



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

EMA EudraVigilance Registration Manual

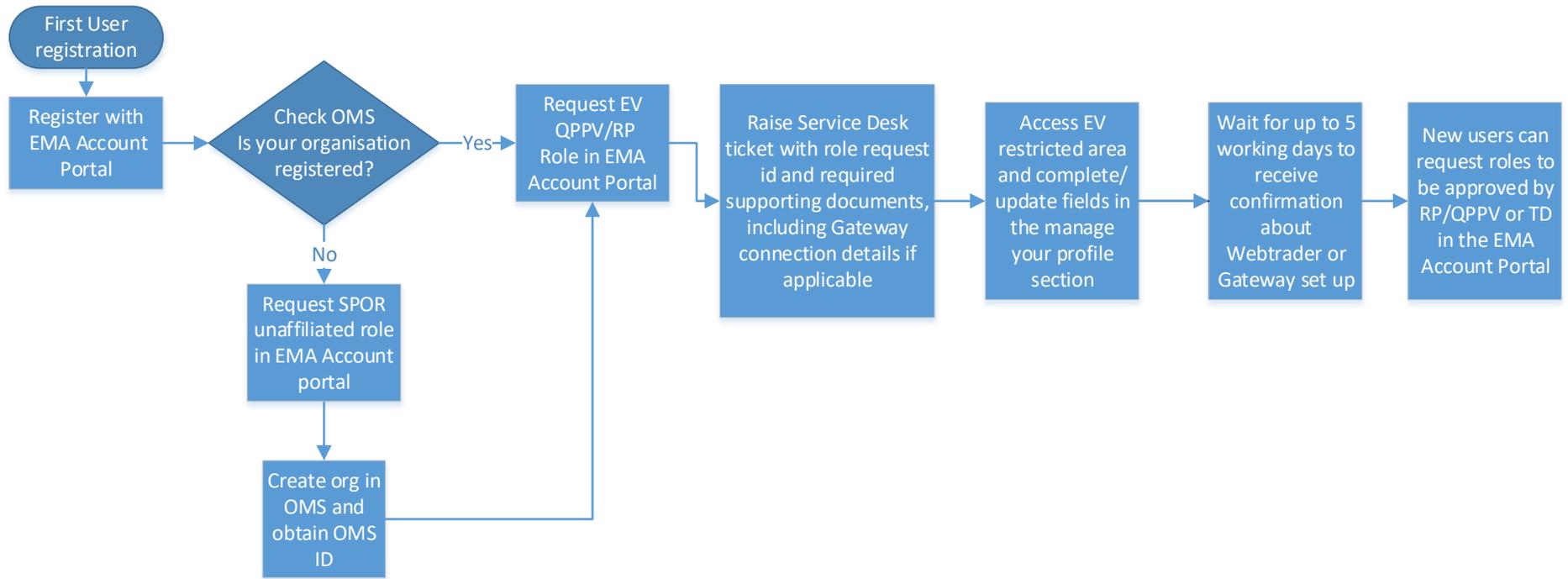


Table of contents

1. Registration overview	5
2. User registration with EMA Account Management portal (IAM)	5
2.1. Registering with the EMA Account Management portal	6
2.2. Log into EMA Account Management portal	12
3. User access management via EMA Account Management portal	12
3.1. EV user access requests for industry and NCA users	13
3.2. EU QPPV or Responsible Person access request	17
3.3. Document submission for EU QPPV/RP authorisation via EMA Service Desk portal ...	17
3.4. Multiple EV roles	21
3.5. EV POST	21
3.6. Role approval for EudraVigilance	22
3.6.1. Approval process managed by EU QPPV/RP/TD	22
3.6.2. EU QPPV/RP/TD user responsibilities	26
3.7. Removing access.....	27
3.7.1. Request your own access removal	27
3.7.2. Revoke access	29
3.8. Manage passwords and usernames in EMA Account Management portal	31
3.8.1. Reset forgotten password	31
3.8.2. Retrieve forgotten username.....	33
3.8.3. Change password in EMA Account Management portal	35
3.8.4. Update security (authentication) questions	36
3.9. Policy violation.....	38
4. Create a new Organisation	40
4.1. Finalise organisation information in EV Human Production and XCOMP	41
4.2. Update organisation details in OMS	44
5. EV Restricted Area Management	45
5.1. EV restricted area and transmission mode for new organisation	45
5.2. Manage organisation hierarchy in the Production system.....	45
5.2.1. Add an Affiliate to a Production system Headquarter	45
5.2.2. Manage Affiliate information	46
5.2.3. Move an Affiliate from HQ A to HQ B	46
5.2.4. Change Affiliate into a HQ organisation	46
5.2.5. Swap an Affiliate to become the new HQ and the previous HQ to become an affiliate.....	46
5.3. Virtual Affiliates	47
5.3.1. Create a Virtual Affiliate in EudraVigilance Production or XCOMP systems	47
5.3.2. Manage Virtual Affiliates.....	49
5.3.3. Virtual Affiliate users.....	49
5.4. Disable organisation profiles: HQ, Affiliates and Virtual Affiliates	49

5.4.1. Disable HQ and Affiliate profiles.....	50
5.4.2. Disable a Virtual affiliate.....	50
5.5. Manage Art 57 QPPV and other user contact details	50
5.5.1. Manage your contact details	51
6. Webtrader and Gateway transmission	52
6.1. For existing organisations i.e. change of transmission mode from Webtrader to Gateway -.....	52
6.2. For new organisations i.e. activating Gateway transmission mode for the first time .	52
7. XCOMP registration process	53
7.1. XCOMP registration for organisations with a Production profile	53
7.2. Managing a XCOMP organisation profile.....	54
7.3. IT system Vendors registration with XCOMP	54
7.3.1. Removal of a Vendor's access from EudraVigilance.....	55
7.3.2. Changing connection details.....	55
Annex 1 - EV "base" and "supplementary" roles.....	56

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



1. Registration overview

Update Note: The EudraVigilance XCOMP (Test system) has been aligned with Production. For more detailed information on the EV XCOMP registration process, please refer to [Section 7](#) of this manual.

To set-up a new organisation in EudraVigilance Production or XCOMP (Test system), a series of steps need to be followed:

1. A person within the organisation needs to be chosen as being responsible for managing the organisation and its users in the EudraVigilance Production system. If the organisation is a marketing authorisation holder the primary responsible person will be a Qualified Person for Pharmacovigilance (QPPV).
2. Register for an EMA user account in the EMA Account Management portal if you do not already have one - see 2. User registration with EMA Account Management portal (IAM)
3. Check Organisation Management System (OMS): if your organisation is not present in OMS it will need to be registered -see 4. Create a new Organisation
4. Submit request to be registered as the responsible person for the organisation -see 3.2. EU QPPV or Responsible Person access request
5. Complete organisation registration details in the EudraVigilance restricted area - see 4.1. Finalise organisation information in EV Human Production and XCOMP
6. The EMA confirms separately to the organisation that their Webtrader or Gateway transmission mode has been set up – see 6.

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

2. User registration with EMA Account Management portal (IAM)

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

It is likely that you already have an [EMA Account Management](#) portal account if you have access to at least one of the following EMA systems:

EudraLink, EudraCT Secure, IT Service Desk portal (JIRA), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR.

Users who are already registered and have credentials for one or more of the systems above do not need to re-register in the [EMA Account Management](#) portal.

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. There is a shortcut to the EV Human Production restricted area on the [EudraVigilance: how to register webpage](#)
- There is a validator on the e-mail address to prevent the creation of duplicate EMA IAM accounts during self-registration

- If you have an account but do not remember the password, you need to click “Forgot your password” on the bottom right of the landing page of the [EMA Account Management](#) portal.

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

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

2.1. Registering with the EMA Account Management portal

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

Note: before registering, click on [“Not sure if you have an EMA account?”](#) on the [EMA Account Management](#) portal page to review the EMA systems for which you could already have access to.

In addition, if you have access to IAM with different e-mail addresses, please raise an EMA Service Desk ticket to request the merge of your IAM accounts so that you have one unique EMA Account. Your current access to current systems will then be combined in this unique account.

If you have duplicated IAM accounts, you will not be able to use one set of login credentials to access all the organisations you are registered with.

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

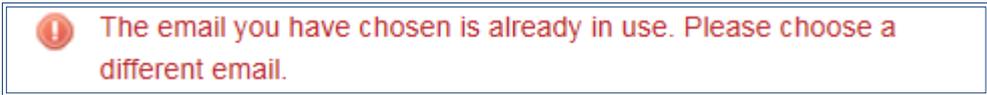
Figure 2. Self-registration form on the EMA Account Management portal

The screenshot shows the 'EMA - Self-service Registration Form'. At the top, it says 'Submit the following form to register.' Below this are several input fields: 'First Name *', 'Last Name *', 'Email *', 'Password *', and 'Confirm Password *'. Each of these fields has a red asterisk next to its label. Below the 'Email' field, there is a note: 'We require a valid/active email address to create an EMA Account.' Below the 'Password' field, there is a note: 'Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.' Below the 'Confirm Password' field, there is a note: 'Please enter a password that you want to use to access your EMA Account. The password must have at least 8 characters and must contain upper case, lower case, numeric and special characters.' At the bottom of the form, there are two more fields: 'Country Code' (a dropdown menu) and 'Mobile (optional)'. Below the 'Mobile' field, there is a note: 'This is an optional field. We will only use this information for security messages or alerts in relation to your account. Please include the international dialling code in front of your mobile number.' At the bottom left of the form is a 'Cancel' button, and at the bottom right is a 'Register' button.

Figure 2. shows the self-registration form.

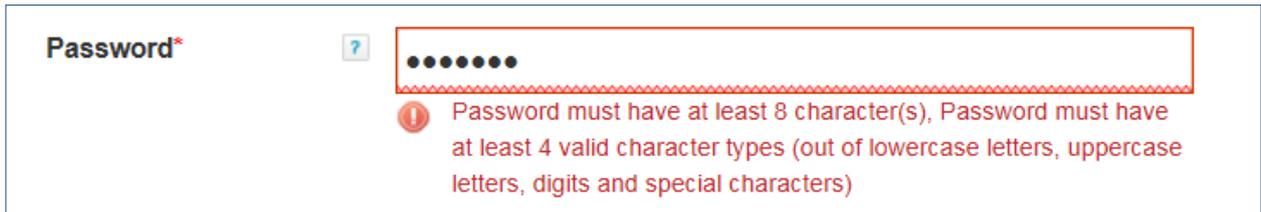
- Mandatory fields are marked by a red asterisk (*)

- Optional field – mobile phone (landline number can be provided too), strongly recommended for cases when e-mail does not work or changes
- Read the “Data protection policy agreement”
- 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
- The password has some mandatory requirements
Note: the characters + and & should be avoided as they will cause issues with access to some EMA applications.

Figure 3. Password requirements



EMA privacy statement

Once you have clicked on “Register”, the system takes you to a page displaying the EMA privacy statement. Please read and agree by ticking the box in the “User Agreement” section at the end of the page and click “I agree”. See Figure 4. below.

Figure 4. EMA privacy statement

to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.

- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the [EMA General privacy statement](#).
- **Right to object** – If the Agency processes your data for the performance of a task in the public interest (without your consent or another lawful basis), you have the right to object to this processing on grounds related to your particular situation.
- **Right to portability** - Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this privacy notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacystatement

7. How long does EMA keep personal data?

Your data will be deleted after 180 days of inactivity on EMA systems (i.e. if you do not use your account on any of the systems). You will receive a reminder before your data will be deleted.

8. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Privacy Statement or the general EMA Privacy Statement, please contact the **Data Controller** at DEDDataprotection@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en

Download the EMA Privacy Statement for the EMA Account Management System

You can download this statement here
ema.europa.eu/en/documents/other/european-medicines-agencys-privacy-statement-ema-account-management-system_en.pdf

User Agreement



By submitting the application form, I declare that I have read and understood the privacy statement, and that I consent to the processing of personal data as explained in the privacy statement.



After agreeing to the statement, you are taken to a screen with security questions.

Security questions

In order to be able to reset forgotten passwords, the user is prompted to set up security questions. See Figure 5. below.

Figure 5. Security questions page

EMA - Self Registration Security Questions

Security Question 1
What is your mother's maiden name?

Answer 1 *

Security Question 2
What is your favorite color?

Answer 2 *

Security Question 3
What is the name of the first street you lived on?

Answer 3 *

Captcha Question *
What is the value of 21 + 43

Captcha Answer *

Cancel Next

- The same list of questions is provided for Q1, Q2 and Q3
- The user must choose 3 different questions
- Click "Next"

Figure 6. Security questions options – scroll-down list

Security Question 1

What is your mother's maiden name?

What is your favorite color?

What is the name of the first street you lived on?

What is your favorite pet's name?

What is the name of your childhood best friend?

- Answer the captcha question (an arithmetic calculation)
- Click 'Next' to go to the registration confirmation page

Figure 7. Captcha questions

Captcha Question *

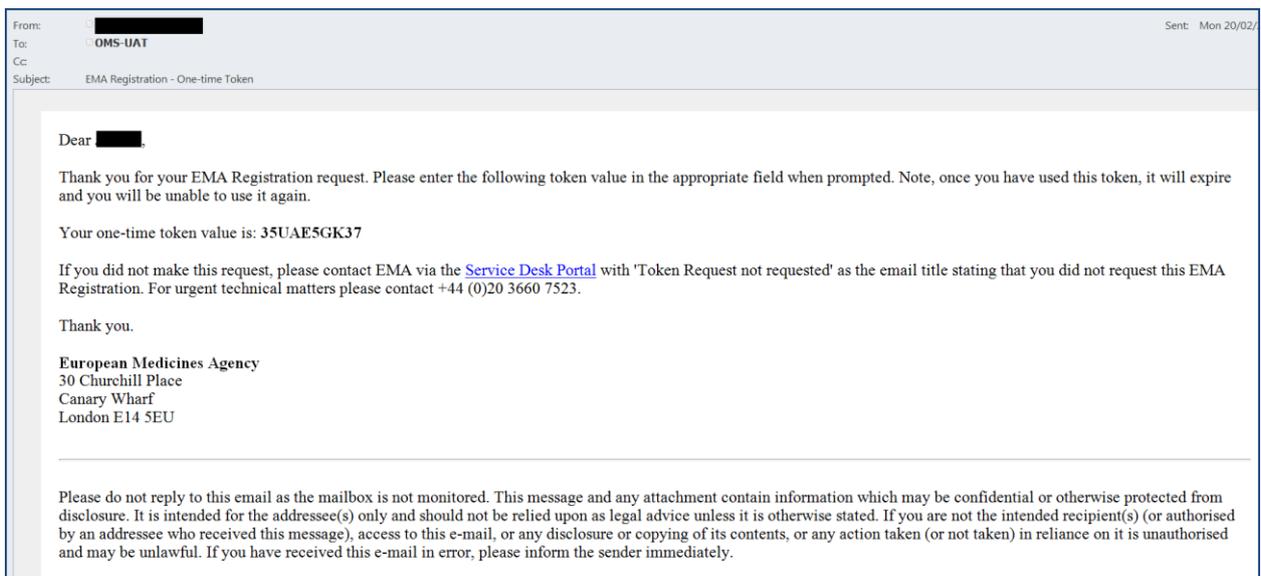
What is the value of 21 + 43

Captcha Answer *

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

Note: if you have forgotten the answer to your security questions or your account is locked, please raise an [EMA Service Desk ticket](#)

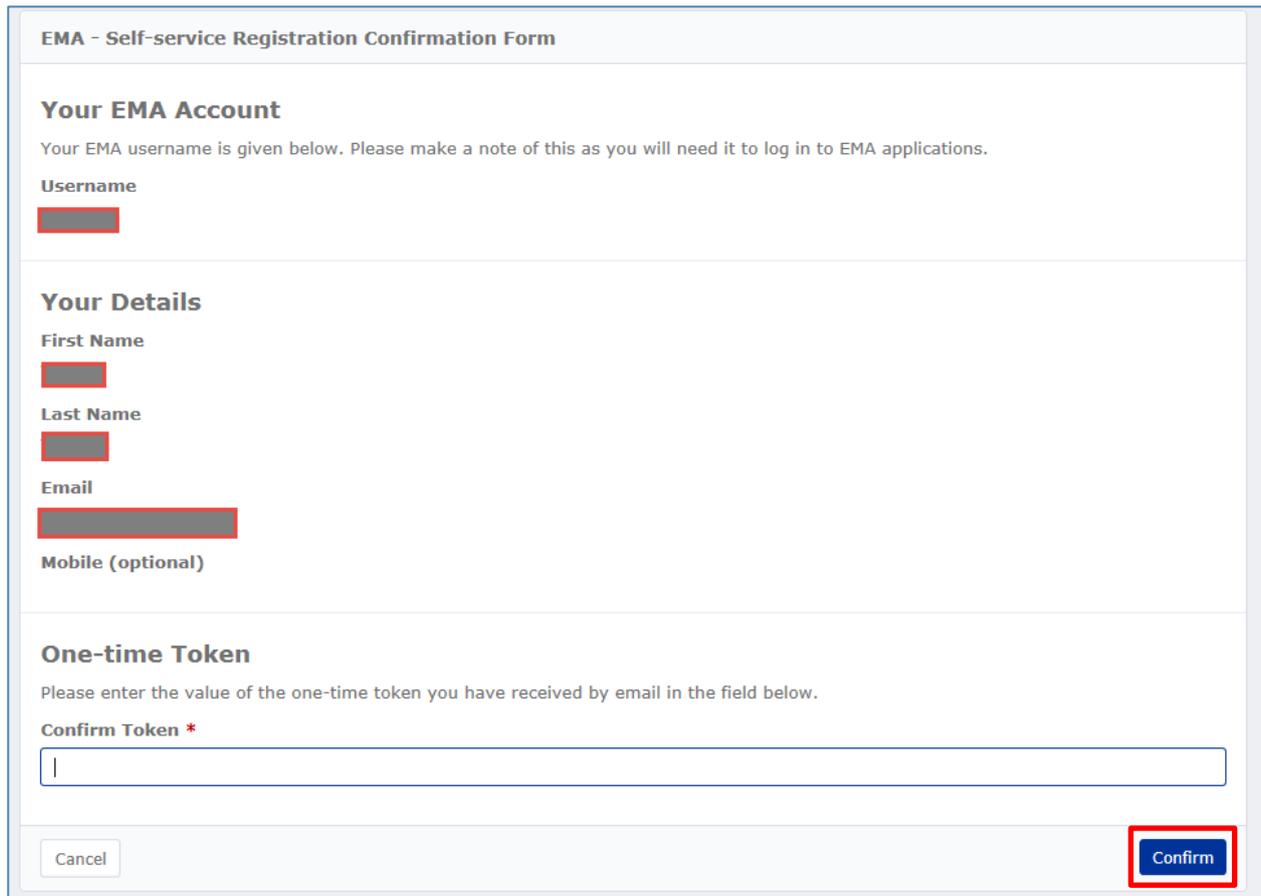
Figure 8. Authorisation token e-mail example



Confirm 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'.

