EMA EudraVigilance Veterinary

Registration manual

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Figure 1. Overview of the Registration process

Flowchart:

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- Check OMS Is your organisation registered?
  - **Yes** → Request EV VET MAH RP Role in EMA Account Portal
  - **No** → Request SPOR unaffiliated role in EMA Account portal → Create org in OMS and obtain OMS ID → (back to Request EV VET MAH RP Role in EMA Account Portal)
- Request EV VET MAH RP Role in EMA Account Portal →
- Raise Service Desk ticket with role request id and required supporting documents, including Gateway connection details if applicable →
- Access EV restricted area and complete/ update fields in the manage your profile section →
- Wait for up to 5 working days to receive confirmation about Webtrader or Gateway set up →
- New users can request roles to be approved by RP/QPPV or TD in the EMA Account Portal

1. Registration overview

To set up a new organisation in the EudraVigilance Veterinary 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 Veterinary system.

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. Responsible Person (RP) access request

5. The EMA confirms separately to the organisation that their Webtrader or Gateway transmission mode has been set up – see 5.

Once the 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 (ServiceNow), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR.

Users who are already registered and have credentials for one or more of 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.

- 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 email will be automatically issued to the email address linked to the username. If you do not receive this email, you need to click "Forgot your username" on the landing page, to receive an email with the username linked to the email address you enter.

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 VET user roles, a list of base roles is provided in the Annex of this manual.

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

2.1. 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 Veterinary 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.

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 the 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.

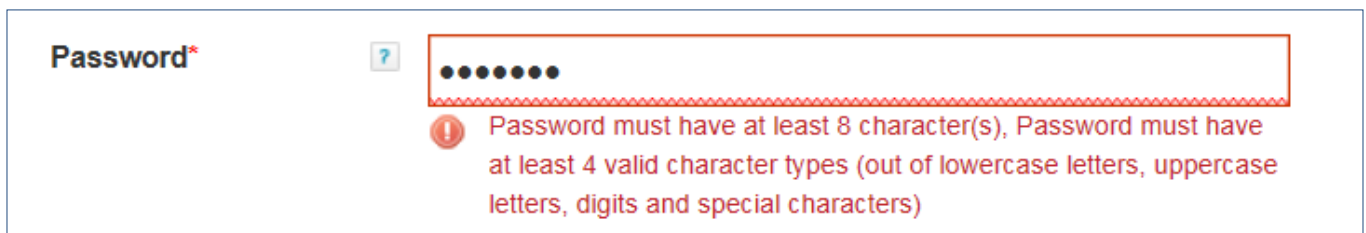**Figure 2.** **Self-registration form on the EMA Account Management portal**

- 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

- 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

> ⚠ The email you have chosen is already in use. Please choose a different email.
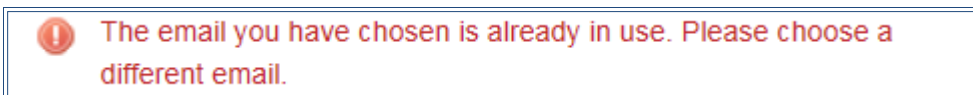
- In such a situation it is better to go back to the landing page and click the "Forgot your username" and "Forgot your password" options

- 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

Password* ❓ ●●●●●●●
⚠ 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)

EMA privacy statement

After completing all mandatory information, you will encounter the 'EMA Privacy Statement' and 'EMA system security principals and responsibilities'. Please read and agree by ticking the box in the 'User Agreement' section at the bottom of the page. Additionally, ensure to tick the 'I'm not a robot' checkbox, then click 'Register' to receive the confirmation token. See Figure 4 below.
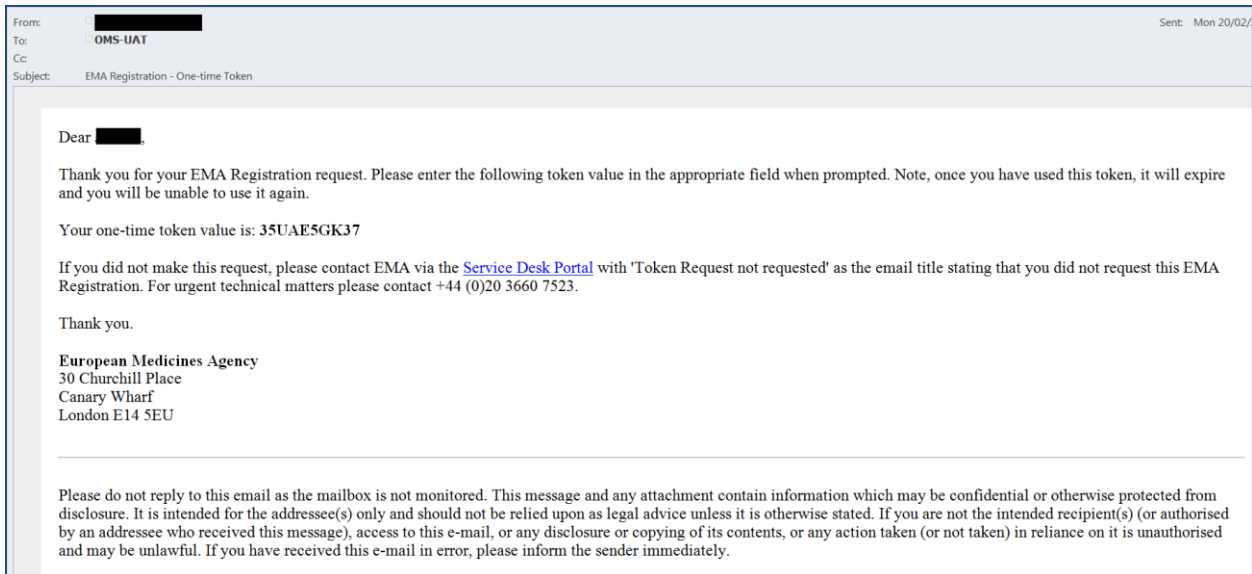
Figure 4. EMA privacy statement

After clicking on the 'Register' button, An e-mail with an authorisation token is sent to the e-mail address provided.

Figure 5. 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'.
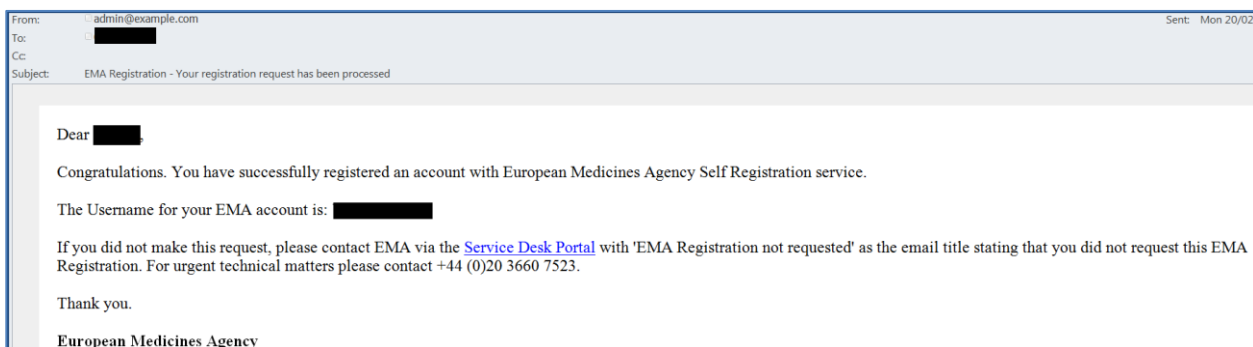
Figure 6. Confirmation of the user registration

- Click "Confirm"

- This creates a new EMA account

- A confirmation e-mail of a successful registration is sent.

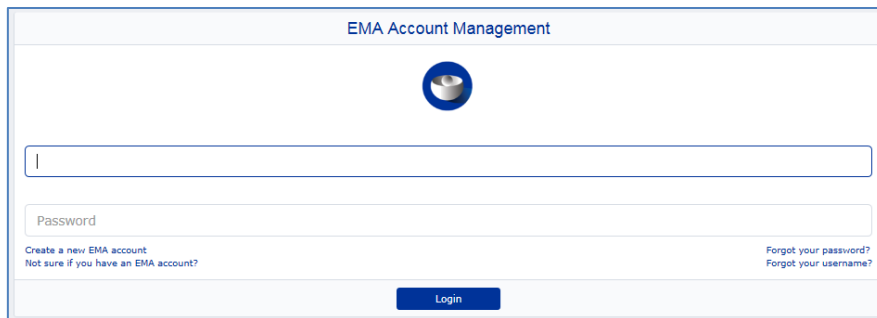**Figure 7.** Registration successful – confirmation e-mail example

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

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.

2.2. Log into EMA Account Management portal

Figure 8. 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 9. EMA Account Management portal dashboard
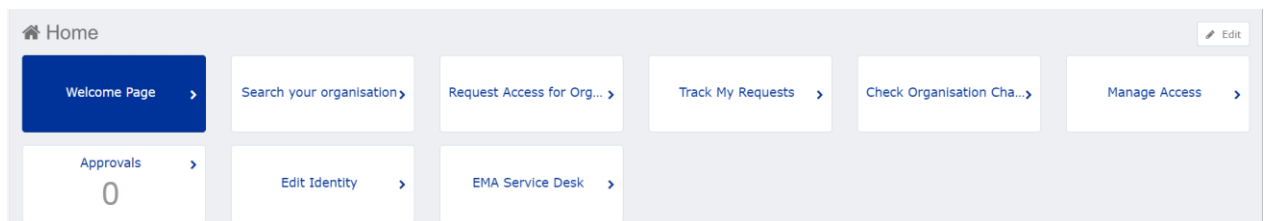

3. User access management via EMA Account Management portal

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

Through this interface the user has the following functionalities:

- Welcome page

- Search for your organisation

- Manage User access

- Request Access for Organisation

- Track requests

- Check Organisation Change Request

- Manage Access

- Approvals

- Edit identity

- EMA Service Desk

Some EV VET roles are organisation-specific but not all of them, EV VET NCA DWH as an example does not depend on a specific organisation. 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 VET roles that can be requested.

