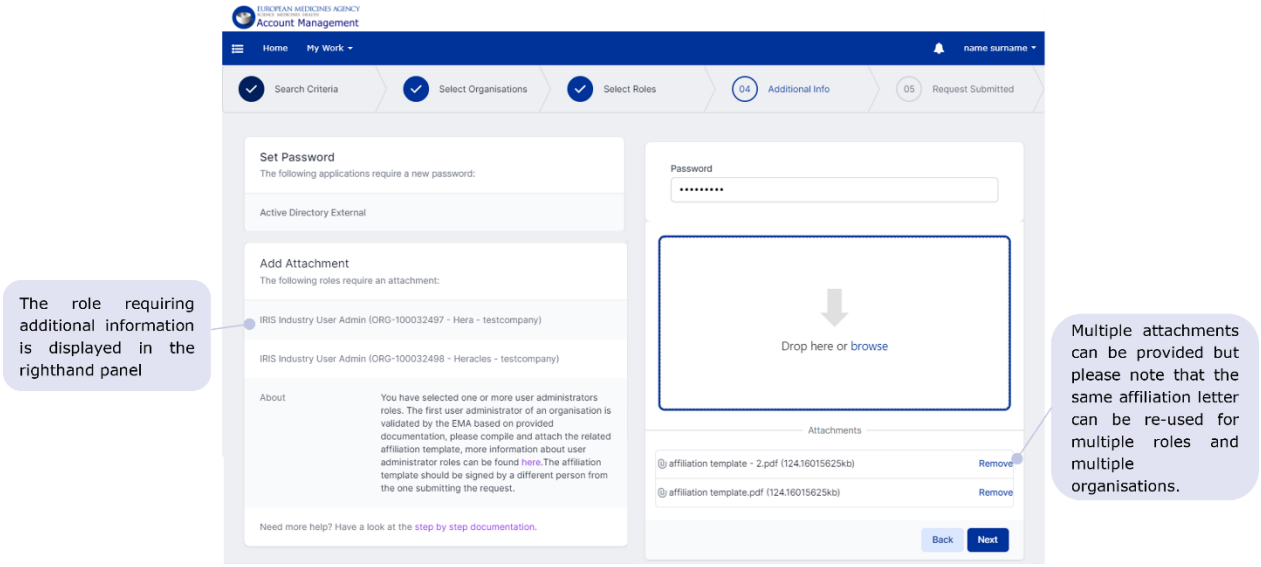
    To select the role of User Administrator (like IRIS User Admin or SPOR Super User) for your organisation, that organisation must first have at least one User Administrator allocated and validated by the EMA. This is done by completing the Affiliation Template and signed by an approved signatory (this 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.

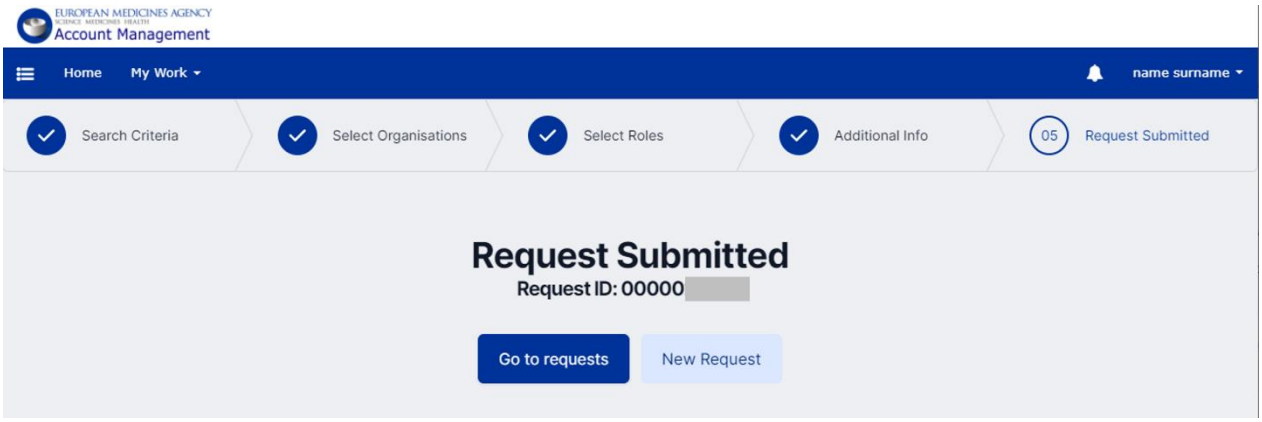
Figure 35 - Additional information window



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.

11. Click "Next".
12. The following window confirms the request has been submitted. You can reference the request ID if any problem arises.

Figure 36 - 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's EV Registration team via an EMA Service Desk request.

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 37 - 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

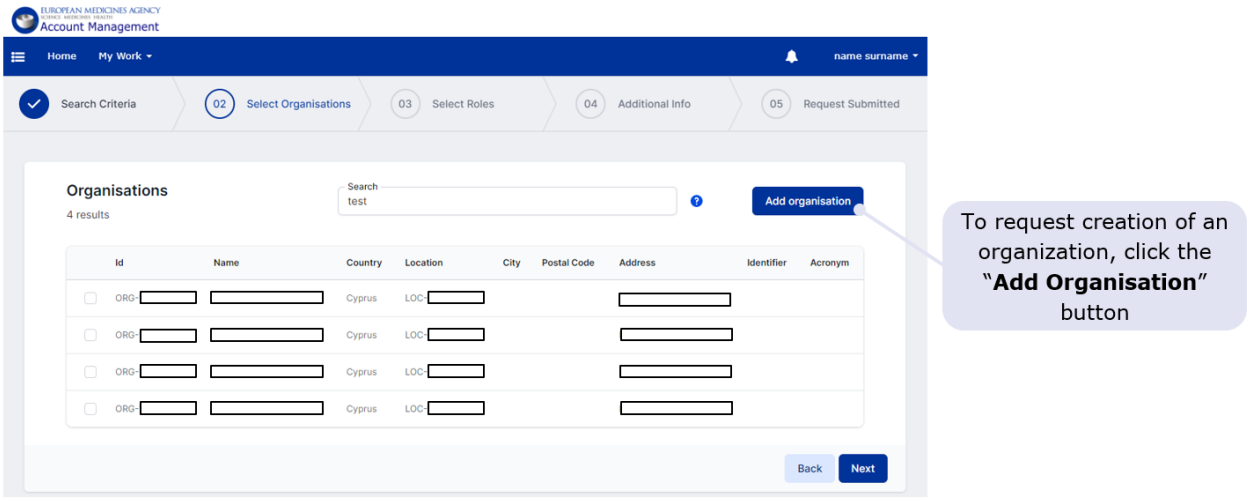
The request for the registration of a new organisation can be done via EMA Account Management portal – see **section 3.3.1.** - or via OMS/SPOR portal – see **section 3.3.2.**

3.3.1. Request of a new Organisation via EMA 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.

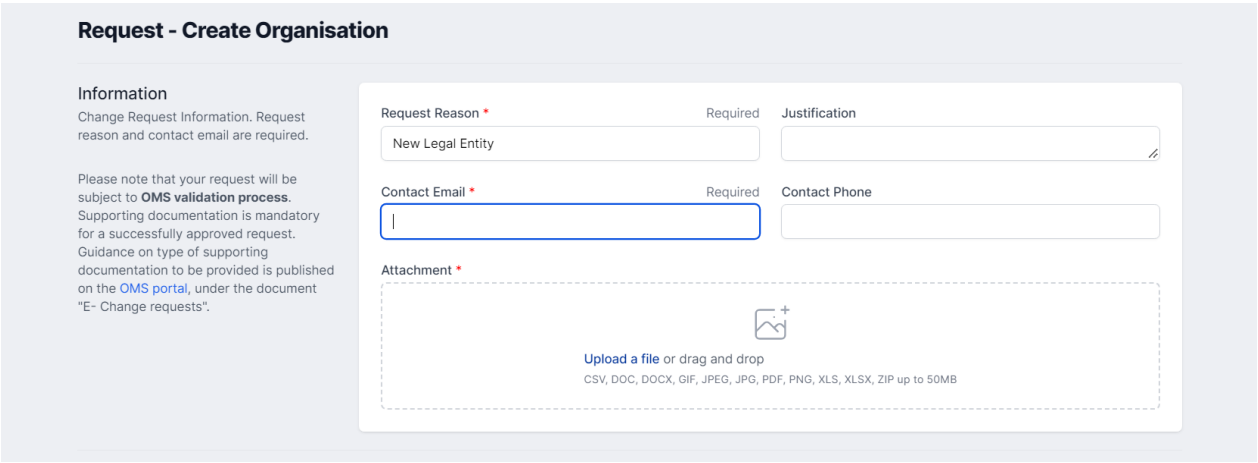
Figure 38 - "Add Organisation" button



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

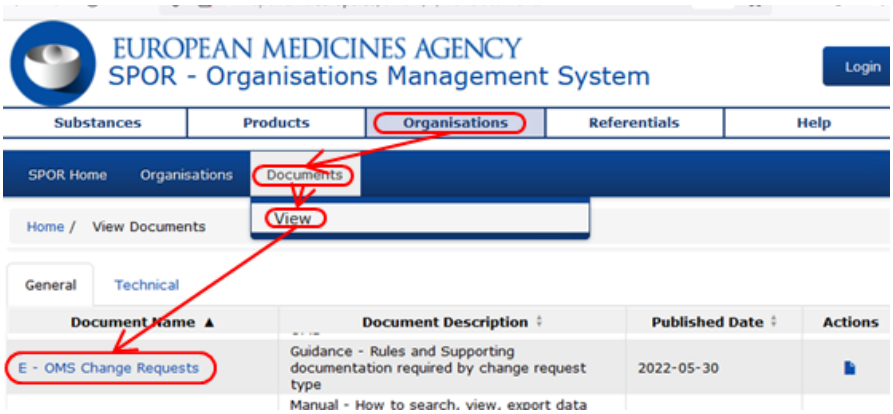
   - ***Change Request Information:*** fill information like "Request Reason" and "contact email". Mandatory fields need to be filled and relevant documentation attached in order for the request to proceed.

Figure 39 – "Create organisation" form



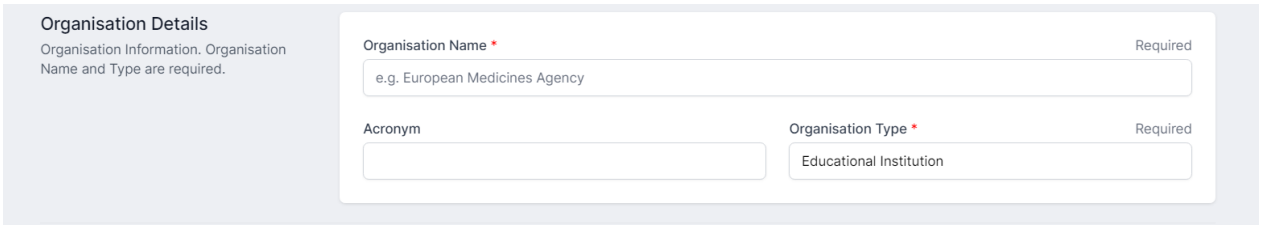
Note: Don't forget to provide mandatory supporting documentation for a successfully approved request. Guidance on type of supporting documentation is published on the Organisation Management Service portal, under the document "E- Change requests".

Figure 40 - Location of the documentation in OMS



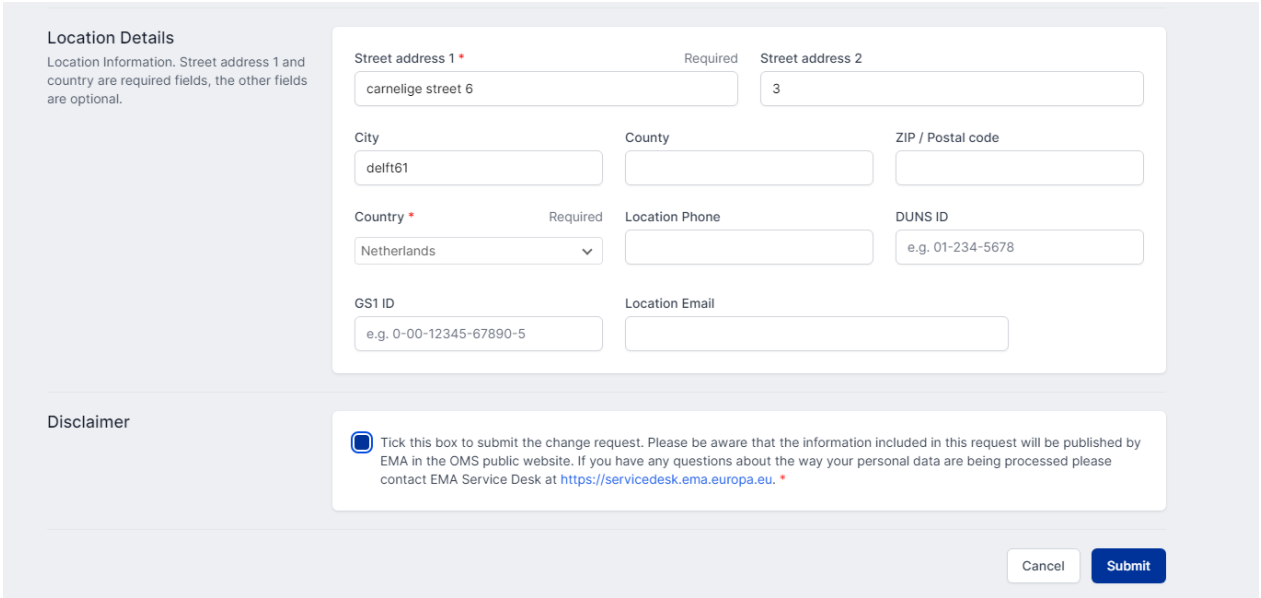
- ***Organisation Details:*** Important information regarding organisation like name and Type needs to be filled in.

Figure 41 - Organisation details



- ***Location Details:*** contains information about the location.

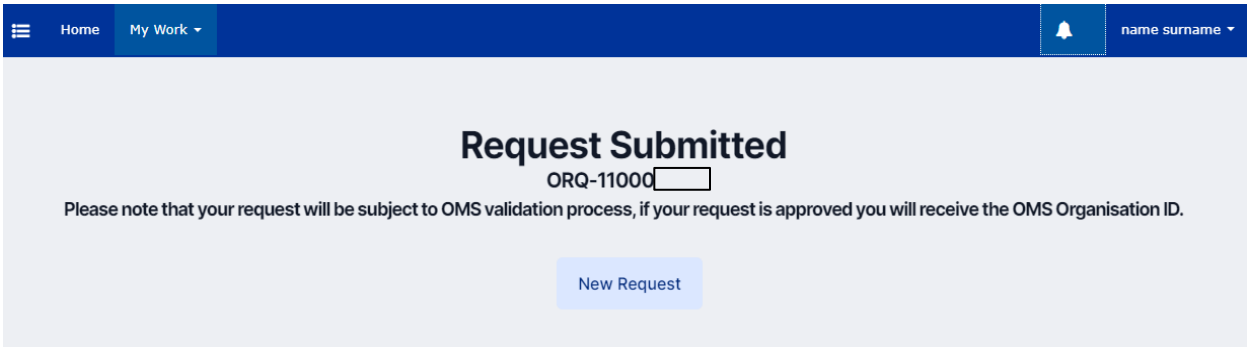
Figure 42 - Location details



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".

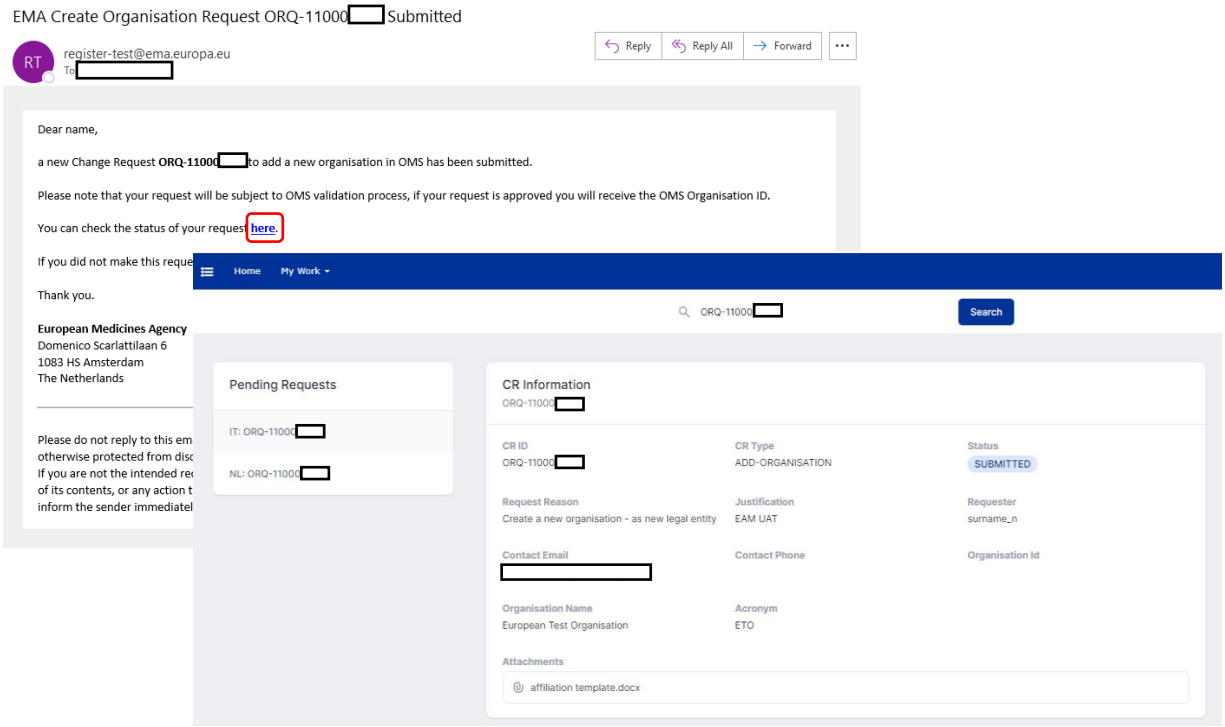
   Note: The ORQ Request number is not the OMS Organisation ID; this will be provided after the OMS Validation process.

Figure 43 - Request submitted message displaying the ORQ Request number



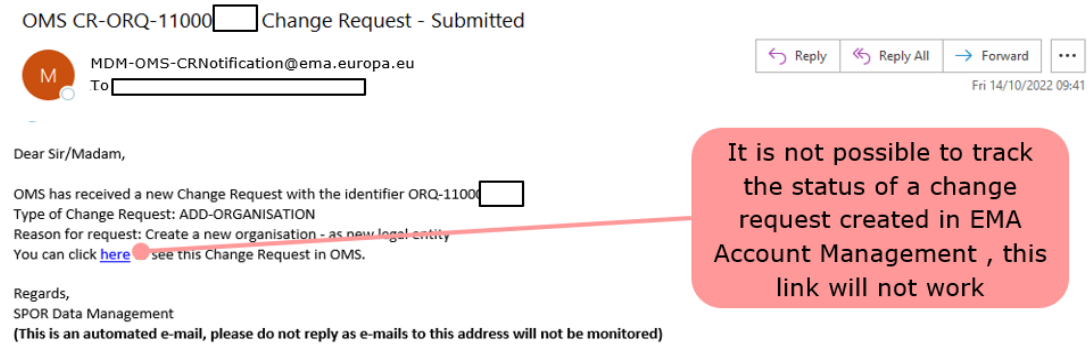
4. Users also receive a confirmation email coming from register@ema.europa.eu with a link to track the status of the submitted request(s).

Figure 44 - 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.

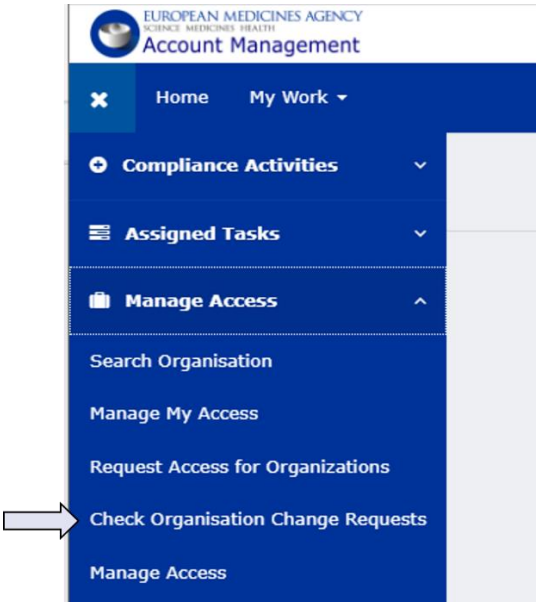
Figure 45 - Change request confirmation email



Tracking the Organisation Change Request

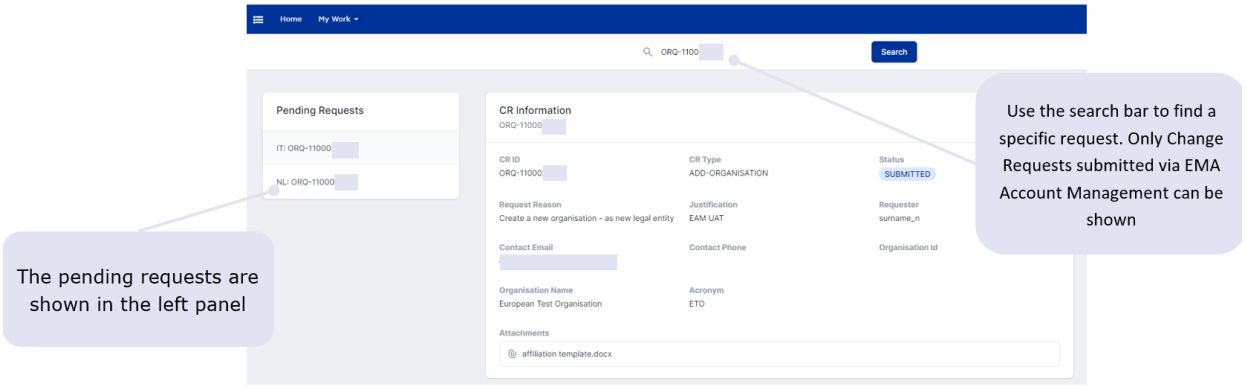
5. Click on "Check Organisation Change requests" under "Manage Access" as shown below.