Figure 9. Confirmation of the user registration



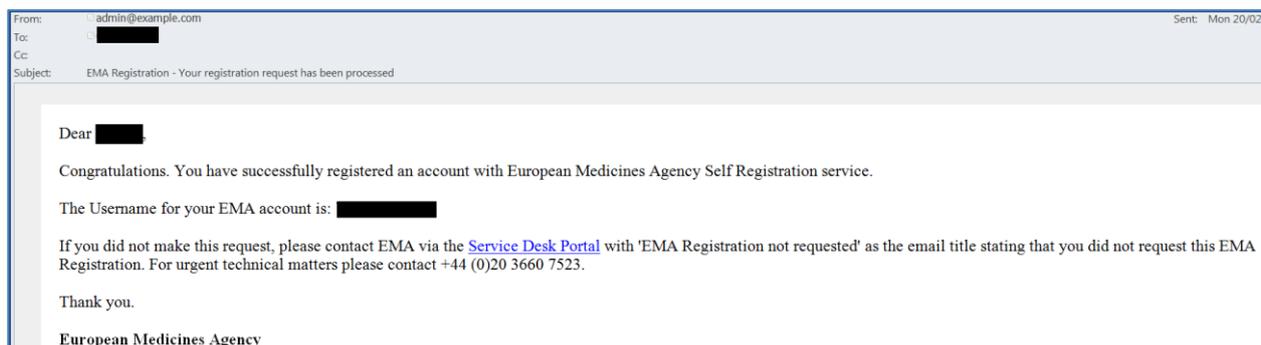
The image shows a web form titled "EMA - Self-service Registration Confirmation Form". It is divided into three main sections: "Your EMA Account", "Your Details", and "One-time Token".

- Your EMA Account:** A heading followed by the text "Your EMA username is given below. Please make a note of this as you will need it to log in to EMA applications." Below this is a label "Username" and a redacted input field.
- Your Details:** A heading followed by labels and redacted input fields for "First Name", "Last Name", "Email", and "Mobile (optional)".
- One-time Token:** A heading followed by the text "Please enter the value of the one-time token you have received by email in the field below." Below this is a label "Confirm Token *" and a text input field.

At the bottom of the form, there are two buttons: "Cancel" on the left and "Confirm" on the right. The "Confirm" button is highlighted with a red border.

- Click "Confirm"
- This creates a new EMA account
- A confirmation e-mail of a successful registration is sent.

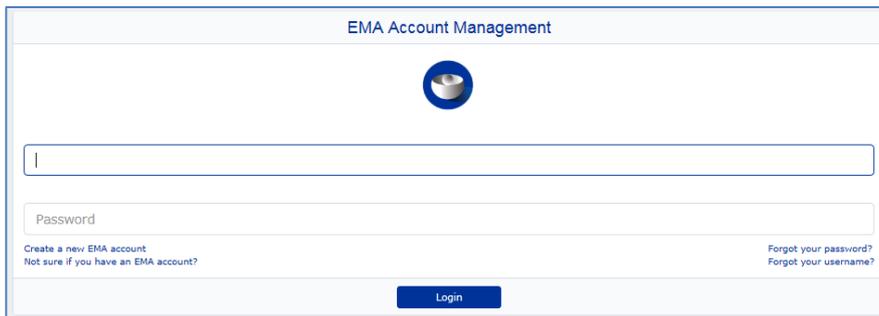
Figure 10. Registration successful – confirmation e-mail example



- Once you have your credentials, log in via [EMA Account Management](#) portal.

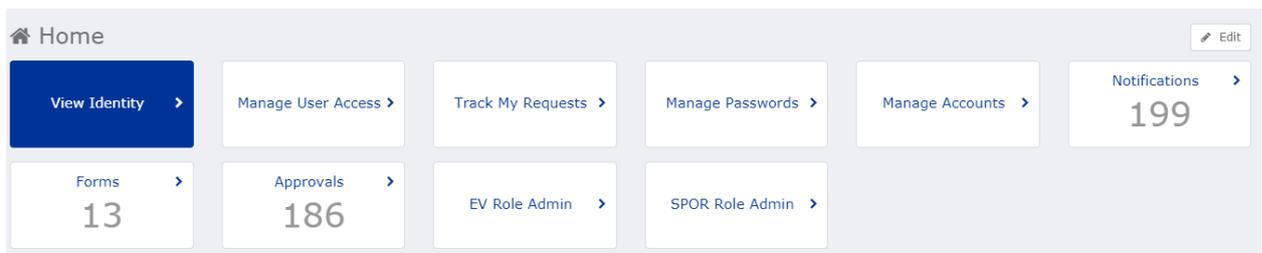
2.2. Log into EMA Account Management portal

Figure 11. Log-in page for registered users



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

Figure 12. EMA Account Management portal dashboard



3. User access management via EMA Account Management portal

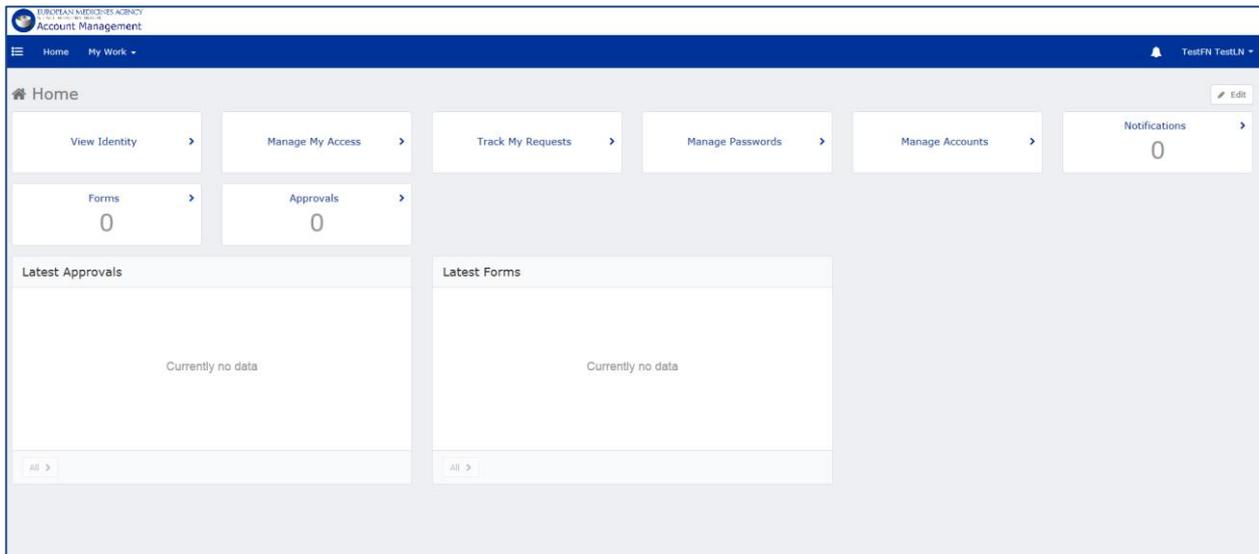
Users can manage their own EMA account via the [EMA Account Management](#) portal dashboard; this includes managing access to EudraVigilance Human Production, EudraVigilance XCOMP and to other EMA systems. The dashboard appears after successfully logging in.

Through this interface the user has the following functionalities that are explained in the sections below:

- View identity
- Manage User access
- Track requests
- Manage passwords
- Manage accounts
- View notifications
- View forms and approvals (applicable for QPPV/RP/TD only)

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 of this manual as it provides descriptions of all the possible EV roles that can be requested.

Figure 13. EMA Account Management portal dashboard

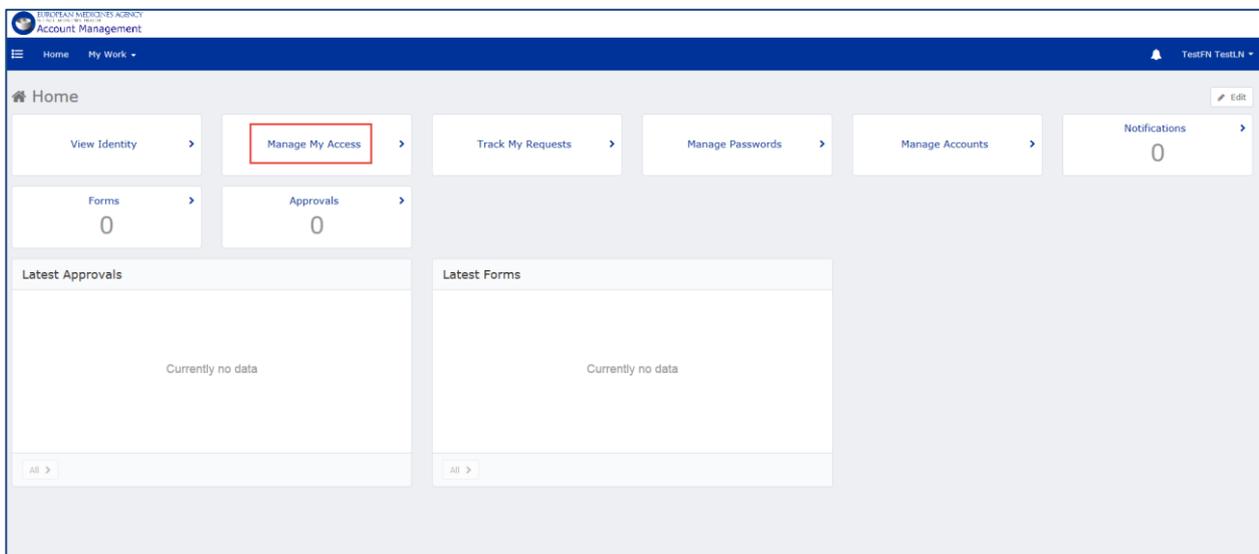


In order to obtain an EV user role, there must be an active QPPV/RP registered for the organisation that the user role is being requested. If there is none, the system will automatically reject the request and the user will need to liaise within their organisation in order to ensure a new QPPV/RP is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

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

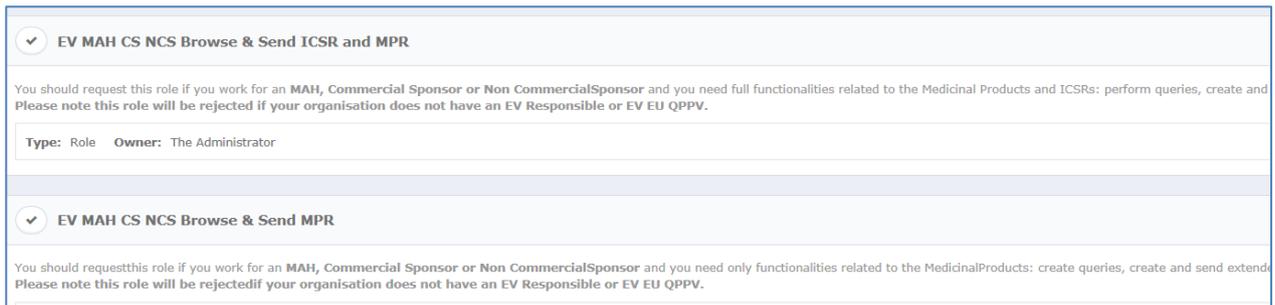
3.1. EV user access requests for industry and NCA users

Figure 14. Manage My Access



- Click on the Tab “Manage My Access”
- Users will see a list of possible roles they can request

Figure 15. Selection of roles – Industry/NCA user



- The various EV roles are listed and described in the Annex 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 3.7.1.) 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.**
Note: please wait for e-mail confirmation that the base role has been successfully removed before requesting the new rule.

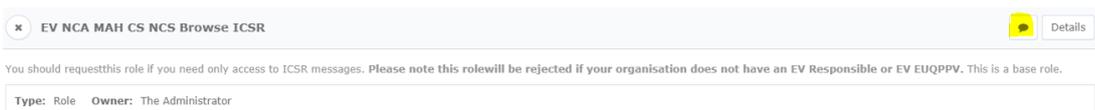


- Click on the  button for the required role, which is on the left-hand side of the screen.
- Once selected, press on "Review"

A confirmation page appears

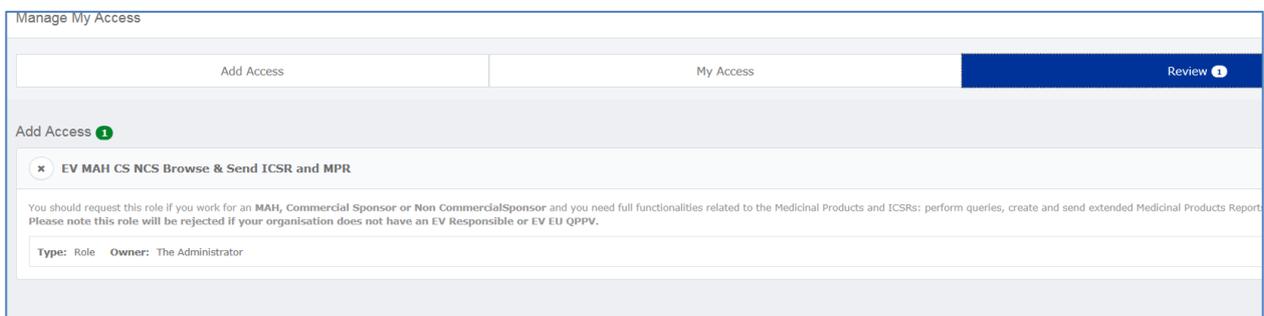
- An optional comment or assignment note can be included for the request.

Figure 16. Comment and Assignment Note



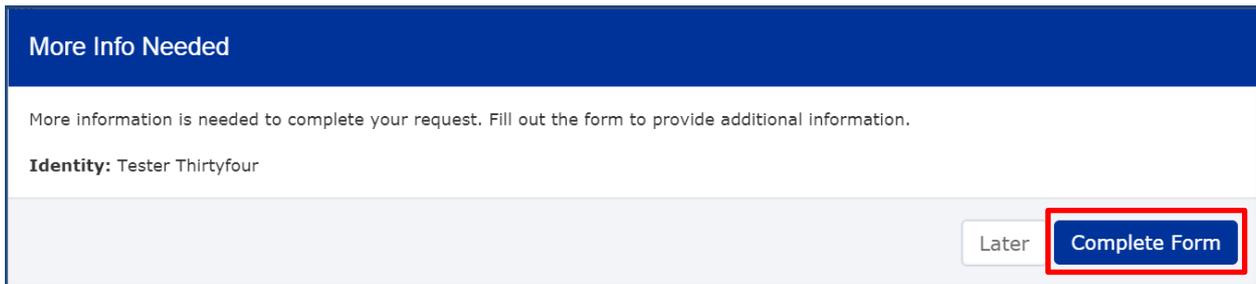
- Click "Submit"

Figure 17. Selection of roles – confirmation page



- In the next step, the user is prompted to provide the organisation for which they are requesting the role – this is required before the EV role request can be completed
- The following screen appears

Figure 18. A trigger to request organisation affiliation



More Info Needed

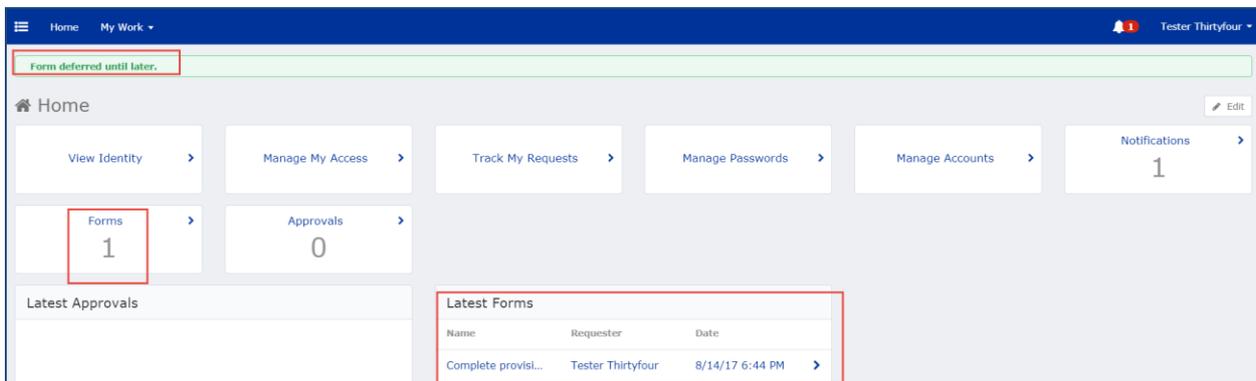
More information is needed to complete your request. Fill out the form to provide additional information.

Identity: Tester Thirtyfour

Later Complete Form

- The user can choose to complete the form later – in this case the form appears on their dashboard in the “Forms” tab

Figure 19. Form deferred



Form deferred until later.

Home

View Identity > Manage My Access > Track My Requests > Manage Passwords > Manage Accounts > Notifications 1

Forms 1 Approvals 0

Latest Approvals

Name	Requester	Date
Complete provisi...	Tester Thirtyfour	8/14/17 6:44 PM >

Otherwise the user continues to complete the request by selecting an organisation

- Click on “complete form”
- The organisation affiliation form appears

Figure 20. Form for choosing the organisation on behalf of which the role is requested

Complete Work Item

Request provisioning form for uattwo_t4

Please supply initial values for account attributes in the forms below.

Request Information

Requester
testfour uattwo

Target Identity

First Name	Last Name	Account ID
testfour	uattwo	testfour uattwo

Assigned Roles
EV MAH EU QPPV (ORG-100007270 - Centrum Onkologii im. prof. Franciszka Lukaszczyka w Bydgoszczy - DELETED)

MDMPermissionDB

No results found
EV MAH CS NCS Browse & Send ICSR and MPR

Search Organisation

bluexxx

Enter an organisation name or OMS ID to search for then select it from the menu below by clicking on the dropdown arrow on the right.