**Figure 10. EMA Account Management portal dashboard**
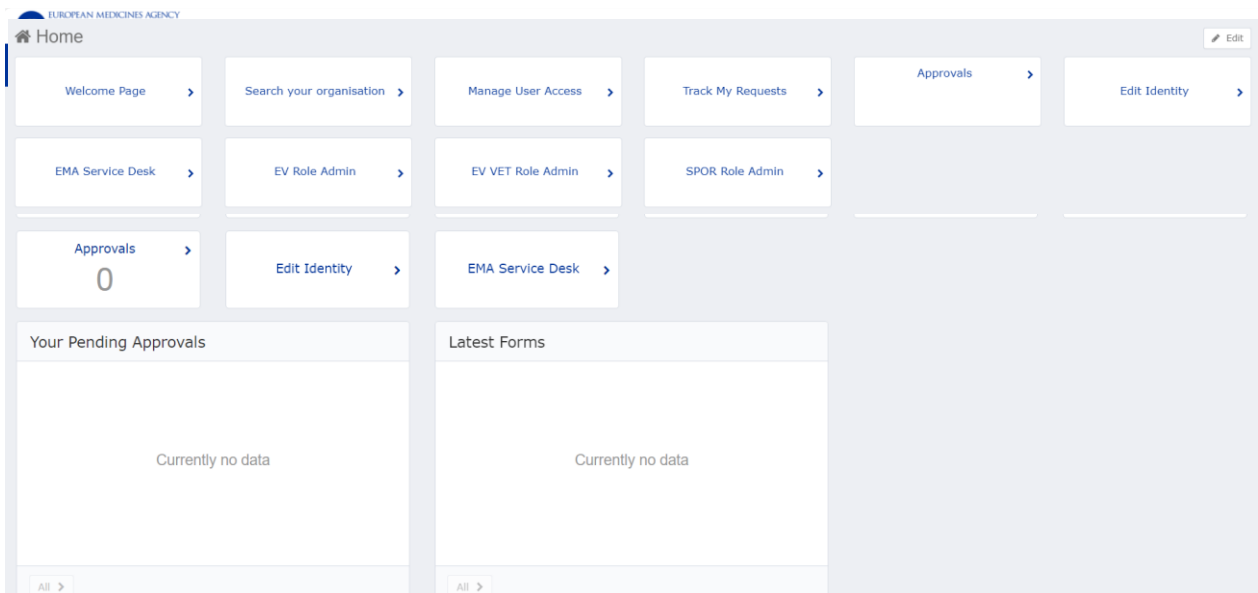
In order to obtain an EV VET user role, there must be an active Responsible (RP) registered for the organisation that the user role is being requested for. If there is none, the system will automatically reject the request and the user will need to liaise within their organisation in order to ensure a new RP is registered.

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

3.1. EV VET user access requests for industry and NCA users

Figure 11. Manage My Access
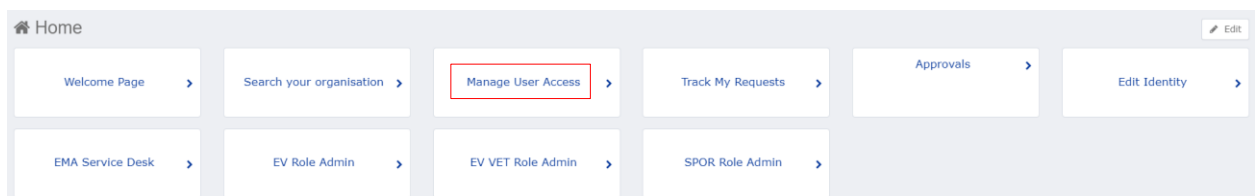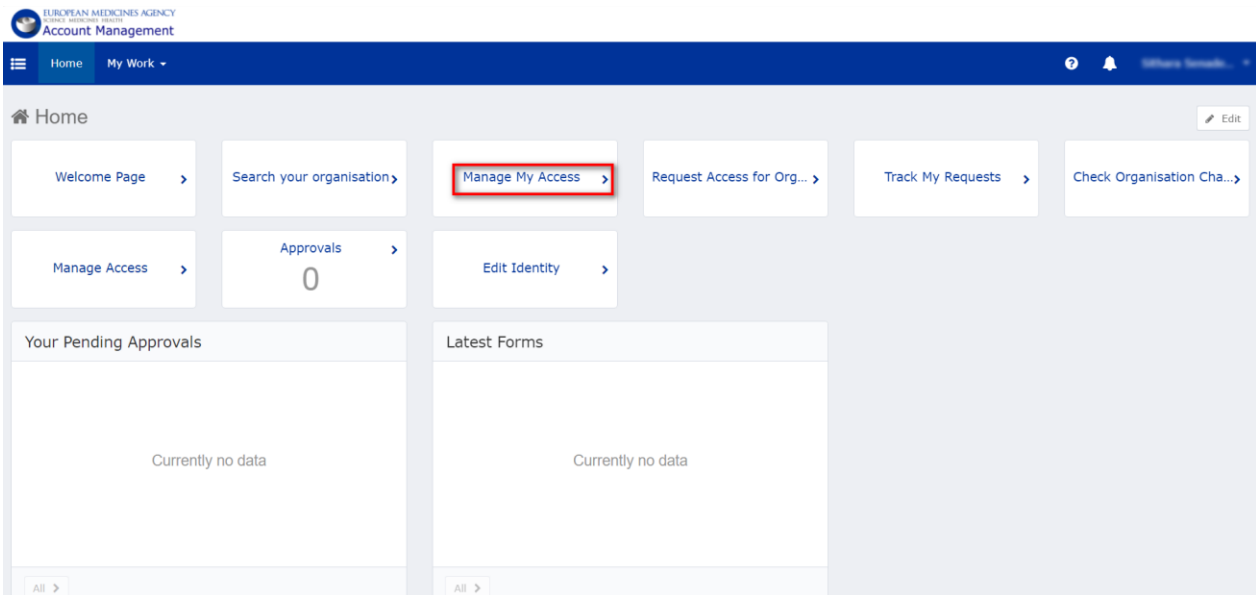
- Click on the Tab "Manage My Access"

- Users will see a list of possible roles they can request

Figure 12. Selection of roles – Industry/NCA user

- The various EV VET roles are listed and described in the Annex of this manual. It is recommended to filter the list by typing "EV VET MAH" or "EV VET NCA" in the search box, for industry or regulatory authority users, respectively, to show a reduced list of roles. If the correct type of roles (MAH or NCA) do not appear, it may be related to the Organisation being wrongly classified in OMS, which can be verified in OMS (https://spor.ema.europa.eu/omswi/#/) and would have to be resolved with an EMA IT Service Desk ticket before roles can be requested.

- 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 3.6.1.) 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.
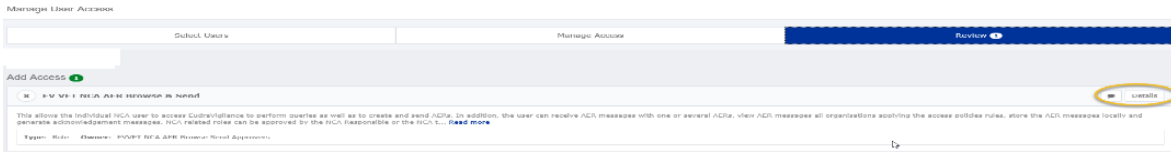
- Click on the button for the required role, which is on the left-hand side of the screen.

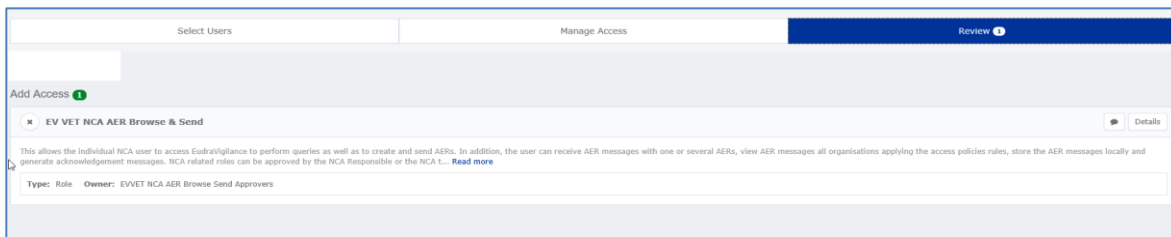- Once selected, press on "Review"

A confirmation page appears.

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

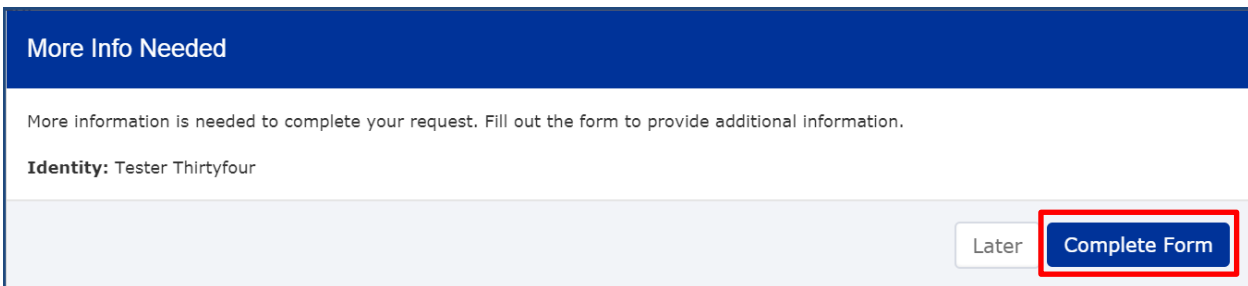**Figure 13. Comment and Assignment Note**

- Click "Submit"

**Figure 14. 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 VET role request can be completed

- The following screen appears

Figure 15. A trigger to request organisation affiliation

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

Figure 16. Form deferred
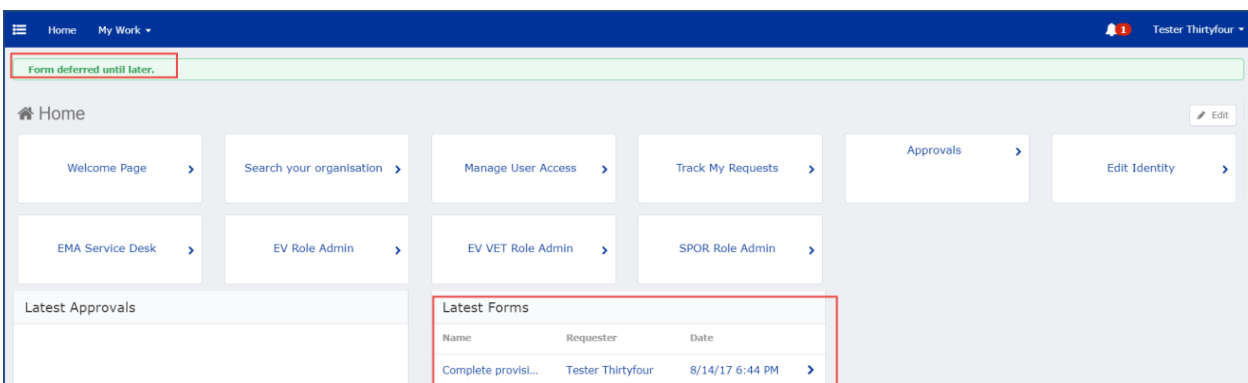
Otherwise, the user continues to complete the request by selecting an organisation.

- Click on "complete form"

- The organisation affiliation form appears

Figure 17. Form for choosing the organisation on behalf of which the role is requested

- 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. *Please note that at least 3 characters (letters or numbers) have to be added in the search box for the organisation field drop down list to populate.*

- 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. This can sometimes take a few seconds to load. Select the correct organisation and click "Submit Request".