Figure 46 - "Check Organisation Change Requests"



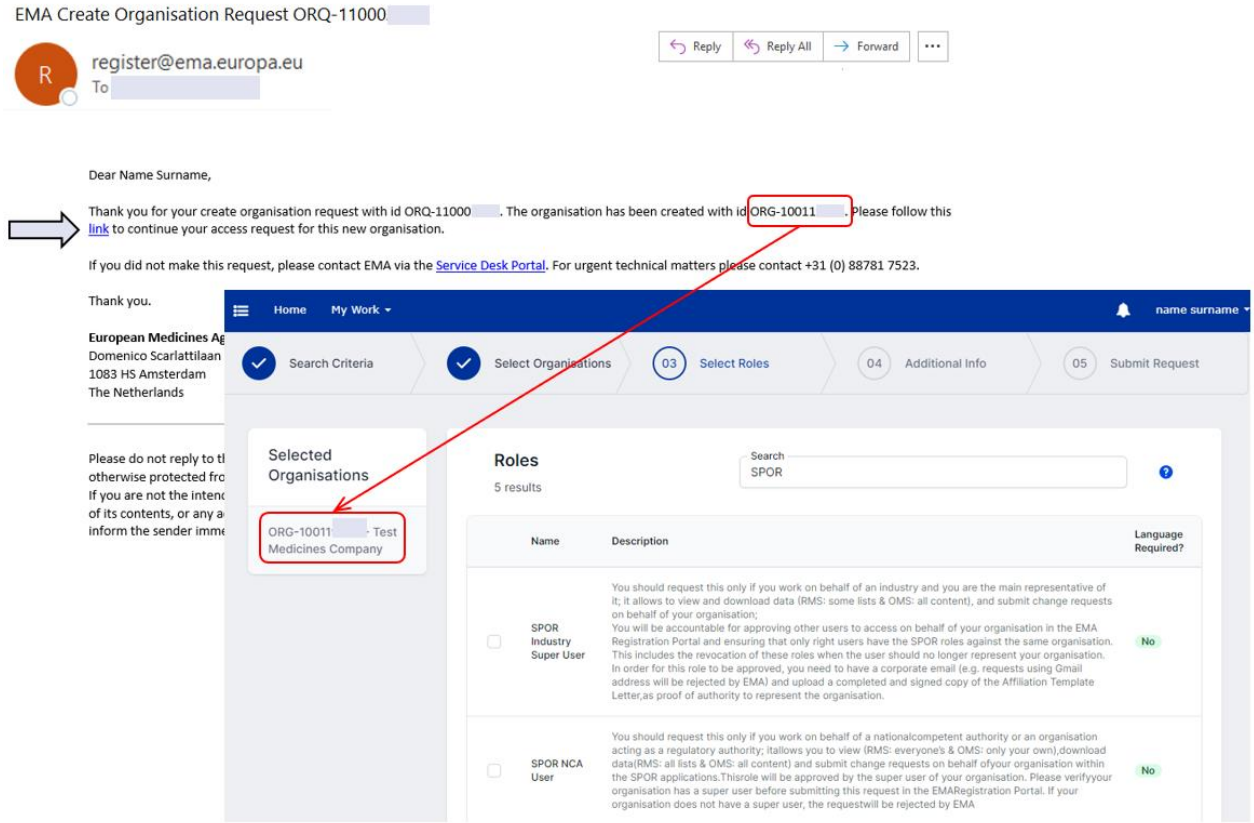
6. Enter the Change Request number starting with "ORQ" or select the change request from the left panel: the corresponding status (Submitted/Rejected/Approved) of the request will be presented.

Figure 47 - Status of the Change Request



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 48 - Notification email following the creation of the organisation

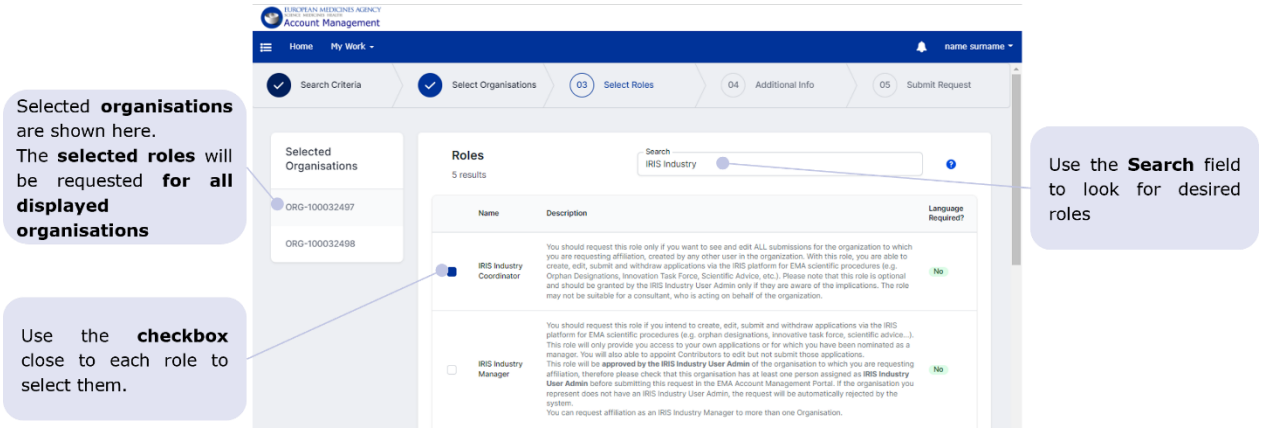


Note: After an organisation becomes available in OMS it could take up to half an hour for the organisation to be also available in EMA Account Management. The organisation becomes available in EMA Account Management when the above email is sent.

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 49 - 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.

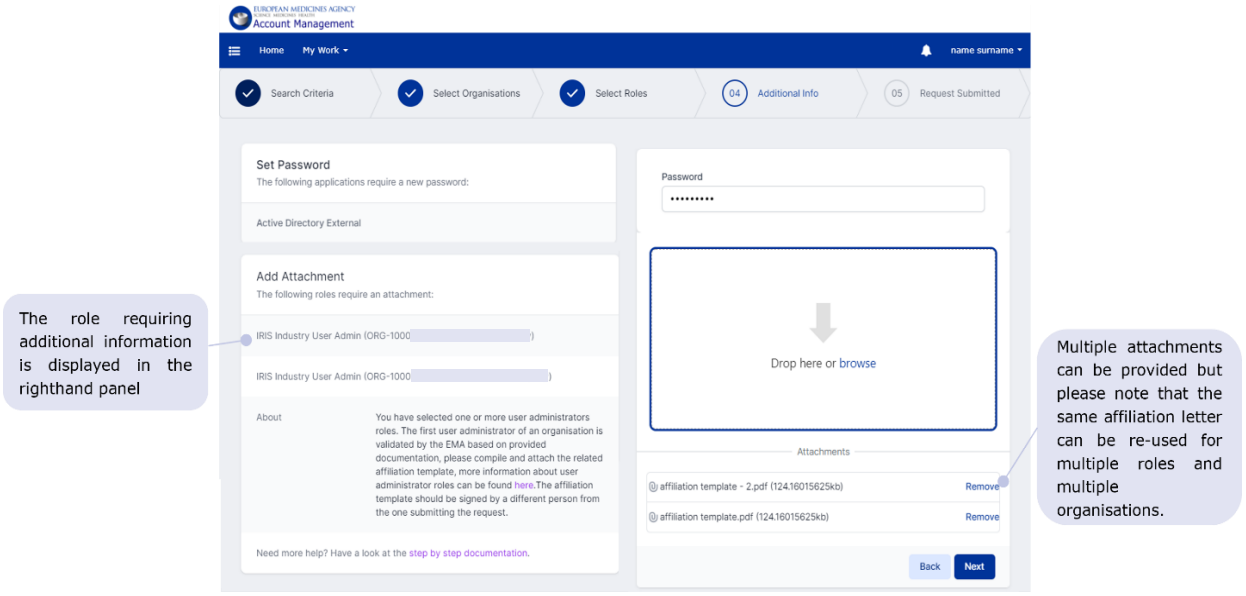
8. The **Additional Information** page is displayed only if the combination of selected organisations and roles requires it. If no additional information is required, your request will be submitted.

   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 50 - Role selection

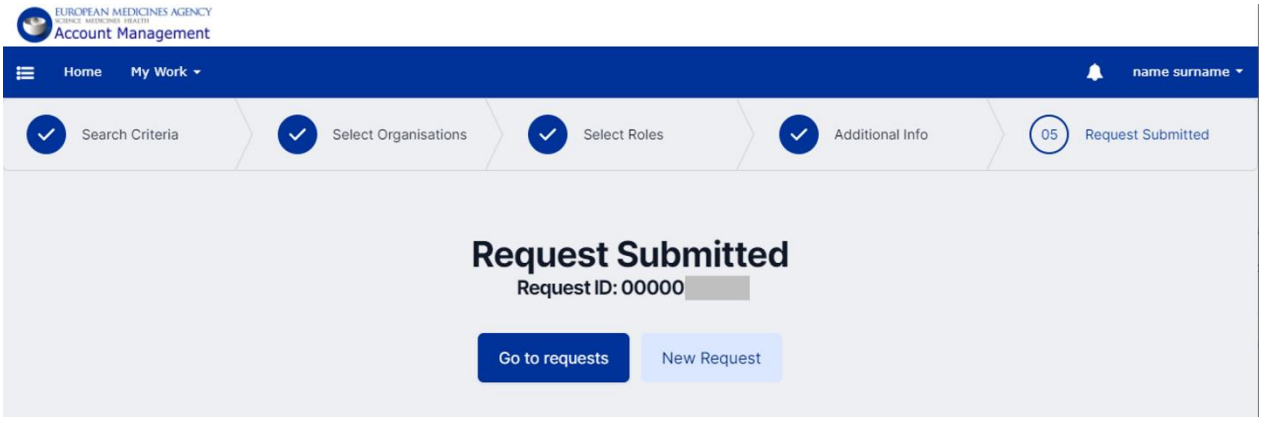


Note: For the first User Administrator the requester's e-mail should preferably be a work email from the same organisation on behalf of which the user is requesting the user access. The EMA will refuse requests coming from Gmail, Yahoo and similar private addresses.

EudraVigilance: When requesting access as a Responsible Person (RP) or EU QPPV/Additional QPPV/Trusted Deputy (TD) please follow the steps described in **section 5.2.** 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 51 - Confirmation message of role request



3.3.2. Request the registration of a new organisation via 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 52** and **Figure 53** show the screens used to request a new organisation and complete the information needed to register a new organisation in SPOR OMS.

Figure 52 - Request the creation of a new organisation

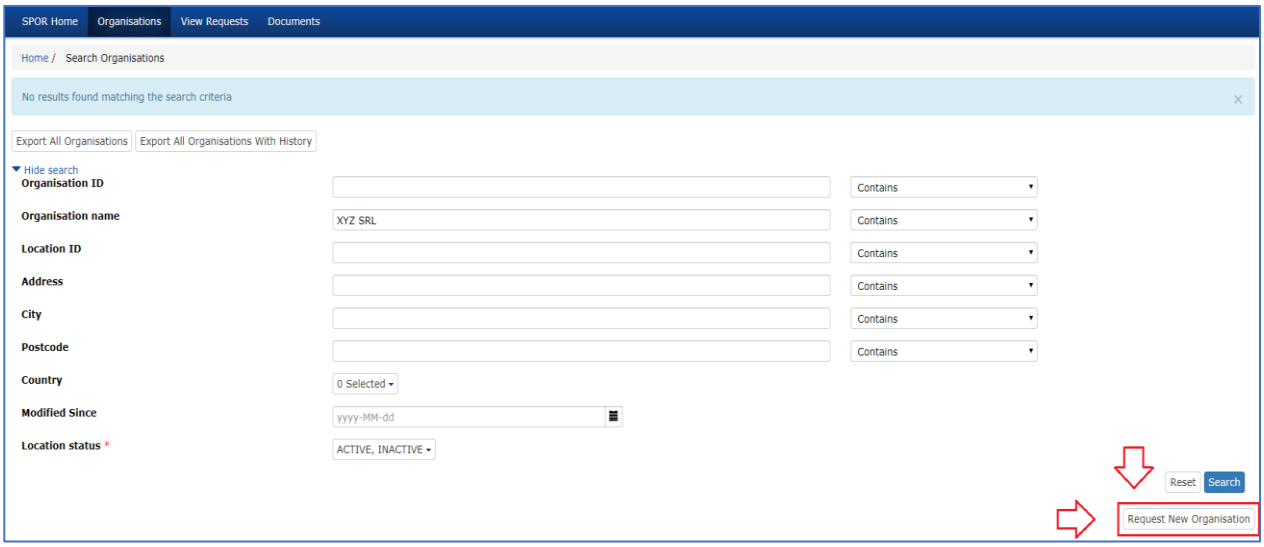
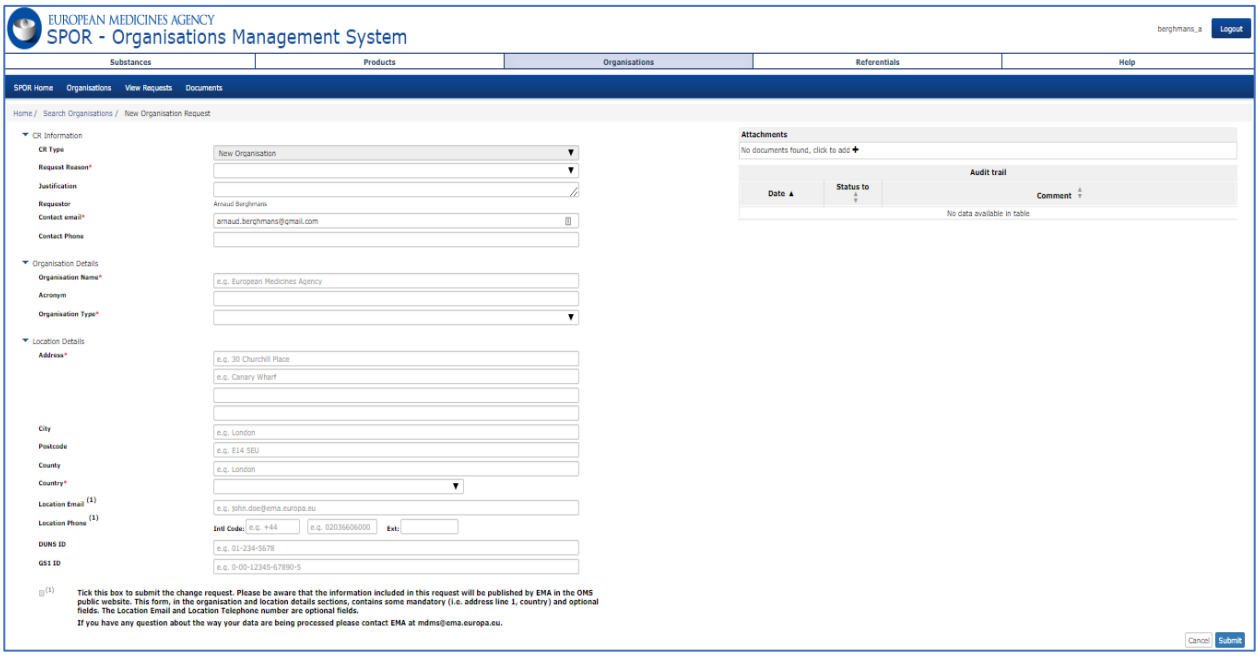


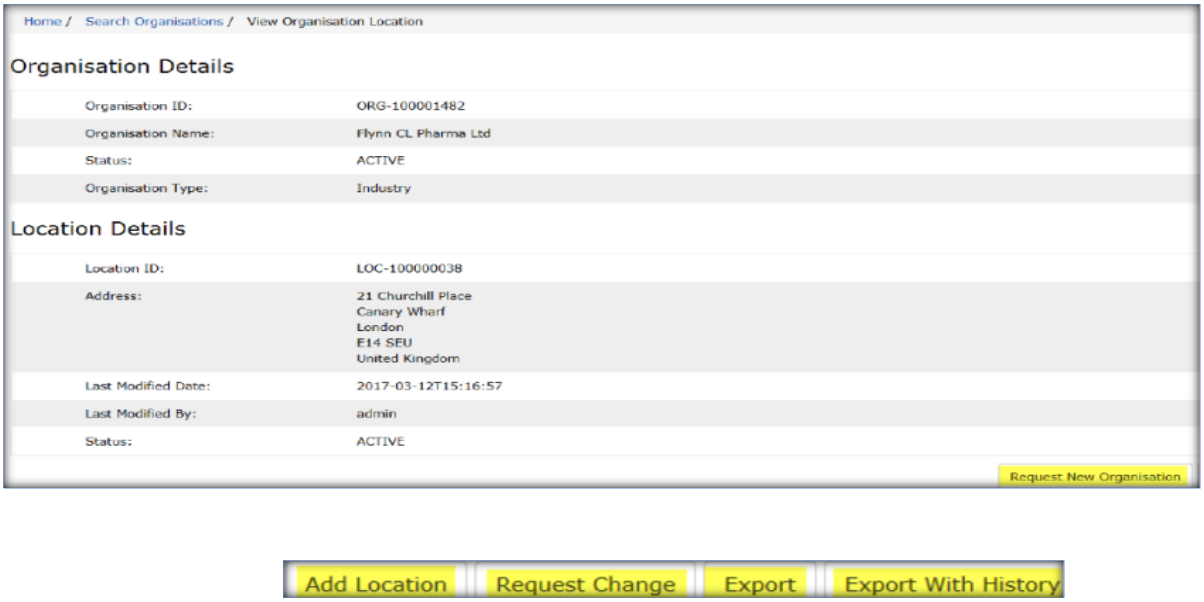
Figure 53 - Fill in the details and submit the new organisation



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 54 - 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 – see **section 5.2.**

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 – see **section 4.1.**

4.1. 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 complete the organisation details in the EudraVigilance restricted area.

To do so, the QPPV/RP should log in to EudraVigilance Production and XCOMP (test environment) and select "Manage your profile" on the left column – see **Figure 55.**

Figure 55 - Menu available in the EudraVigilance restricted area

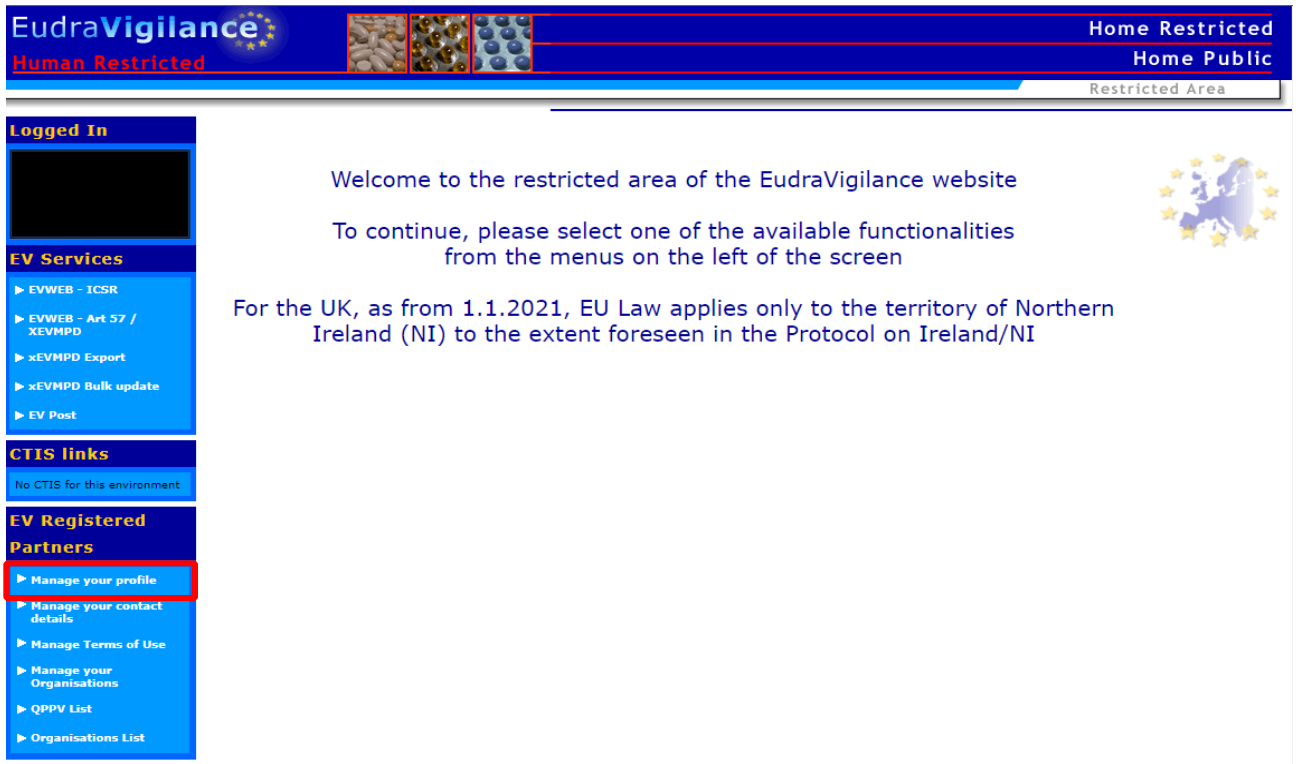
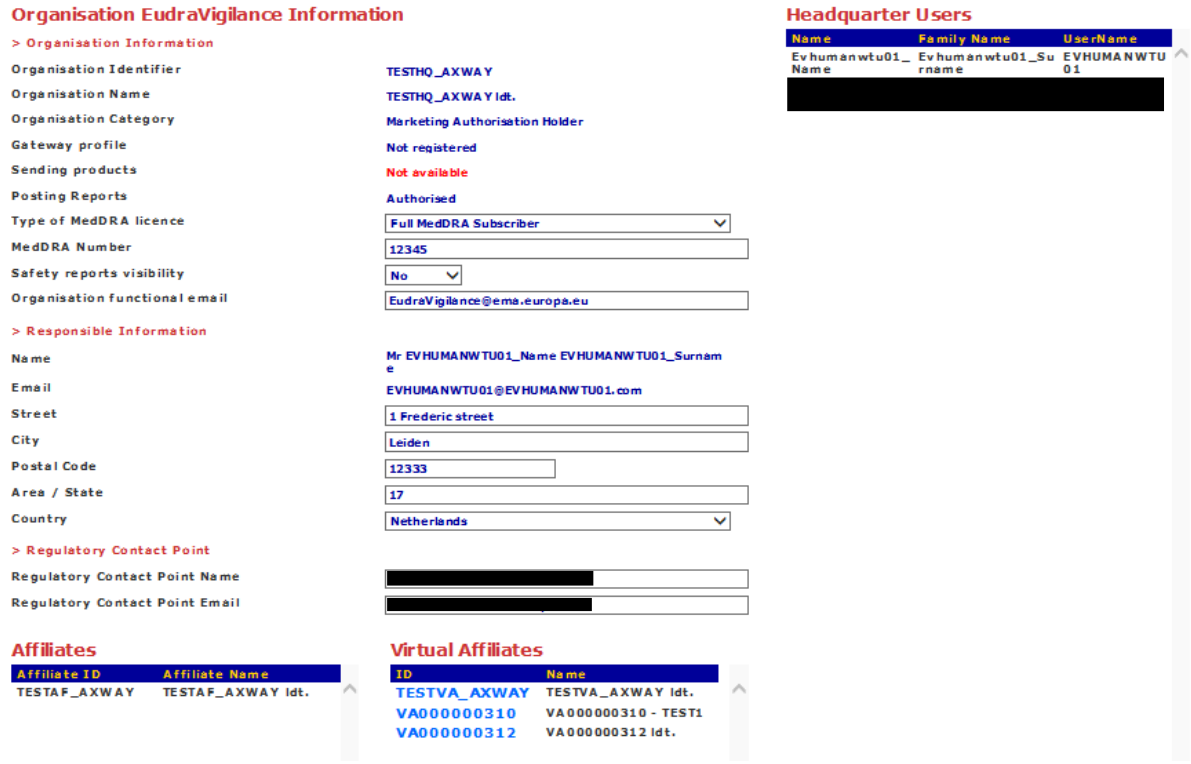


Figure 56 - View of EU QPPV/RP/TD Restricted Area



The QPPV/RP should 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 an EMA 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 "Low Revenue MedDRA EudraVigilance Fee waiver" if your organisation qualifies for a MedDRA fee waiver.