Organisation *

In case you cannot find your organisation in the list, please verify that it has been registered correctly with OMS [http://spor-
uat.ema.europa.eu/omswi/#/](http://spor-uat.ema.europa.eu/omswi/#/)

- The user needs to add an organisation name in "Search organisation" field (see above, highlighted in red), the organisation can also be searched by its OMS ID. The OMS ID can be found through using SPOR web user interface (<https://spor.ema.europa.eu/omswi/#/>). Please note that this webpage does not work with Internet Explorer.
- Once the name of the organisation or OMS ID has been inserted, move the cursor outside the box.
- Click the arrow on the right-hand side of Organisation field box to display all potential candidates. Select the correct organisation and click "Submit Request".
- If you are the first user (i.e. QPPV/RP) of the organisation, the request will go to EMA for approval. However, you will also need to provide some additional documents in order for the role to be approved (see [New Organisation First User QPPV/RP or Change of EU QPPV/RP](#) guideline for further details).
- All other role requests will go to the registered EU QPPV/RP/TD of the organisation for approval.

Note: the Trusted Deputy (TD) role 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.

3.2. EU QPPV or Responsible Person access request

- **IMPORTANT:** The SPOR Super User Industry role (required to raise change requests in SPOR) is not managed by the EV Registration team. Requests for this role are managed by the OMS/SPOR team; queries about such requests for this role need to be submitted to [EMA Service Desk](#).
- To request an EU QPPV/RP role, whether first user or change of QPPV/RP, the process detailed in the [New Organisation First User QPPV/RP or Change of EU QPPV/RP](#) guideline should be followed. **Please ensure you have no current base or supplementary role with the organisation before requesting the QPPV/RP role for that organisation and that the previous QPPV/RP role has been confirmed as being removed.**
- A QPPV/RP role request will be rejected by the system automatically if there is still a QPPV/RP registered for the organisation profile.
- Of note, an organisation profile is enabled in EudraVigilance when there is an enabled and registered QPPV/RP. During a change of QPPV/RP, the organisation profile will appear as disabled until the process has been completed. Active users linked to this profile will see a message stating “your organisation is disabled”.
- The registration process of Responsible Person for NCAs is the same as for QPPV/RP for Industry and sponsors of clinical trials.
- There can only be one EU MAH EU QPPV role or Responsible Person role (for Commercial Sponsor and Non-Commercial Sponsor or EV affiliate profiles) per organisation.
- The registration or change of QPPV/RP in the Production environment will be reflected automatically in XCOMP (test environment).

Note:

- The EU QPPV/RP or TD will automatically be able to access all the virtual affiliates (VA) of the HQ profile.
- For legacy organisations: only those profiles that share the same OMS ID with the HQ will be accessible by the EU QPPV/TD/RP of the HQ without having a role in the affiliate. If the OMS ID of the EV profile of the affiliate organisation is different from the OMS ID of the EV HQ profile, then RP/QPPV/TD users need to request RP/TD role for the affiliate profile to have administrator visibility. Please also note HQ QPPVs are responsible for the HQ/Affiliate and Virtual affiliate profiles, regardless of who appears as RP in the Affiliate profiles.

3.3. Document submission for EU QPPV/RP authorisation via EMA Service Desk portal

- In order to support the EU QPPV/RP access, the requestor needs to submit a series of documents that confirms that they represent the organisation selected in the request – see [New Organisation First User QPPV/RP or Change of EU QPPV/RP](#). As the EMA Management Account portal does not support submission of documents in the form of attachments, the required documents need to be submitted through an EMA Service Desk access request quoting the Request ID number (generated by the [EMA Account Management](#) portal).

- The request ID is found in the “Track my Requests” tab in the [EMA Account Management](#) portal (see Figure 21. Track My requests)

Figure 21. Track My requests

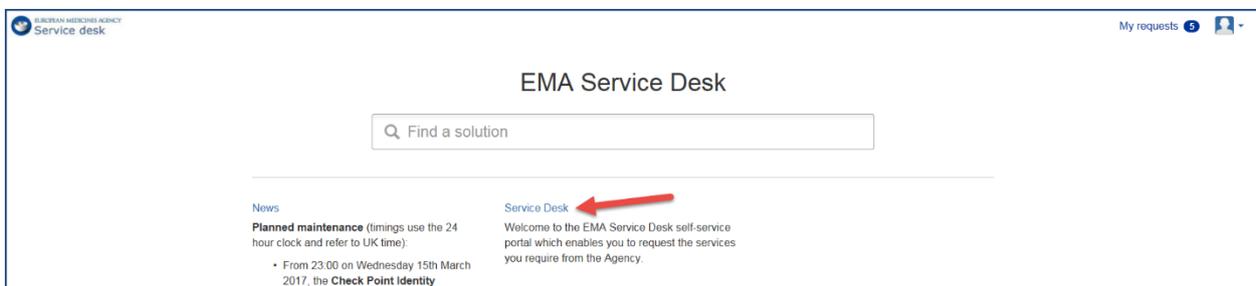


- Navigate to the EMA Service Desk portal and the log in page appears

Figure 22. IT Service Desk log in page

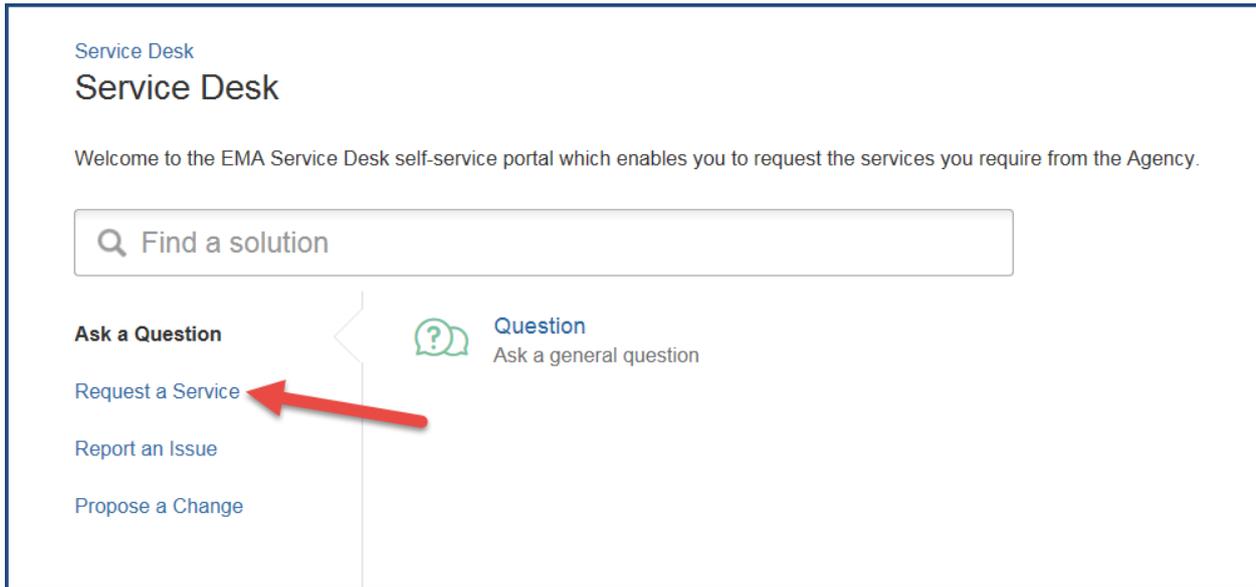
- The log in credentials are the same as those used for the [EMA Account Management](#) portal, SPOR and other EMA systems
- Click on Service Desk link to progress

Figure 23. IT Service Desk landing page



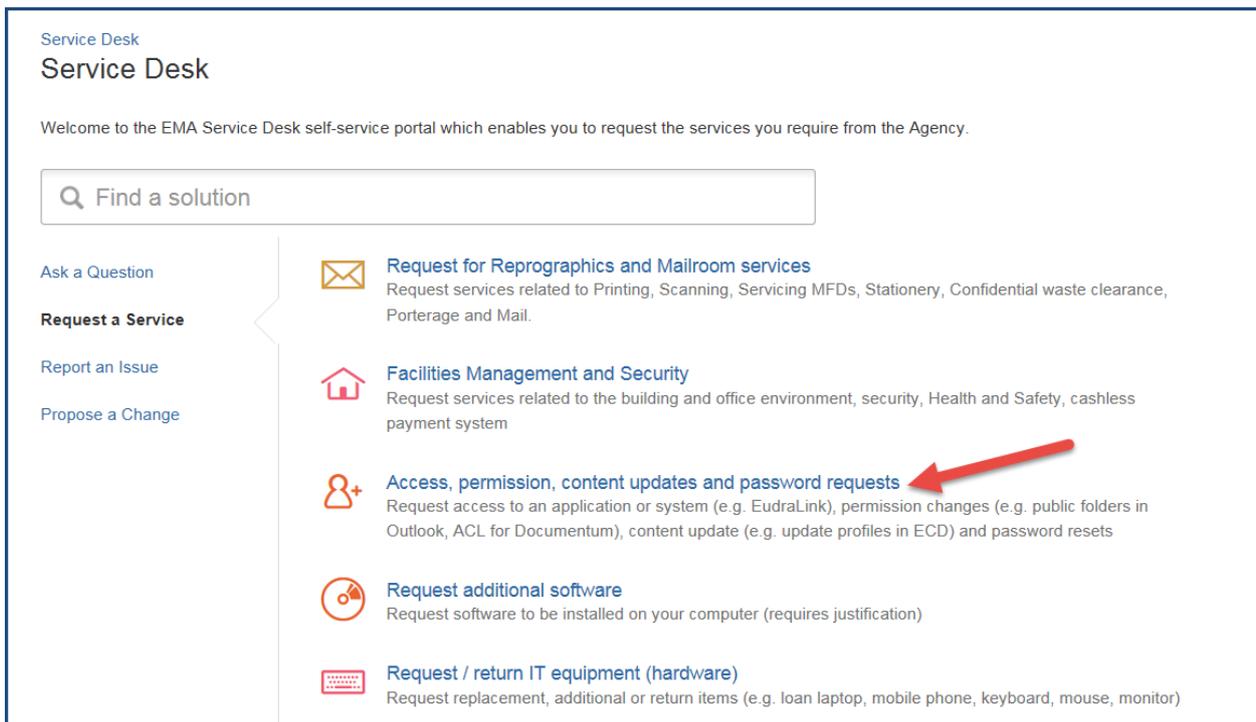
- Select “Request a Service”

Figure 24. Service Desk options



- On the list of services, select the "Access, permission, content updates and password requests"

Figure 25. Service options



A service request form opens so that you can submit the requested information and documents:

Figure 26. Service request

Service Desk / Service Desk

Access, permission, content updates and password requests

Raise this request on behalf of

Subject
EV EU QPPV/RP - First User Validation Please add a title for the request

Software
Search for an object Please describe the type of request (access, permission or password reset). If a request for access or permission change

Description
Justification for the request is mandatory. Please provide the name of the manager that is authorised to approve this request, if needed. Please indicate how it is affecting your ability to work, other people, and how urgent it is

Attachment (optional)
Drag and drop files, paste screenshots, or browse Please upload any attachments you consider useful

Create Cancel

- “Registration of new Organisation – EV EU QPPV/Responsible validation - Request ID xxxxx” should be mentioned in the subject field, together with the EMA Account Management portal request ID number that is automatically generated when a role is requested through the [EMA Account Management](#) portal.
- The request ID is found in the “Track my Requests” tab in the [EMA Account Management](#) portal (see Figure 21. Track My requests above)
- In the description field, state your name, organisation and explain that you are requesting EU QPPV/RP role access
- Upload the documents as stated in the [EudraVigilance registration documents](#) file, completed with all the necessary information, including the OMS ID. If a Gateway transmission mode is required, attach a completed Gateway connection form and an encryption security certificate in the Service Desk request.
- Click on “Create”
- The EMA approves or rejects the EU QPPV/RP request and notifies the requestor of the outcome.
- The EMA confirms separately to the organisation that their Webtrader or Gateway transmission mode has been set up.

- The QPPV/RP completes the organisation information in the EV Human and XCOMP restricted area.

3.4. Multiple EV roles

- Industry users can have multiple roles assigned in the [EMA Account Management](#) portal, each of these base roles must belong to a different organisation, e.g. there cannot be 2 base roles requested for the same organisation. This enables users to work on behalf of several organisations.
 - Each user role will be linked to a unique organisation
 - Managing multiple organisations as an EU QPPV/RP/TD requires multiple EV MAH EU QPPV/RP/TD user roles with the associated organisations
 - The users will need to submit individual access requests for each of the roles
 - Each of the user access requests will be approved by the respective EU QPPV/RP of the organisation for which the role is requested unless it is a first EU QPPV/RP for this organisation, in which case EMA would approve
 - Each organisation should have at least one registered EU QPPV/RP (EMA recommends two administrators - that is the required QPPV/RP and at least one Trusted Deputy).
 - An organisation can also have multiple users with different levels of access and multiple trusted deputies.
- An organisation may have different subsidiary organisations, each with its own organisation ID
 - Organisation structures and hierarchies are not defined in OMS – for example, there is no recognition of HQ or affiliates.
 - The trusted deputy of the headquarters does not automatically have access to the trusted deputy role for the affiliates; the trusted deputy role will need to be requested for the concerned affiliates (this does not apply to Virtual Affiliates).

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

3.5. EV POST

EV POST is an additional transmission mode that users who have organisation profiles set up with Webtrader transmission can use.

In order to have this transmission enabled, the QPPV/RP/TD 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.
2. Test the functionality with the QAT testing team. More information about the testing process can be found on the [EudraVigilance: electronic reporting](#) webpage.
3. Once this functionality is tested and validated, the QPPV or RP must request the activation of the EV POST function in Production by raising a Service Desk request addressed to the EV Registration team, providing proof of completed testing.

Note: In order to be able to access EV POST, users must be working with a Webtrader profile and have MPR browse or MPR browse and send rights. These rights are contained within the QPPV/RP and Trusted Deputy roles. All other users must request these rights separately.

3.6. Role approval for EudraVigilance

- The EU QPPV/RP for each organisation will be approved by EMA after they select the NCA/industry EU QPPV/RP role through the request access tab in the [EMA Account Management portal](#) and submit the required documents via [EMA Service Desk](#) access request, as described in section 3.3.
- When their access is granted, the user will receive a confirmation e-mail and the role will appear in the [EMA Account Management portal](#) Identity tab > access section.
- The EU QPPV/RP/TD user can then approve EV access requests for other users within their organisation.
- A role will be rejected if the system finds a clash (another role for the same organisation profile is already present). It is important to first revoke all the existing active roles for a single user profile before requesting a new base role for that user.

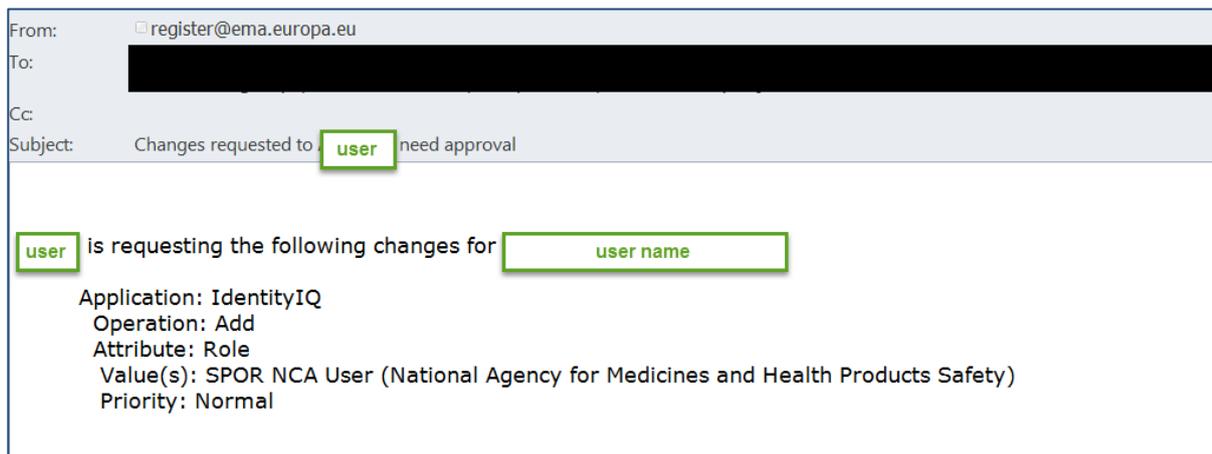
Clarification: An organisation can have multiple users with the same role, but a user needs to ensure they only have 1 base role per organisation profile. It is very important that for the new EU QPPV/RP to ensure that the previous EU QPPV/RP has removed their role and that this request has been approved. For TD and standard users, please ensure **all** (base and supplementary) roles for your organisation are removed before you request a new one.

- Additional roles trigger automatic role request rejections.

3.6.1. Approval process managed by EU QPPV/RP/TD

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

Figure 27. E-mail alert for a new EV role request

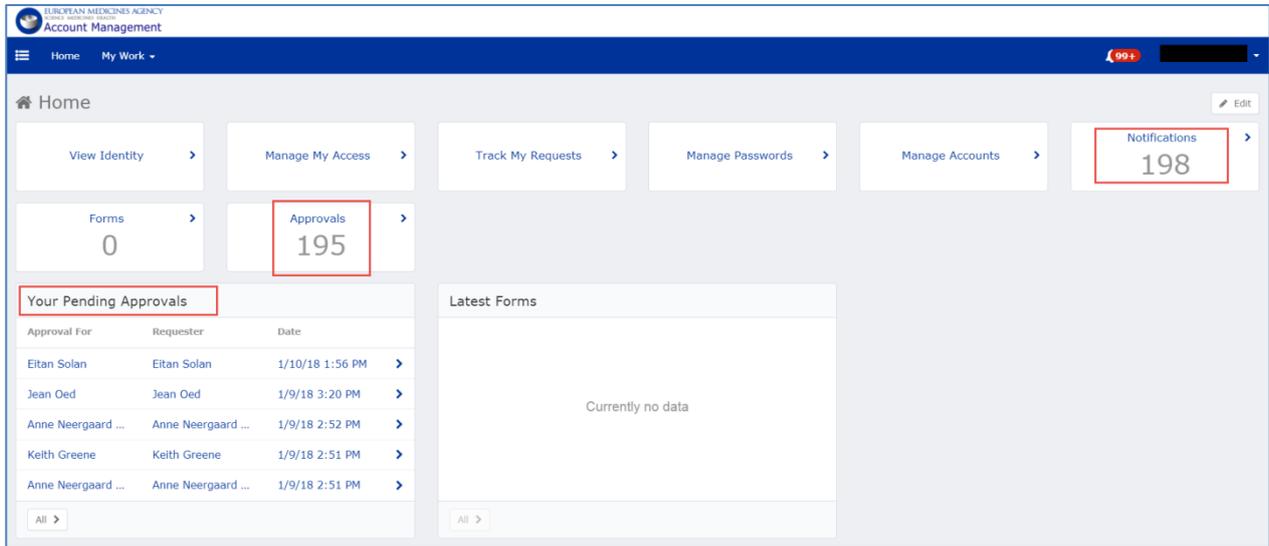


The EU QPPV/TD/RP needs to log in to

- The [EMA Account Management](#) portal homepage appears with a task to solve under the Notifications/Approvals. Approvers will receive a notification of this approval request in the inbox of their email address registered in the [EMA Account Management](#) portal.