- If you are the first user, i.e. Responsible Person (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 RP/TD of the organisation for approval.

Note: The Trusted Deputy (TD) role is approved by the 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. Responsible Person (RP) 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 IT Service Desk.

- To request a RP role, whether first user or change of 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 EV VET role with the organisation before requesting the RP role for that organisation and that any previous RP user has been confirmed as being removed.**

- A RP role request will be rejected by the system automatically if there is still a RP registered for the organisation profile.

- Of note, an organisation profile is enabled in EudraVigilance when there is an enabled and registered RP. During a change of RP, the organisation profile will appear as disabled until the process has been completed. Active users linked to this profile will see a message stating "your organisation is disabled".

- The registration process of RP for NCAs is the same as for RP for pharmaceutical companies (MAHs).

- There can only be one Responsible Person role (for NCAs, pharmaceutical companies (MAHs) or EV VET affiliate profiles) per organisation.

- The registration or change of RP in the Production environment will be reflected automatically in XCOMP (test environment).

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

- In order to support the RP access, the requestor needs to submit a series of documents that confirms that they represent the organisation selected in the request – 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 Role Request ID number (generated by the EMA Account Management portal).

- The Role Request ID is found in the "Track my Requests" tab in the EMA Account Management portal (see Figure 18. Track My requests)

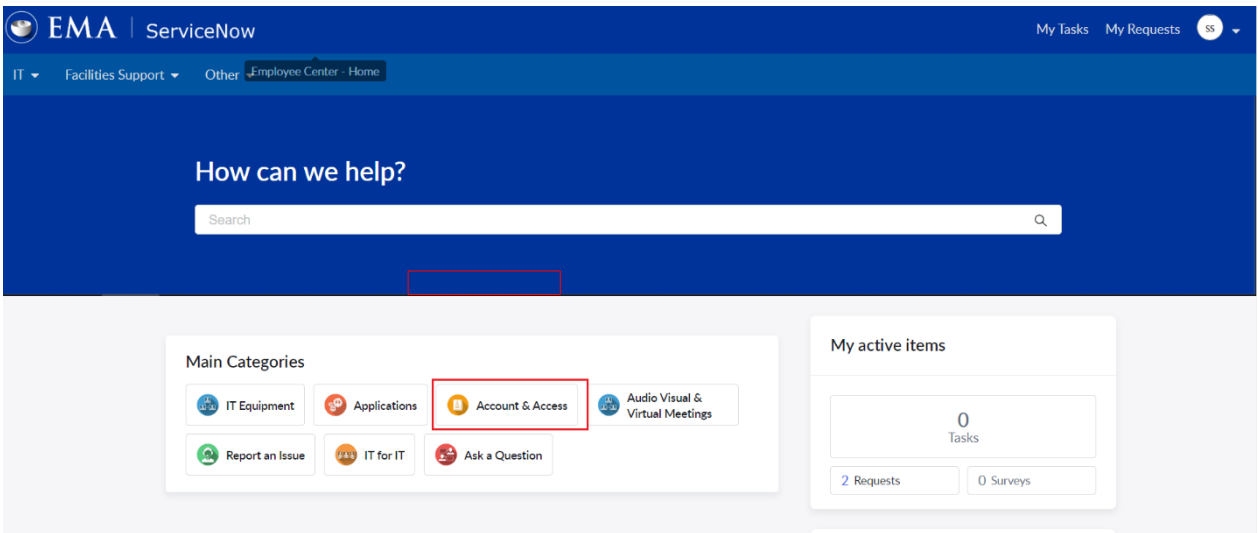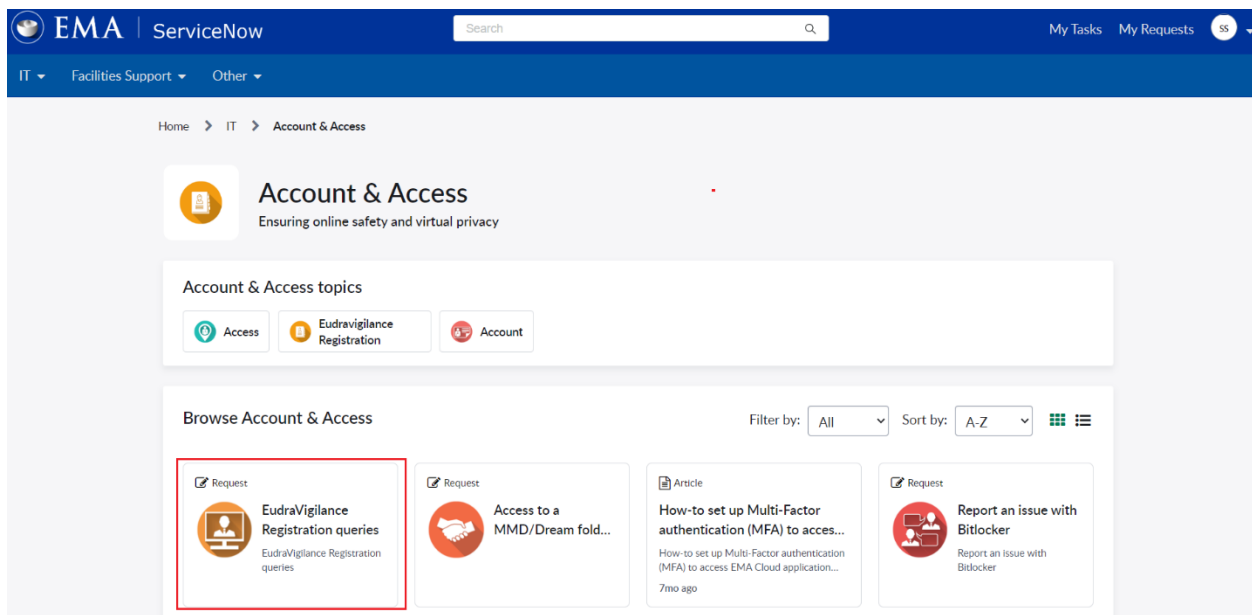**Figure 18. Track My requests**
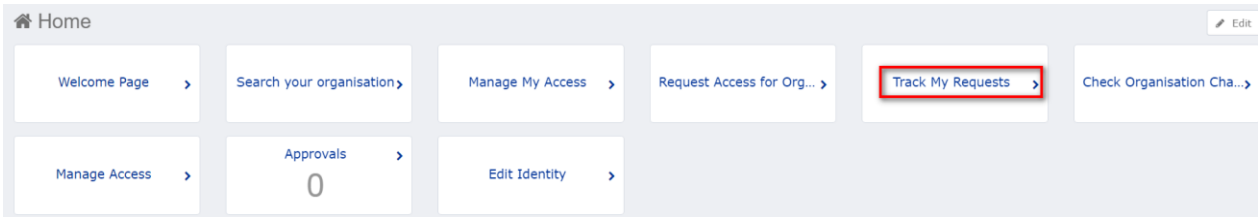
1. Log in to Service Desk portal: https://support.ema.europa.eu/esc

2. Click on "Account and Access"

Figure 19. IT service desk landing page

- Select "EudraVigilance Registration queries"

Figure 20. Service Desk options

- Once click on the link, user can submit the requested information and documents:

Figure 21. Service request

- "Registration of new Organisation – EV VET Responsible Person validation – Role Request ID xxxxx" should be mentioned in the <u>Summary</u> field, together with the EMA Account Management portal request ID number that is automatically generated when a role is requested through the <u>EMA Account Management</u> portal.

- The Role Request ID is found in the "Track my Requests" tab in the <u>EMA Account Management</u> portal (see Figure 18. Track My requests above)

- In the description field, state your name, organisation ID and explain that you are requesting an EV VET RP role access. **Please clearly state that the request relates to EudraVigilance Veterinary.**

- Upload the required registration documents as stated in the <u>EV VET registration documents</u> guideline, completed with all the necessary information, including OMS ID (include the EV VET ID if the organisation was registered in the EudraVigilance Veterinary system before November 26, 2019) as well as transmission mode, so that the Gateway team can activate the organisation's transmission mode.

- Click on "Create"
- The EMA approves or rejects the RP request and notifies the requestor of the outcome.

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.

  - o Each user role will be linked to a unique organisation

  - o Managing multiple organisations as a RP/TD requires multiple EV VET MAH RP/TD user roles with the associated organisations

  - o The users will need to submit individual access requests for each of the roles for each organisation

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

  - o Each organisation should have at least one registered RP (EMA recommends two administrators - that is, the required RP and at least one Trusted Deputy)

  - o 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

  - o Organisation structures and hierarchies are not defined in OMS – for example, there is no recognition of HQ or affiliates

  - o The trusted deputy of the headquarter 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

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

## 3.5. Role approval for EudraVigilance

- The RP for each organisation will be approved by EMA after they select the NCA/MAH RP role (e.g. "EV VET NCA Responsible" or "EV VET MAH Responsible") 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 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 base 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.
- Additional roles trigger automatic role request rejections.

Clarification: An organisation can have multiple users with the same role. It is very important for the new RP to ensure that the previous RP has removed their role and that this request has been approved. For TD and standard users, please ensure **all** roles for your organisation are removed before you request a new one.
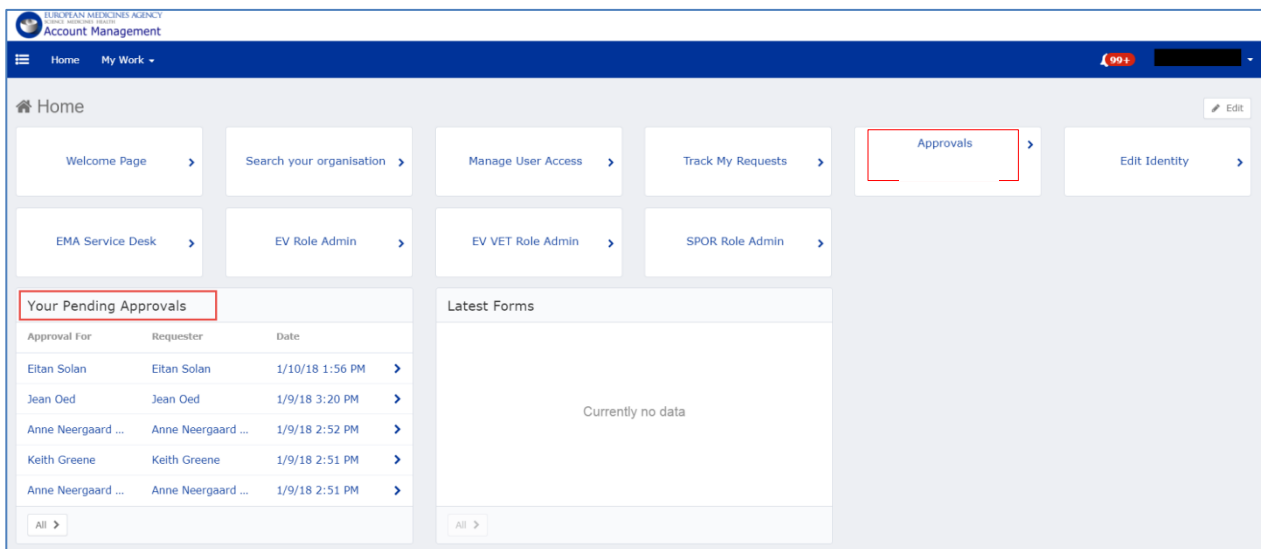
3.5.1. Approval process managed by the RP/TD