  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 and your organisation **also** qualified for the MedDRA fee waiver as stated on the EMA's website, 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.

  Please note that if your organisation does **NOT** qualify for the MedDRA fee waiver, despite being registered (or not) as an SME, then your organisation must acquire a full MedDRA license. For more information, please also visit:

  - https://www.meddra.org/subscription/special-licences
  - https://www.meddra.org/subscription-rates
- **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, an individual's email address rather than functional mail box is recommended.
- **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.**

4.2. 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 an EMA Service Desk request addressed to the EV Gateway 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 one of the following rights, as applicable: ICSR Browse & Send, MPR Browse & Send or Browse and Send ICSR and MPR. These rights are contained within the QPPV/RP and Trusted Deputy roles. All other users must request these roles separately – see **Annex 1**.

5. EudraVigilance user access management

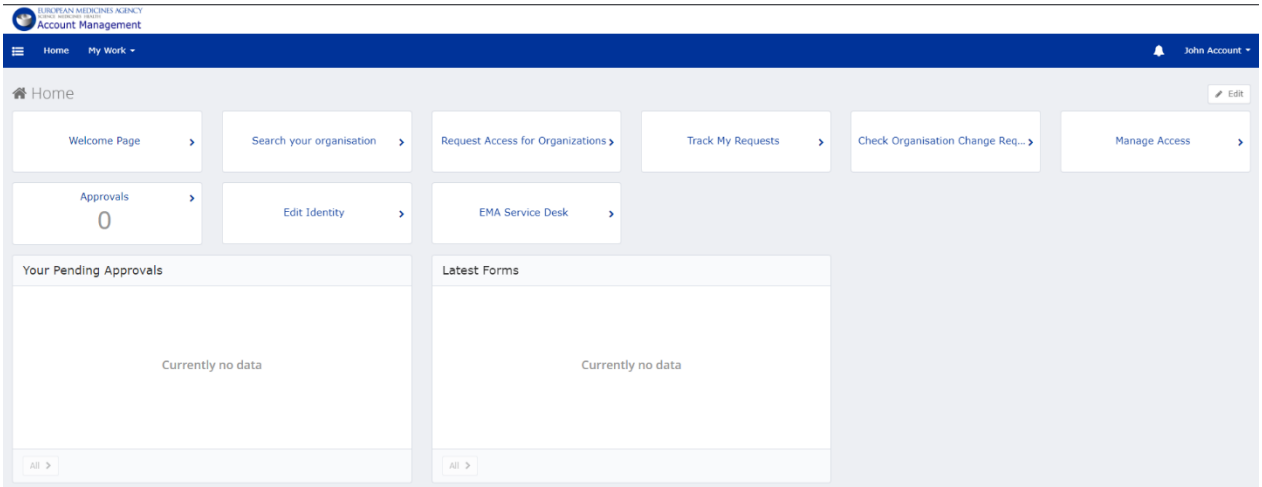
Users can manage their own EMA account via the EMA Account Management portal dashboard; this includes managing access to EudraVigilance Human Production, EudraVigilance XCOMP and to other EMA systems. The dashboard appears after successfully logging in.

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 57 - 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 – see **section 5.2.** for more information on how to request EU QPPV/RP access.

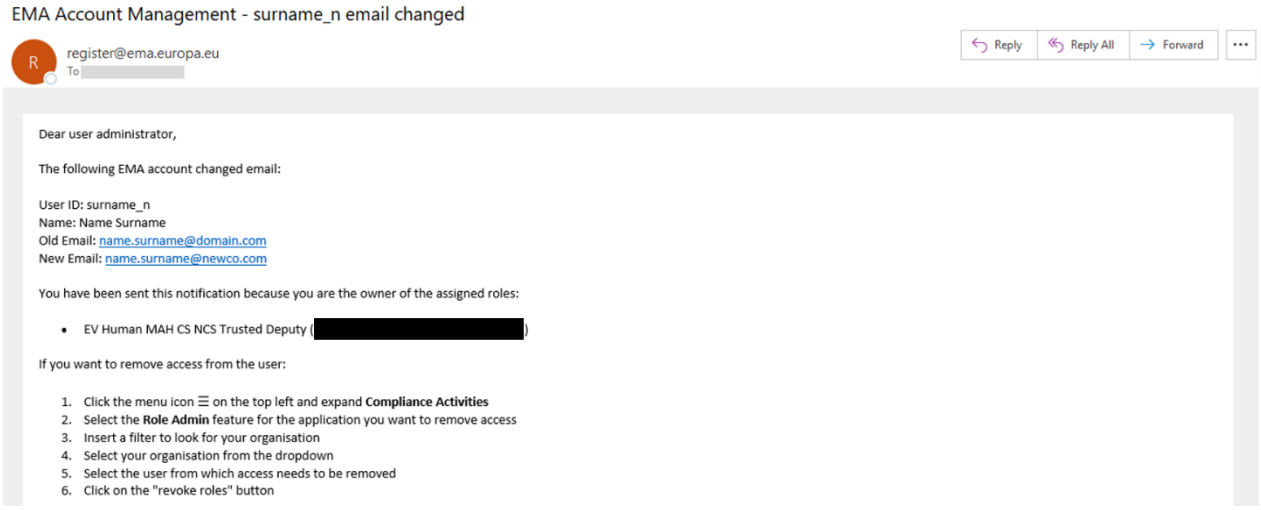
Moreover, if there is no active QPPV/RP registered for the organisation profile, the organisation will appear as disabled in EV and no user will be able to access it until the new QPPV/RP user is registered.

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 (see also **section 5.1.1.**).
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 5.6.2.**).
5. To review changes related to the user's 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 58 - Update to the user's email



Important note:

- 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.

5.1.1. Biannual review of the EV roles

Following the updates to the account management portal in order to simplify the user management by the **QPPV/RP** users and their **Trusted Deputies**, a further update was implemented in June 2023 to ensure the regular review of user access within an organisation: **twice a year** the QPPV/RP user of an organisation will be asked to review the list of users within their organisation and the access role that has been assigned to them; this review can also be performed by user with the Trusted Deputy role for EudraVigilance.

The QPPV/RP user and Trusted Deputy will be sent an e-mail confirming the review process has started and it will include a link to the EMA account management portal review screen. There, the QPPV/RP/Trusted Deputy will see a list of users of their organisation(s) and needs to tick box to either confirm user access should remain or for their access to be removed/revoked.

The review should be completed within one month. If the QPPV/RP (or Trusted Deputy) does not complete this review of user access within the **one-month** time frame, then all unassessed users will have their access **revoked automatically**. If these revoked users still need access, they will then need to **re-request** this access via the EMA account management portal for the QPPV/RP (or Trusted Deputy) to approve.

This official review process is scheduled to be performed twice a year (March and September).

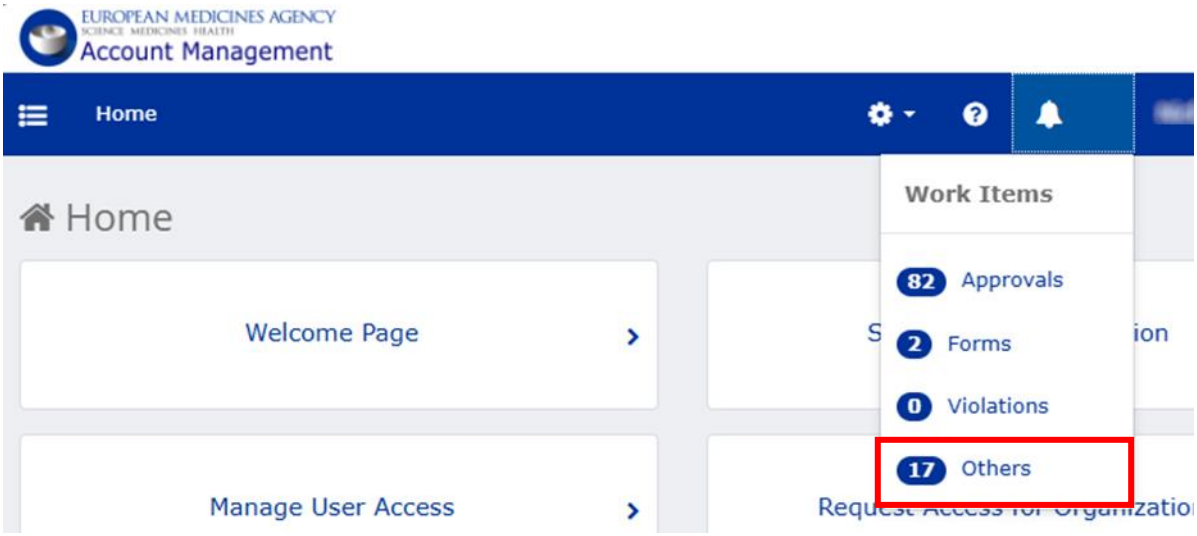
Organisations should note that **they are responsible for removing user access if a user leaves their organisation or changes their role within an organisation where access to EudraVigilance data is no longer needed**. **Organisations should not wait for the twice-yearly review to remove access**, this is just an additional control to the normal day to day user management that each organisation should perform.

Guidance on how to use the EMA account management portal to manage users is provided on the following web page: User Administrator Guide·- EMA Account Management (europa.eu).

The images below illustrate the approval/revocation process by the QPPV/RP or Trusted Deputy:

1. After logging into the EMA account management portal, the QPPV/RP or Trusted Deputy accesses the Work Items "Others", where the list of tasks is displayed. By clicking on "View", the list of users for that Access Review task will be displayed – see **Figure 59.**
2. Then, the QPPV/RP or Trusted Deputy will have to review each user that is listed and either approve or revoke the access for that user. Alternatively, the QPPV/RP or Trusted Deputy can do a bulk approval or revocation by going to "Bulk Decisions". The bulk approval/revocation can be done for all users of that task or just for the page displayed – see **Figure 60.**
3. Lastly, the QPPV/RP or Trusted Deputy signs-off the decisions.

Figure 59 – Work Item "Others" and Access Review tasks



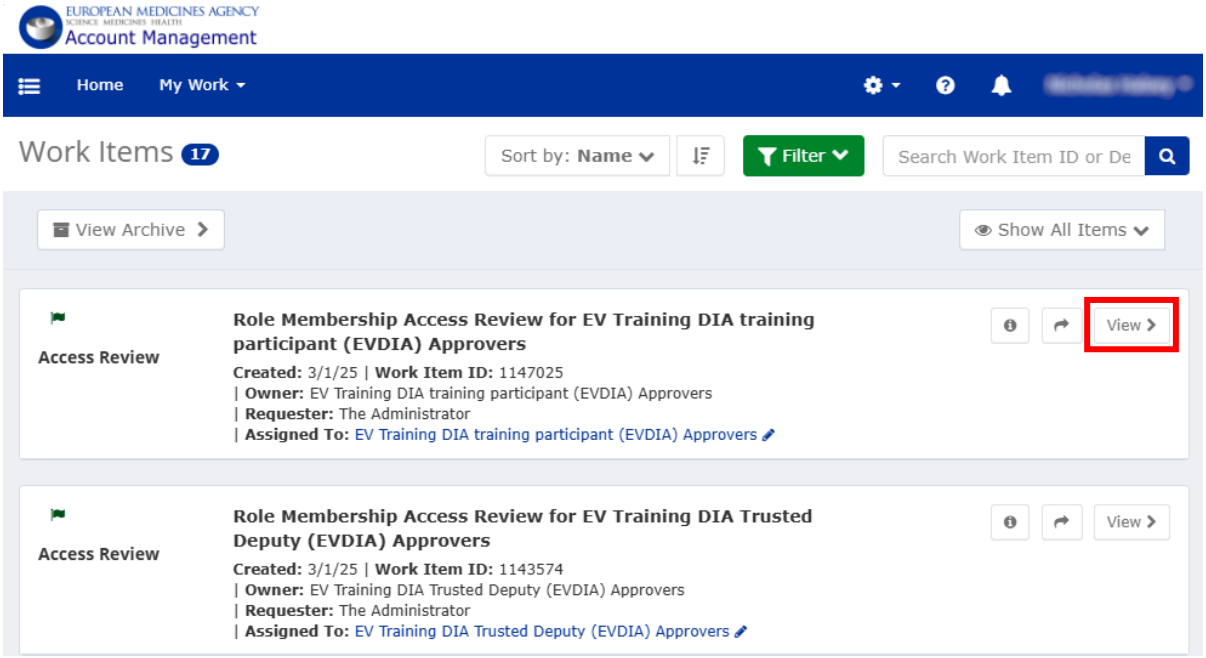
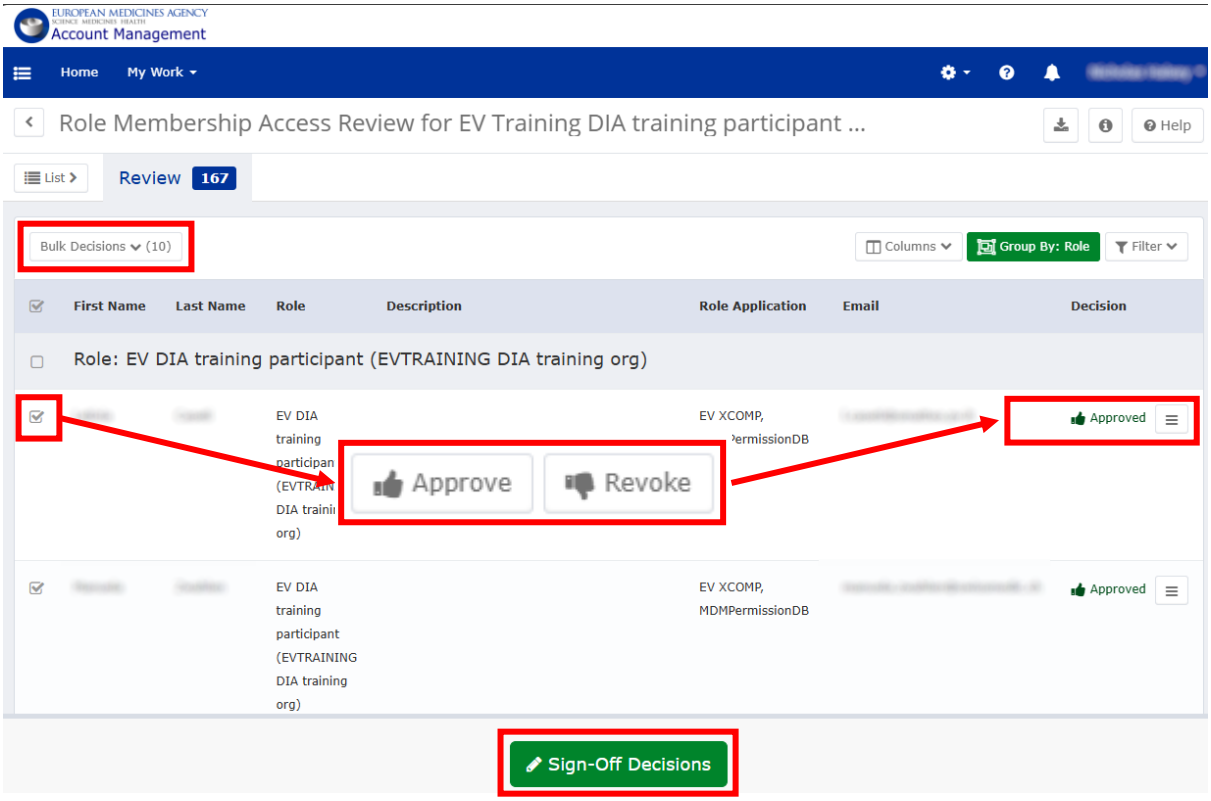


Figure 60 – Access Review screen



5.2. EU Qualified Person for Pharmacovigilance (QPPV) or Responsible Person (RP) access request

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/National Competent Authority (NCA), it will be a **Responsible Person (RP)**. **Please ensure you have no current base or supplementary roles with the organisation before requesting the QPPV/RP role for that organisation and that the previous QPPV/RP role has been removed** – see **section 5.6.** on how to revoke/remove EV roles. A QPPV/RP role request will be rejected by the system automatically if there is still a QPPV/RP registered for the organisation profile.

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.

In order to request an EU QPPV/RP role, please follow the steps below.

1. The primary responsible person should log in to EMA Account Management portal and follow the steps described in **section 5.3.** ;
2. Once the role has been requested in EMA Account Management portal, an EMA Service Desk ticket should be raised to the EudraVigilance Registration team quoting the Request ID number and attaching the required documents listed on New Organisation First User QPPV/RP or Change of EU QPPV/RP, as applicable – see below;