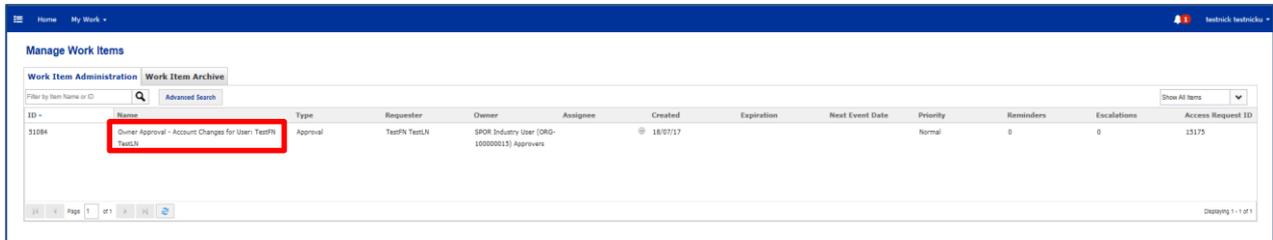
- This request also appears in the “Your Pending Approvals” box and in the dashboard inbox (see Figure 28. EU QPPV/RP’s homepage with a new access request in the inbox)

Figure 28. EU QPPV/RP’s homepage with a new access request in the inbox



Click on Approvals – overview of the request appears

Figure 29. Request overview



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

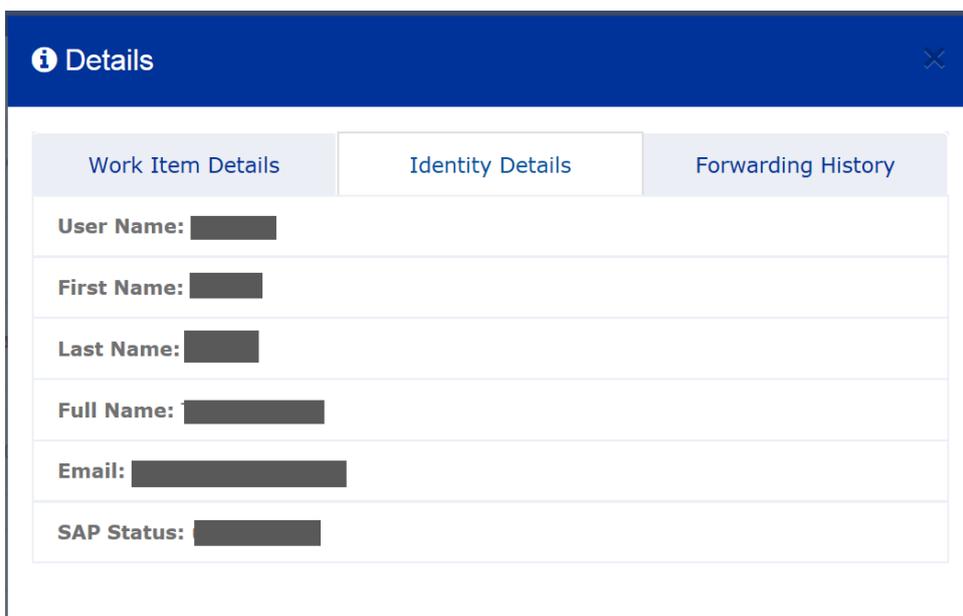
Figure 30. Request approval page – approval details



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 31. View requestor's identity details

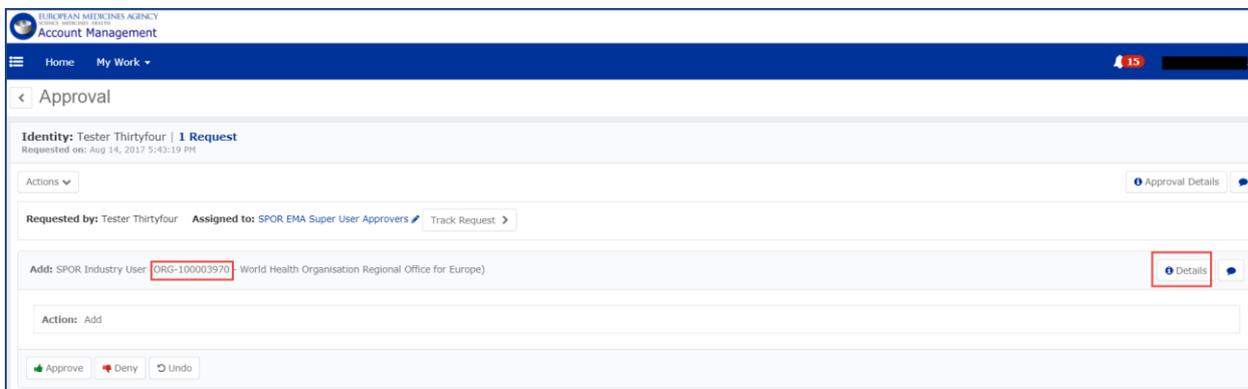


The screenshot shows a 'Details' window with three tabs: 'Work Item Details', 'Identity Details', and 'Forwarding History'. The 'Identity Details' tab is active and displays the following fields:

User Name:	[REDACTED]
First Name:	[REDACTED]
Last Name:	[REDACTED]
Full Name:	[REDACTED]
Email:	[REDACTED]
SAP Status:	[REDACTED]

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

Figure 32. Request approval page with approval item details and organisation ID



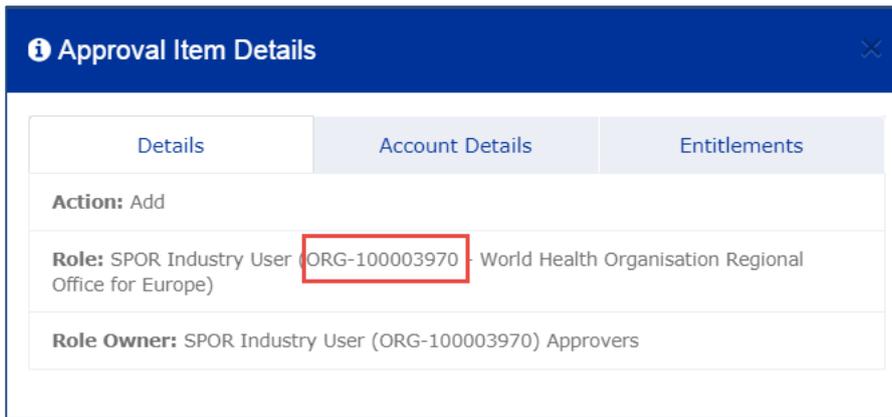
The screenshot shows the 'Approval' page in the EMA Account Management system. The page displays the following information:

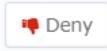
- Identity: Tester Thirtyfour | 1 Request
- Requested on: Aug 14, 2017 5:43:19 PM
- Requested by: Tester Thirtyfour
- Assigned to: SPOR EMA Super User Approvers
- Add: SPOR Industry User | **ORG-100003970** | World Health Organisation Regional Office for Europe

Buttons for 'Approve', 'Deny', and 'Undo' are visible at the bottom. A red box highlights the 'ORG-100003970' ID and the 'Details' button next to it.

Approval item details also include the affiliated organisation ID. The organisation must be the same as the organisation of the Role Owner User (Figure 33.).

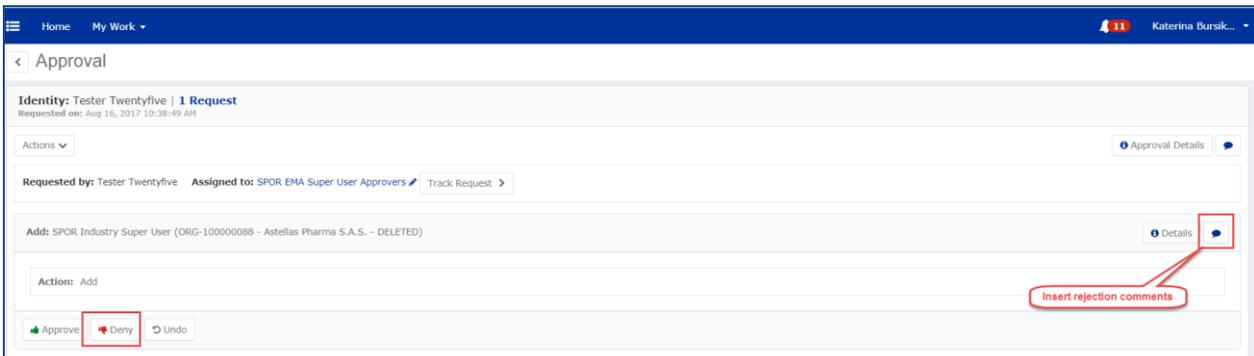
Figure 33. Approval item details



- Go back to the approval page
- Select the approve  or deny  icon as appropriate

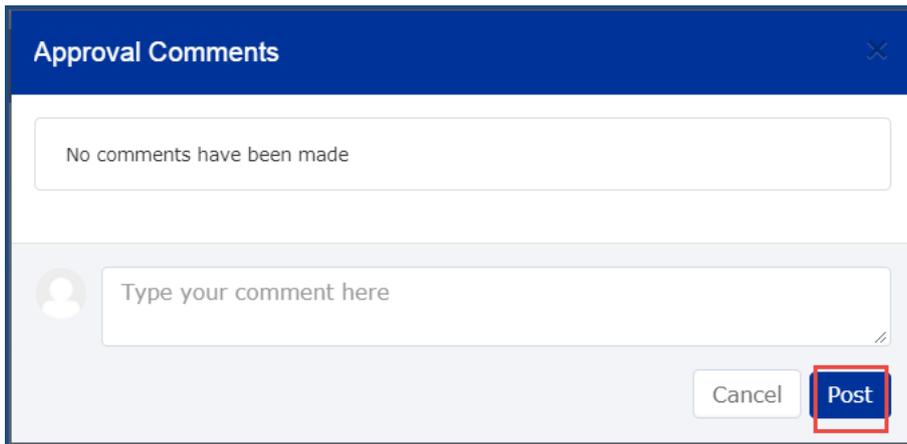
We recommend the QPPV/RP/TD inserts a comment before rejecting a role so that the user can be informed as to what the issue was and can make a modified new request if needed.

You can also add a comment before approving them. Comments should be inserted BEFORE approving or rejecting a role



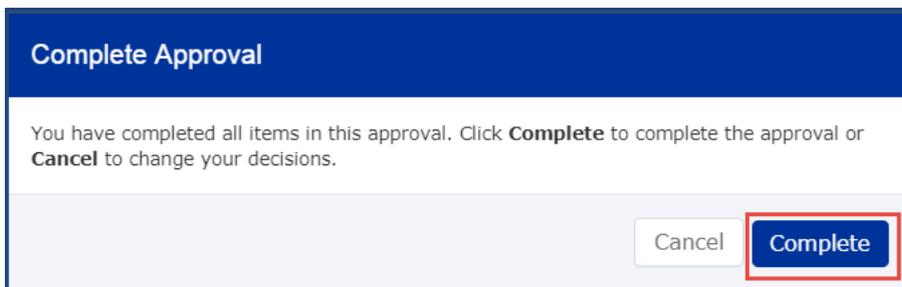
A pop-up window appears – enter your comments and click “post”

Figure 34. Insert rejection comments – pop-up window



- Click "Complete" (both for approve and deny)

Figure 35. Complete approval



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

3.6.2. EU QPPV/RP/TD user responsibilities

The EU QPPV/RP has an obligation to manage/maintain access for the users in their organisation

- The EU QPPV/RP/TD needs to confirm that the users indeed work for the organisation before granting the requested access
- The EU QPPV/RP/TD approves and removes access for the users of their organisation via EMA Account management portal
- It is the responsibility of the EU QPPV/RP to make sure that only users that require access to EV for their work are given access. For most organisations we recommend at least 1 QPPV/RP, 1 Trusted Deputy and 1 standard user.
- When a user no longer works for an organisation or their work changes so that they no longer require EV access, the EU QPPV/RP should disable their access in the [EMA Account Management](#) portal by revoking their roles via EV Role Admin tab (see section 3.7.2.1.).

- Access to the EV system on behalf of an organisation is the responsibility of the EU QPPV/RP/TD and EMA will not check
- For Access reviews and compliance forms, kindly refer to the [EudraVigilance Registration FAQ document](#), found on the [EudraVigilance: how to register webpage](#)

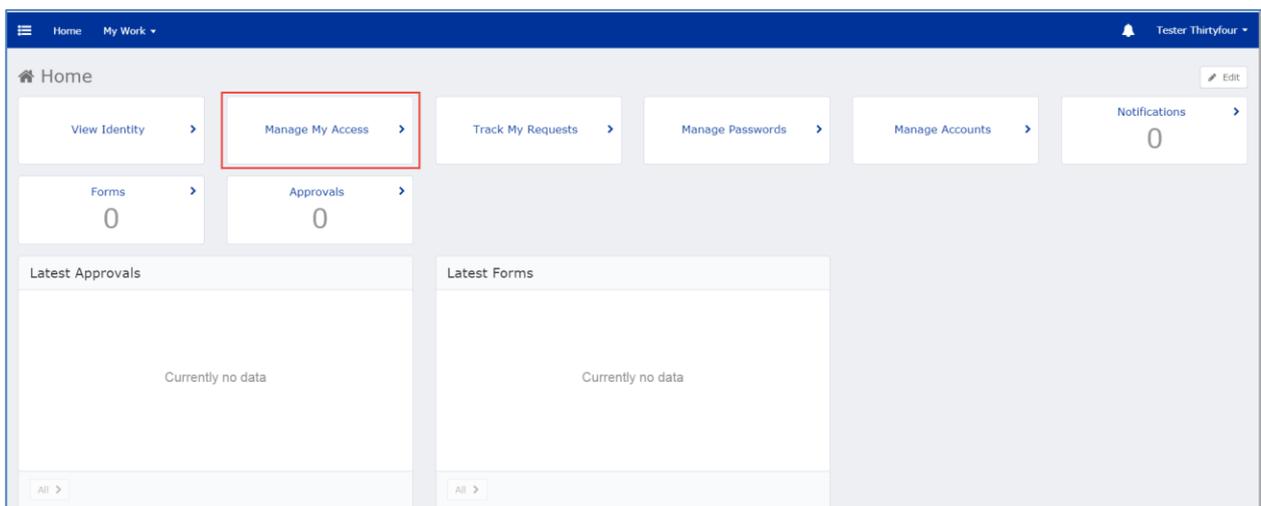
3.7. Removing access

3.7.1. Request your own access removal

A user can request their access to be removed

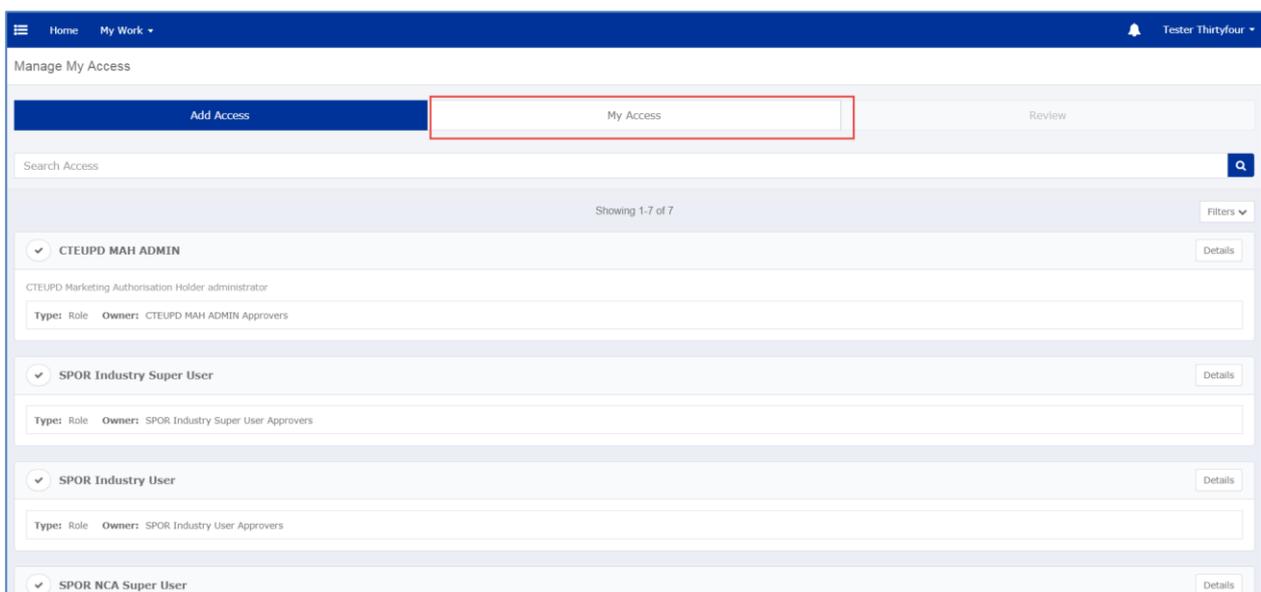
- Go to the homepage
- Click on “Manage my Access”

Figure 36. Manage my access



Go to “My Access”

Figure 37. My access

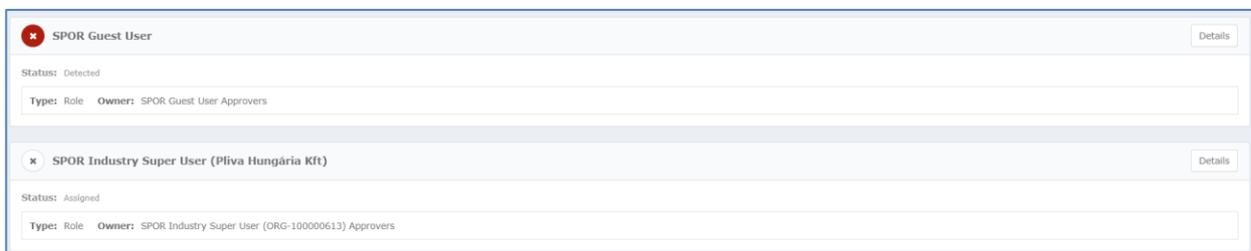




Select the role to be removed – click on  - it turns red.