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

Figure 22. E-mail alert for a new EV role request
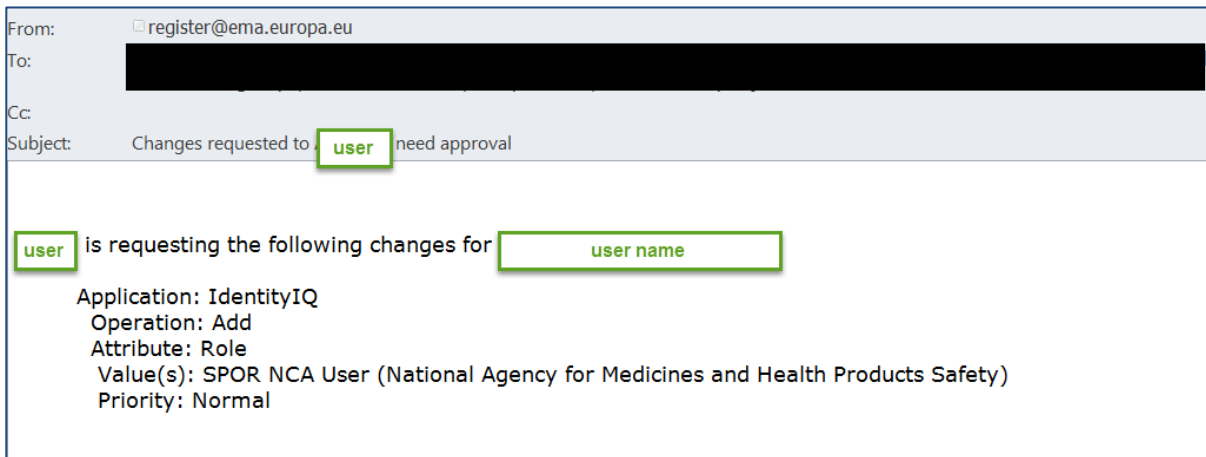
- The RP&TD needs to log in to the EMA Account Management portal.

- The request appears in the "Approvals" tab and "Your Pending Approvals" field.

Figure 23. RP's homepage with a new access request in the inbox

- Click on Approvals – overview of the request appears

Figure 24. Request overview

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

Figure 25. 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 26. View requestor's identity details

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

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

- After checking the approval details, close the window and proceed with checking the approval item details back on the approval page
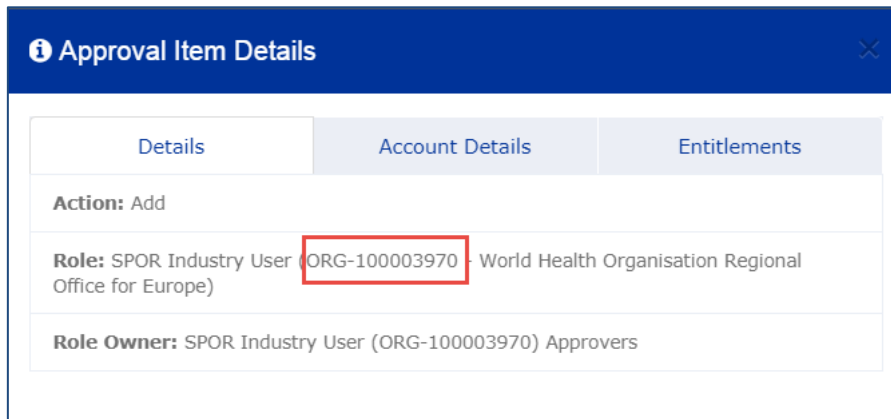
Figure 27. Request approval page with approval item details and organisation ID

- Approval item details also include the affiliated organisation ID. The organisation must be the same as the organisation of the Role Owner User (Figure 28.).

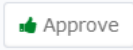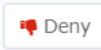**Figure 28. Approval item details**

- Go back to the approval page

- Select the approve [👍 Approve] or deny [👎 Deny] icon as appropriate. We recommend that the RP/TD inserts a comment before rejecting a role so that the user can be informed as to what the issue was and can make a modified new request if needed. You can also add a comment before approving them. Comments should be inserted BEFORE approving or rejecting a role.
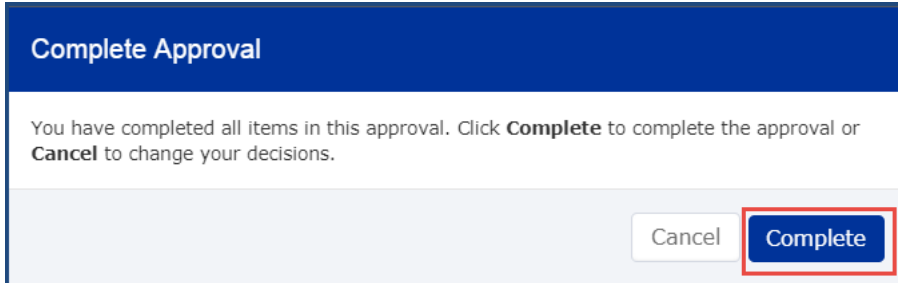
Figure 29. Approval item details
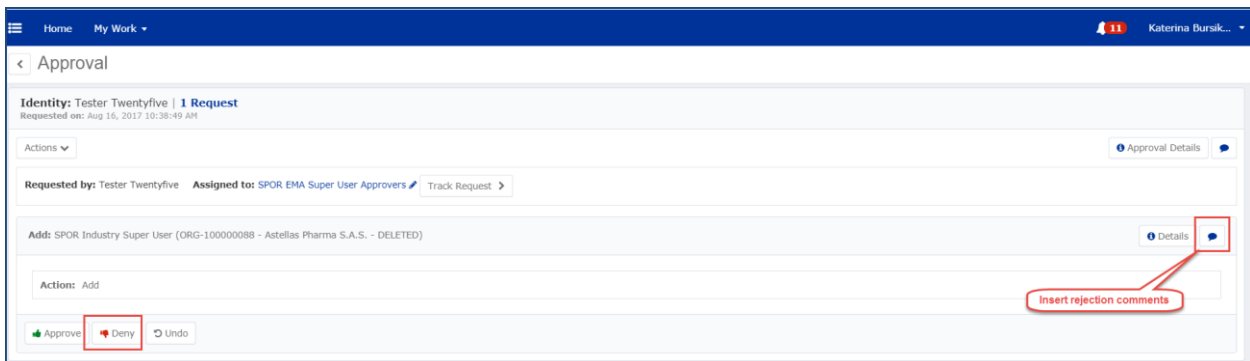
- A pop-up window appears – enter your comments and click "post"

Figure 30. Insert rejection comments – pop-up window
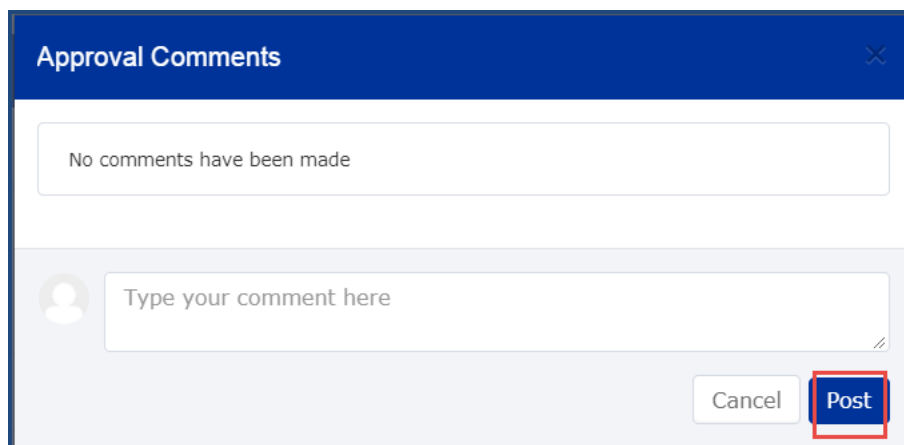
- Click "Complete" (both for approve and deny)

Figure 31. 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)

3.5.2. RP/TD user responsibilities

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

- The RP/TD needs to confirm that the users indeed work for the organisation before granting the requested access

- The RP/TD approves and removes access for the users of their organisation via EMA Account management portal

- It is the responsibility of the 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 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 RP should disable their access in the EMA Account Management portal by revoking their roles via EV Role Admin tab (see section 3.6.2.1.).

- Access to the EV system on behalf of an organisation is the responsibility of the RP/TD and **EMA will not check**
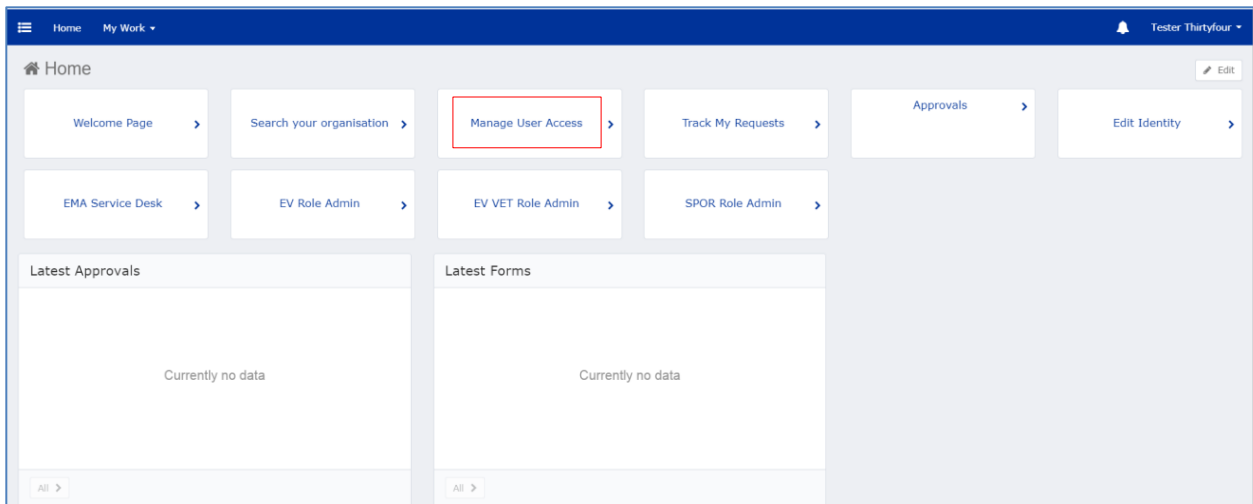
3.6. Removing access