Figure 61 - Service Desk home screen

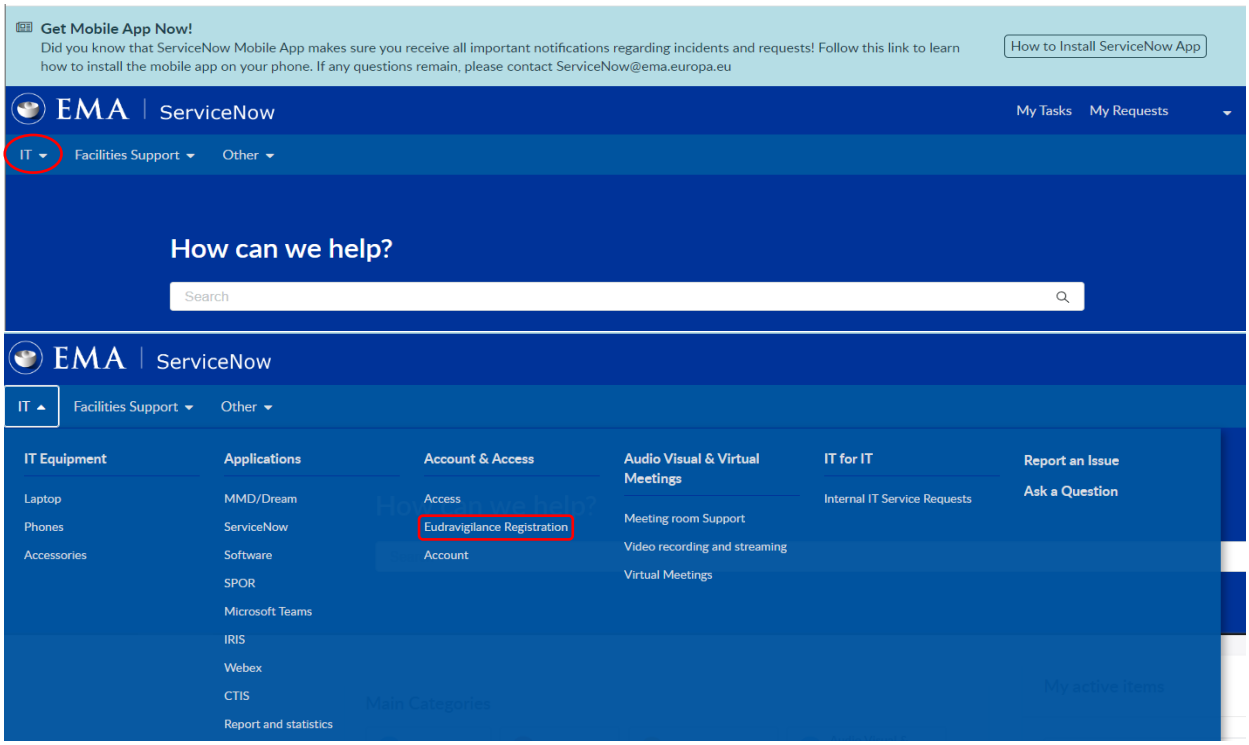


Figure 62 - EudraVigilance Registration queries

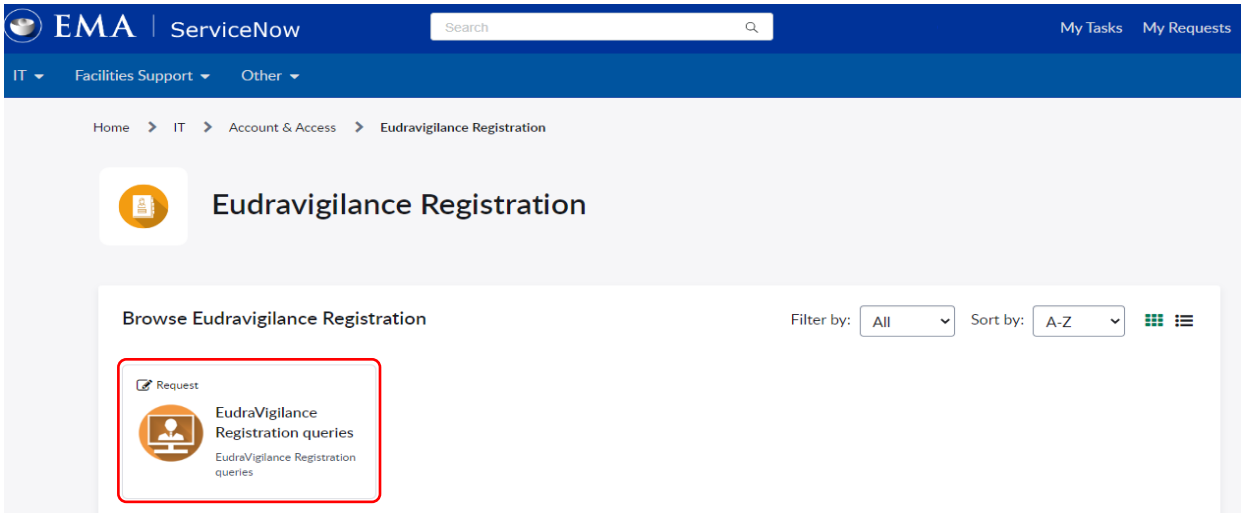


Figure 63 - EudraVigilance Registration form

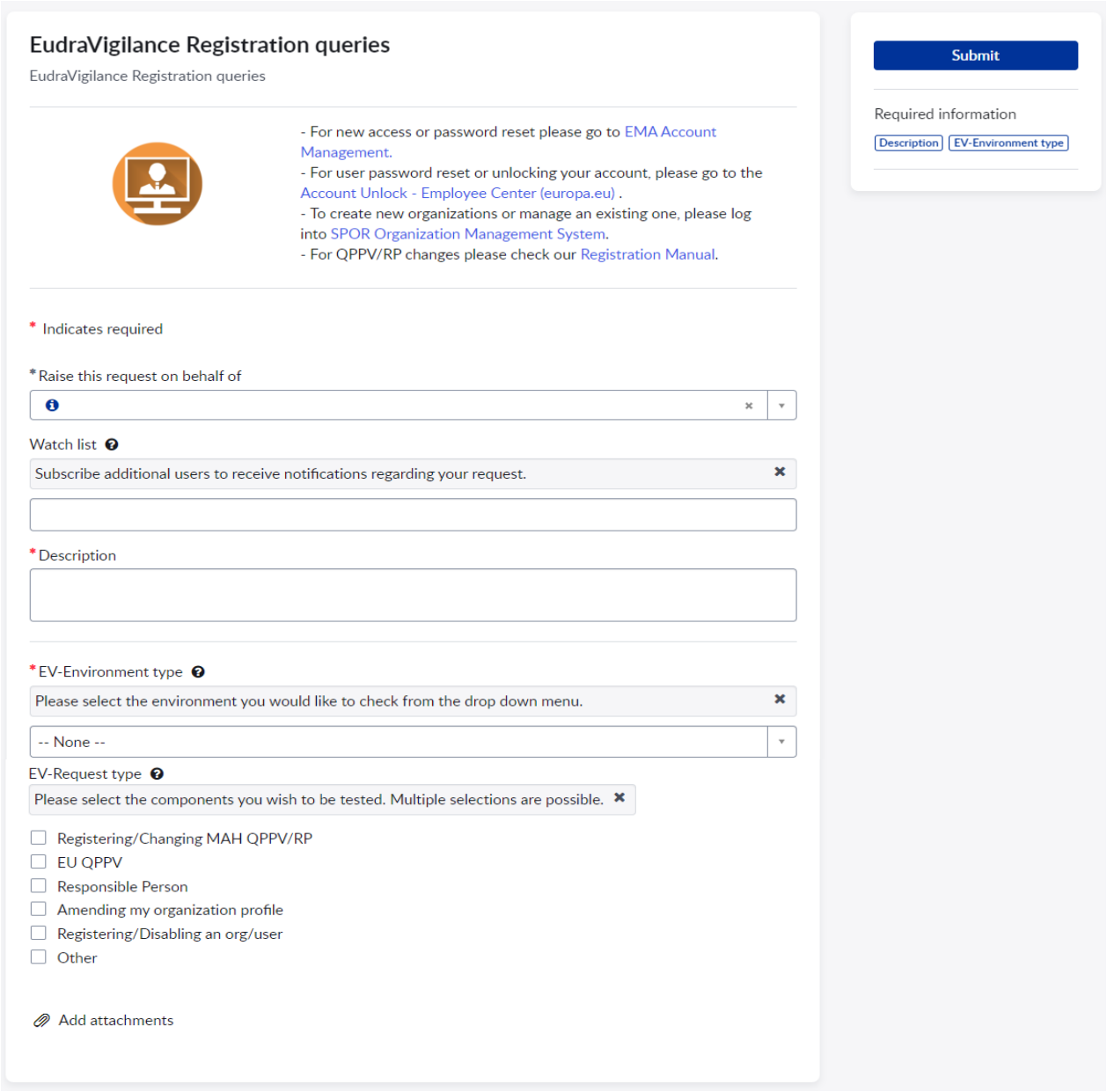
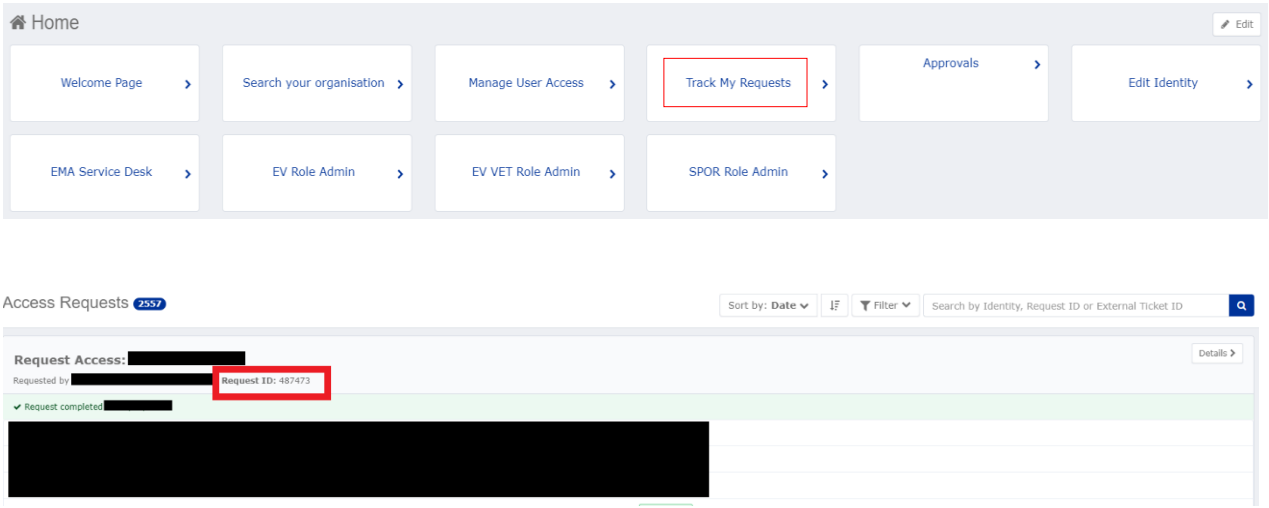


Figure 64 - Track My requests & Role Request ID



3. The EudraVigilance Registration team will then confirm all the required documents provided and approve your EU QPPV/RP role request.

Important note:

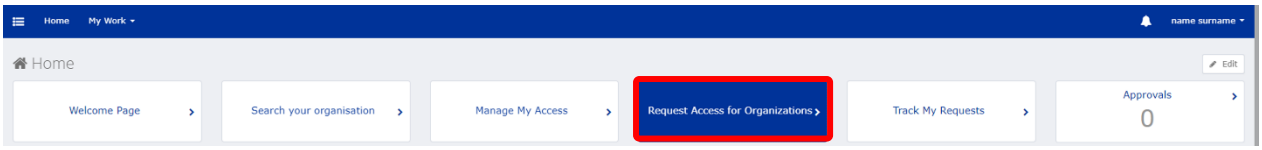
- For **first user registrations**, the EU QPPV/RP will need to finalise the registration of the organisation with EV by following the steps described in **section 4.1.** of this manual.
- For **EU QPPV changes**, the EU QPPV should update their products in the XEVMPD since the EU QPPV change is not automatically reflected in the products submitted. For more information on this, please refer to **section 2.1.1.2. Business process to notify a change of a QPPV** and **Process map 10 – Amendment of an AMP entity** of the document Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004.
- 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 RP for **National Competent Authorities** is the same as for EU QPPV for MAHs;
- There can only be **one EU QPPV/RP per organisation**;
- The registration or change of EU QPPV/RP/Trusted Deputy in the Production environment will be reflected automatically in EV XCOMP (and Virtual affiliates, if applicable).

5.3. Request of EV user access

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:

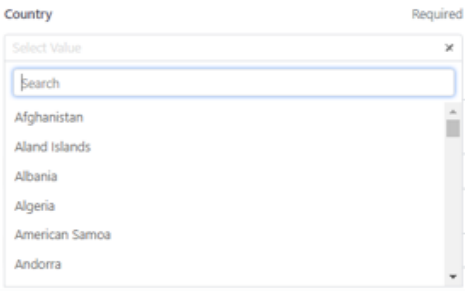
1. On the home page click on "Request Access for Organisations" tab.

Figure 65 - Request Access for organisations



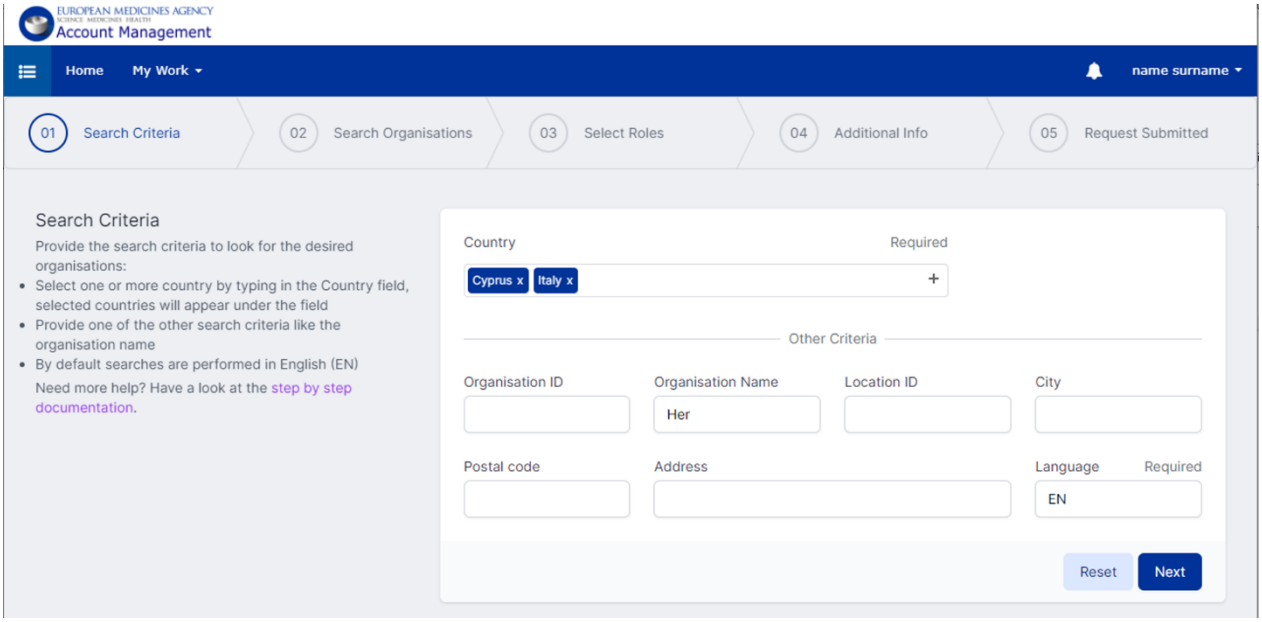
2. The first page to be displayed in the "Request Access for Organisations" page is the "Search Criteria" to look for an organisation. Under the word **Country** click into the dropdown box, and in the Search box type the country (in which the organisation is located). You can select or enter more than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

Figure 66 - Country search box



3. 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 67 - Organisations screen

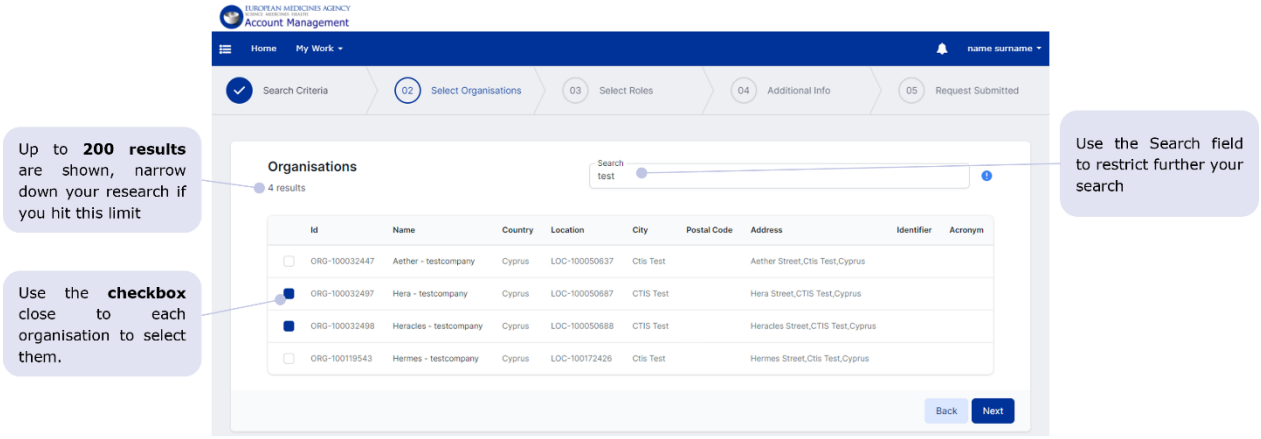


Note: all organisation names are stored in EMA Organisation Management Service (OMS) in English, if you wish to look for an organisation name in a different language you have to change the language to the related ISO code. Please note not all organisations have a local translation of their name in the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

4. 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 68 - 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.

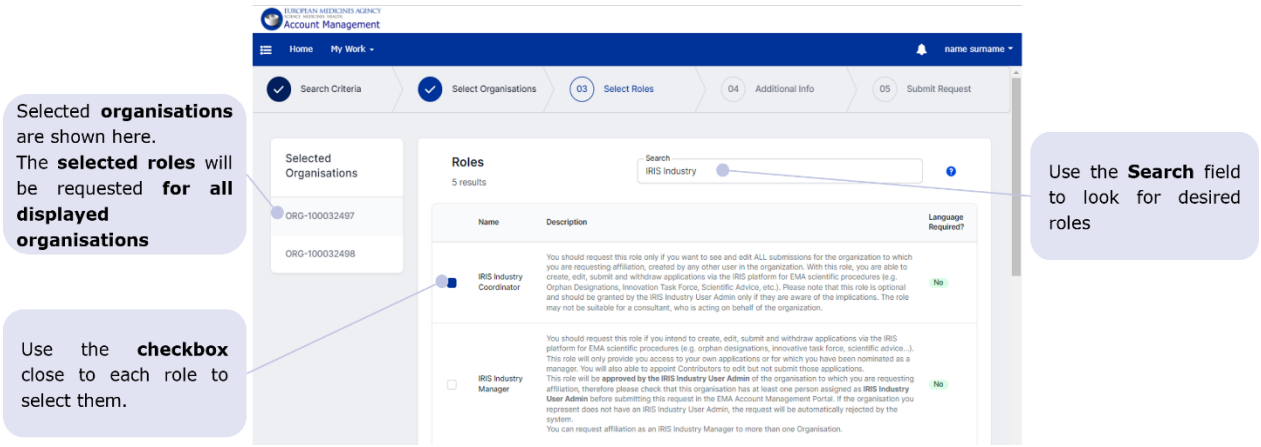
Alternatively, it is possible to request the insertion/creation of an organisation directly in the EMA Account Management portal.

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

5. 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 69 - 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-XXXXXXXXX. Your organisation must have one or more users who have been granted user admin role to approve such requests*".

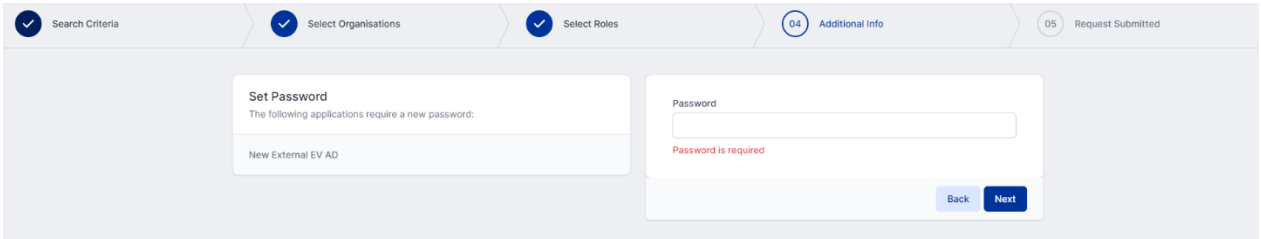
Make sure to select a User Administrator role first. A detailed explanation of the approval model can be found here.

6. 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.

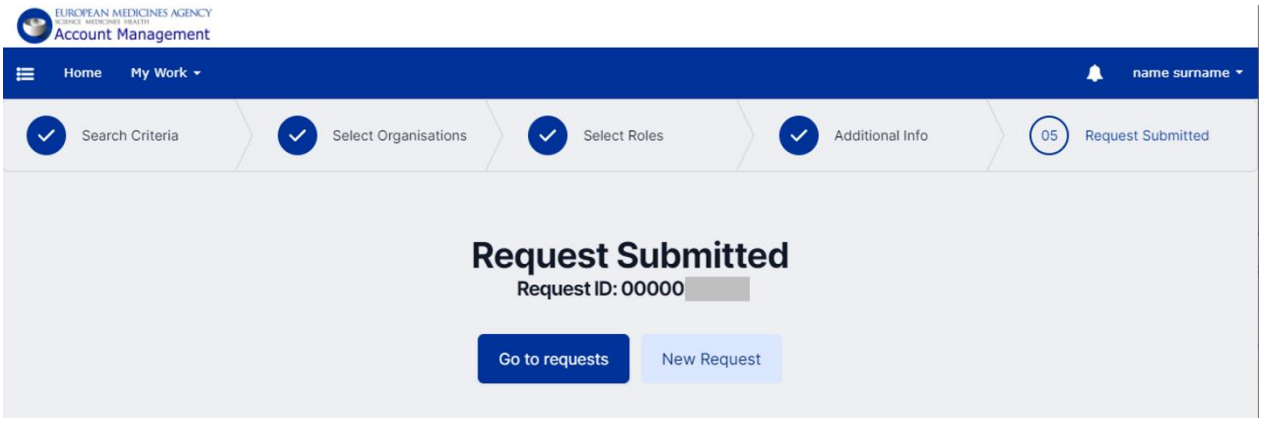
   Click "Next".

Figure 70 - Additional information window



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

Figure 71 - Request submitted window



Important note:

- 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 5.2.** above.
- All EV roles are listed and described in the **Annex 1** 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 5.6.**) 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.

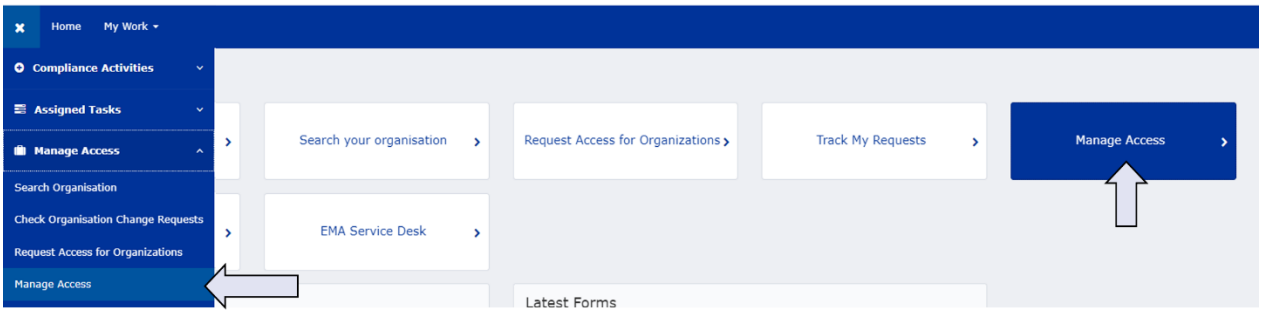
5.4. View the list of users for an organisation

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.

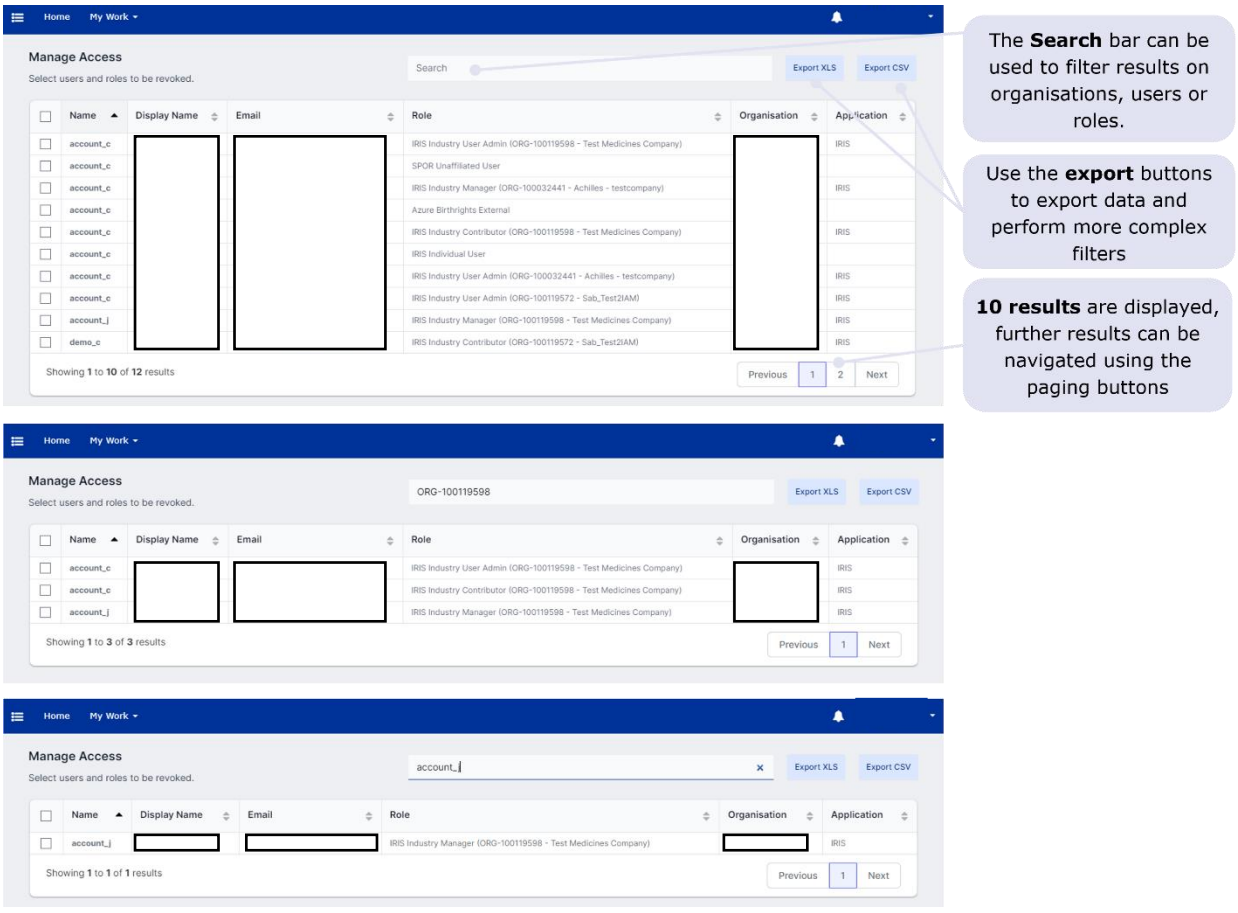
1. On the home page click on the "Manage Access" tab or, on the top left menu, select "Manage Access" and then "Manage Access".

Figure 72 - Manage Access



2. 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 73 - List of users



5.5. 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 ticket as described in **section 5.2.**

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.