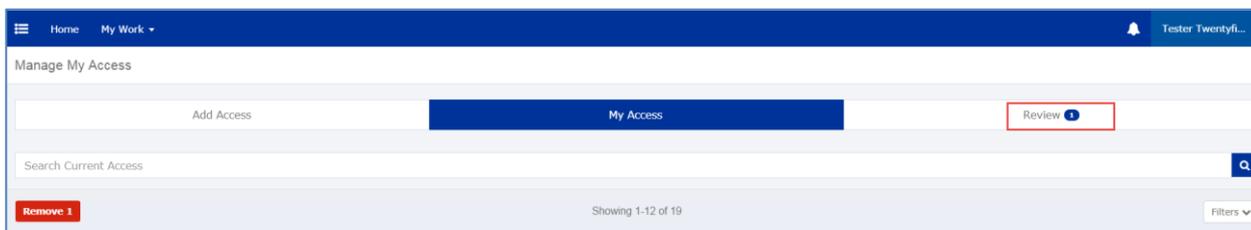
Please note in this section the user will also find many entries called “entitlements”. Do not pay attention to these, as they are triggered by the system and it is not relevant for role removal.

Figure 38. Role to be removed



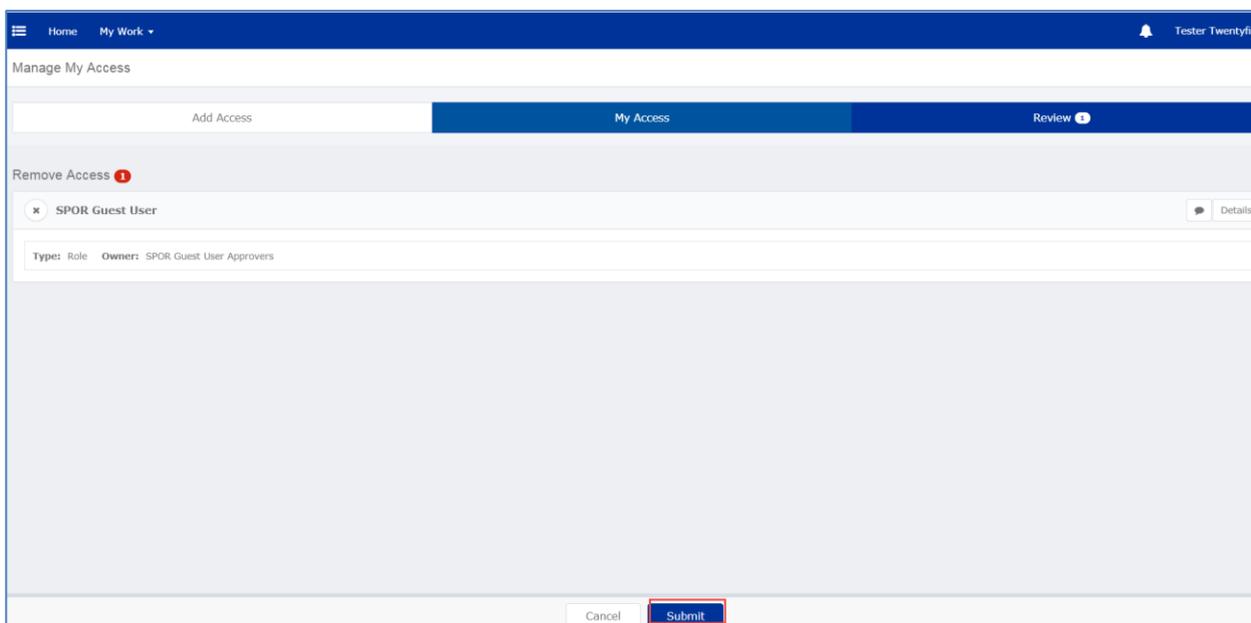
Scroll up the page and click “Review”

Figure 39. Review access removal



Click “Submit”

Figure 40. 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.

Of note, the EMA does not automatically approve the role removal of a QPPV/RP, EMA should be notified of the role removal request by raising a ticket with [EMA Service Desk](#), providing the removal request ID generated by EMA Account Management portal.

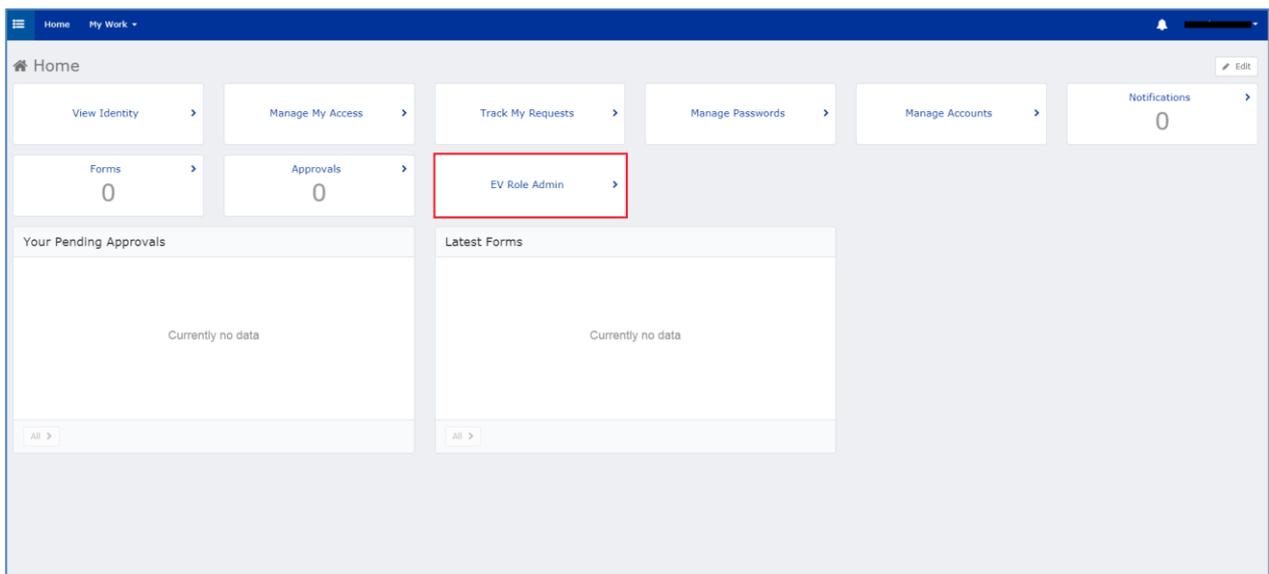
3.7.2. Revoke access

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

3.7.2.1. *Revoke an EV user role as an EU QPPV/RP/Trusted Deputy*

- Navigate to the [EMA Account Management](#) Portal
- Provide EMA credentials in the "Username" and "Password" fields
- Click on the "Login" button
- On the homepage, click the "EV Role Admin" tab

Figure 41. EV Role Admin



- Select the application (EV (EudraVigilance)) and organisation
- Once the application and organisation are selected, select the user you want to remove the access from
- All roles for the selected EV profile are removed. There is no possibility to remove only some roles.

Figure 42. EV Role Management

The screenshot shows a web interface titled "EV Role Management". It contains several form fields and buttons:

- Application ***: A dropdown menu with "EV (EudraVigilence)" selected.
- Search Organisation**: A text input field containing "ORG-100010705". Below it is a note: "Enter an organisation name or OMS ID to search for then select it from the menu below."
- Organisation ***: A dropdown menu with "ORG-100010705 - IAM 2 NCA RK2 - DELETED" selected. Below it is a note: "In case you cannot find your organisation in the list, please verify that it has been registered correctly with OMS <http://spor-dev.ema.europa.eu/omswi/#/>".
- User ***: A dropdown menu that is currently empty and is highlighted with a red border.
- Buttons**: "Cancel" and "Revoke Roles" (in blue) are located at the bottom of the form.

- Click on "Revoke Roles" button

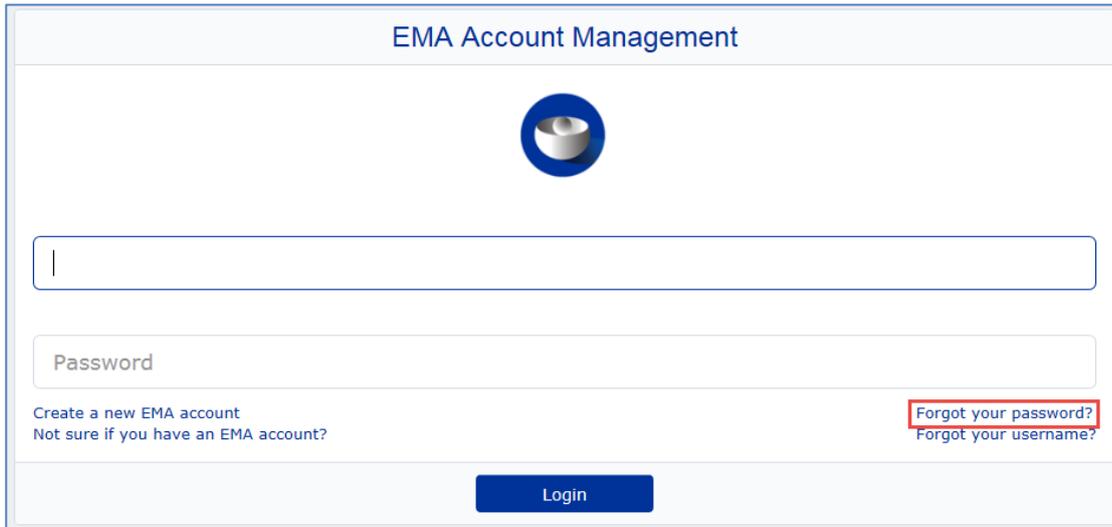
Note: EU QPPV/RPs can request their role to be removed in the system (section 3.7.1) but must contact EMA via Service Desk for the EV Registration team to approve the role removal request. Otherwise, the role of this QPPV/RP will not successfully be removed from the organisation profile.

3.8. Manage passwords and usernames in EMA Account Management portal

3.8.1. Reset forgotten password

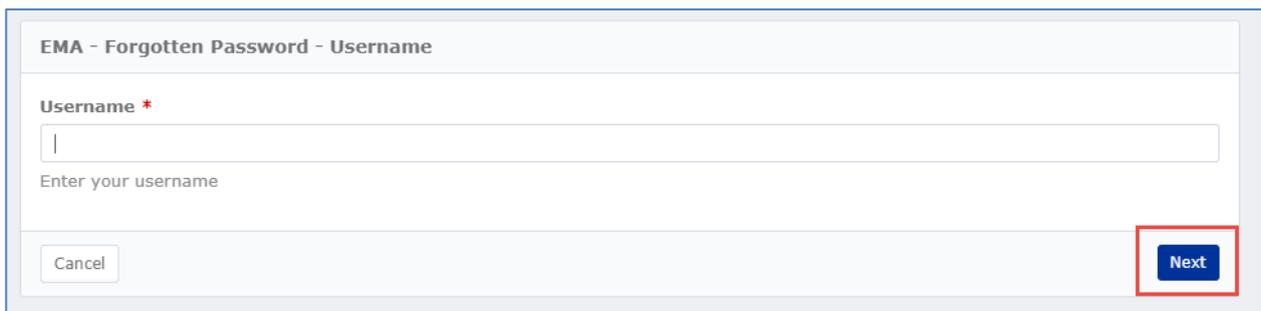
- A forgotten password can be reset with the help of the security questions
- Navigate to <https://register.ema.europa.eu/>
- Click the 'Forgot your password?' link.

Figure 43. EMA Account Management Portal and forgotten password link



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

Figure 44. Input username to retrieve forgotten password



- 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 45. Answering the security questions

The screenshot shows a web form titled "EMA - Forgotten Password - Security Questions". It contains two sets of questions. Each set includes a dropdown menu for the question and a text input field for the answer. The first set is labeled "Security Question 1" and "Answer 1 *". The second set is labeled "Security Question 2" and "Answer 2 *". At the bottom left is a "Cancel" button, and at the bottom right is a "Next" button highlighted with a red box.

The screenshot shows a password field with a red border and a red dashed underline. To the left of the field is a question mark icon. Below the field is a red warning icon and a message: "Password must have at least 8 character(s), Password must have at least 4 valid character types (out of lowercase letters, uppercase letters, digits and special characters)".

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

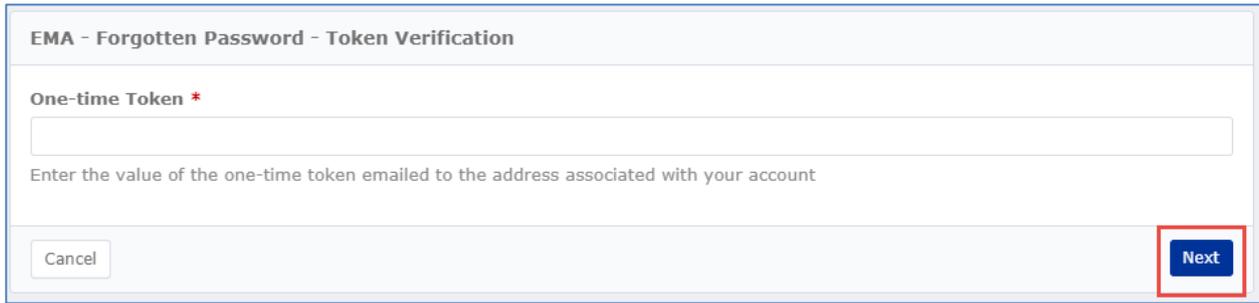
- An e-mail with a registration token is sent to the registered e-mail address

Figure 46. E-mail containing one-time token

The screenshot shows an email interface. The header includes "From: register-test@ema.europa.eu", "To: [redacted]", "Cc:", "Subject: EMA Password Reset - One-time Token", and "Sent: Thu 01/06/2017 11:03". The main body of the email starts with "Dear [redacted]", followed by a thank you message and a request to enter a token. The token value "MPVH9JMC54" is highlighted with a red box. Below this is contact information for the EMA and a disclaimer at the bottom.

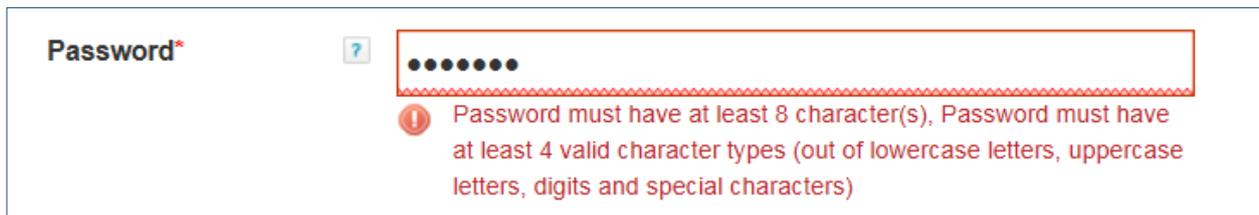
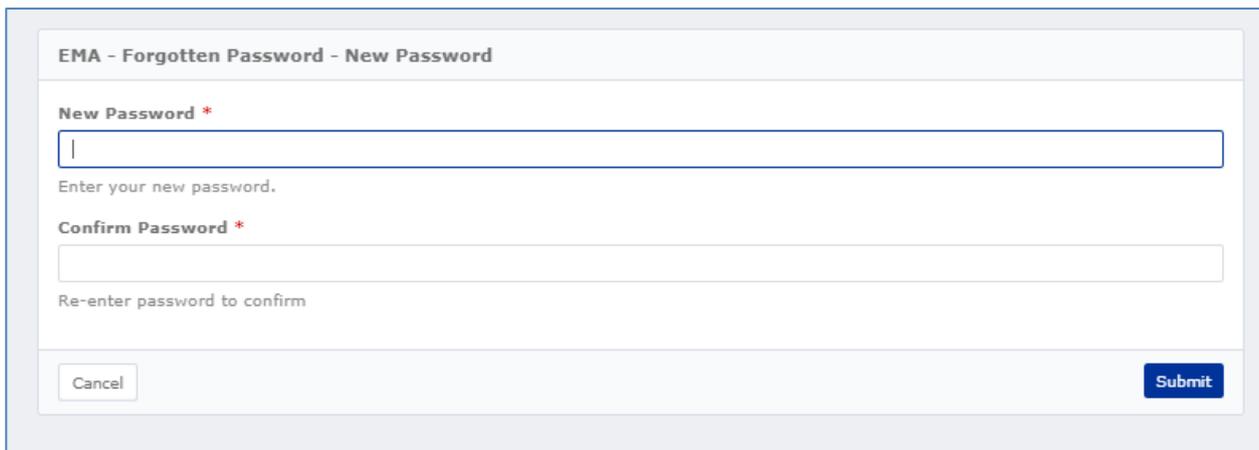
- Input this token in the 'One-time Token' field and click 'Next'.