3.6.1. Request your own access removal
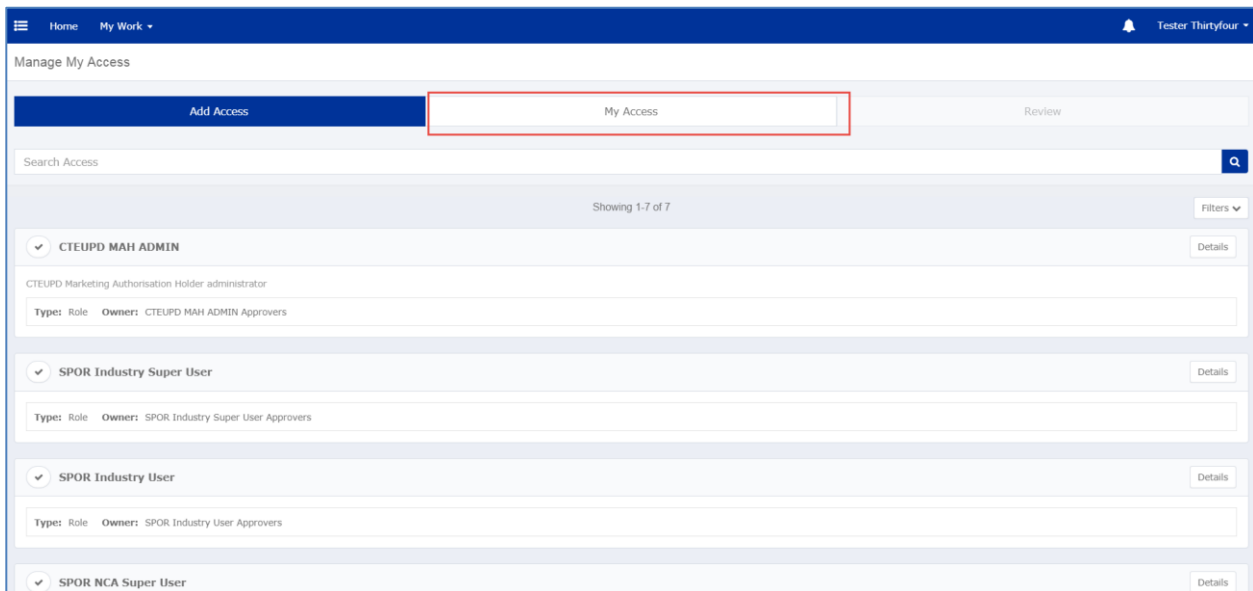
A user can request their access to be removed

- Go to the homepage

- Click on "Manage my Access"
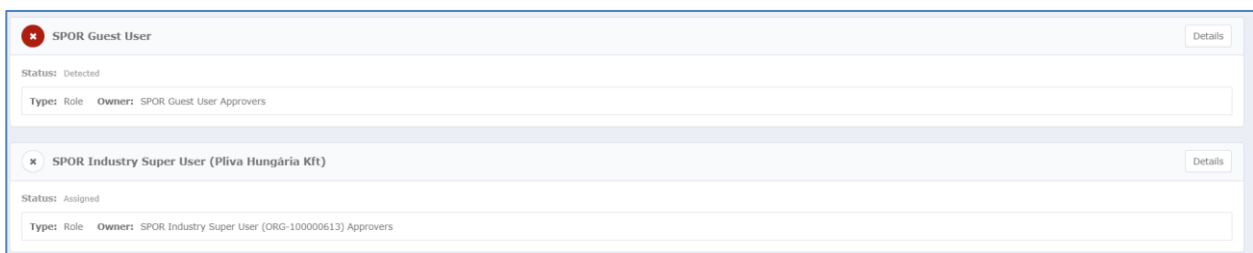
Figure 32. Manage my access

Go to "My Access"

Figure 33. My access

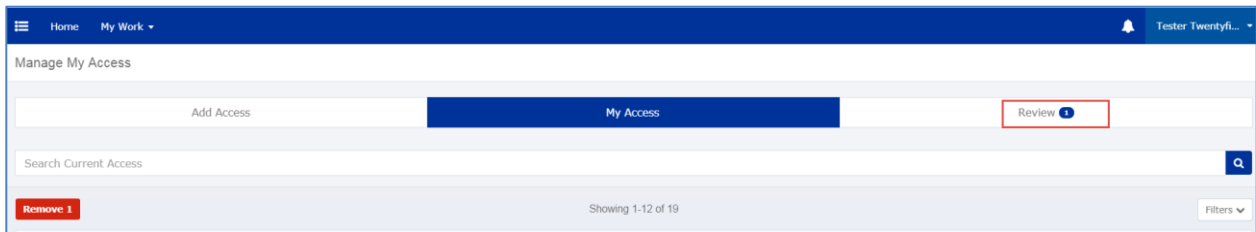Select the role to be removed – click on [✖] - it turns red.

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.
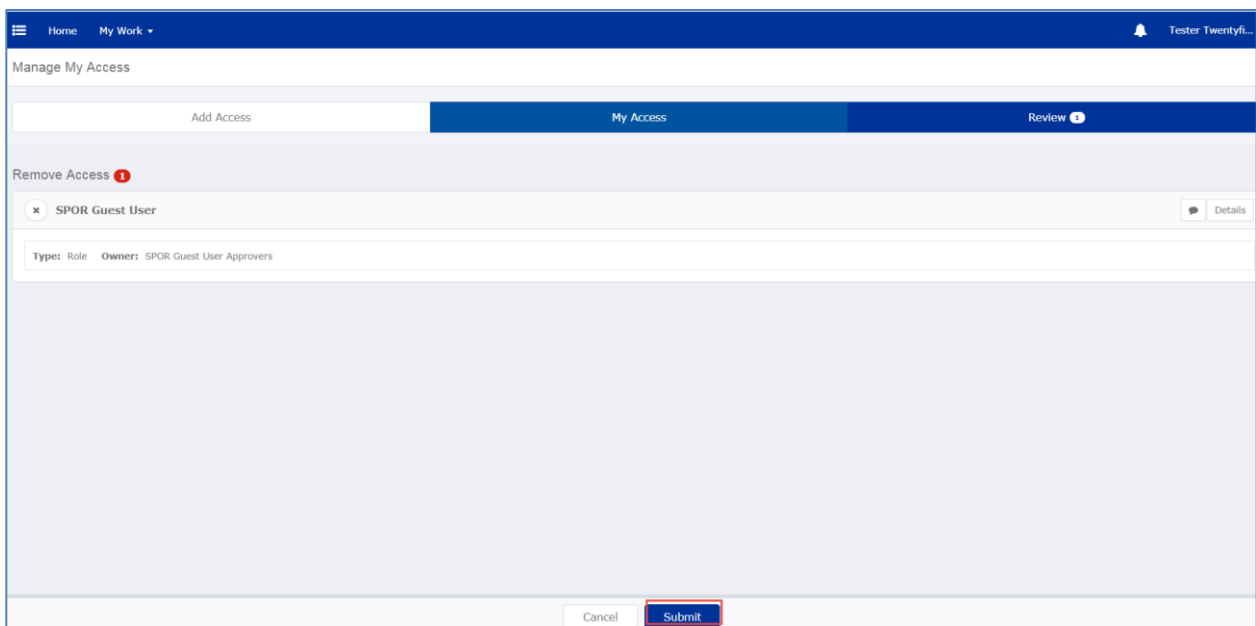
Figure 34. Role to be removed

Scroll up the page and click "Review"

Figure 35. Review access removal

Click "Submit"

Figure 36. Submit access removal

The system will automatically approve the removal of the role for all roles **except for the RP**, whose request will go to EMA for approval.

Important note: the EMA does not automatically approve the role removal of a RP. EMA should be notified of the role removal request by raising a ticket with [EMA service desk](), providing the EMA Account Management portal request ID.

3.6.2. Revoke access

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

3.6.2.1. Revoke an EV user role as a 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 37. EV Role Admin
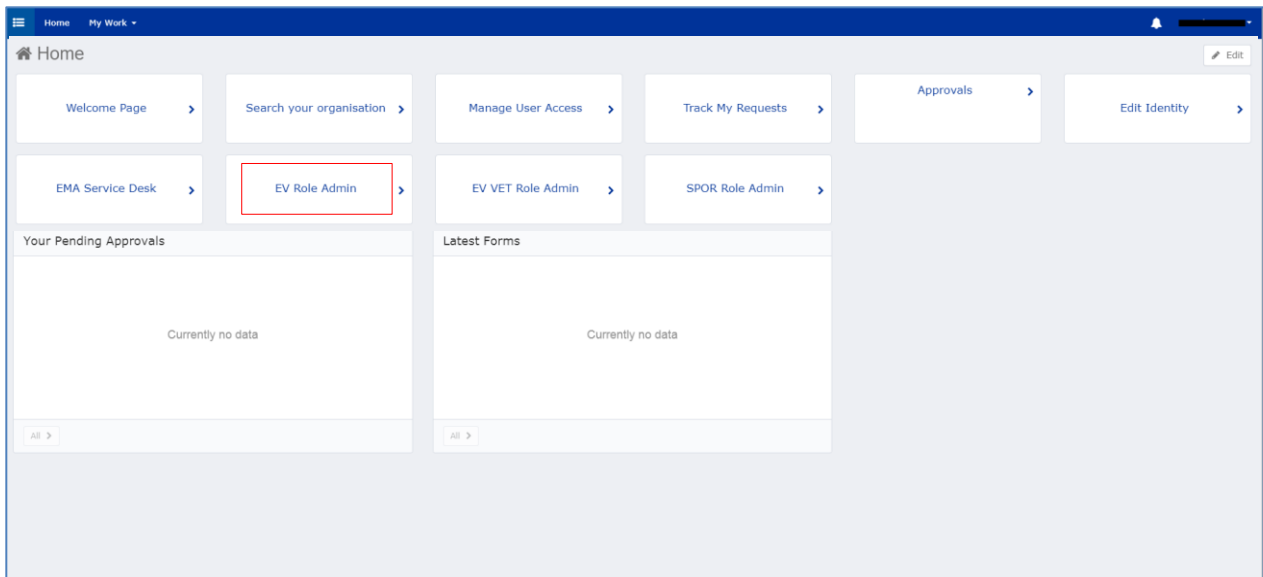
- Select the application "EV (EudraVigilance)" and organisation

- 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.