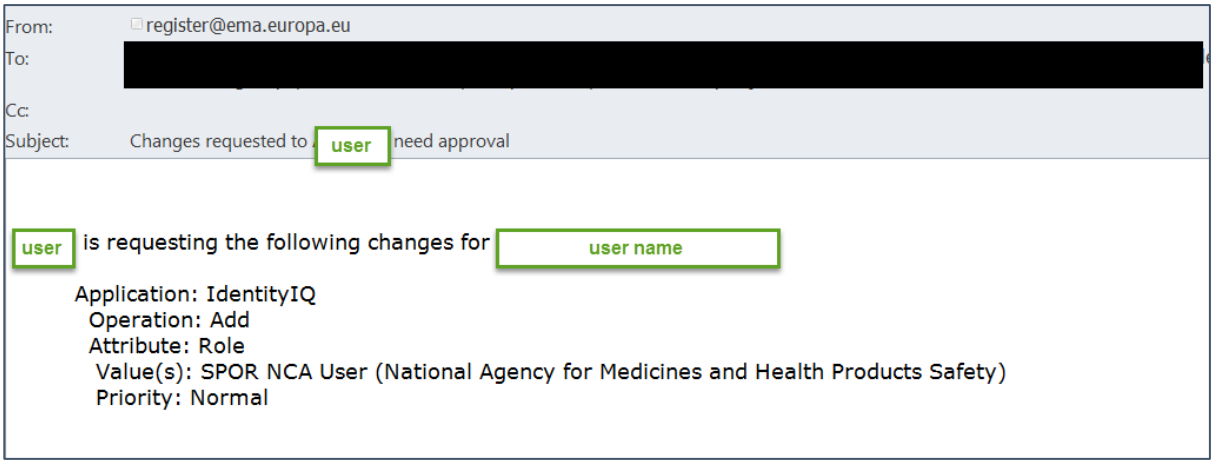
A role will be rejected if the system finds a clash (for instance, if another role for the same organisation profile is already present). It is important to first revoke all the existing active EV roles for a single user profile before requesting a new base role for that user.

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 EV base and supplementary roles for your organisation are removed before you request a new one.

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

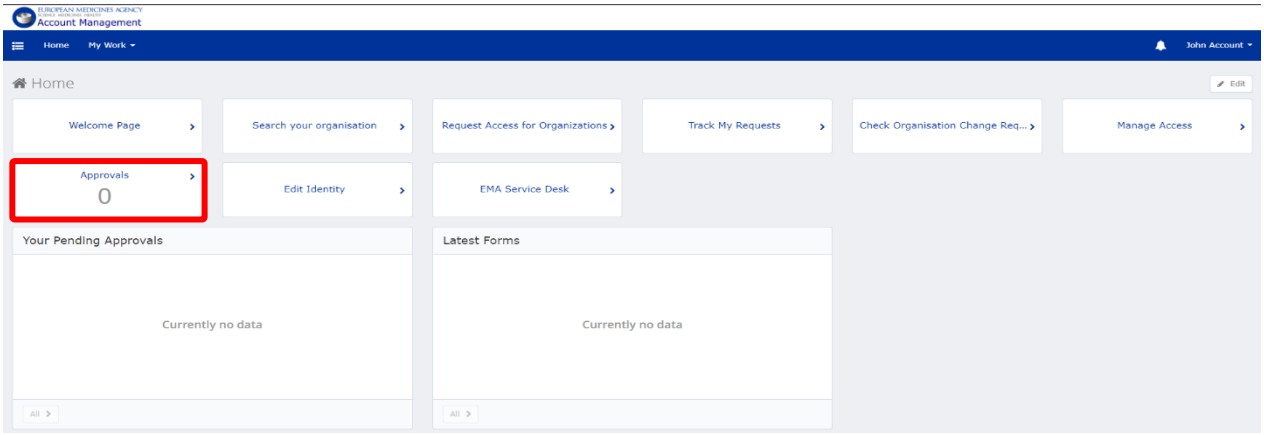
Once a request is sent for a user role, the EU QPPV/RP/TD receives an e-mail stating the name of the user, the role requested and the organisation affiliation.

Figure 74 - E-mail alert for a new EV role request



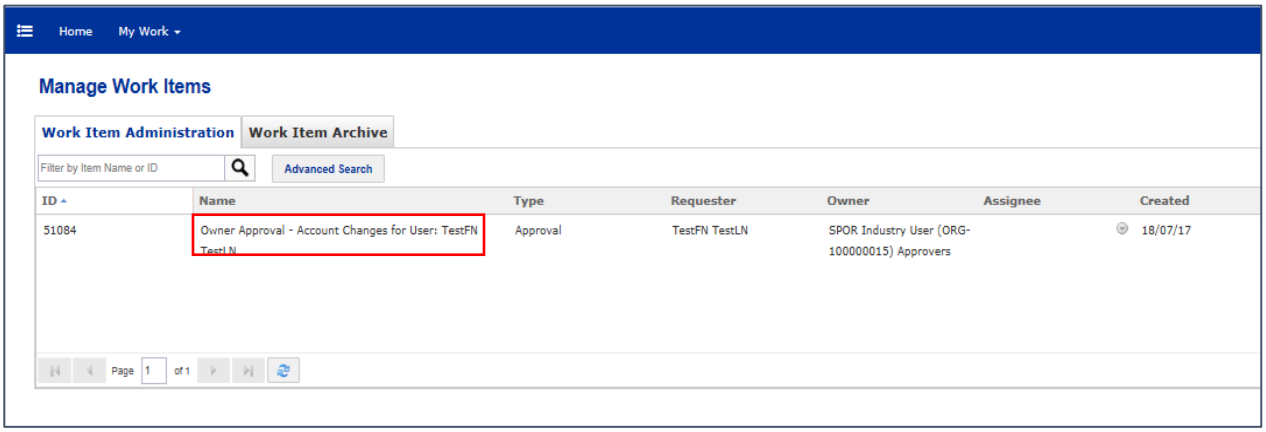
1. The EU QPPV/TD/RP needs to log in to the EMA Account Management portal.
2. The request appears in the "Approvals" tab and "Your Pending Approvals" field.

Figure 75 - EU QPPV/RP's homepage with a new access request in the inbox



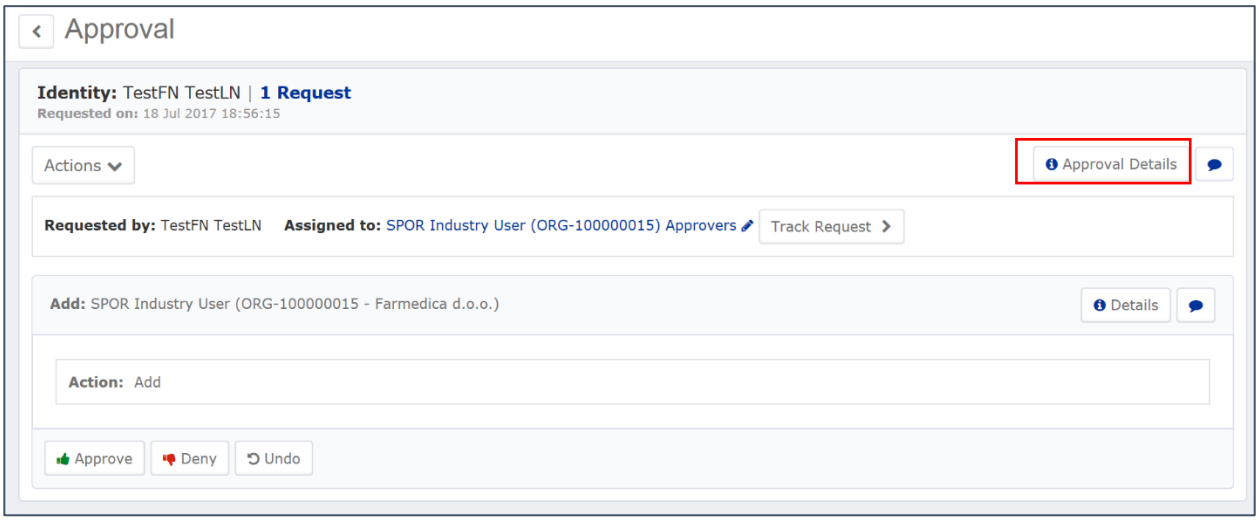
3. Click on Approvals – overview of the request appears.

Figure 76 - Request overview



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

Figure 77 - Request approval page – approval details



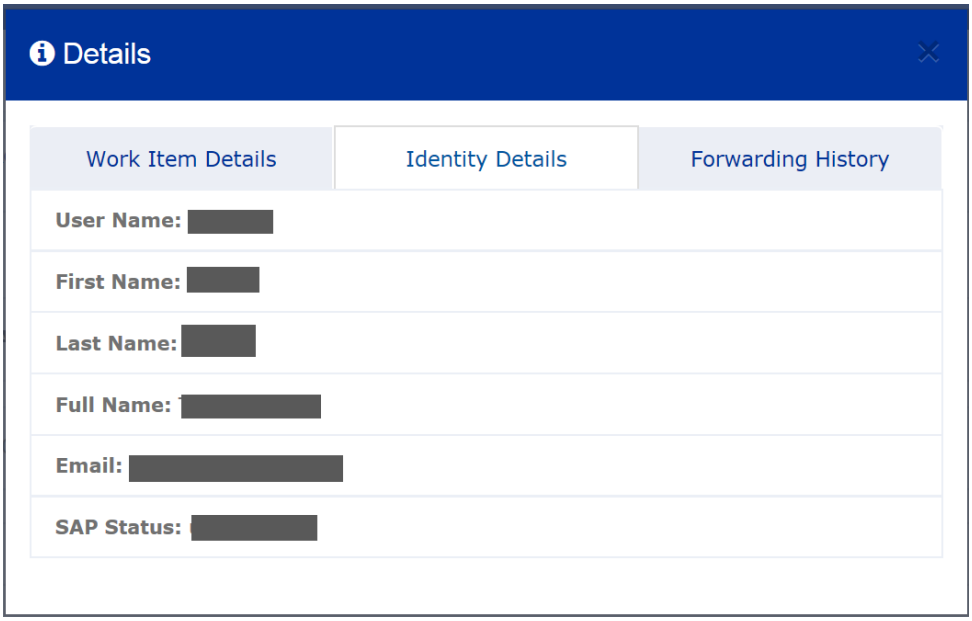
5. Click on "Approval details" – the options include:

   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 78 - View requestor's identity details

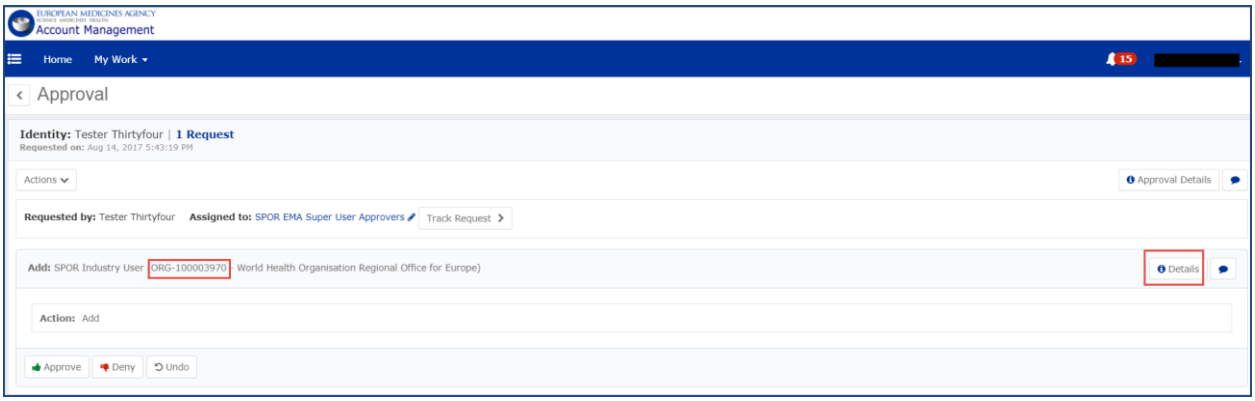


The requester's e-mail should normally be a work e-mail from the same organisation the user is requesting the EV access.

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

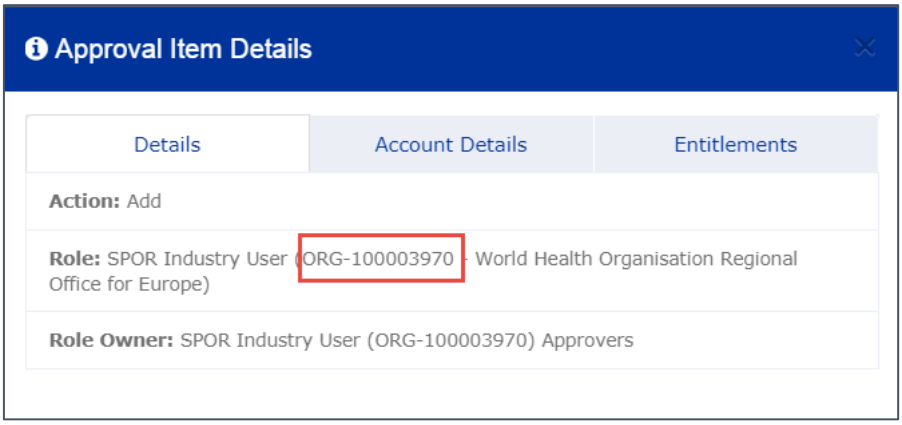
6. After checking the approval details, close the window and proceed with checking the approval item details back on the approval page.

Figure 79 - 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 80 - Approval item details



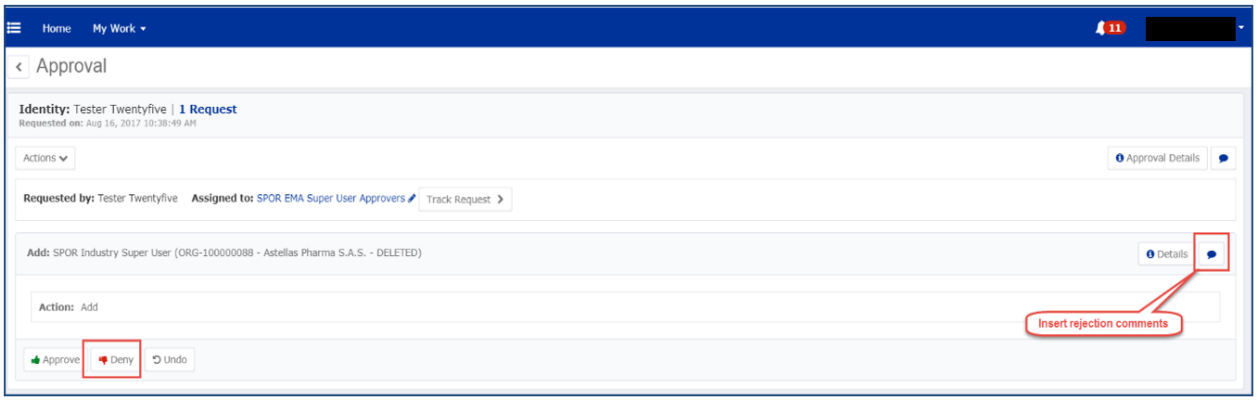
8. Go back to the approval page.

9. Select the approve 

or deny 

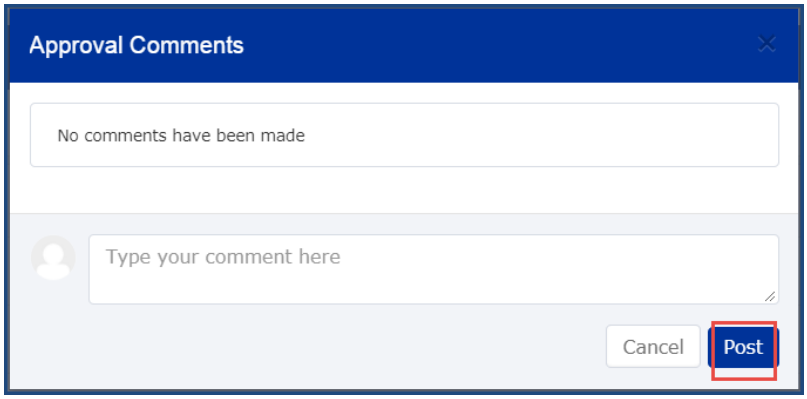
icon as appropriate. We recommend the QPPV/RP/TD inserts a comment before rejecting a role so that the user can be informed as to what the issue was and can make a modified new request if needed. You can also add a comment before approving them. Comments should be inserted BEFORE approving or rejecting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

Figure 81 - Approval item details



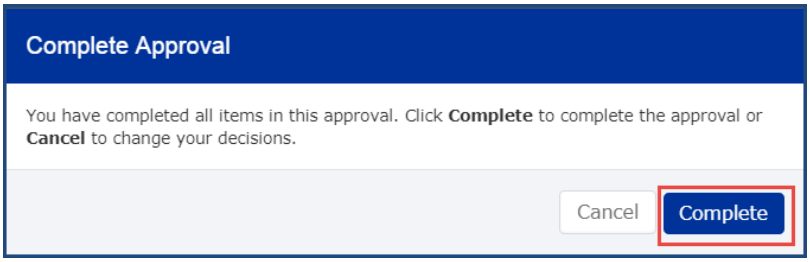
10. A pop-up window appears – enter your comments and click "post".

Figure 82 - Insert rejection comments – pop-up window



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

Figure 83 - 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).

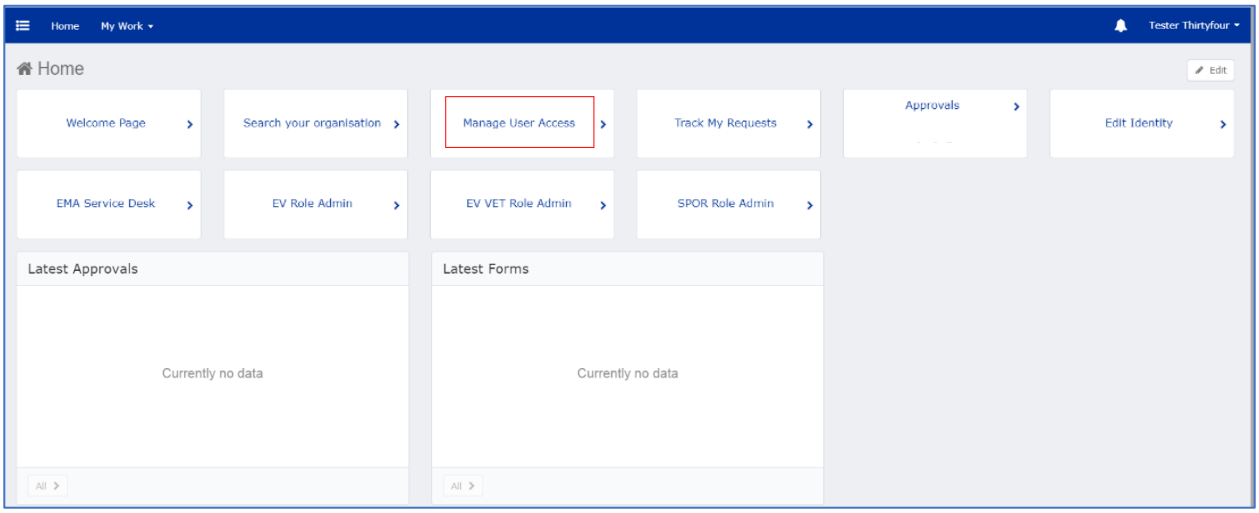
5.6. Remove/revoke user access

5.6.1. 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 5.6.2.** for details.

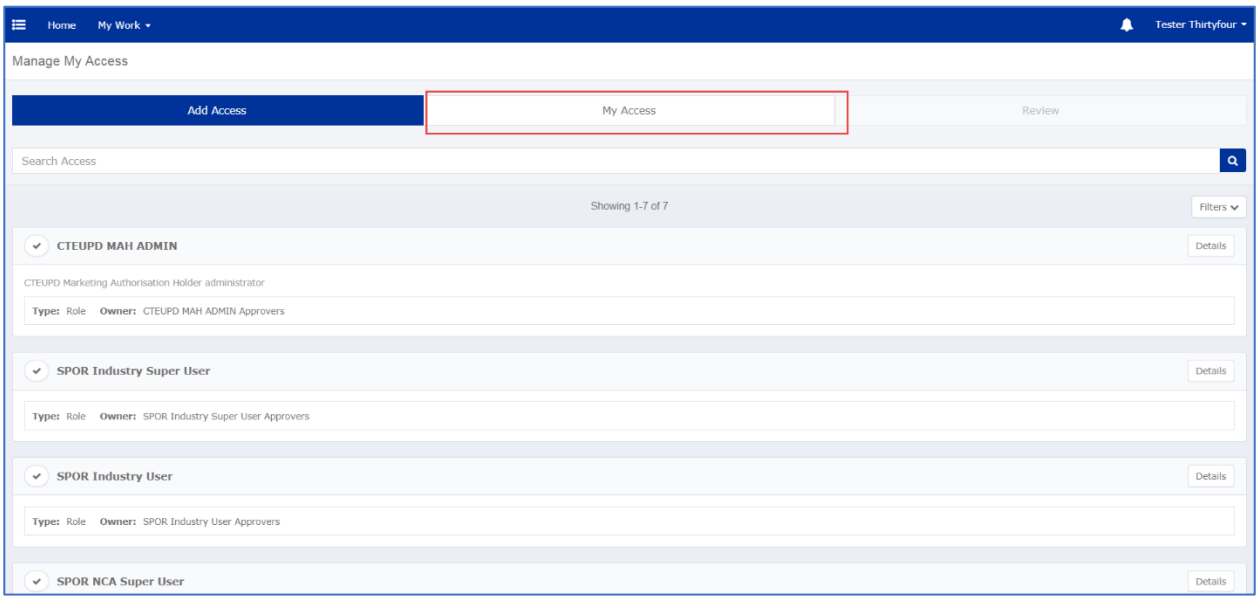
1. Go to the homepage
2. Click on "Manage my Access"

Figure 84 - Manage my access



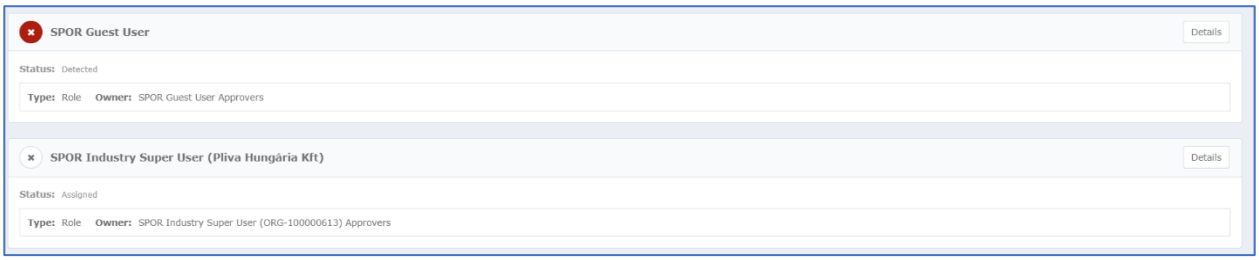
3. Go to "My Access"

Figure 85 - My access



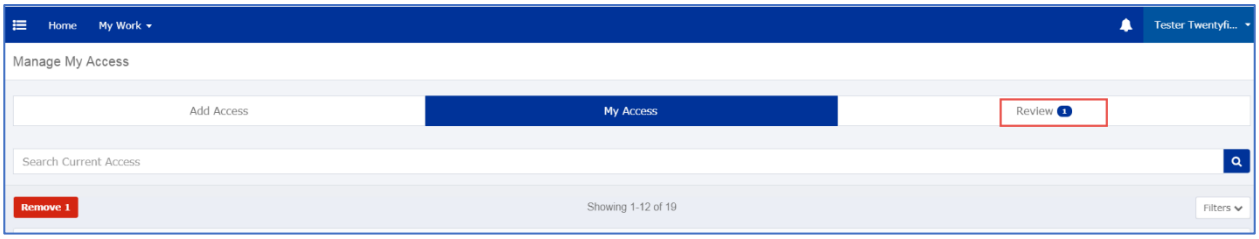
4. Select the role to be removed – click on  - it turns red.