Figure 47. Insert one-time token



- 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: the characters '+' and '&' should not be used as some EMA systems will not accept these characters in a password
- Enter your new password in the 'New Password' and 'Confirm Password' boxes and click 'Submit'
- The password is reset

Figure 48. Enter new password

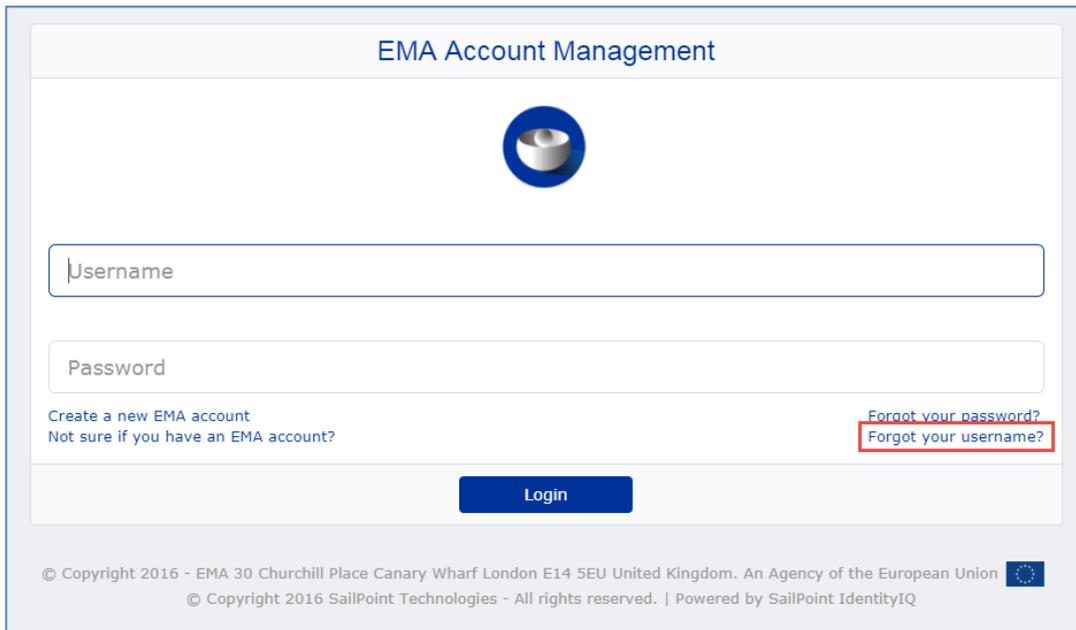


Note: If your account is locked, please contact Service Desk via phone: +31 (0)88 781 7523

3.8.2. Retrieve forgotten username

- Navigate to <https://register.ema.europa.eu/>
- Click the 'Forgot your Username?' link

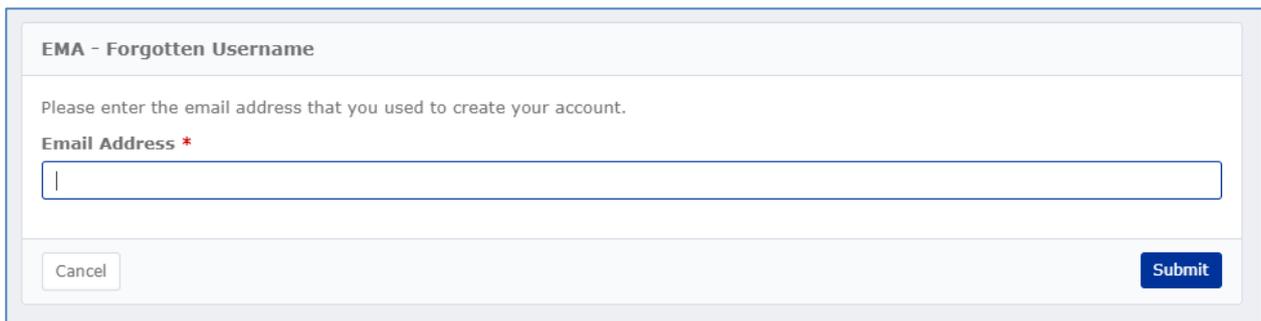
Figure 49. EMA Account Management portal and forgotten username link



The image shows the EMA Account Management login page. At the top, it says "EMA Account Management" in blue. Below that is a circular logo with a white cup inside a blue circle. There are two input fields: "Username" and "Password". Below the "Password" field, there are two links: "Create a new EMA account" and "Not sure if you have an EMA account?". To the right of these links, there are two more links: "Forgot your password?" and "Forgot your username?". The "Forgot your username?" link is highlighted with a red box. Below the links is a blue "Login" button. At the bottom, there is a copyright notice: "© Copyright 2016 - EMA 30 Churchill Place Canary Wharf London E14 5EU United Kingdom. An Agency of the European Union" and "© Copyright 2016 SailPoint Technologies - All rights reserved. | Powered by SailPoint IdentityIQ".

- Enter the email address you used to register in the [EMA Account Management](#) portal and click 'Submit'

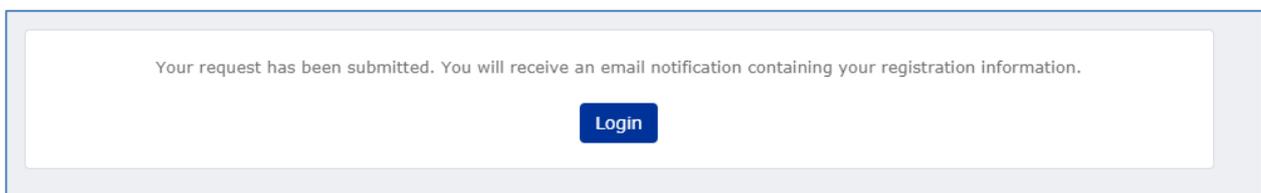
Figure 50. Enter e-mail address to retrieve forgotten username



The image shows the "EMA - Forgotten Username" form. It has a title "EMA - Forgotten Username" and a subtitle "Please enter the email address that you used to create your account." Below that is a label "Email Address *" and an input field. At the bottom, there are two buttons: "Cancel" and "Submit".

- Confirmation of the request is displayed

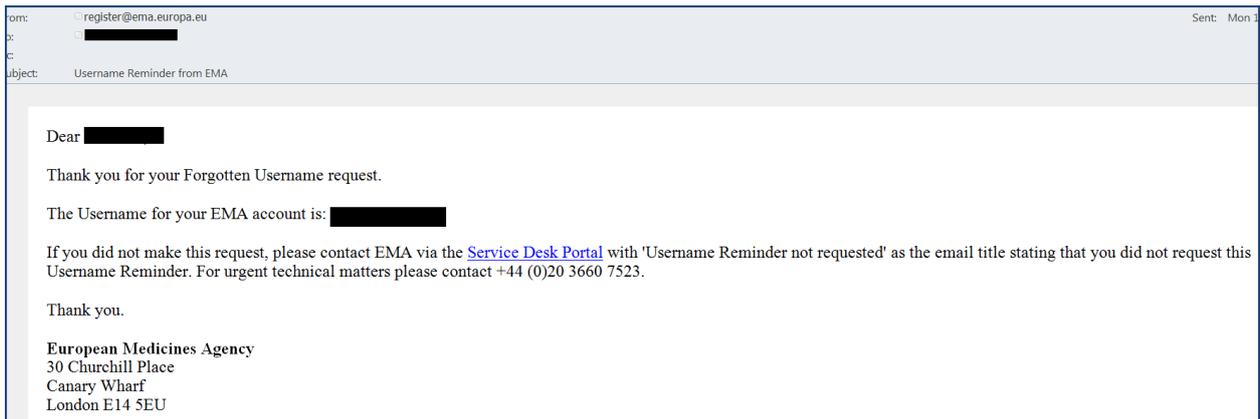
Figure 51. Confirmation of the forgotten username request



The image shows a confirmation message: "Your request has been submitted. You will receive an email notification containing your registration information." Below the message is a blue "Login" button.

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

Figure 52. E-mail to the user containing a forgotten username

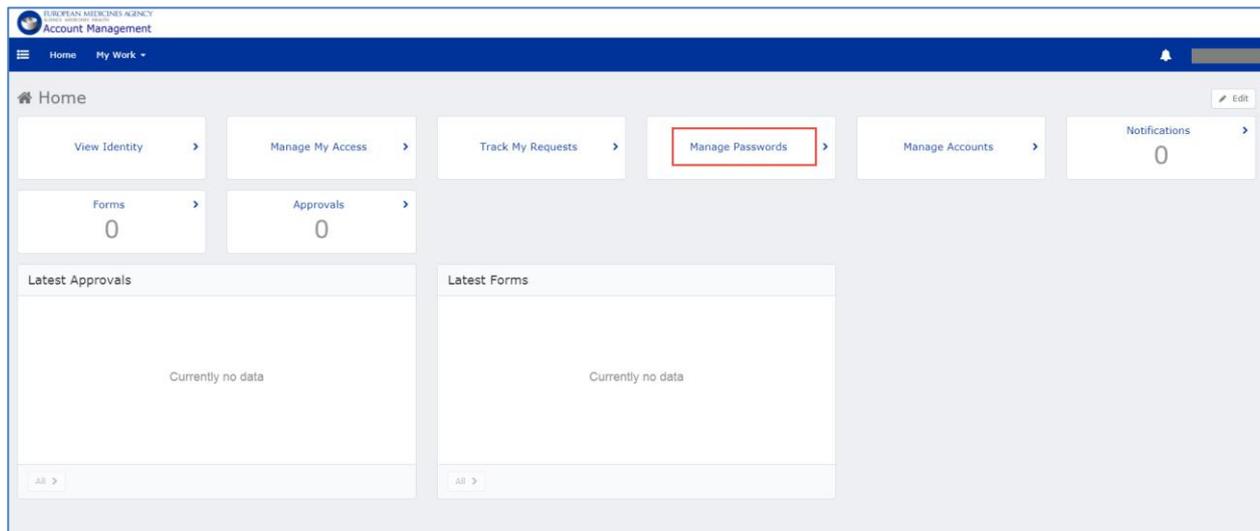


- Log in with your username and password

3.8.3. Change password in EMA Account Management portal

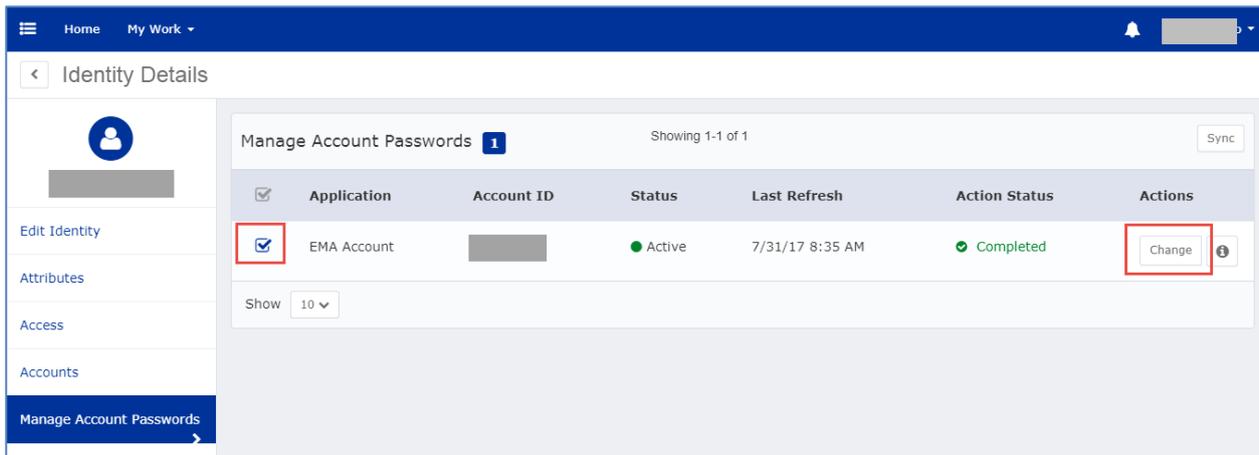
- Log in to the EMA Account Management portal
- Click on the 'Manage Passwords' link on your Home page

Figure 53. Change password in the EMA Account Management portal



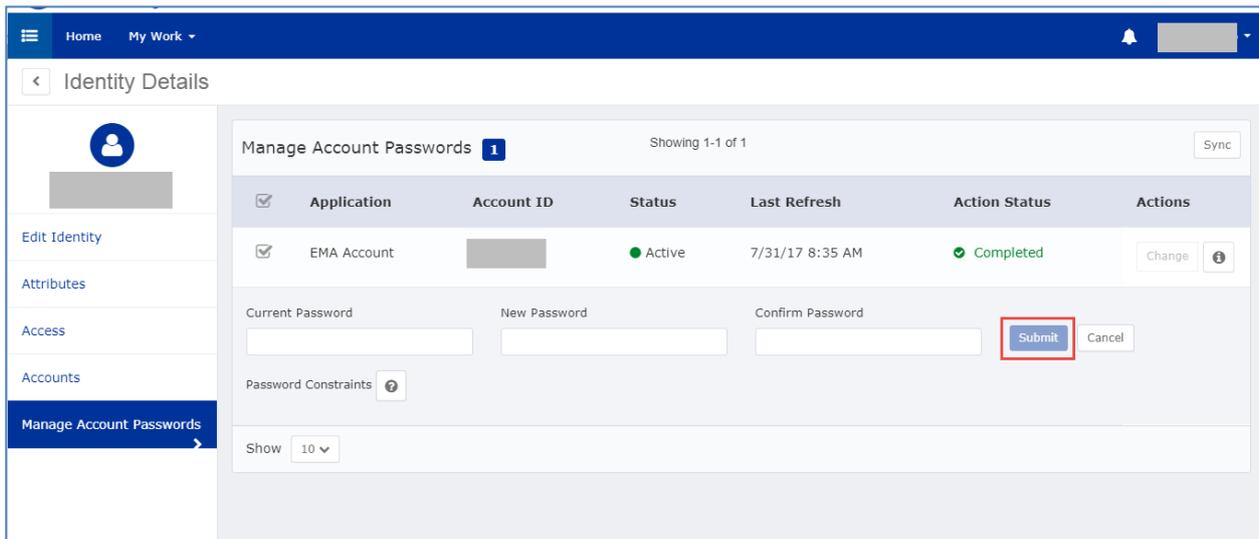
- Select your EMA Account by clicking on the checkbox in front of the account for the EMA Account Application, press 'Change'

Figure 54. Manage passwords screen in the EMA Account Management portal



- Type your current password in the 'Current Password' field and the new password in the 'New Password' and 'Confirm Password' fields. However please note, the characters '+' and '&' should not be used in a password
- Click the 'Submit' button

Figure 55. New password and submit

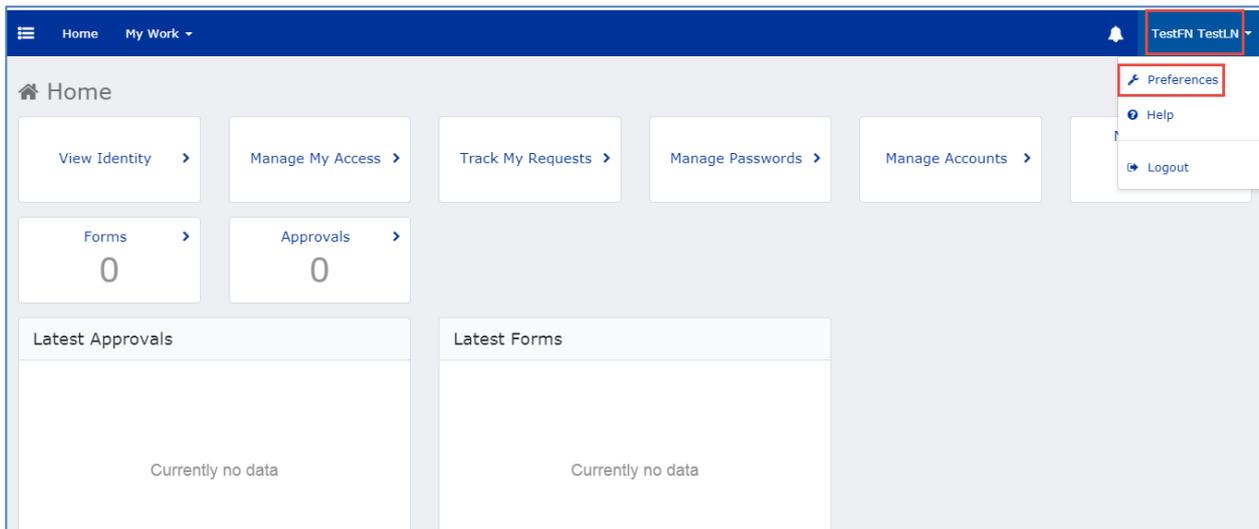


3.8.4. Update security (authentication) questions

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:

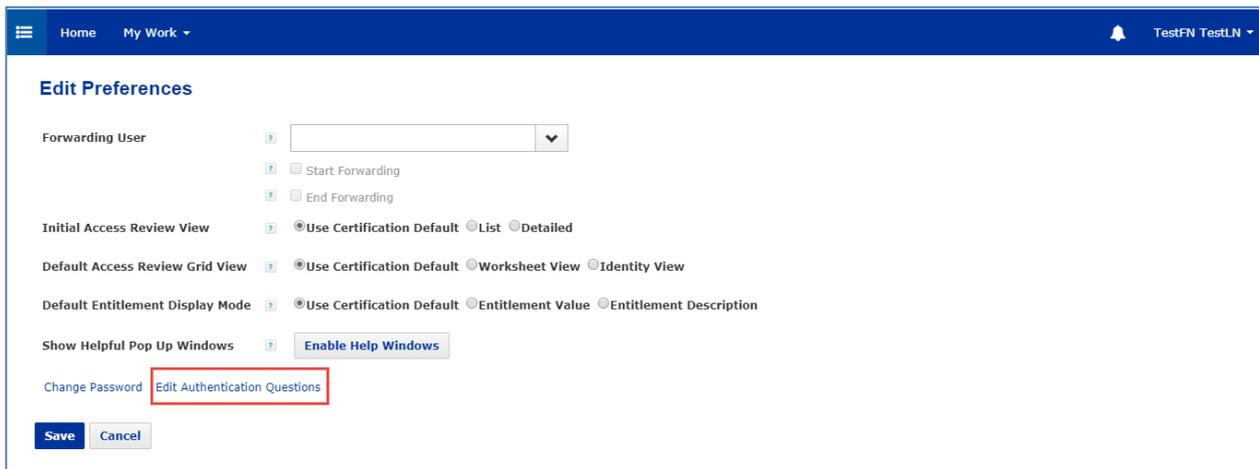
- Login to the [EMA Account Management](#) portal
- Click on the username link on the top right corner of the homepage and click 'Preferences'

Figure 56. Access my preferences



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

Figure 57. Edit preferences



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

Figure 58. Selecting security (authentication) questions

The screenshot shows the 'Edit Preferences' interface. Under the 'Authentication Questions' section, there are three questions with corresponding answer fields. The 'Save' button at the bottom left is highlighted with a red box.

3.9. 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

Figure 59. Policy violation examples

The screenshot shows a 'Policy Violations will occur' warning in a red box. Below the warning, there are two 'Add Access' entries for 'SPOR Industry Super User' and 'SPOR NCA Super User'. Each entry shows 'Type: Role' and 'Owners: SPOR Industry Super User Approvers'.