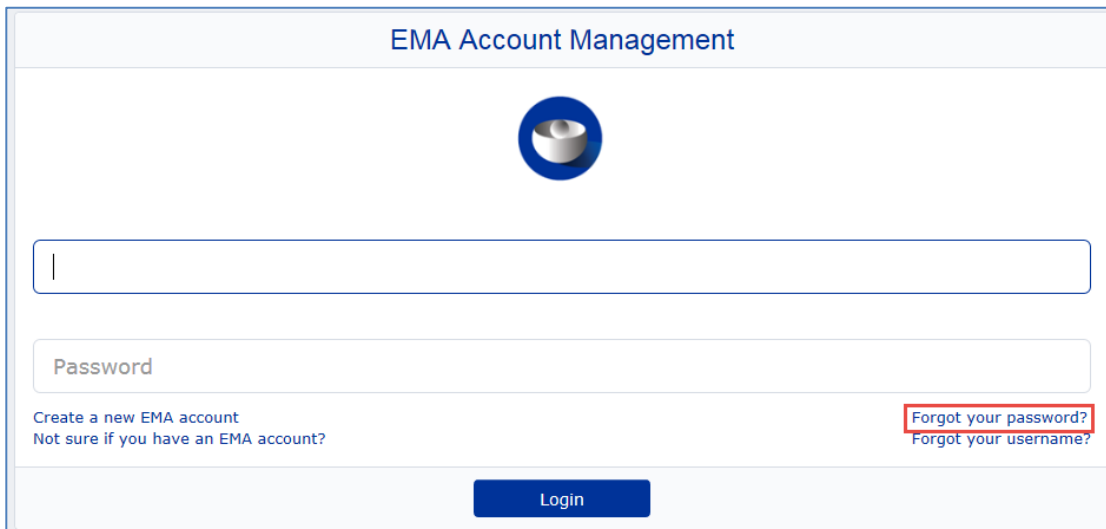**Figure 38. EV Role Management**

- Click on "Revoke Roles" button

Important note: RPs can request their role to be removed in the system (section 2.7.1), but must contact EMA via EMA service desk for the EV Registration team to approve the role removal request. Otherwise, the role of this RP will not be removed successfully from the organisation profile.

3.7. Manage passwords and usernames in EMA Account Management portal

3.7.1. Reset forgotten password

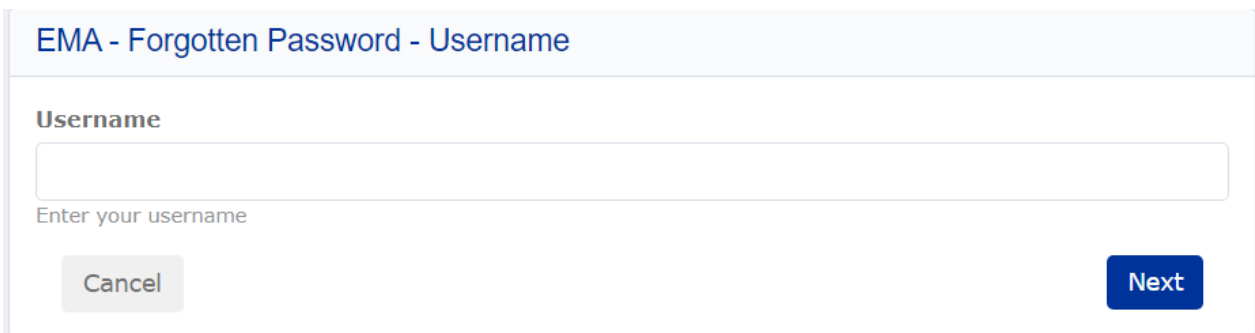- A forgotten password can be reset by verifying the token sent to your email account.

- Navigate to Forgot password (europa.eu)

- Click the 'Forgot your password?' link.

Figure 39. EMA Account Management Portal and forgotten password link

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

Figure 40. Input username to retrieve forgotten password

Token Verification

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

Figure 41. E-mail containing one-time token

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

Figure 42. 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' to reset the password.

- Enter new password

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

3.7.2. Retrieve forgotten username

- Navigate to https://register.ema.europa.eu/

- Click the 'Forgot your Username?' link

Figure 43. EMA Account Management portal and forgotten username link

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

Figure 44. Enter e-mail address to retrieve forgotten username

- Confirmation of the request is displayed

Figure 45. Confirmation of the forgotten username request

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

Figure 46. E-mail to the user containing a forgotten username

- Log in with your username and password

3.7.3. Change password in EMA Account Management portal

- Log in to the EMA Account Management portal

- Click on the "Edit Identity" link on your Home page

Figure 47. Change password in the EMA Account Management portal
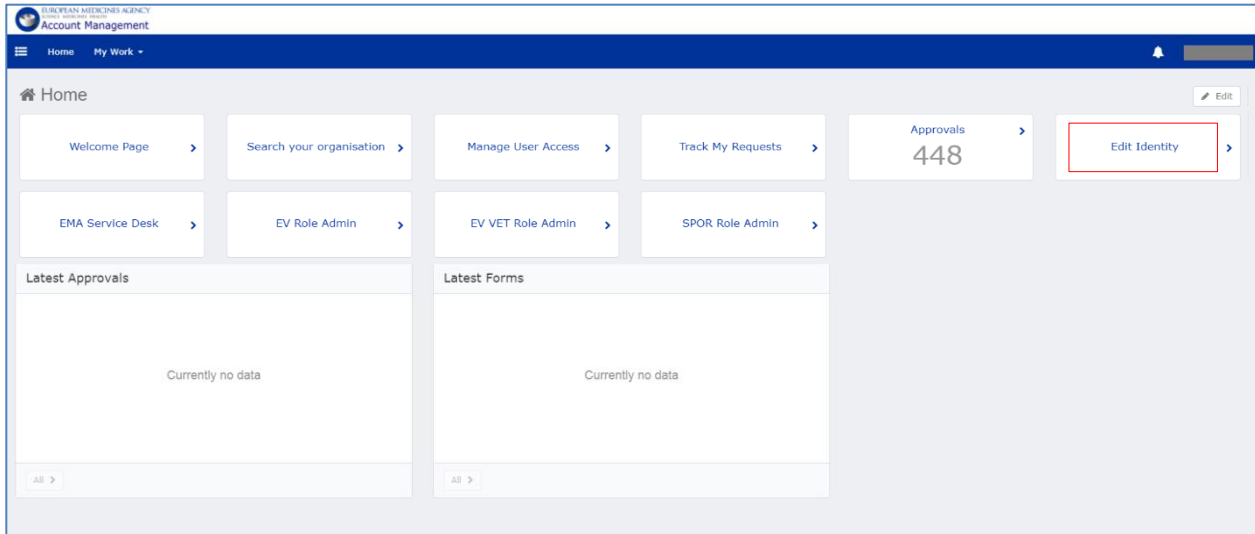
- Select your EMA Account by clicking on the checkbox in front of the account for the EMA Account Application, press 'Change'

Figure 48. Manage passwords screen in the EMA Account Management portal
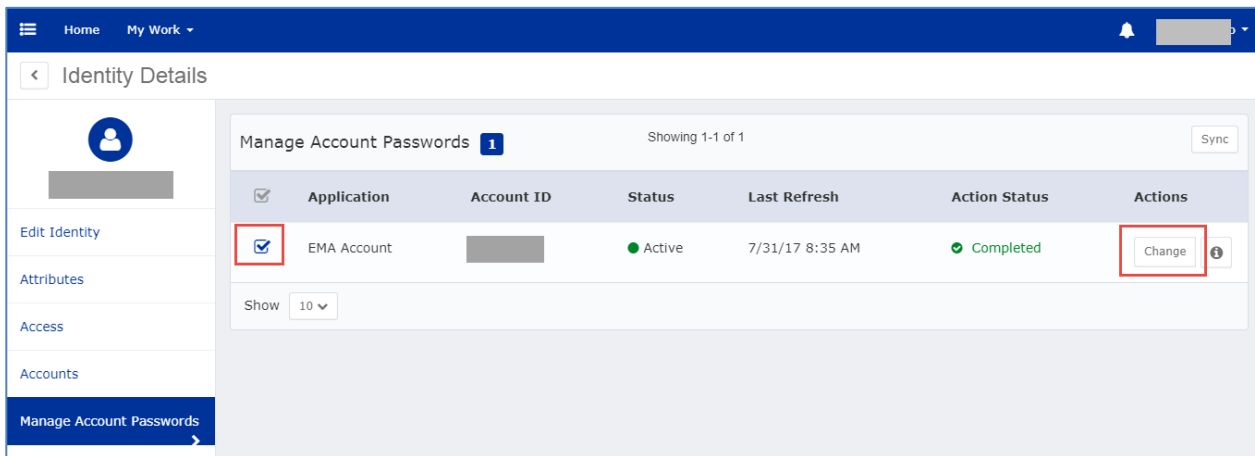
- Type your current password in the 'Current Password' field and the new password in the 'New Password' and 'Confirm Password' fields
  However please note, the characters '+' and '&' should not be used in a password

- Click the 'Submit' button

Figure 49. New password and submit
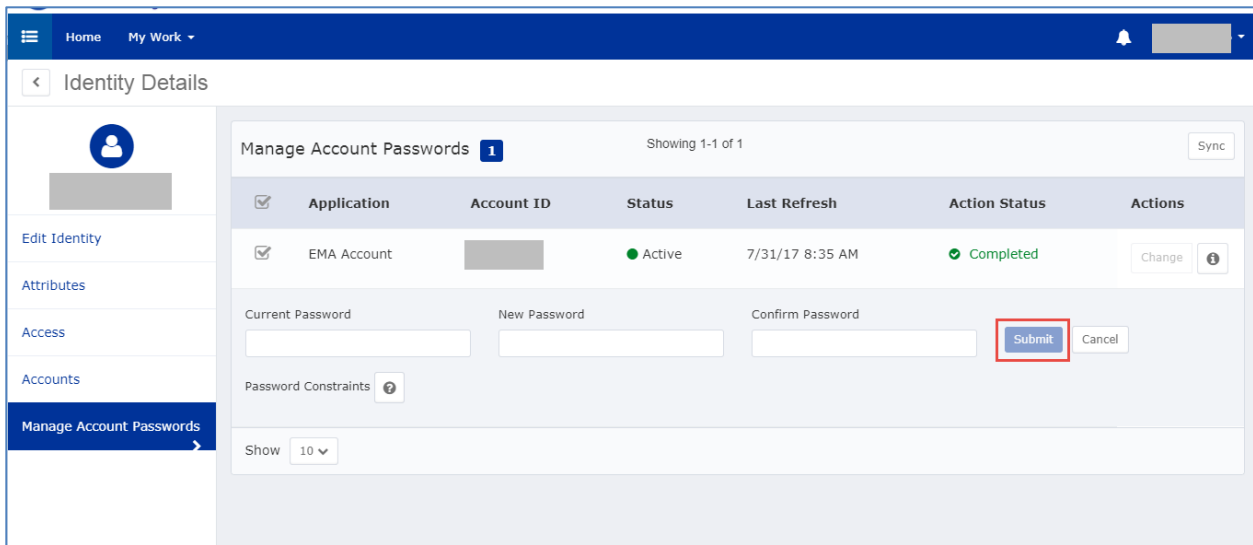
3.7.4. Update security (authentication) questions