Figure 86 - Role to be removed



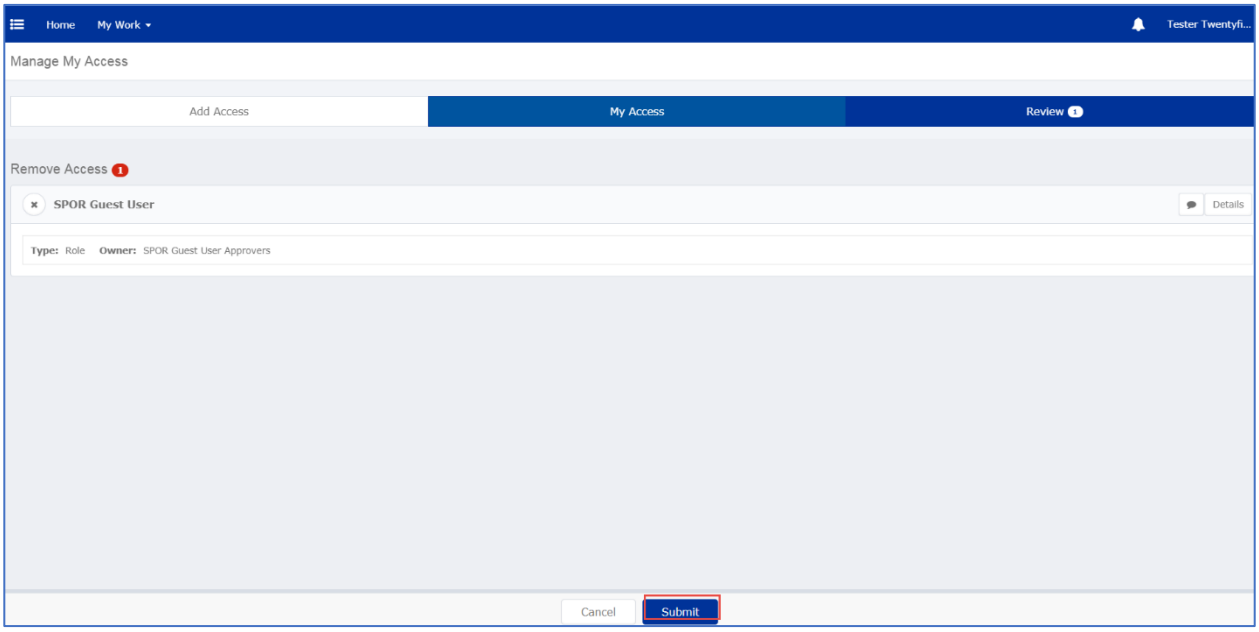
5. Scroll up the page and click "Review".

Figure 87 - Review access removal



6. Click "Submit".

Figure 88 - 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 portal, providing the removal request ID generated by EMA Account Management portal.

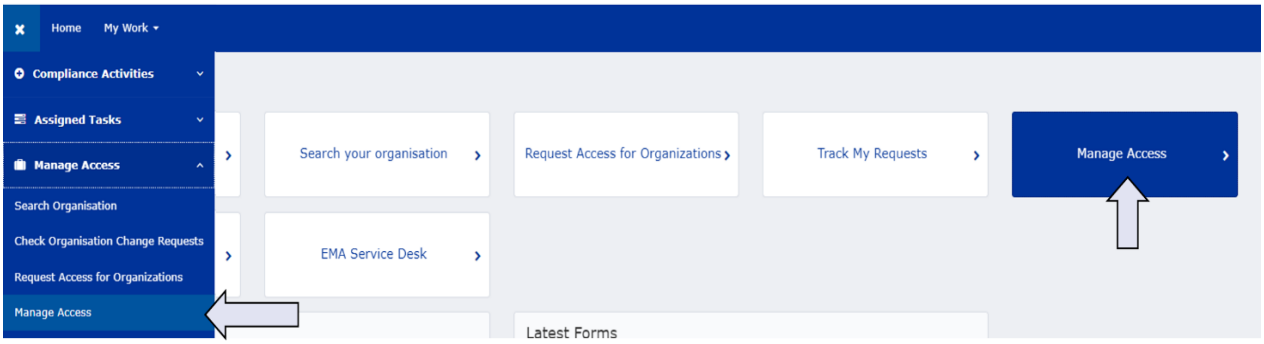
5.6.2. Revoke an EV user role by the EU QPPV/RP or Trusted Deputy

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.

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 5.6.1.** or this can be done by the EU QPPV/RP or TD of the organisation. The EU QPPV/RP/ TD should follow the steps below to remove access for a user within their organisation:

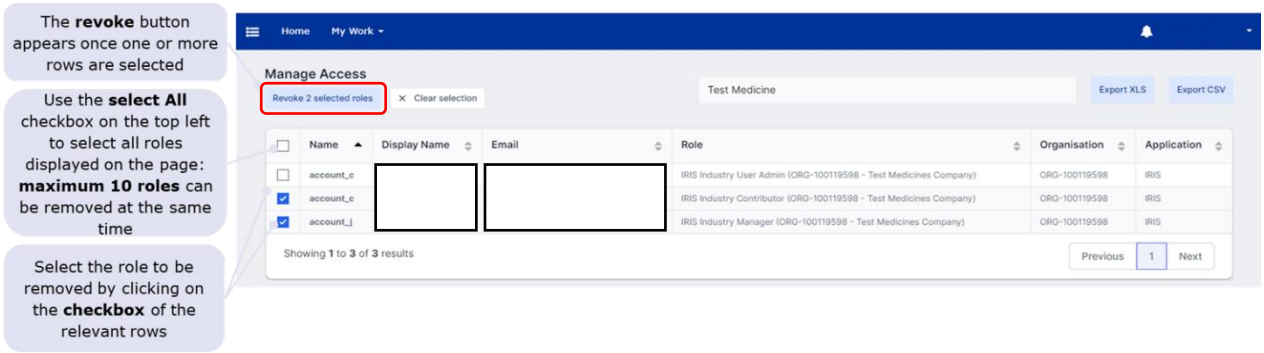
1. The EU QPPV/RP or Trusted Deputy accesses the EMA Account Management portal and does the login.
2. On the home page, clicks on the "Manage Access" tab or, on the top left menu, selects "Manage Access" and "Manage Access".

Figure 89 - Manage Access



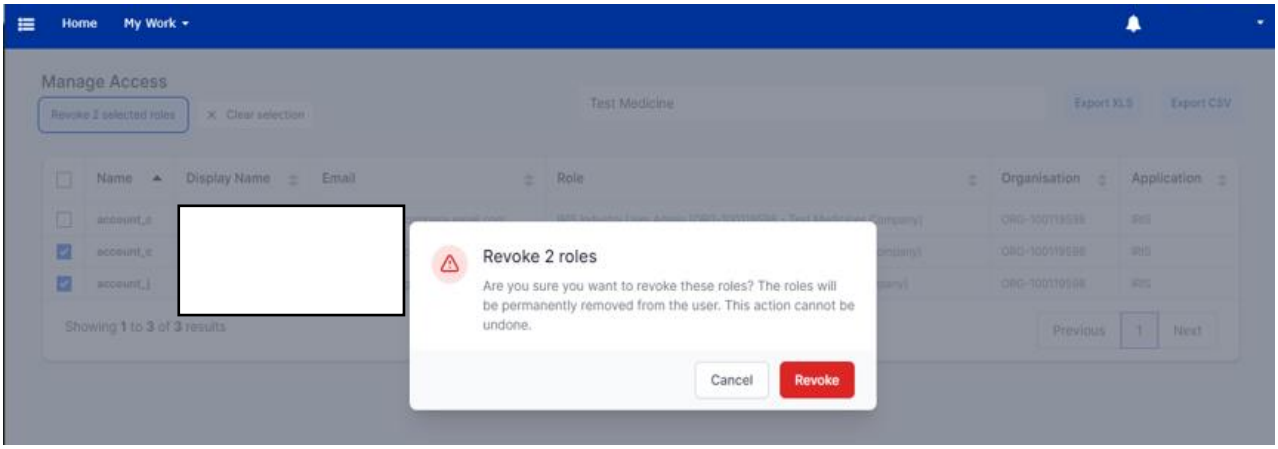
3. Selects the roles to be removed by clicking on the checkbox of the relevant row(s); once selected, the "revoke selected roles" button appears as per image below.

Figure 90 - Selection of users having their access revoked



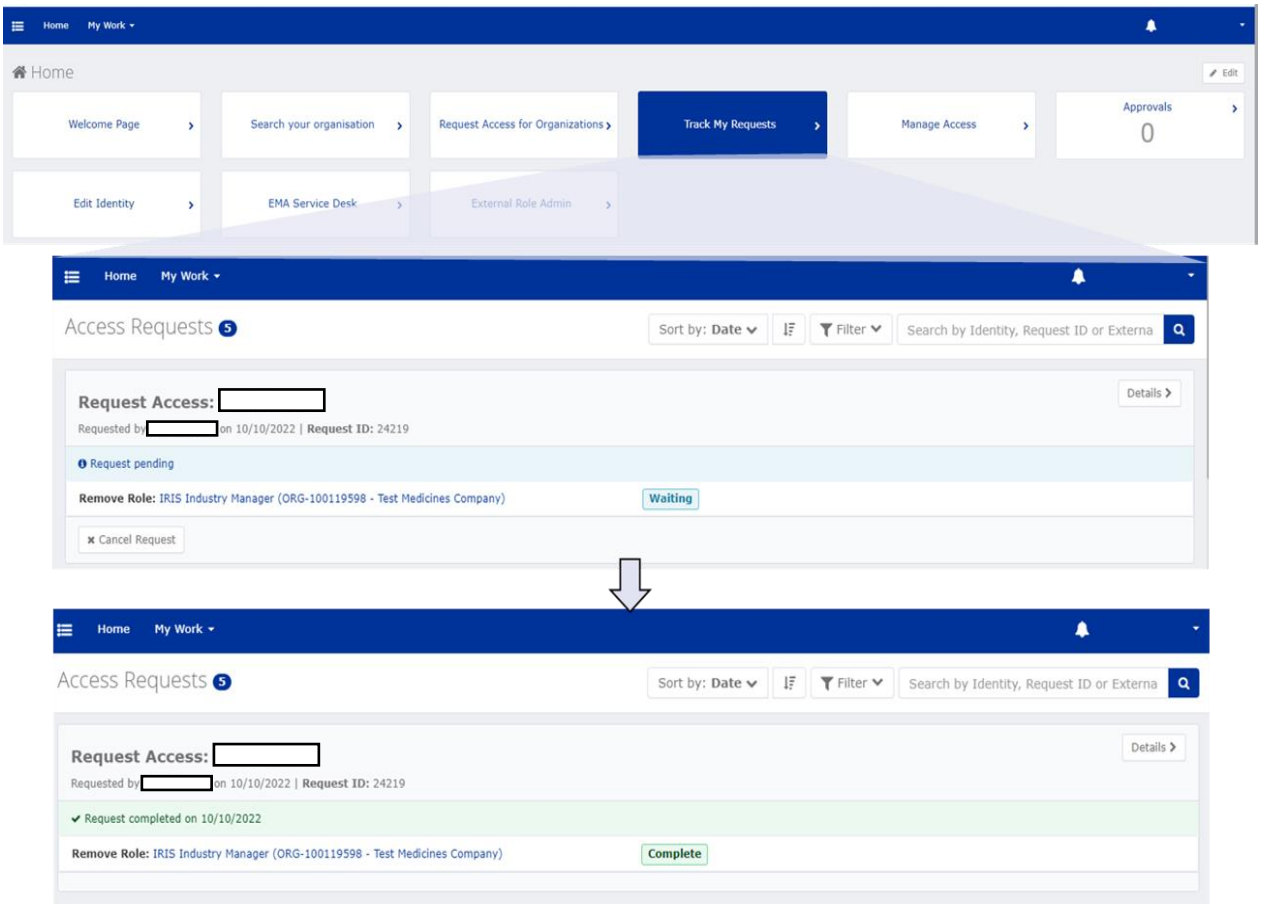
4. Once the EU QPPV/RP or Trusted Deputy clicks on the "revoke selected roles" button, a confirmation pop-up message is displayed.

Figure 91 - 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 Requests" tab.

Figure 92 - 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.

5.7. 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 registration 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).

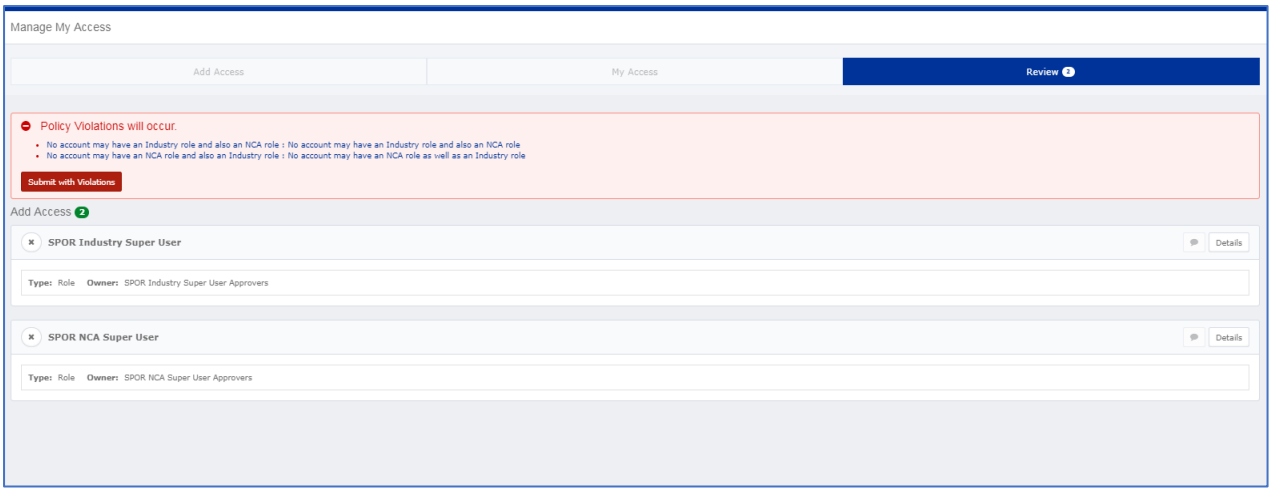
The list of possible EV roles is provided in the **Annex 1** of this manual.

5.8. 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 93** shown below.

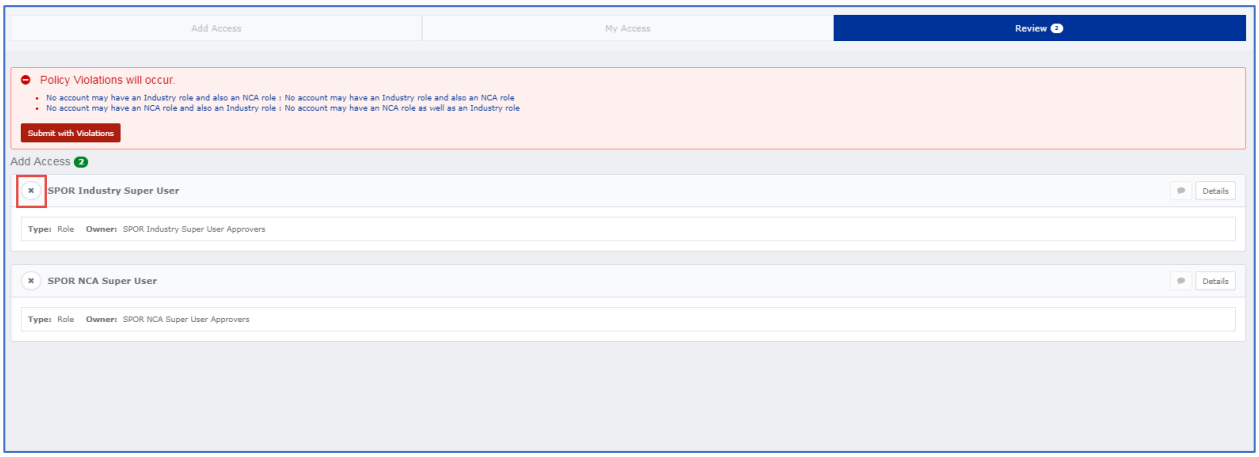
Figure 93 - Policy violation examples



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 94 - Policy violation solution – remove a role



6. EudraVigilance Organisation Management

After the registration of the EU QPV/RP, users will not be able to access to EVWEB or XEVMPD until a transmission mode is set up –see **section 6.1.** for more information on this.

Once the transmission mode is set up, the administrator user can manage your organisations hierarchy so that the EV profiles arrangement fulfils your needs. We recommend keeping profiles as clean as possible, though. If you can work with just 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 – see **section 6.2.** for more information on this.

6.1. EV restricted area and transmission mode for new organisation

The **Webtrader transmission mode for submission of ICSRs and XEVPRM reports via EVWEB is set up by default for all newly registered organisations** and it will be activated once a confirmation by the EMA Gateway support team has been received via an EMA Service Desk request that the transmission mode registration has been completed.

As for the **Gateway** set up, please go to **section 6.1.1.**

6.1.1. Gateway transmission mode set-up

If an organisation wishes to set up the Gateway transmission mode (i.e., to submit the cases to EMA directly via their pharmacovigilance database), they should follow the steps below:

1. Create an EMA 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 EV XCOMP first. In the form, please make sure that you have included the EV 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 EMA 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 EMA Service Desk request 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.
4. Gateway transmission mode will be activated after confirmation is received from the EMA that the Gateway set up has been completed. More information can be found on the EudraVigilance: how to register webpage, in the section "Required action before EudraVigilance Registration", under "Transmission mode for reporting".

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

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 affiliates 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 EudraVigilance Production system. In the EV XCOMP system only virtual affiliates can be created**.

6.2.1.1. Merge organisations (merge 2 HQs)

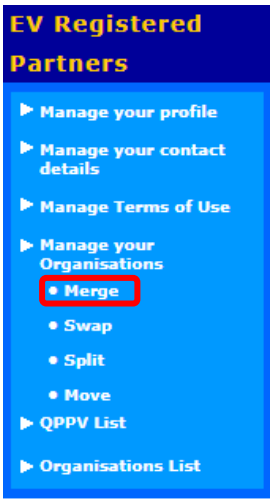
In order to merge a HQ profile for it to become an affiliate under another HQ profile, please follow the steps below.

1. Make sure that the merging organisations are fully registered, including having a EU QPPV/RP user. An organisation without a QPPV/RP has a disabled status and cannot be merged through this process.
2. The EU QPPV/RP of each organisation must log in to the Restricted Area and update the organisation details if needed.
3. Both organisations must have the same EU QPPV/RP user, this is to prevent organisations being accidently merged. If the EU QPPV/RP user cannot be the same, go to step 8.

Note: 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.

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

Figure 95 - EudraVigilance restricted area: Manage your organisations – Merge



5. 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 96 - Merge request of two organisations

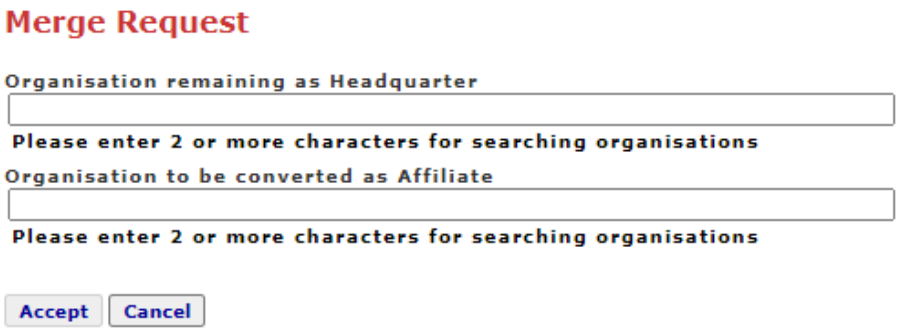


Figure 97 - Insert Merge request of two organisations

Note: In general, it is not possible to perform multiple operations for the same organisation(s) at the same time. However, it is possible to merge an organisation involved in another ongoing merge

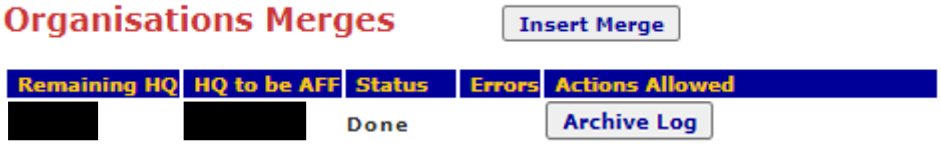
process if that organisation remains as the HQ in both the merge requests. If that's not the case, then it is not possible to carry out the second merge request (whilst the first is still ongoing).

6. 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 Request", or to delete the request by clicking on "Cancel Request".

Figure 98 - The Merge request appears with status "Pending".

7. After being processed by the system, the status of the merge request will change to "Done". Go to step 10.

Figure 99 - The Merge request appears with status "Done".



Note: After a merge request has been processed, clicking on "Archive Log" will only hide the record of that merge operation, 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.

8. If the EU QPPV/RP user cannot request the merge, a cover letter on official company headed paper, dated, and signed, should be created. The letter must be signed by the EU QPPV/RPs of all involved organisations and it should contain the following information clearly explained:
    i. The EV ORG ID of the HQ profile;
    ii. Organisation category and name of the HQ profile,
    iii. EV Org ID, organisation category and name of the new affiliate to be added to the HQ.
9. An EMA Service Desk ticket addressed to EV Registration team should be raised to request the merge attaching the signed letter.
10. The EV Registration team confirms the merge has been done.
11. End of process.

Important notes:

- The messages (XEVMPD and ICSR) are not transferred to the new HQ during and after the merge process so the new HQ will not get in its inbox a copy of the ICSRs and product messages that were sent by the now new affiliate.
- Any ICSR submitted by the affiliate EV ID will remain connected to the same organisation that submitted the case(s).
- The products submitted by the now new affiliate EV ID will be moved to the new HQ when the affiliate is moved.
- If following an organisation merger, the new subsidiary won't send any more data to EV (XEVMPD and/or ICSRs) as that/those task(s) is/are now assumed out by the new HQ organisation, the EMA still recommends that a merger of the 2 organisations is done in EV. This way, the data now being sent to EV by the HQ (on behalf of the subsidiary) will be correctly linked to the new HQ in EV.

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 through this process.
2. The QPPV/RP of each swapping organisation must log in to the Restricted Area and update the organisation details if needed.
3. Both organisations must have the same EU QPPV/RP user, this is to prevent organisations being accidently swapped. If the EU QPPV/RP cannot be the same, go to step 8.

Note: The registered Virtual Affiliates of the swapped (old) 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.