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 60. Policy violation solution – remove a role

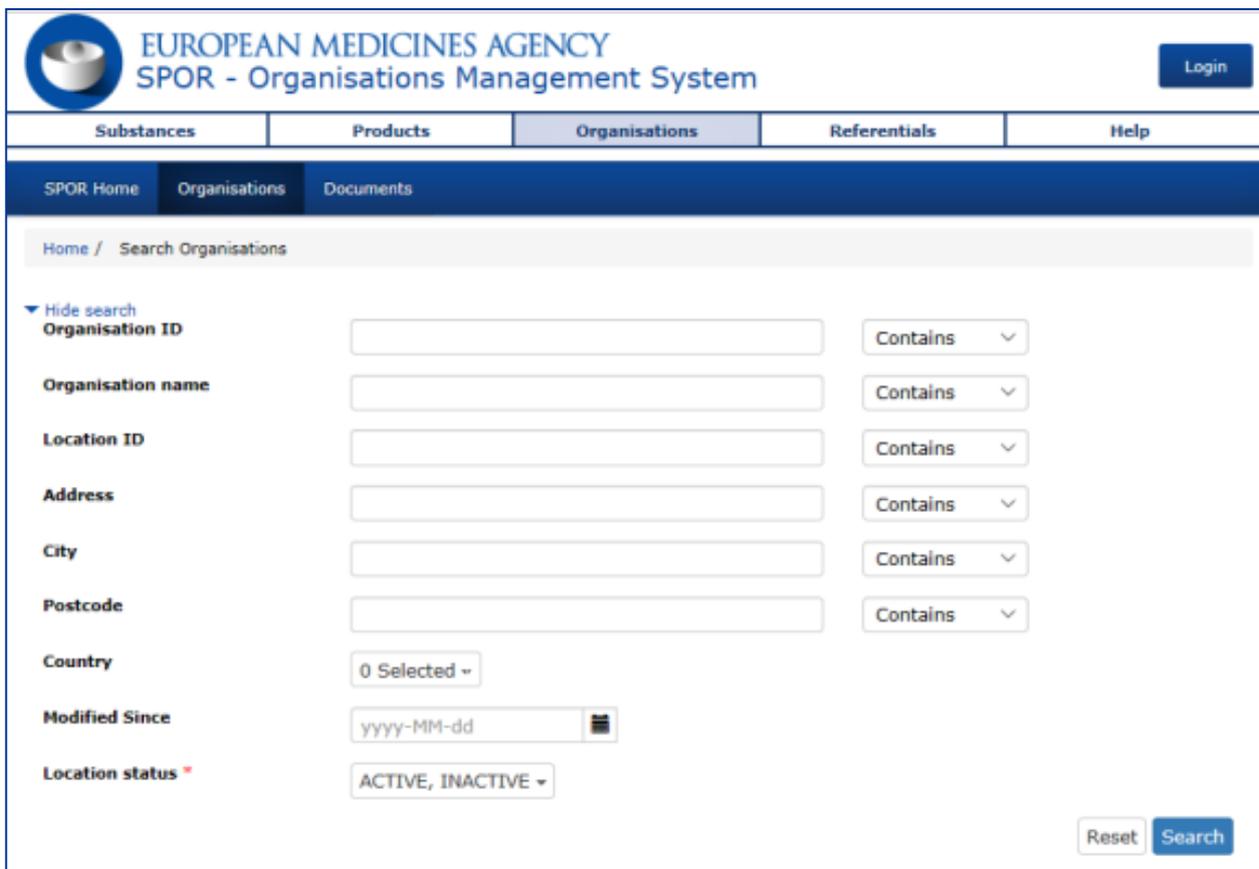
The screenshot displays a web interface with a top navigation bar containing 'Add Access', 'My Access', and 'Review'. Below the navigation bar, a red warning box states 'Policy Violations will occur.' with two bullet points: 'No account may have an Industry role and also an NCA role' and 'No account may have an NCA role and also an Industry role'. A 'Submit with Violations' button is located below the warning. Underneath, the 'Add Access' section shows two roles: 'SPOR Industry Super User' and 'SPOR NCA Super User'. Each role entry includes a 'Details' button and a 'Type: Role' label. The 'SPOR Industry Super User' role is highlighted with a red box around its 'x' icon.

4. Create a new Organisation

To create a new organisation:

1. Follow the process in Figure 1. to register on the EMA Account Management portal and request "SPOR Unaffiliated Role"
2. Log into [SPOR Organisations](#) (Please note that this webpage does not work with Internet Explorer)
3. 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 61. Search for an Organisation in OMS



The screenshot shows the 'Search Organisations' page in the SPOR system. At the top, there is a header with the EMA logo and the text 'EUROPEAN MEDICINES AGENCY SPOR - Organisations Management System'. A 'Login' button is in the top right. Below the header is a navigation bar with tabs for 'Substances', 'Products', 'Organisations', 'Referentials', and 'Help'. The 'Organisations' tab is active. Below this is a sub-navigation bar with 'SPOR Home', 'Organisations', and 'Documents'. The main content area has a breadcrumb 'Home / Search Organisations'. A 'Hide search' link is on the left. The search criteria are listed on the left, each with an input field and a 'Contains' dropdown menu: 'Organisation ID', 'Organisation name', 'Location ID', 'Address', 'City', 'Postcode', 'Country' (with a '0 Selected' dropdown), 'Modified Since' (with a date input 'yyyy-MM-dd' and a calendar icon), and 'Location status' (with a dropdown 'ACTIVE, INACTIVE'). 'Reset' and 'Search' buttons are at the bottom right.

4. If your organisation cannot be found, a new tab appears "Request New Organisation". Please follow the steps on how to register that appear in the Manuals "Change request validation in OMS" and "OMS Web User Manual " available on the [SPOR Organisations](#) web page (under the "Documents" tab).

Figure 62. Request the creation of a new organisation

SPOR Home Organisations View Requests Documents

Home / Search Organisations

No results found matching the search criteria

Export All Organisations Export All Organisations With History

Hide search

Organisation ID Contains

Organisation name XYZ SRL Contains

Location ID Contains

Address Contains

City Contains

Postcode Contains

Country 0 Selected - Contains

Modified Since yyyy-MM-dd

Location status* ACTIVE, INACTIVE

Reset Search

Request New Organisation

Figure 63. Fill in the details and submit the new organisation

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / New Organisation Request

CR Information

CR Type New Organisation

Request Reason*

Justification

Requestor Arnaud Berghmans

Contact email* arnaud.berghmans@gmail.com

Contact Phone

Organisation Details

Organisation Name* e.g. European Medicines Agency

Acronym

Organisation Type*

Location Details

Address* e.g. 30 Churchill Place
e.g. Canary Wharf

City e.g. London

Postcode e.g. E14 5EU

Country e.g. London

Country*

Location Email (1) e.g. john.doe@ema.europa.eu

Location Phone (2) Int Code: e.g. +44 Ext: e.g. 02036605000

DUNS ID e.g. 01-234-5678

GS1 ID e.g. 0-00-12345-67890-9

Attachments

No documents found, click to add +

Date	Status to	Comment
No data available in table		

(1) Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The location Email and Location Telephone number are optional fields. If you have any question about the way your data are being processed please contact EMA at mdms@ema.europa.eu.

Cancel Submit

4.1. Finalise organisation information in EV Human Production and XCOMP

Once you receive confirmation via email that your organisation in OMS has been created successfully, the first user must go to [EMA Account Management](#) portal and request the relevant EU QPPV or RP role for this organisation (See Section 3.2.).

When the role is approved, access your restricted area view for the Production or XCOMP (Test system) and select "Manage my profile" on the left column.



Figure 64. View of EU QPPV/RP/TD Restricted Area

Organisation EudraVigilance Information

> Organisation Information

Organisation Identifier	TESTHQ_AXWAY
Organisation Name	TESTHQ_AXWAY Idt.
Organisation Category	Marketing Authorisation Holder
Gateway profile	Not registered
Sending products	Not available
Posting Reports	Authorised
Type of MedDRA licence	Full MedDRA Subscriber
MedDRA Number	12345
Safety reports visibility	No
Organisation functional email	EudraVigilance@ema.europa.eu

> Responsible Information

Name	Mr: EVHUMANWTU01_Name EVHUMANWTU01_Surname
Email	EVHUMANWTU01@EVHUMANWTU01.com
Street	1 Frederic street
City	Leiden
Postal Code	12333
Area / State	17
Country	Netherlands

> Regulatory Contact Point

Regulatory Contact Point Name	Luca Test
Regulatory Contact Point Email	luca.test@ext.ema.europa.eu

Affiliates

Affiliate ID	Affiliate Name
TESTAF_AXWAY	TESTAF_AXWAY Idt.

Virtual Affiliates

ID	Name
TESTVA_AXWAY	TESTVA_AXWAY Idt.
VA000000310	VA000000310 - TEST1
VA000000312	VA000000312 Idt.

Headquarter Users

Name	Family Name	UserName
Evhumanwtu01_Name	Evhumanwtu01_Surname	EVHUMANWTU01
Luca bolognesi_Name	Luca bolognesi_Surname	lucabolognesi

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.

- **Organisation Category** – Industry is MAH, Regulatory is NCA, or choose between Commercial or Non-Commercial Sponsor according to the type of your organisation.
- **Transmission mode/ Gateway profile** – Organisations will show as “Not registered” by default. Sending ICSR reports and XEVMPD messages using EVWEB will not be possible until a confirmation by the EMA is received that the transmission mode registration 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 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 (See section 3.3). 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.

Further information can be found in the [EudraVigilance: how to register](#) webpage in “Transmission mode for reporting” section.

- **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 EV POST function has been enabled for organisations using EVWEB. In order to have this functionality enabled organisations need to complete testing with the EMA - see [EudraVigilance: Electronic Reporting](#) for details of the process. Once this process has been completed successfully please submit a Service Desk request in order for this field to be updated.
- **Type of MedDRA licence** – Select “Full MedDRA subscriber” if you have a MedDRA licence or MedDRA Fee waiver if your organisation qualifies for not requiring a licence. Please review the MedDRA MSSO website to confirm if you qualify for the special licence (<https://www.meddra.org/subscription/special-licences>) as a non-commercial organisation or as a small/micro-sized company. If you consider yourself as a small/micro-sized 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.

Note: If you are accessing as an SME fee waiver organisation, please enter your SME registration number. If you in the process of registering with the SME office please enter “SME application sent”. Once the SME registration is complete please return to this page in order to enter the SME number.

- **Safety Reports Visibility** – Select if you wish users of your affiliate organisations to have access to the reports sent by the HQ or other affiliates.
- **Organisation Functional email** – Functional email that is available at all times, which does not change (i.e., pharmacovigilance@company.com) in case EMA needs to contact the organisation if the EU QPPV/RP or Trusted Deputy are not available.
- **Regulatory Contact Point** – It is mandatory for MAH organisations to have a regulatory contact point in case the EU QPPV is missing or for any legal enquiries.
- **Responsible Information** – Further Contact details for the EU QPPV/RP which are required legally.

Once these are added, please click on “update”. Please note that after the first update the “organisation category” can only be changed subsequently through raising an [EMA Service Desk](#) request.

4.2. Update organisation details in OMS

For updates required for your organisation details such as address, name, etc., please log into the [SPOR](#) portal and select “Change Request”. For a more detailed explanation of the step by step process and required documents, please refer to the “Change request validation in OMS” and “OMS Web User Manual” on the [SPOR](#) portal (under tab “Documents”).

Figure 65. Change Request in OMS

Organisation Details	
Organisation ID:	ORG-100001482
Organisation Name:	Flynn CL Pharma Ltd
Status:	ACTIVE
Organisation Type:	Industry

Location Details	
Location ID:	LOC-100000038
Address:	21 Churchill Place Canary Wharf London E14 5EU United Kingdom
Last Modified Date:	2017-03-12T15:16:57
Last Modified By:	admin
Status:	ACTIVE

[Request New Organisation](#)



Note: Please be aware that in order to change your organisation details in OMS, you need to have a **SPOR Super User role** for Industry or NCA. This role must be requested via the [EMA Account Management portal](#) and will be sent to the EMA for approval.

This **Super User role** is NOT to be confused with EU QPPV/RP which is the main user of an EV profile. SPOR Super User relates only to OMS.

In order for this information to be updated in EudraVigilance you will need to log into the EudraVigilance restricted area and select the new or updated OMS Location ID and save the changes.

5. EV Restricted Area Management

5.1. EV restricted area and transmission mode for new organisation

- The first time an organisation (profile) is created in EV Human Production, the EU QPPV/RP needs to fill in all the blank fields in the EV Restricted Area.
- The EU QPPV/RP will need to add their address, functional email and Regulatory contact point information in the EV Restricted area, then select "update" for the information to be registered and saved in the system.
- The transmission mode will not be activated until a confirmation by the EMA has been received that the transmission registration has been completed.

Note: the address that appears in the EV restricted area is the address of the EU QPPV/RP. The address of the organisation is stored in OMS and can only be amended via an OMS change request (see section 4.2).

5.2. Manage organisation hierarchy in the Production system

Only EU QPPVs/RPs/TDs have access to Affiliate and Virtual Affiliate view.

If user administrator rights are required for an affiliate profile, the QPPV/RP or TD must request the relevant role in [EMA Account Management portal](#) for the affiliate profile as well.

Note: We recommend keeping profiles as clean as possible. If you can work with profiles as HQ profiles instead of affiliating them, please do so.

5.2.1. Add an Affiliate to a Production system Headquarter

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

5.2.1.1. **To add an Affiliate from an existing EV profile** - create a cover letter on official company headed paper, date and sign it. **The letter must be signed by the QPPV/RPs of all involved organisations.** Add the following information clearly explained:

- i) EV ORG ID of the HQ profile
- ii) Organisation category of the HQ profile
- iii) EV Org ID, organisation category and name of the new affiliate to be added to the HQ

Important note: Organisations must make sure that their HQ organisation category displays correctly within the EudraVigilance Restricted Area. When a merge is completed, the category of the merged affiliate profile(s) is aligned with the category of the HQ profile. If the QPPV/RP of the HQ profile has not done so, they must log in to the EudraVigilance Restricted Area and update the HQ organisation details, paying attention to the organisation category.

Please also note: the existing organisation profile you will be merging must have a registered QPPV/RP before the merge can be performed. An organisation without a QPPV/RP has a disabled status and cannot be merged. The QPPV/RP of the merging affiliate must also log in to the Restricted Area for this affiliate and update the affiliate organisation details.

Then raise an EMA Service Desk access request, attach the signed letter to the ticket and request a merge.

5.2.1.2. **To add a new affiliate with no profile in EV** – please first create the new organisation as a headquarter as explained in section 4 and then proceed with steps above in 5.2.1.1

Please note: the new organisation profile you will be merging must have a registered QPPV/RP before the merge can be performed. An organisation without a QPPV/RP has a disabled status and cannot be merged. The QPPV/RP of the merging affiliate must also log in to the Restricted Area for this affiliate and update the affiliate organisation details.

5.2.2. Manage Affiliate information

Please submit a change request via [OMS Platform](#) if you wish to change address related information.

To remove a user, the EU QPPV\RP or TD will need to do so via their [EMA Account Management](#) portal, accessing the EV Role admin tab, filling in the name of the organisation and the user name.

To amend user's rights, the user will need to request removal of their current role and then request the new role that can be approved by the EU QPPV\RP or TD.

5.2.3. Move an Affiliate from HQ A to HQ B

Create a cover letter on official company headed paper, dated and **signed by the QPPV/RPs of all involved organisations**. Please ensure the following information has been provided:

- i) HQ Org ID where the affiliate should be moved to
- ii) Organisation category of the HQ profile where the affiliate should be moved to
- iii) Org ID and name of the affiliate profile which is to be moved (provide a list of affiliate profiles if more than one is to be moved)

Please refer to the Important Notes in section 5.2.1.1. above.

Then raise an EMA Service Desk ticket addressed to EV technical team, requesting a merge/swap and attach the signed letter.

5.2.4. Change Affiliate into a HQ organisation

Create a cover letter on official company headed paper, dated and **signed by the QPPV/RPs of all involved organisations**. Please ensure the following information has been provided:

- i) Org ID and name of the affiliate profile which is to be changed to become a HQ profile

Then raise an EMA Service Desk ticket addressed to EV technical team, requesting a merge/swap and attach the signed letter.

5.2.5. Swap an Affiliate to become the new HQ and the previous HQ to become an affiliate

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

- i) HQ Org ID to be turned into an affiliate
- ii) Affiliate Org ID which is to be changed to become the new HQ profile

Then raise an EMA Service Desk ticket addressed to EV technical team, requesting a swap and attach the signed letter.

Please note that when merging a HQ profile to another HQ profile, all registered affiliates and virtual affiliates of the merging profile will be re-linked to the new HQ. Users with EV contributor role will need to re-request the contributor role for the new HQ organisation.

5.3. Virtual Affiliates

Users with EU QPPV, Responsible Person or Trusted Deputy role can create virtual affiliates.

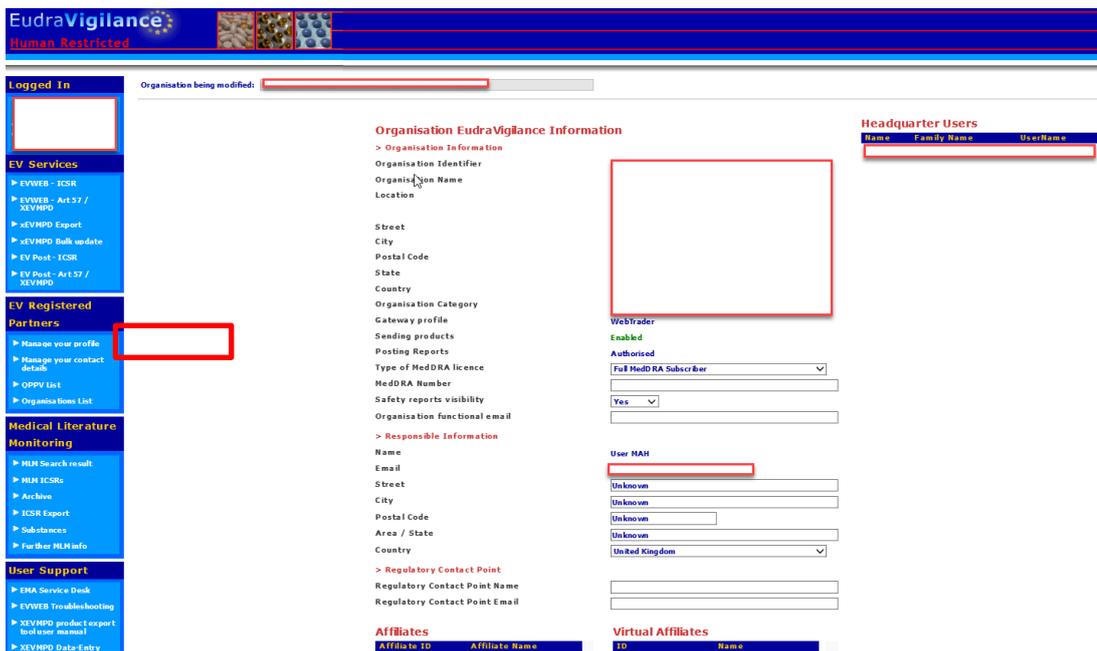
Note: Ensure that any user to be added to the Virtual affiliate has an account with EMA and has requested the EV Contributor role for the headquarter profile.