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:
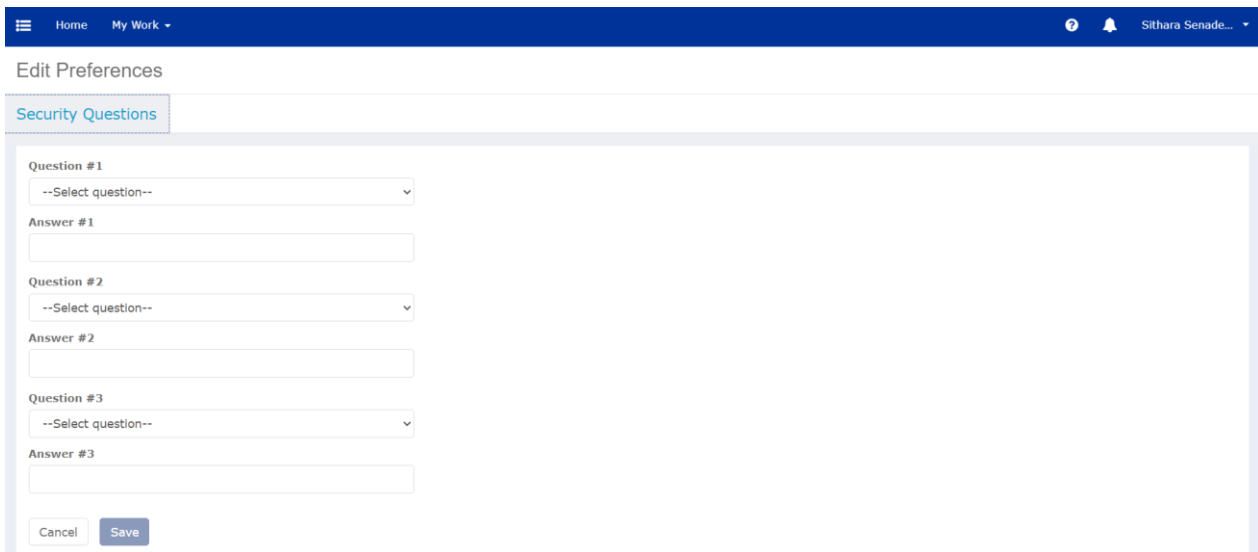
- Login to the EMA Account Management portal

- Click on the username link on the top right corner of the homepage and click 'Preferences'

Figure 50. Access my preferences
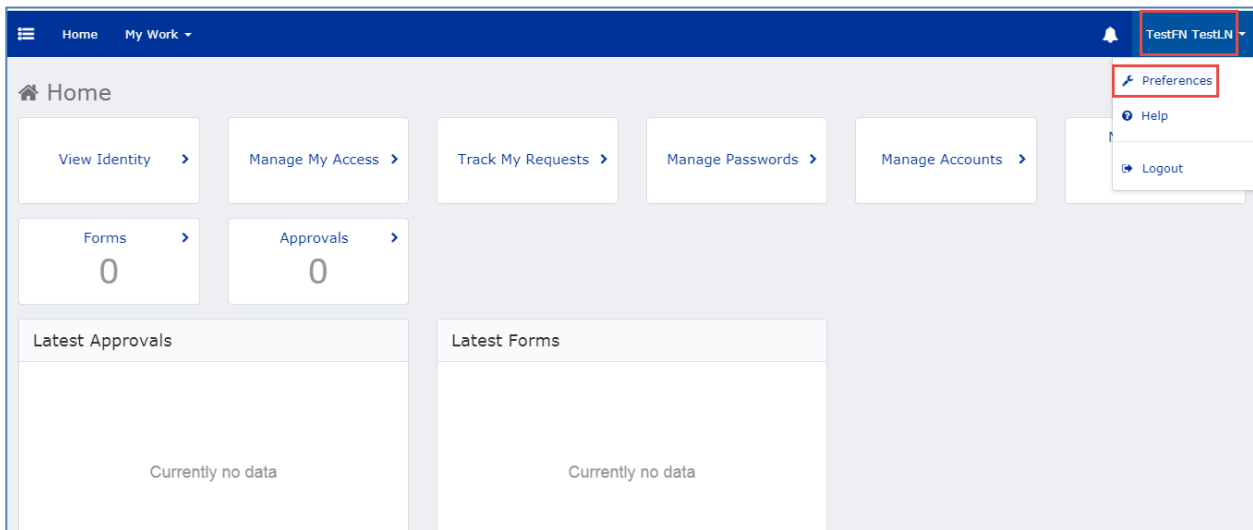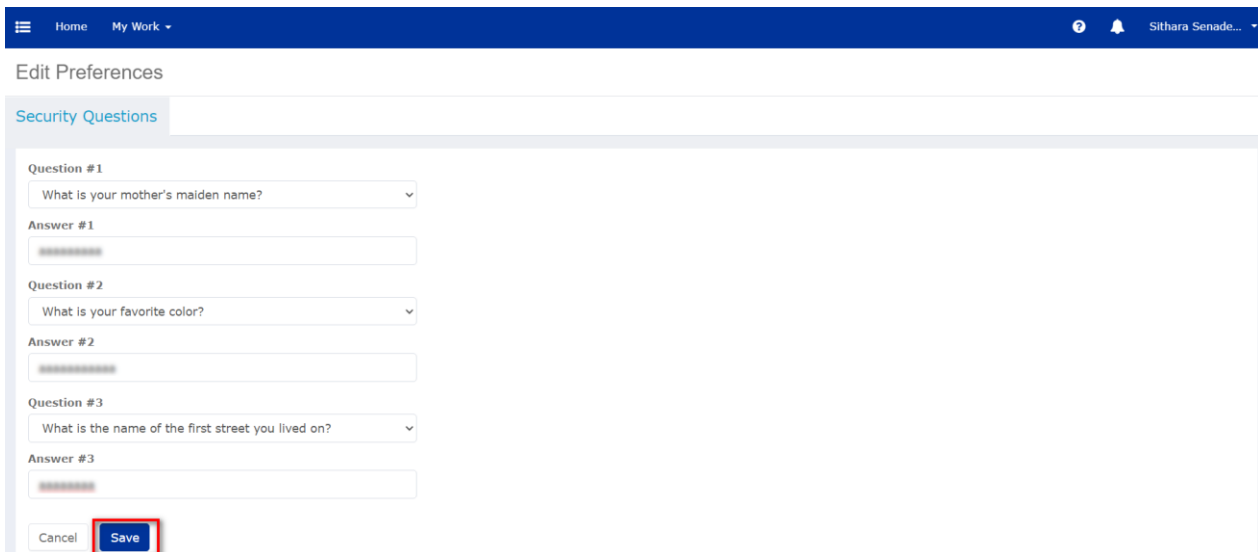
An option to edit preferences appears where the user can add the security (authentication) questions.

Figure 51. Edit preferences

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

Figure 52. Selecting security (authentication) questions

3.7.5. Set-up Multifactor authentication

Accessing for the first time the EV Vet Production system will require additional security steps to be configured. After having signed in, multifactor authentication prompt will be displayed. Follow the next steps to provide the necessary security information:

1. Select your country, add your phone number, select method option "Send me a code by text message" and click "Next";

Figure 53. Set-up phone authentication information by text message
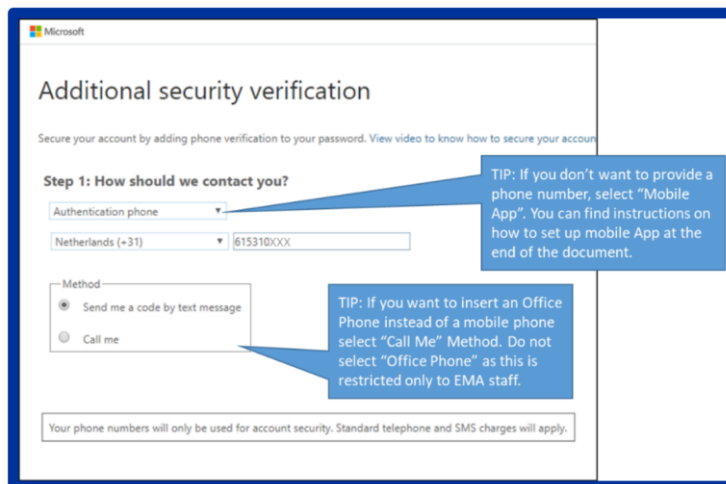
2.   Check your phone for an SMS;

Figure 54. Text message sample of verification code
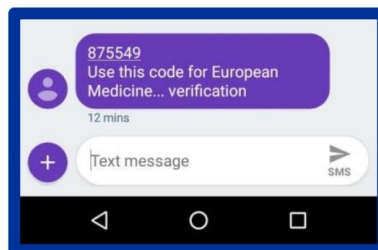
3.   Enter the 6-digit code and click Verify;

Figure 55. Verification code validation
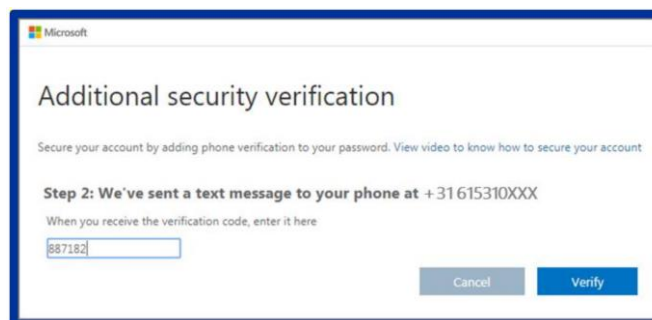
You may need to refresh the page after logging in once, the next time you log in you will only need to go as far as step 2 shown above.

Note: Should you need to change your phone number or wish to switch authentication methods e.g. from phone to a mobile app you will need to raise a query via the EMA Service Desk.

3.7.6. How to set-up Additional Security Verification
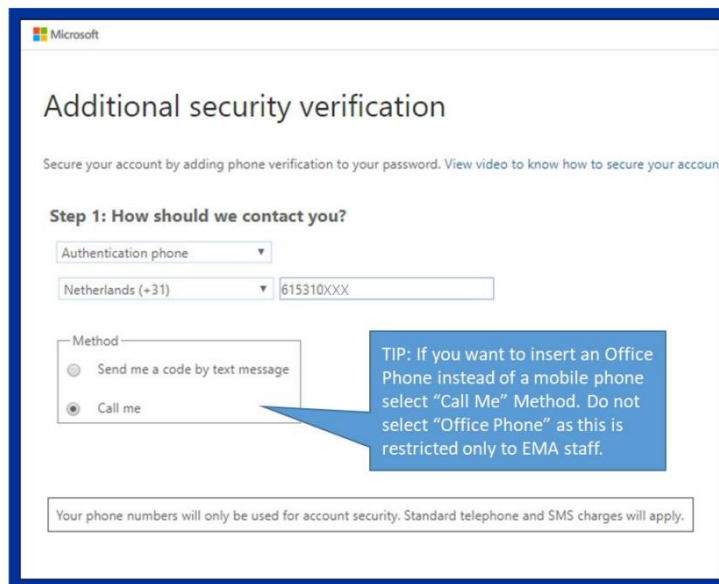
If you prefer to not use a mobile phone number to receive a text message you can select two additional options:

1. "Call me Method"

2. "Mobile App"

3.7.6.1. Call me Method

1. Select your country, add your phone number, select method option "Call me" and click "Next";

Figure 56. Set-up phone authentication information by call

2. You will receive a call, please answer the call and press the hash key #.

Figure 57. Phone call confirmation
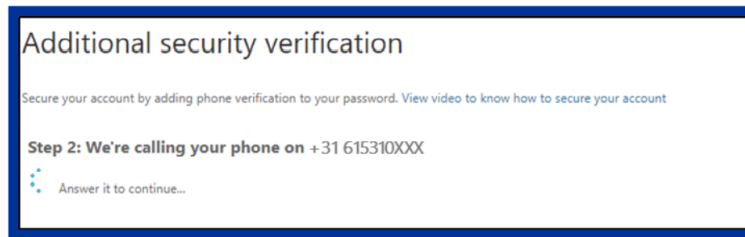
3. Click "Finished" and you will be redirected to the EV VET Production system.