4. 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 100 - EudraVigilance restricted area: Manage your organisations – Swap

5. 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 101 - Swap request of two organisations

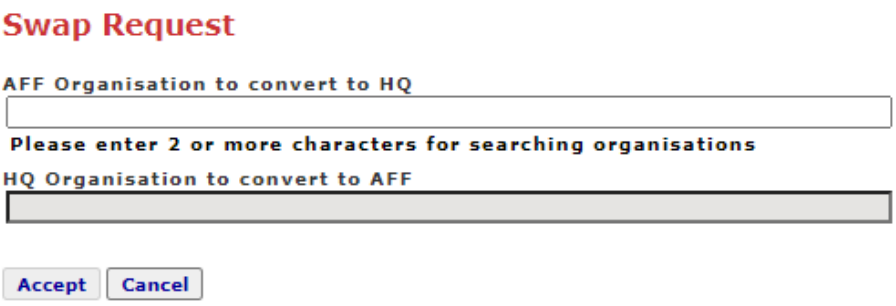
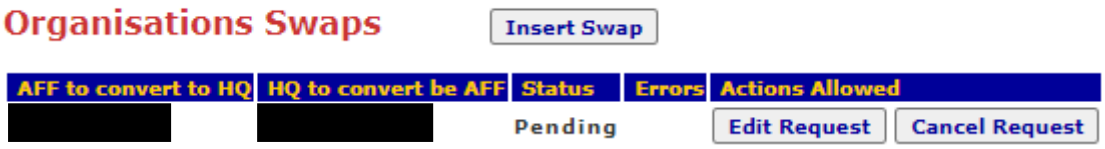


Figure 102 - Insert a Swap request of two organisations

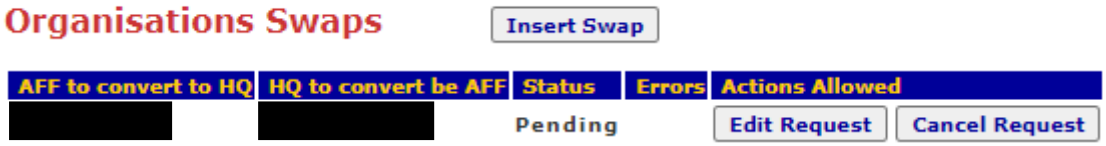


Note: It is <u>not</u> possible to perform multiple operations for the same organisation(s) at the same time.

6. The pending swap request appears with status "Pending" in the Swap area. <u>Please note that the swap operations are executed on a weekly basis, every Friday night</u>. While the swap

request is pending, it is possible to make changes to it by clicking on "Edit Request", or to delete the request by clicking on "Cancel Request".

Figure 103 - The Swap request appears with status "Pending".



7. After being processed by the system, the status of the swap request will change to "Done". Go to step 10.

Figure 104 - The Swap request appears with status "Done".

Note: After a swap request has been processed, clicking on "Archive Log" will only hide the record of that swap operation, 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.

8. If the EU QPPV/RP user or Trusted Deputy cannot request the swap, a cover letter on official company headed paper, dated and signed, should be created. The letter must be signed by the QPPV/RPs of all involved organisations and it should contain the following information clearly explained:
    i. The EV Org ID of the HQ that is going to become an Affiliate;
    ii. The EV Org ID of the Affiliate that is going to become the new HQ profile.
9. An EMA Service Desk ticket addressed to EV Registration team should be raised to request the merge attaching the signed letter.
10. The EV Registration team confirms the swap has been done.
11. End of process.

Important notes:

- The messages (XEVMPD and ICSR) are not transferred to the new HQ during and after the merge process so the new HQ will NOT get in its inbox a copy of the ICSRs and product messages that were sent by the now new affiliate.
- Any ICSR submitted by the affiliate EV ID will remain connected to the same organisation that submitted the case(s).

- The products submitted by the now new affiliate EV ID will be moved to the new HQ when the affiliate is moved.

6.2.1.3. Split organisations (split an affiliate so that it becomes a new HQ)

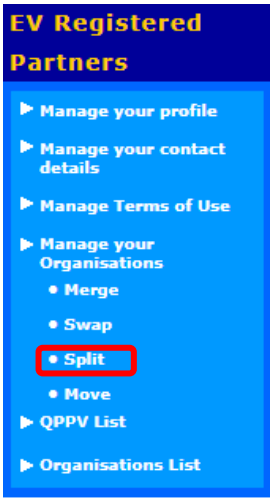
In order to split an affiliate that is already registered under a HQ profile to become a new, independent, HQ profile, please follow the steps below:

1. Make sure that the splitting organisations are fully registered, including having a EU QPPV/RP user. An organisation without a QPPV/RP has a disabled status and cannot be split through this process.
2. The QPPV/RP of each organisation must log in to the Restricted Area and update the organisation details if needed.
3. Both organisations must have the same EU QPPV/RP user, this is to prevent organisations being accidently split. If the EU QPPV/RP cannot be the same, go to step 7.

Note: All registered Virtual Affiliates of the split Affiliate profile will remain with the same profile. Users with EV Contributor role to the Virtual Affiliates associated with the previous Affiliate profile will not need to re-request the contributor role for the new HQ organisation.

4. The EU 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 "Split".

Figure 105 - EudraVigilance restricted area: Manage your organisations – Split



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

Figure 106 - Split request of two organisations

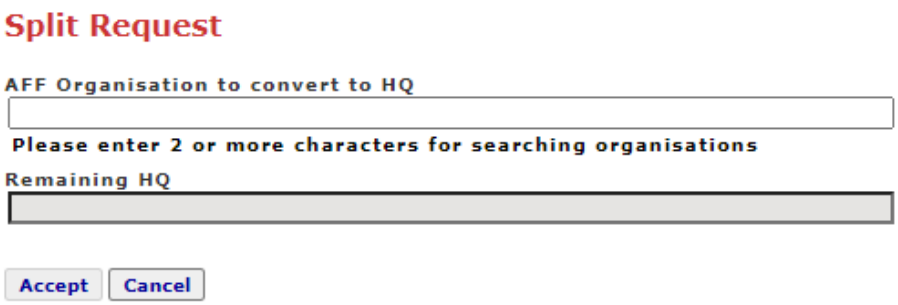


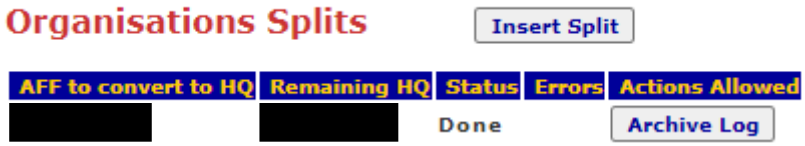
Figure 107 - Insert a new Split request of two organisations

Note: It is not possible to perform multiple operations for the same organisation(s) at the same time.

6. The split request is immediately processed by the system and automatically reflected in EV. The split request will have the status "Done". Go to step 10.

Note: After a split request has been processed, clicking on "Archive Log" will only hide the record of that split operation, meaning that the split itself won't be reverted; the record will be marked as "disabled" and it will be filtered from the split log history.

Figure 108 - The Split request appears with status "Done".



7. If the EU QPPV/RP user or Trusted Deputy of the HQ cannot request the split, a cover letter on official company headed paper, dated and signed, should be created. The letter must be signed by the EU QPPV/RP of the HQ organisation and it should contain the following information clearly explained:
    i. The EV ORG ID of the HQ from which the affiliate is going to be split;
    ii. The EV ORG ID of the Affiliate to be split (and converted into a new HQ).
8. An EMA Service Desk ticket addressed to EV Registration team should be raised to request the merge attaching the signed letter.
9. The EV Registration team confirms that the split has been done.

10. End of process.

Important notes:

- Any ICSR data submitted by the affiliate EV ID will remain connected to the same organisation that submitted the case(s).
- The products submitted by the affiliate EV ID will NOT be moved to the new HQ when the affiliate is moved, as the XEVMPD data will still be owned by the previous HQ.
- The products submitted by the HQ's ID will need to be transferred from the former HQ's profile to the new HQ's profile when the affiliate becomes a stand-alone HQ organisation. To do so, after the split you will need to raise a EMA Service Desk request addressed to the XEVMPD team requesting the transfer of XEVMPD ownership of Authorised Medicinal Products (AMPs) in the Article 57 database. Clearly state the following on your request:

    i. The number of AMPs for which the ownership should be changed;

    ii. The list of EV Codes (in Excel file if more than 10) for which the ownership should be changed;

    iii. The new HQ EV organisation ID to which the EV Codes should be assigned;

    iv. The new QPPV Code that should be referenced in the AMPs;

    v. The new PSMFL EV Code that should be referenced in the AMPs.

    Please refer to the document Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004 for information how to submit a PSMFL entity in the XEVMPD.

    Please note that it is important for the EU QPPV to be registered under the new HQ organisation profile and for the Master File Location (MFL) entity to be submitted in the XEVMPD under the new HQ organisation profile, even if conceptually they do not change (e.g.: same person remains the QPPV or the PSMF remains in the same location as before). The system will not accept the QPPV/MFL information associated with the previous organisation, as the product data ownership changes and products, MFL entity and the EU QPPV need to have the same owner HQ.

    Once the transfer of XEVMPD ownership was performed, the EV Codes will appear in EVWEB under the ID of the new HQ organisation. This means that this organisation will be able to maintain these AMPs (e.g. update, nullify, invalidate) by submitting an XEVPRM with the relevant operation type assigned to the AMPs.

6.2.1.4. Move organisations (move affiliates from one HQ to another HQ)

In order to move an affiliate that is already registered under an HQ (HQ1) - profile to sit as affiliate of a new/existing HQ profile – HQ2 -, please follow the steps below:

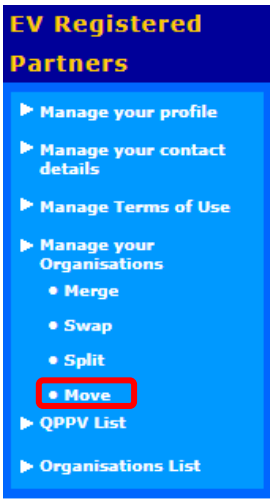
1. Make sure that both organisations are fully registered, including having a EU QPPV/RP user. An organisation without a QPPV/RP has a disabled status and cannot be moved through this process.
2. The EU QPPV/RP of each organisation must log in to the Restricted Area and update the organisation details if needed.

3. Both organisations must have the same EU QPPV/RP user. This is to prevent organisations being accidently moved. If the EU QPPV/RP is not the same (or cannot be the same), go to step 7.

Note: The registered Virtual Affiliates of the moved Affiliated profile will remain linked to the same profile. Users with EV Contributor role to the Virtual Affiliates associated with the affiliate profile will NOT need to re-request the contributor role for the moved affiliate organisation.

4. The EU QPPV/RP of the organisations accesses the Restricted Area and under "EV Registered Partners", clicks on "Manage your Organisations" and then on "Move".

Figure 109 - EudraVigilance restricted area: Manage your organisations – Move



5. If no move was yet requested, a new screen appears: the two organisations (the legal affiliate to be moved and the target HQ (HQ2)) should be selected accordingly in the corresponding fields; click on" Accept", followed by" Ok" and the move is done. If, on the other hand, previous moves were already requested, in order to insert a new move, the QPPV/RP clicks on" Insert Move" and then selects the two organisations.

Figure 110 - Move request

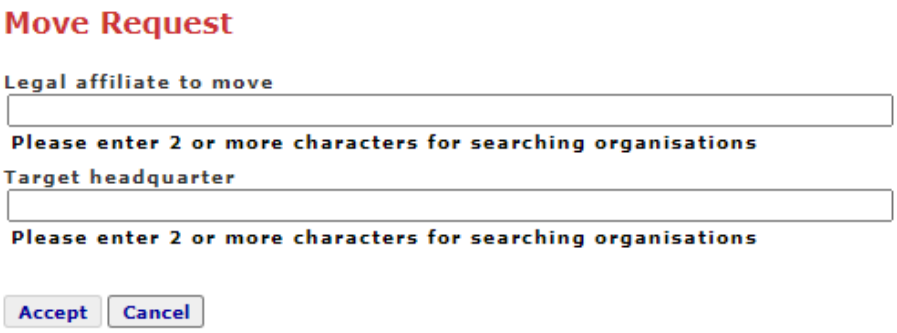


Figure 111 - Insert Move request of two organisations

Note: It is not possible to perform multiple operations for the same organisation(s) at the same time.

6. The move request is immediately processed by the system and automatically reflected in EV. The move request will have the status "Done". Go to step 10.

Note: After a move request has been processed, clicking on "Archive Log" will only hide the record of that move operation, meaning that the swap itself won't be reverted; the record will be marked as "disabled" and it will be filtered from the move log history.

Figure 112 - The Move request appears with status "Done".

7. If the EU QPPV/RP user or Trusted Deputy of the HQ cannot request the move, a cover letter on official company headed paper, dated and signed, should be created. The letter must be signed by the EU QPPV/RP all the involved organisations and it should contain the following information clearly explained:
    i. The EV ORG ID of the HQ1 from which the affiliate is being moved;
    ii. The EV ORG ID of the Affiliate that is going to be moved from HQ1 to HQ2;
    iii. The EV ORG ID of the HQ2 to which the affiliate needs to be moved to.
8. An EMA Service Desk ticket addressed to EV Registration team should be raised to request the move attaching the signed letter.
9. The EV Registration team confirms the move has been done.
10. End of process.

Important notes:

- Any ICSR submitted by the affiliate EV ID will remain connected to the same organisation that submitted the case(s).
- The products submitted by the affiliate EV ID will NOT be moved to the new HQ when the affiliate is moved, as the XEVMPD data will still be owned by the previous HQ.
- The products submitted by the now new HQ's ID will need to be transferred from the former/old HQ's profile to the new HQ's profile when the affiliate is moved. To do so, after the

move you will need to raise a EMA Service Desk request addressed to the XEVMPD team requesting the transfer of XEVMPD ownership of Authorised Medicinal Products (AMPs) in the Article 57 database. Clearly state the following on your request:

i. The number of AMPs for which the ownership should be changed;

ii. The list of EV Codes (in Excel file if more than 10) for which the ownership should be changed;

iii. The new HQ EV organisation ID to which the EV Codes should be assigned;

iv. The new QPPV Code that should be referenced in the AMPs;

v. The new PSMFL EV Code that should be referenced in the AMPs.

Please refer to the document Detailed guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57(2) of Regulation (EC) No. 726/2004 for information how to submit a PSMFL entity in the XEVMPD.

Please note that it is important for the EU QPPV to be registered under the new HQ organisation profile and for the Master File Location (MFL) entity to be submitted in the XEVMPD under the new HQ organisation profile, even if conceptually they do not change (e.g.: same person remains the QPPV or the PSMF remains in the same location as before). The system will not accept the QPPV/MFL information associated with the previous organisation, as the product data ownership changes and products, MFL entity and the EU QPPV need to have the same owner HQ.

Once the transfer of XEVMPD ownership was performed, the EV Codes will appear in EVWEB under the ID of the new HQ organisation. This means that this organisation will be able to maintain these AMPs (e.g. update, nullify, invalidate) by submitting an XEVPRM with the relevant operation type assigned to the AMPs.

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.

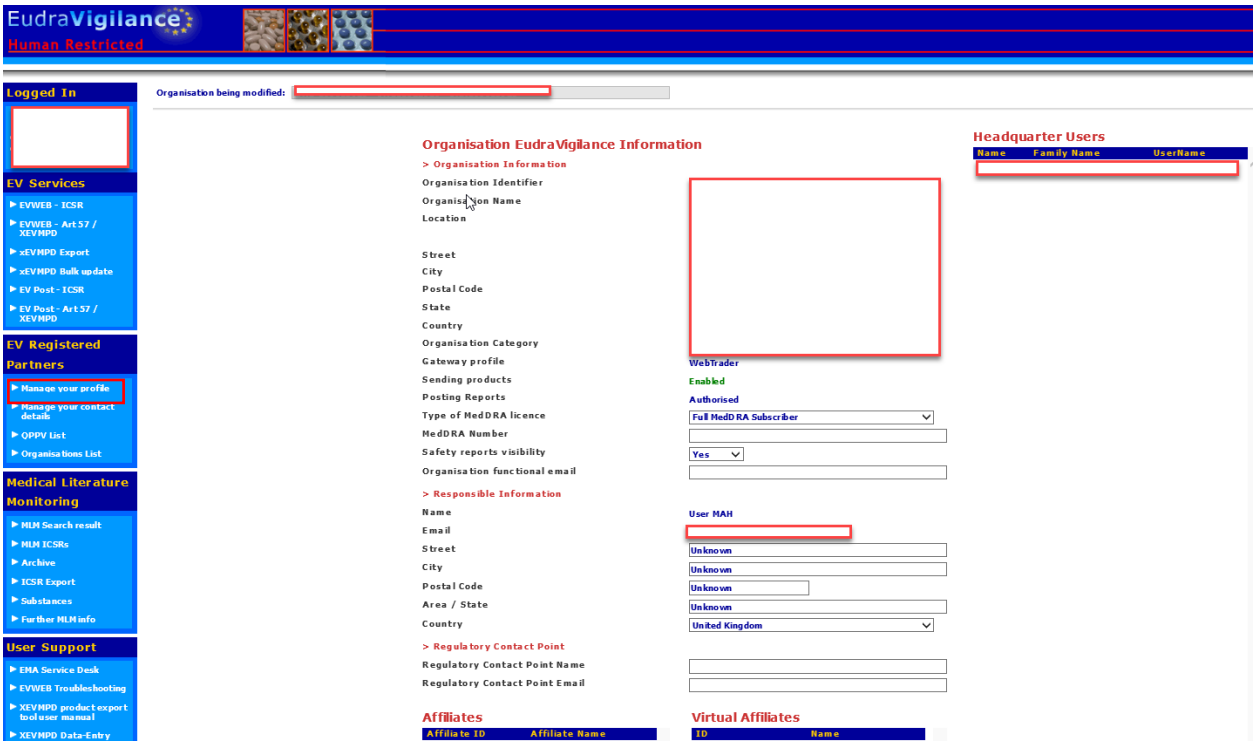
d. A MAH has more than one PV system and needs them to be manged by different users/profiles

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.

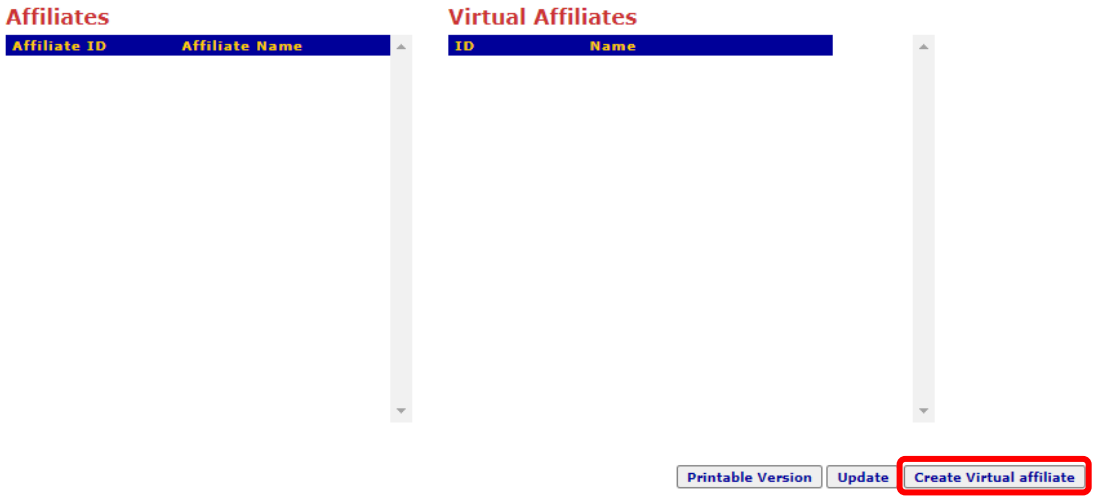
1. EU QPPV/RP/TD logs into EV Human Production and selects “Manage my Profile” from the left-hand side column.

Figure 113 - Access your Restricted area view



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

Figure 114 - 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".

Note: By default, the QPPV/RP of the HQ organisation will also automatically be assigned as the "Virtual Affiliate Responsible". It is not possible to assign this "role" to a user other than the QPPV/RP.

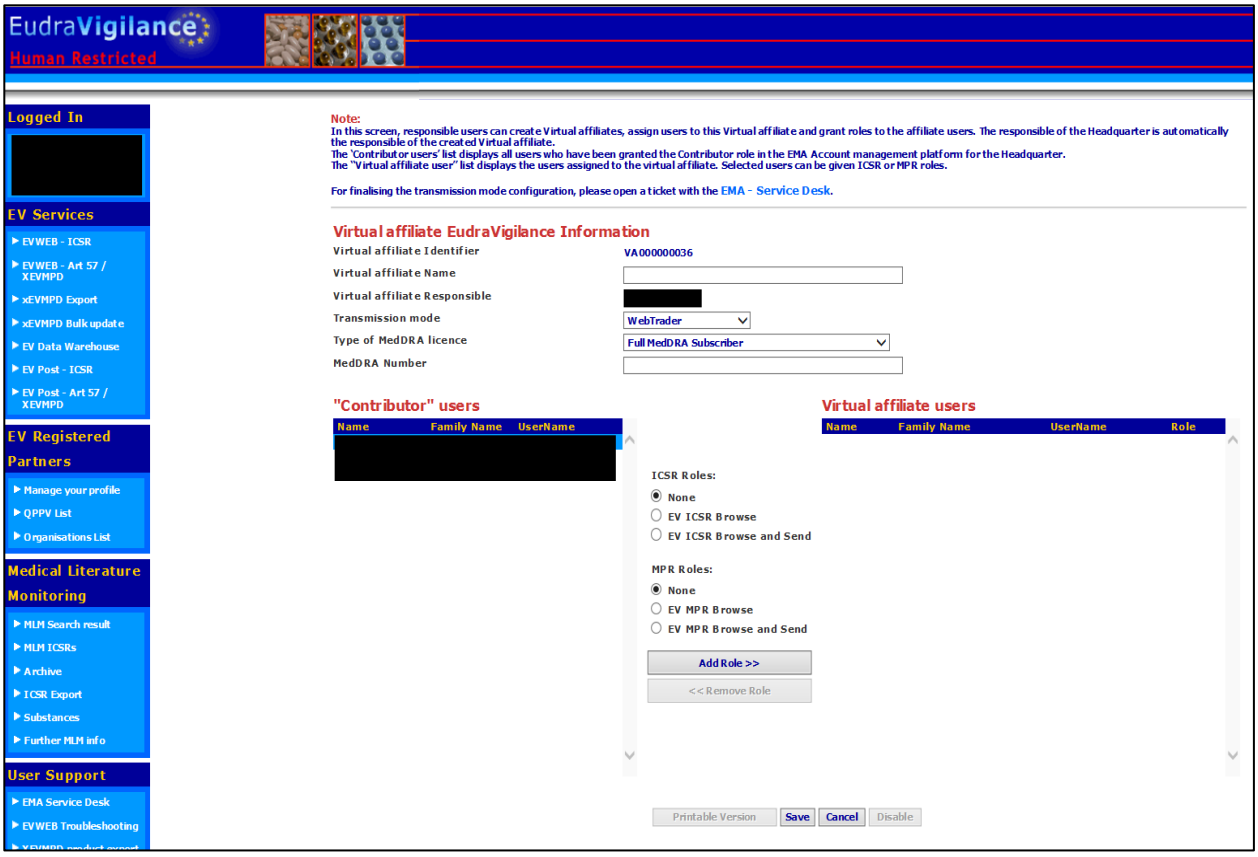
6. Set up the transmission mode/gateway profile – organisations will show as "Not registered" by default. ICSR reports and XEVMPD messages cannot be sent using EVWEB until a Gateway profile has been registered. A Service Desk request should be raised addressed to EMA Gateway support team, quoting the 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 webpage EudraVigilance: how to register section "Transmission Mode for reporting", under "Required actions before EudraVigilance registration".