Virtual affiliates should be created for CROs working on behalf of an organisation and where additional transmission modes are needed, e.g. if an organisation is submitting ICSR via Gateway and needs a Webtrader transmission profile to submit XEVMPD product messages.

5.3.1. Create a Virtual Affiliate in EudraVigilance Production or XCOMP systems

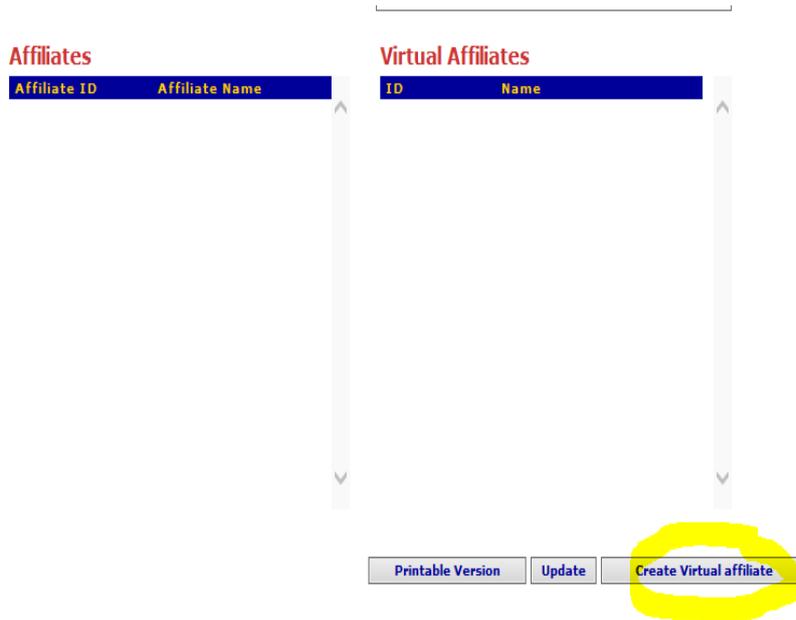
1. EU QPPV/RP or TD logs into EV Human Production and selects "Manage my Profile" from the left-hand side column

Figure 66. Access your Restricted area view



- Click on the "Create Virtual Affiliate" button from the bottom menu

Figure 67. Creation of Virtual Affiliate



- Fill in all the details of the organisation
- 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"

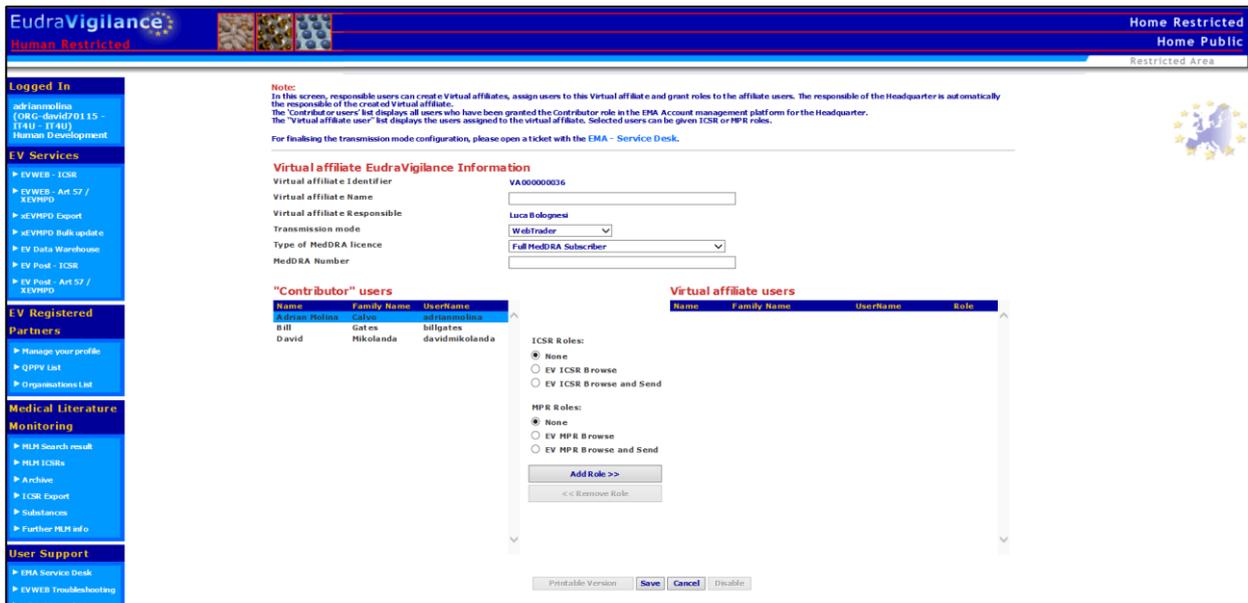
Transmission mode/ Gateway profile – Organisations will show as "Not registered" by default. ICSR reports and XEVMPD messages cannot be sent using EVWEB until a Gateway profile has been registered. A Service Desk request should be raised for this quoting the Virtual Affiliate routing ID number, as well 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. (See section 3.3). Gateway organisation profiles cannot be used for sending products via the EVWEB tool, if you need to send products using EVWEB please register a virtual affiliate or legal affiliate with a Webtrader profile.

For documentation to set up a Gateway transmission mode, kindly refer to the [EudraVigilance: how to register](#) webpage Section "Transmission Mode for reporting"

- Once all information is added, click "Save"

Figure 68. Virtual Affiliate view and action buttons



5.3.2. Manage Virtual Affiliates

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

- Remove a user by selecting the “Remove Role” (below “Add Role”) in between Contributor User and Virtual Affiliate user columns.
- Disable a Virtual Affiliate selecting the “Disable” button (in the menu on the bottom part of the page). Revoke Contributor user role in [EMA Account Management](#) portal if required (see section 3.7.2.1.) and Raise an [EMA Service Desk request](#) to our Gateway team with your ORG ID and Name to request the disabling of the transmission mode.
- Change User rights by selecting user and changing the access rights in the middle, then click “Update”.
- Update information in the Virtual Affiliate Information fields

5.3.3. Virtual Affiliate users

- In order to be part of the virtual affiliate profile, please note the following scenarios:
 - a) You are a user in the HQ profile – you do not need to request any further role. The QPPV/RP of the HQ profile will have you in the list of potential EV contributor users for them to manually add a role for you directly in the virtual affiliate profile
 - b) You are a new user – please log into [EMA Account Management portal](#) and request the EV contributor role to the HQ profile. Once this role is approved by the TD/RP or QPPV of the HQ profile, you will be added in the list of users that the QPPV/RP can add to this virtual affiliate profile.

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

This action can only be undertaken by the EU QPPV/RP or TD for a HQ profile.

5.4.1. Disable HQ and Affiliate profiles

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

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

- i. The QPPV/RP user should log into the [EMA Account Management](#) portal and revoke all user roles (3.7.2. Revoke access) for the organisation
- ii. 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 5.2.2. "Manage affiliate information" above).
- iii. The QPPV/RP user should log in to the [SPOR OMS platform](#) and create a change request to deactivate the organisation.
- iv. 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 affiliates). The organisation ID is the routing ID that needs to be disabled.

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

- i. The QPPV/RP user should log into the [EMA Account Management](#) portal, revoke all user roles (3.7.2. Revoke access) for the organisation and request the removal of their own QPPV/RP role (3.7.1 Request your own access removal). The role removal request ID should be communicated to the EMA via a Service Desk ticket in order to approve the removal of their role.
- ii. 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 5.2.2. "Manage affiliate information" above).
- iii. Raise an [EMA Service Desk](#) ticket to request that the organisation is disabled in the EudraVigilance system and that it is disconnected from the EMA Gateway. Please provide the EudraVigilance organisation ID for each profile to be disconnected (HQ and affiliates).

5.4.2. Disable a Virtual affiliate

- i. The QPPV/RP user or trusted deputy should log into the EudraVigilance restricted area HQ profile concerned, open the virtual affiliate at the bottom of the page and remove all the users from the virtual affiliate and then select the "disable" button.
- ii. Raise an EMA Service Desk ticket to request that the organisation is disconnected on the EMA Gateway. Please provide the EudraVigilance organisation ID for each profile to be disconnected.

5.5. Manage Art 57 QPPV and 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 that 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.

5.5.1. 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.

Figure 69. Manage your contact details



Figure 70. Review of contact details

EudraVigilance User Information

> Contact Information

Name:	<input type="text" value="John"/>
Family Name:	<input type="text" value="Smith"/>
Title:	<input type="text"/>
Department:	<input type="text"/>
Street:	<input type="text" value="Domenico Scarlattilaan 6"/>
City:	<input type="text" value="Amsterdam"/>
Postal Code:	<input type="text" value="1083 HS"/>
Area/State:	<input type="text"/>
Country:	<input type="text" value="Netherlands"/>
Telephone (country code/number/extension):	<input type="text" value="31"/> - <input type="text" value="555"/> - <input type="text" value="1701"/>
Mobile (country code/number):	<input type="text" value="31"/> - <input type="text" value="6661701"/>
Fax (country code/number/extension):	<input type="text"/> - <input type="text"/> - <input type="text"/>
Email:	<input type="text" value="John.smith@mah.org"/>

[Printable Version](#) [Update](#)

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

6. Webtrader and Gateway transmission

1. Webtrader transmission mode for submission of ICSRs and XEVPRM reports via EVWEB will be activated once the organisation receives confirmation from the EMA that the transmission registration has been completed. This activation occurs overnight.
2. Gateway profiles will be activated also after confirmation is received from the EMA that the Gateway set up has been completed. For this, an encryption certificate and a completed [Gateway connection form](#) should be provided either in the initial registration request for an organisation or as a subsequent Service Desk request, addressed for the attention of the Gateway Support team. More information can be found in the section "Transmission mode for reporting" on the [EudraVigilance: how to register](#) webpage.

If you are changing transmission mode from Webtrader to Gateway or you are requesting Gateway transmission for the first time:

6.1. For existing organisations i.e. change of transmission mode from Webtrader to Gateway

1. Create a [Service Desk](#) request addressed to the Gateway team and attach a completed [Gateway connection form](#) and encryption certificate for transmission mode change in the EV XCOMP (Test system) first. In the form please make sure that you have included the XCOMP Organisation ID as it is displayed in the EV XCOMP restricted area. The EV XCOMP IDs follow format ORX#####.
2. When confirmation from the Gateway team is received, a separate [Service Desk](#) request should be raised in order to complete quality assurance testing.
3. Once testing is completed successfully, activation of the Gateway profile in Production can then be requested, again by raising a call to [Service Desk](#) for the attention of the Gateway support team, attaching a confirmation email with successful completion of testing, as well as a completed [Gateway connection form](#) and encryption security certificate for Production. In the Gateway connection form please make sure you have included the Production organisation ID as it is displayed in the EV Production restricted area.

6.2. For new organisations i.e. activating Gateway transmission mode for the first time

1. After the first user QPPV/RP role has been approved by the EV Registration team, organisations will receive confirmation of the role approval. If a Gateway connection form and an encryption security certificate, applicable to EV XCOMP (Test system), were provided with the initial organisation registration request, the organisation will also receive a separate confirmation from the EMA that the Gateway set up has been completed.
2. Proceed as per points 2 and 3 of section 6.1 above.

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

7. XCOMP registration process

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

From 26th March 2020, for a transition period, **legacy XCOMP Gateway profiles** (i.e. those that already have a XCOMP organisation ID and are registered as Gateway partners) can continue to be used to send 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.

All Webtrader XCOMP organisations, including those that use the EV POST function, will not exist on the EMA Gateway portal or the XCOMP Restricted Area anymore. All registered users under such legacy profiles, as well as all EVWEB/ EV POST function users will no longer be able to access the EVWEB ICSR, XEVMPD applications and the XCOMP restricted area. They will need to be re-registered under a new XCOMP organisation registration, which is generated automatically for each Production HQ organisation profile. To be able to use XCOMP again, users need to re-register by following the process described in section 7.1.

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

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

7.1. XCOMP registration for organisations with a Production profile

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. The QPPV/RP role is automatically assigned in the XCOMP test system. This also applies to organisations that have existing registrations in the EudraVigilance Production system as of 26th March 2020.

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

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

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

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

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

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

5. If additional users need access to XCOMP EVWEB applications, users need to request the XCOMP specific role:

“EV Human XCOMP User”

This role can be requested through the EMA Account Management portal, following the steps outlined in section 3.1. . A user needs to be registered on the portal in order to request XCOMP access (see section 2.1. for details). Users do not need to have roles associated with the Production profiles of their organisations in order to have access to XCOMP EVWEB applications (i.e. a user can request a “EV XCOMP User” role without having access to Production).

Please note: When requesting a XCOMP role via the EMA Account Management portal, users should use the same OMS Organisation ID for the EudraVigilance Production system (i.e. ORG-####). The above mentioned XCOMP specific **ORX####** EudraVigilance IDs will not show within the portal.

7. Once the XCOMP access request is submitted, the registered QPPV/RP or trusted deputy for the organisation will be notified and they will be able to approve the request following the steps outlined in section 3.6.1.

7.2. Managing a XCOMP organisation profile

Disabling of a XCOMP profile:

When the main QPPV/RP role for an organisation is removed via the EMA Account Management portal for Production, this automatically removes the same role in the XCOMP system. The removal of this role deactivates the organisation in both the Production and XCOMP test systems.

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

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

7.3. IT system Vendors registration with XCOMP

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

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

1. Register in the [EMA Account Management portal](#)
2. Request "SPOR unaffiliated role" via the portal
3. Register the Vendor organisation in the [Organisation Management System](#) (OMS) – for more information see Section 4. of this manual.
4. Request the base role "EV Human XCOMP Vendor Responsible person" via the [EMA Account Management portal](#)
5. Raise a [Service Desk](#) call via the EV Registration section including the role request ID generated by the EMA Account Management portal. The approval of the "EV XCOMP Vendor Responsible person" role will be confirmed to the Vendor by the EV Registration team. In the Service Desk call Vendors should also attach a completed [Gateway connection form](#) and an encryption security certificate. The relevant EV XCOMP vendor organisation ID should be included in the connection 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 provide the Vendor with the EMA connectivity details.
6. When the Gateway set-up is complete, the Vendor is notified and can commence testing.

Note: Vendors do not receive access to EVWEB in EV XCOMP.

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

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

7.3.1. Removal of a Vendor's access from EudraVigilance

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

7.3.2. Changing connection details

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

More information about Vendor registration in XCOMP can be found on the [EudraVigilance registration webpage](#) in the "[IT Vendors and third party service providers](#)" section.

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

To change role in a profile, please remove all the roles you have (see section 3.7.) and then request the role again.

EV Production Base Roles	
EV Human NCA Responsible	Request this role, if you work for an NCA/Regulatory Agency and you are the main responsible for the Pharmacovigilance in your organisation profile. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human MAH EU QPPV MAH affiliate must request RP role	Request this role, if you work for a MAH and you are the main QPPV. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human CS/NCS Responsible	Request this role, if you work for a Commercial Sponsor or a Non-Commercial Sponsor and you are the main responsible for the Pharmacovigilance in your organisation profile. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access.
EV Human NCA Trusted Deputy	Request this role, if you work for an NCA/Regulatory Agency and you are supporting the main responsible for Pharmacovigilance in the administrative tasks. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access. Please note, this role will be rejected, if your organisation does not have an EV NCA Responsible.
EV Human MAH/CS/NCS Trusted Deputy	Request this role, if you work for an MAH, Commercial Sponsor or Non Commercial Sponsor and you are supporting the main responsible for Pharmacovigilance in the administrative tasks. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access. Please note, this role will be rejected, if your organisation does not have an EV MAH EU QPPV or an EV CS/NCS Responsible.
EV Human NCA/MAH/CS/NCS Browse ICSR	Request this role, if you need only access to ICSR messages. Please note, this role will be rejected, if your organisation does not have an EV Responsible or EV EU QPPV.
EV Human ICSR Browse & Send	Request this role if you need to perform queries, create and send ICSRs, receive safety messages, store the safety messages locally and generate acknowledgement messages.
EV Human NCA/MAH/CS/NCS Browse MPR	Request this role, if you need only access to Medicinal Products - L2A Access.
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 (L2A access): create queries, create and send extended Medicinal Products Reports or generate acknowledgement messages.
EV Human MAH/CS/NCS Browse and Send ICSR and MPR	Request this role, if you work for an MAH, Commercial Sponsor or Non Commercial Sponsor and you need full functionalities related to the Medicinal Products (L2A access) and ICSRs: perform queries, create and send extended Medicinal Products Reports, create and send ICSRs.
EV Human NCA/MAH/CS/NCS Browse ICSR and MPR	Request this role, if you need basic functionalities related to the Medicinal Products (L2A access) and ICSRs.
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.
EV Production Supplementary Roles	
Note: EVDAS roles are only for NCA and MAH HQ profile users	
EV Human MAH Additional QPPV	Request this role only, if you are NOT the EU QPPV user for that profile, work for an MAH organisation and you need a QPPV Code. Please note that you can only request this after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR).
EV Human L2B Access	Request this role only, if you are authorised to visualize personal data of the patients by your QPPV. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS Human NCA Administrator	Request this role only, if you work for an NCA/Regulatory Authority and need browse access to EVDAS. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS Human NCA Scientific	Request this role only, if you work for an NCA/Regulatory Authority and need access to ICSR forms. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS Human NCA Art57	Request this role only, if you work for an NCA/Regulatory Authority and need access to Art57 data. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).
EVDAS MAH Scientific	Request this role only, if you work for an MAH and need access to EVDAS/ICSR forms. Please note that you can only request this, after you have been granted a base role (i.e. Browse ICSR, Browse and Send ICSR and MPR etc).

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