7. Once all information is added, click "Save".

Figure 115 - 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 5.6.2.**) 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 (VA) profile, please note the following scenarios:

1. You are a **user registered in the HQ profile** – you do not need to request any further role. The EU QPPV/RP will have you in the "Contributor users" list of the Virtual Affiliate EV profile and can manually add a role for you for a specific VA profile.
2. You are **not registered in the HQ profile and need Virtual Access** – please follow the steps described in **section 5.3.** to request the "**EV Contributor**" role to the HQ profile. Once this role is approved by the EU QPPV/RP/TD, you will be added to the "Contributor users" list of the virtual affiliate(s) profile and then the EU QPPV/RP will be able to add a role for you for a specific VA profile.

6.2.3. Manage OMS deprecated organisations / organisation mergers

If an organisation becomes deprecated in OMS, you'll need to liaise with the EMA's OMS team to understand what the issue is and what specific actions are required from your end. Thus, please raise an EMA Service Desk ticket to our OMS team.

Please note that if your organisation becomes disabled in OMS, you'll temporarily lose access to EudraVigilance and, therefore, you'll not be able access EVWEB to send cases to EV (including via EVPOST or Gateway connection).

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 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 EU QPPV/RP should log in to EMA Account Management portal and remove/revoke all users roles for the organisation to be disabled and request the removal of their own EU QPPV/RP role – see **section 5.6.**
4. Raise a EMA Service Desk ticket addressed to EV Registration team to request the organisation to be disabled in EV with the EU QPPV/RP role removal request ID and ORG ID of the organisation to be disabled. A confirmation will be received by EV Registration team that the organisation(s) have been disabled.
5. The EU 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:

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. 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 EU QPPV/RP should log in to EMA Account Management portal and remove/revoke all users roles for the organisation to be disabled and request the removal of their own EU QPPV/RP role – see **section 5.6.**
4. Raise a EMA Service Desk ticket addressed to EV Registration team to request the organisation to be disabled in EV with the EU QPPV/RP role removal request ID and ORG ID of the organisation to be disabled. A confirmation will be received by EV Registration team that the organisation(s) have been disabled.

6.3.2. Disable a Virtual affiliate

In order to disable a Virtual Affiliate (VA), please follow the steps below.

1. If the virtual affiliate has a transmission mode set up (either Webtrader or Gateway) an EMA Service Desk ticket to request that the VA is disconnected on the EMA Gateway should be raised. Please provide the EudraVigilance organisation ID for each profile to be disconnected;
2. The QPPV/RP/TD should log into the EudraVigilance Restricted Area for the HQ profile concerned;
3. Open the virtual affiliate concerned from the list at the bottom of the manage organisation profile page;
4. Remove access for all the users from the virtual affiliate and press the save button to update the system;

5. Re-open the virtual affiliate concerned from the list at the bottom of the manage organisation profile page;
6. 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 Article 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.**

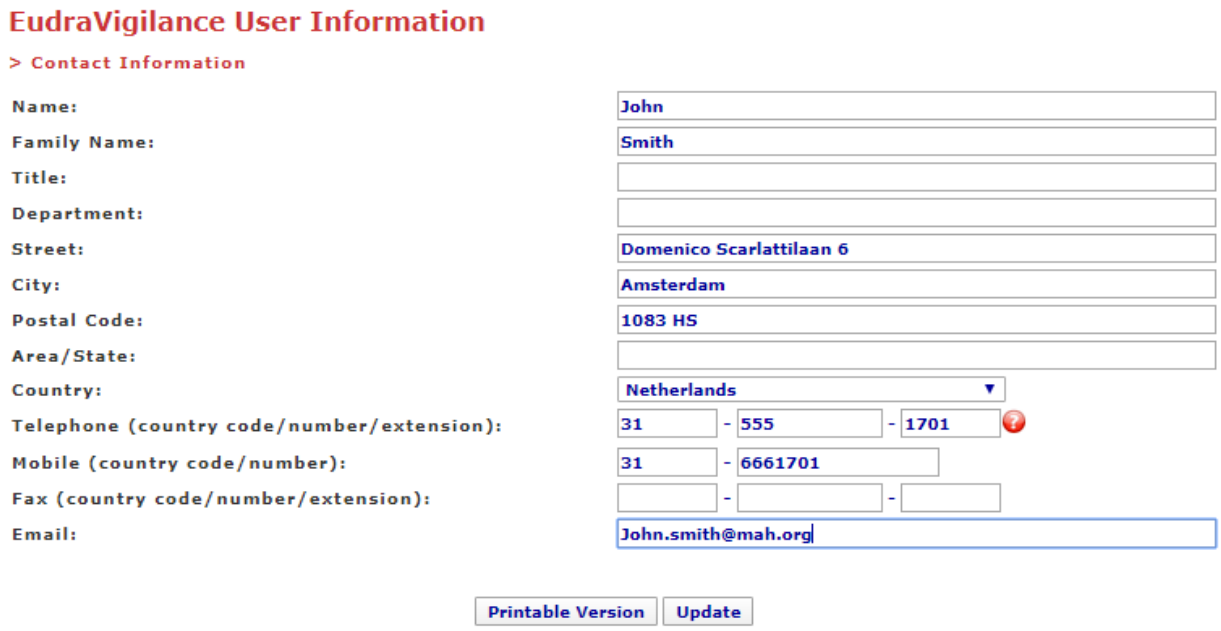
For QPPV users the update of this contact information will immediately affect all the associated authorised medicinal products linked to their organisation profile (QPPV code).

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 116 - Manage your contact details

Figure 117 - Review of contact details



Important note: The user must do the following changes to allow the update of the information:

- Country field is mandatory

- In mobile phone it is mandatory to write only numbers without the "+" sign

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 Account Management portal (or 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 EudraVigilance EV XCOMP (test environment) – see **section 7.1.** for more information on how to register with EV XCOMP.

As for **Pharmacovigilance IT system vendors** which are **not** permitted to be registered in the EudraVigilance Production system, please go to **section 7.4.**

Important note:

- The newly created EV XCOMP Organisation ID now follows a similar format to the Production system by using the same numerical digits of the OMS organisation ID and the prefix "**ORX"** rather than "**ORG"** that is used in the Production system.
- **Legacy XCOMP Gateway profiles** (i.e. those that already have a XCOMP organisation ID that does not have the format with the prefix "ORX" 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 profiles** (including those that use the EV POST function), can no longer be used and users registered under those legacy profiles will no longer be able to access the EVWEB ICSR, XEVMPD applications and the XCOMP restricted area. The XCOMP profiles will need to be re-registered under a new XCOMP organisation ID, which is generated automatically for each Production HQ organisation profile. To be able to use XCOMP again, users will also need to re-register for the new XCOMP profile.

For existing organisations to continue to have access to the XCOMP Restricted Area, please follow the steps below:

1. The EU QPPV/RP must change their password via the EMA Account Management portal first – see **section 2.3.**
2. The EU QPPV/RP should then access the EV XCOMP restricted area using the same login details that they use for EV Production and complete the organisation details as per described in **section 4.1.** of this manual. This will activate the new XCOMP profile within the registration system.

7.1. EV XCOMP registration for organisations with a EV 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 **EV XCOMP organisation profile is created automatically** for that organisation and **the QPPV/RP role is automatically assigned** in the EV XCOMP. This also applies to organisations that have existing registrations in the EudraVigilance Production system as of 26th March 2020.

The Webtrader transmission mode is set up for all newly created organisations, both in EV Production and EV XCOMP. If your organisation has not been set up or a Gateway transmission mode is needed, please follow the steps described in **section 6.1.**

7.2. EV XCOMP User Access

If any additional user (i.e. other than EU QPPV/RP/Trusted Deputy) need access to EV XCOMP profile, the "**EV Human XCOMP User**" role should be requested by following the steps described in **section 5.3.** of this manual. Please note that users with EU QPPV/RP/TD roles – see Annex 1 – do no need to request additional EV XCOMP base roles since these roles already give access to XCOMP.

Important note:

- Users need to be registered with EMA Account Management portal in order to request XCOMP access - see **section 2.1.** for details.
- Users do not need to have roles associated with the EV Production profiles of their organisations in order to have access to EV XCOMP (i.e. a user can request a "EV Human XCOMP User" role without having access to Production).
- When requesting an EV XCOMP role via the EMA Account Management portal, users should use the same OMS Organisation ID for the EudraVigilance Production system (i.e. ORG-XXXXXXXXX). The above-mentioned EV XCOMP ORG ID with the prefix "ORX" will not show within the portal.

7.3. EV XCOMP organisation profile management

7.3.1. Organisation hierarchy in EV XCOMP profiles

The addition of **Affiliates** to EV XCOMP HQ organisations is not supported and so, none of the merge, swap, split, and/or move operations are available in EV XCOMP.

Virtual Affiliates can be created the same way as for EV Production environment – see **section 6.2.2.** – for secondary test profiles.

7.3.2. Disable EV XCOMP organisations

Disabling an EV XCOMP organisation profile only, while the corresponding Production profile remains active, is not possible.

In order to disable one organisation both in EV Production and EV XCOMP, please follow the instructions detailed in **section 6.3.1.**

Important note:

- When the main EU QPPV/RP role for an organisation is removed via the EMA Account Management portal for Production, this **automatically removes the same role in the EV XCOMP system**. The removal of this role deactivates the organisation in both the Production and XCOMP test systems.
- Virtual Affiliates in EV XCOMP can be disabled in the same way as for EV Production – see **section 6.3.2.**

7.4. IT system Vendors registration with EV XCOMP

The process for registering IT system Vendors in EV XCOMP follows the same process as for other organisations for the EV Production EudraVigilance system. The main difference is that the nominated Responsible person (RP) for EudraVigilance will choose the Vendor specific base role "**EV Human XCOMP Vendor Responsible person**". The RP will need to perform the following steps in order to successfully complete their registration in XCOMP:

1. Register in the EMA Account Management portal – see **section 2.1.**
2. Register the Vendor organisation in the Organisation Management System (OMS)/SPOR portal – see **section 3.**
3. Request the base role "**EV Human XCOMP Vendor Responsible person**" via the EMA Account Management portal by following the steps described in **section 5.3.**
4. Raise an EMA Service Desk request addressed to EV Registration section including the role request ID generated by the EMA Account Management portal. The EV Registration team will approve the role.
5. When the Vendor role has been approved, a separate EMA Service Desk request 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.
6. When the gateway set-up is complete, the Vendor is notified and can commence testing.

Important 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 (QAT) team via the EV QAT Service Desk portal. 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.

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

7.4.1. Change of Vendor's Gateway connection details

If a Vendor needs to change their Gateway connection details, they should raise a EMA Service Desk request addressed to the Gateway support team, including the Vendor organisation name, EV ORG ID and Routing ID, as well as the Vendor's new connection details.

7.4.2. Removal of RP Vendor's access/Disable Vendor organisation in EV XCOMP

In order to remove/revoke the RP Vendor role, the registered RP should request the deactivation of their role via the EMA Account Management portal by following the steps described in **section 5.6.1.**

An EMA Service Desk request addressed to EV Registration team should be raised, providing the removal request ID generated by the EMA Account Management system.

The removal of the RP Vendor will deactivate the EV XCOMP profile.

8. Non-Commercial Sponsors (NCS) additional support

Some organisations such as universities and hospitals can have complex independent internal structures that make the registration and user management difficult to manage. This section aims to provide further information on the registration, user and organisation management for NCS

8.1. Registration of a Non-Commercial Sponsor organisation in EV

The registration of a NCS organisation follows the same process described in **section 3.3.**

There are some steps you can clarify with the EV Registration team by raising a ticket via the EMA Service Desk portal:

- Check if the organisation is already registered with EV. If not, the organisation should be created.
- If the organisation is already registered, the EV Registration team can check if there is any RP/TD already registered with the organisation.

The EV Registration team may guide you on the next steps to be taken or put you in contact with the current RP/TDs.

8.2. Non-commercial sponsors User Access & Management

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. See **section 5.3.** for more information on how to request EV roles. The required documents should be provided to the EV Registration team.

Important note:

- If you are a non-commercial sponsor and have not completed the ICSR and XEVMPD training provided by the EMA and set as a requirement for the registration of the RP with EudraVigilance, and do not have any other user trained, you can alternatively provide a declaration where you commit to complete the EV training after the registration of the RP with EV Production and XCOMP. It is not possible to register the RP only for XCOMP. The EV Registration team will approve the RP role so that you can perform the EV training, but will not activate the transmission mode until the training as been completed.
- You can find all the information on EV training on EudraVigilance training and support webpage.
- For questions related to XEVMPD training please contact the Article 57/XEVMPD team via the EMA Service Desk portal. As for ICSRs training, please contact the due team via email - evtraining@ema.europa.eu.

The RP will be able to approve and manage all the subsequent users within their organisation. The RP can also approve other administrator users – i.e. users with the **EV Human MAH/CS/NCS Trusted Deputy (TD)** role -, to help the RP with this task. The EV Registration team can also remove user access.

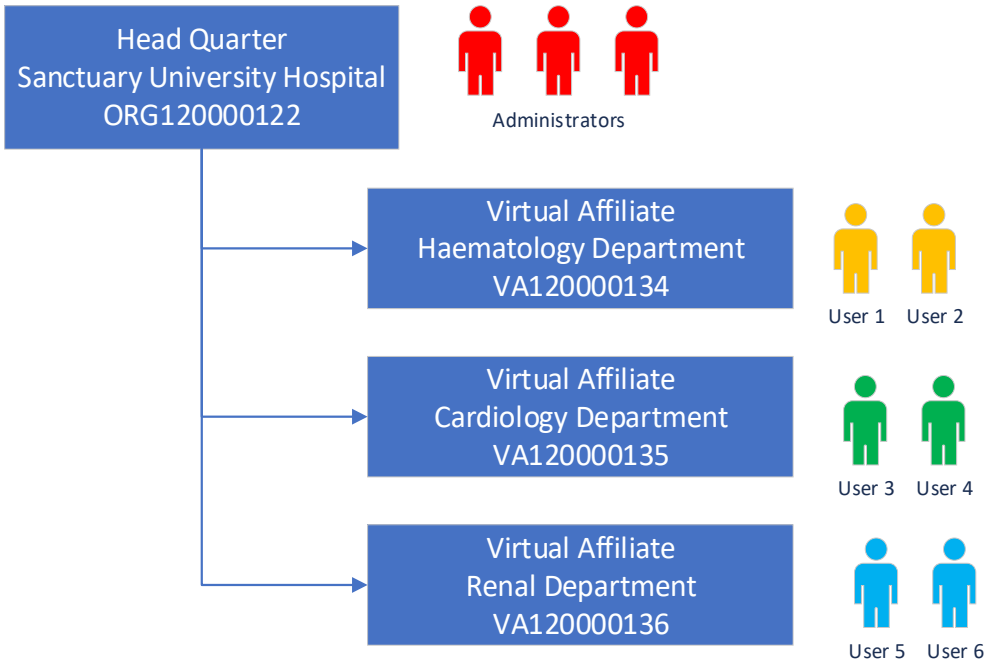
8.3. Non-commercial Sponsors Organisation Management

The RP/TD need to consider if users access needs to be limited, i.e. if one group of users should not have access to the data submitted/managed by another group of users.

The RP/TD can organise users into groups so that the data submitted by one group is not accessible by a different group by creating **Virtual Affiliates** under the HQ profile – see **section 6.2.2.** – and there are two main approaches that can be used:

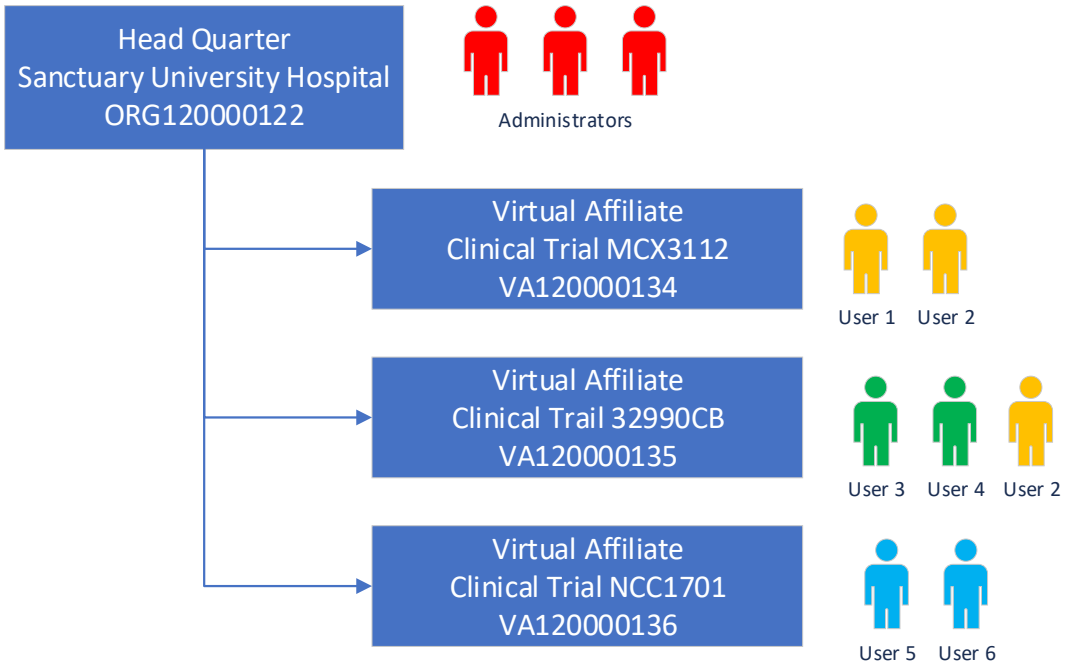
- The first option is to create virtual affiliates that are arranged by **departments (or similar internal structures)**. In this case, users in the same department can access the data submitted by their department and will not have access to the data submitted by other departments. This set up is shown in **Figure 118** below.

Figure 118 - Organisational structure using virtual affiliates arranged by departments



- The second option is to create virtual affiliates that are arranged by **clinical trials (or research groups)** being run by the organisation. In this case, users working on the same clinical trial/research group can access the data submitted by their group and will not have access to other clinical trials/research groups data. It is also possible for a specific user to be assigned to more than one clinical trial/research group if needed whilst restricting other users to a specific clinical trial/research group. This set up is shown in **Figure 119** below.

Figure 119 - Organisational structure using virtual affiliates arranged by clinical trials/research groups



Please note that RP/TDs will always be able to access all the data submitted by the whole organisation.

The RP/TDs 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 in **section 6.2.2.**

For assistance in registering Virtual affiliates and assigning users to these profiles, please contact the EV Registration team via EMA Service Desk portal. For more information on organisations hierarchy management in EV Production, please refer to **section 6.2.**

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

To change role in a profile, please remove all the roles you have (see **section 5.6.**), and then request the role again. The different EV Base and Supplementary roles for EV PROD and XCOMP currently available are listed in the 3 tables that follow. Please choose the applicable role(s) to your situation.

EV Production Base roles

The table below lists the **EV Production Base roles**. Please note that some roles grant user access to EV PROD only, whereas other roles grant access to both EV PROD and XCOMP at the same time. If access to XCOMP is also needed and the EV Production Base role selected does not grant access to XCOMP, then an EV XCOMP Base Roles should also be requested- please refer to **Table 3 - EV XCOMP Base Roles**.

Table 1 - **EV Production Base Roles**

Role	Description	Notes
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 the same permission in **EV PROD** and **XCOMP** environments. It is not necessary to request additional XCOMP role to have access to XCOMP.
EV Human MAH EU QPPV	Request this role if you work for a MAH and you are the main EU QPPV. This role allows you to grant and revoke access to users and manage the organisation hierarchy.	This role grants the same permission in **EV PROD** and **XCOMP** environments. It is not necessary to request additional XCOMP role to have access to XCOMP.
EV Human CS/NCS Responsible	Request this role if you work for a Commercial Sponsor/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 the same permission in **EV PROD** and **XCOMP** environments. It is not necessary to request additional XCOMP role to have access to XCOMP.
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 the same permission in **EV PROD** and **XCOMP** environments. It is not necessary to request additional XCOMP role to have access to XCOMP. This role will be rejected if your organisation does not have an EV NCA Responsible.

Role	Description	Notes
EV Human MAH/CS/NCS Trusted Deputy	Request this role if you work for an MAH, Commercial Sponsor/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 the same permission in **EV PROD** and **XCOMP** environments. It is not necessary to request additional XCOMP role to have access to XCOMP. Please note, this role will be rejected if your organisation does not have an EV Human MAH EU QPPV or an EV Human CS/NCS Responsible.
EV Human NCA/MAH/CS/NCS Browse ICSR	Request this role if you need only access to ICSR messages.	This role grants permission only to the **EV PROD** environment. 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.	This role grants permission only to the **EV PROD** environment.
EV Human NCA/MAH/CS/NCS Browse MPR	Request this role, if you need only access to browse Medicinal Products in the XEVMPD.	This role grants permission only to the **EV PROD** environment.
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.	This role grants permission only to the **EV PROD** environment.
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).	This role grants permission only to the **EV PROD** environment.

Role	Description	Notes
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).	This role grants permission only to the **EV PROD** environment.
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.	This role grants permission only to the **EV PROD** environment. 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

The table below lists the **EV PROD Supplementary roles**. The roles listed only grant users access to the EV PROD environment. If access to XCOMP is also needed, then an EV XCOMP Base Roles should also be requested- please refer to **Table 3 - EV XCOMP Base Roles**.

Table 2 - EV Production Supplementary Roles

Role	Description	Notes
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).	This role grants permission only to the **EV PROD** environment.
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).	This role grants permission only to the **EV PROD** environment.

Role	Description	Notes
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).	This role grants permission only to the **EV PROD** environment. EVDAS roles are only for NCA and MAH HQ profile users
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).	This role grants permission only to the **EV PROD** environment. EVDAS roles are only for NCA and MAH HQ profile users
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).	This role grants permission only to the **EV PROD** environment. EVDAS roles are only for NCA and MAH HQ profile users
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).	This role grants permission only to the **EV PROD** environment. EVDAS roles are only for NCA and MAH HQ profile users

EV XCOMP Base roles

The table below lists the **EV XCOMP Base Roles**. Please note that there is no need to request EV XCOMP Base roles if you already have one EV Production Base role that grants you access to XCOMP (The MAH EU QPPV, Responsible or Trusted Deputy roles already give you access to EV XCOMP).

Table 3 - EV XCOMP Base Roles

Role	Description	Notes
EV Human XCOMP User	You should request this role if you want to access XCOMP environment and your EV Production base role does not grant you access to XCOMP. Before requesting this role a EU QPPV/Responsible person for your organisation must be appointed.	This role grants permission only to the **EV XCOMP** environment.

Role	Description	Notes
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 only.	This role grants permission only to the **EV XCOMP** environment.