You may need to refresh the page or re-enter the UPD portal. At your next login you will see the following screen:

Figure 58. Sign-in request
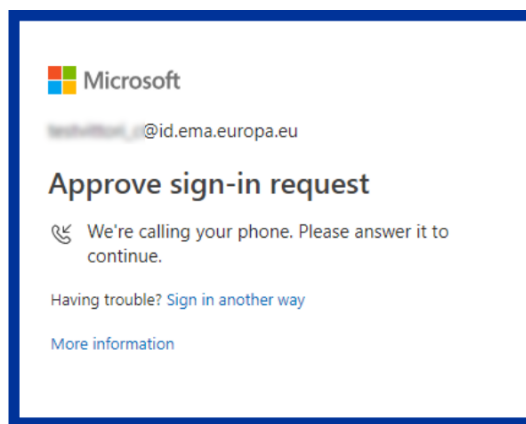
3.7.6.2. Mobile App

1. Please select "Mobile app" from the drop-down list then tick the first option: "Receive notifications for verification" and then select the "Set up";

Figure 59. Mobile App verification set-up
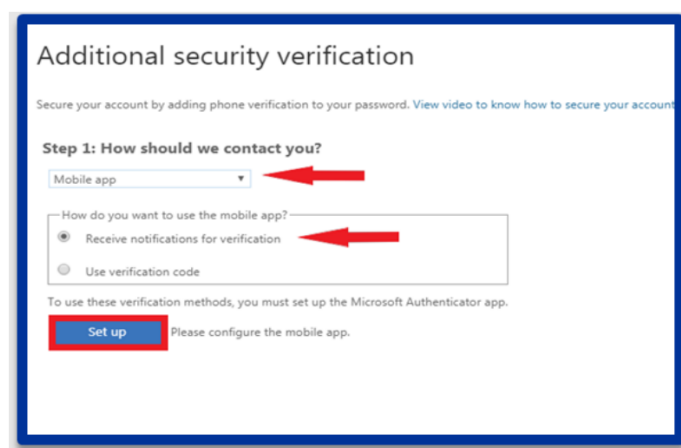
2. The following window will appear with instructions to download the mobile app on your phone;

Figure 60. QR code verification
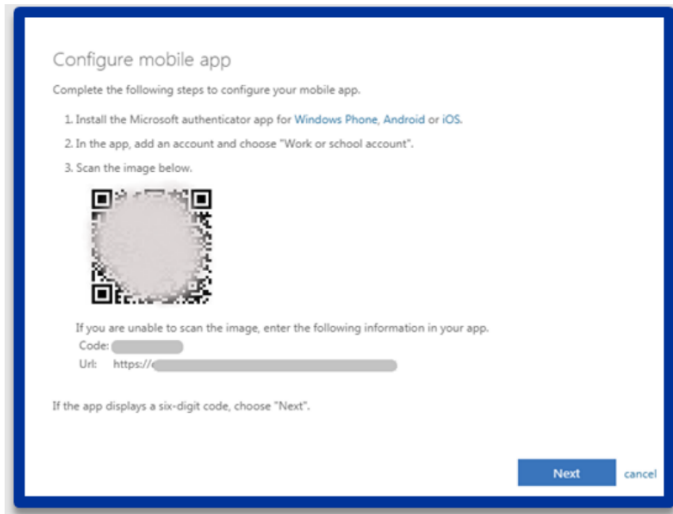
3. This step is done on your smartphone: Download the Microsoft Authenticator app from your smartphone. Once installed, select "Add Account" and "Work or school Account" and scan the QR Code;

Figure 61. App verification screen flow
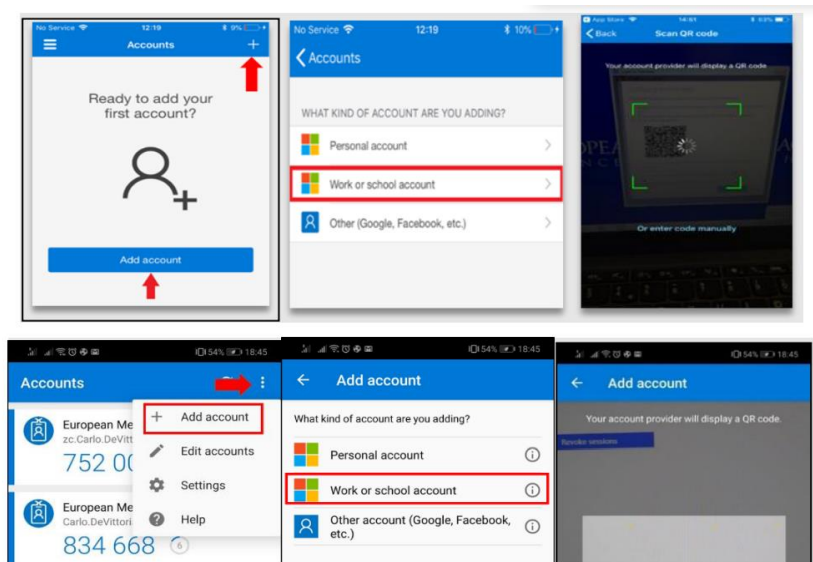
4. Follow the instructions and you will be prompted on this screen. This step doesn't require any action on your side, it's just a summary of the previous steps, please select "Cancel" to finalize the process.

Figure 62. Verification finalization

3.8. Policy violation

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

- If the policy is breached, a warning appears

Figure 63. Policy violation examples

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

- Remove a role to proceed by pressing ⊠

- Or submit the request with violation

- Or cancel request

Figure 64. Policy violation solution – remove a role

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 65. Search for an Organisation in OMS

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 66. Request the creation of a new organisation

Figure 67. Fill in the details and submit the new organisation

4.1. Finalise organisation information in EV VET 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 RP role - see Section 3.2 Responsible Person (RP) access request.

4.2. Update organisation details in OMS

To update data in the OMS Dictionary, you will need to create a change request on the SPOR portal - http://spor.ema.europa.eu/omswi/#/. Please, refer to Guidance on how to create a change request (F - OMS Web User Manual) available in the documents section.

Figure 68. Change Request in OMS

4.3. Manage Organisation Hierarchy

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

Organisation Hierarchies can be created and managed in EV VET following the steps described in below sections.

Important 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.

4.3.1.1. MERGE organisations

In order to move a HQ profile to sit as an affiliate under another HQ profile; or move an affiliate that is already registered under one HQ profile to sit as an affiliate under another HQ profile, please follow the steps below. Criteria to select the affiliate organisation to be part of the Hierarchy, should be considering only the affiliates who have a role as an MAH and also any other organisations for which the QPPV have PharmacoVigilance responsibilities.

1. Make sure that in the case that the merging organisations have a RP assigned, this is correctly registered (see section 3).

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

    i)   OMS ORG ID of the HQ profile

    ii)   OMS ORG ID and name of the new affiliate to be added to the HQ.

OMS Organisation ID can be found in [SPOR OMS Platform](#).

3. Raise a EMA Service Desk ticket to request the merge attaching the signed letter.

*It is possible to create Hierarchy with organisations that are created in OMS but have no Routing ID or RP assigned. In this case and to define the responsible person, each company should follow the instructions from the QPPV(s) of the relevant company(s) involved. Each MAH company may decide if additional internal sign-off might be necessary depending on the local situation of the affiliate organisations.

4.3.1.2. SPLIT organisations

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

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

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

2. Raise a EMA Service Desk ticket to request the split attaching the signed letter.

4.3.1.3. SWAP organisations

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

1. Make sure that both organisations have a RP registered. An organisation without a RP has a disabled status and cannot be merged.

2. Create a cover letter on official company headed paper, dated and signed. The letter must be signed by the RPs of all involved organisations. 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

3. Raise a EMA Service Desk ticket to request the swap attaching the signed letter.

4.4. Disable organisation profiles: HQ and Affiliates

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

4.4.1. Disable HQ and Affiliate profiles

The process is the same for both HQ and affiliate profiles.

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.   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 4.3.1.2. SPLIT organisations).

ii.   Raise an EMA Service Desk ticket to request that the organisation is disconnected on the EMA Gateway. Please provide the organisation ID for each profile to be disconnected (HQ and/or affiliates). The organisation ID is the routing ID that needs to be disabled.

iii.   The RP user should log in to the SPOR OMS platform and create a change request to deactivate the organisation in OMS.

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

i.   If an affiliate is to remain enabled, i.e., as a legal entity with reporting obligations, before disabling the HQ profile in EudraVigilance please ensure that the affiliate is separated from the HQ profile (see section 4.3.1.2. SPLIT organisations).

ii.   The RP user should log into the EMA Account Management portal, revoke all user roles for the organisation and request the removal of their own RP role (3.6.). The RP role removal request ID should be communicated to the EMA via a Service Desk ticket to approve the removal of their role.

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. Webtrader and Gateway transmission

1. Webtrader transmission mode for submission of AERs 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, a completed Gateway connection form and encryption certificate 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 EudraVigilance Veterinary webpage.

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

5.1. 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 VET Test system) first. In the form, please make sure that you have included the XCOMP Organisation ID.

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 certificate](#) for Production. In the Gateway connection form please make sure you have included the Production Organisation ID.

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

1. After the first user 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 VET 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.

6. EV VET EXTERNAL TEST (XCOMP) registration process

The EudraVigilance Veterinary External test (XCOMP) registration process has been integrated with the EMA Identity and Access Management (IAM) system. This means that when MAHs and NCAs manage the user accesses and maintain data on their organisations, this will be automatically synchronized with EV VET XCOMP Test environment.

XCOMP Test environment is only available for EudraVigilance Veterinary web platform (EVWEB) and not for Data Analysis system (DWH).

Pharmacovigilance IT system vendors are not permitted to register in the Production EudraVigilance system nor the XCOMP Test environment. In the case that a Vendors needs to access the XCOMP Test system, should be handled through the registered organisations for which the Vendor is providing the service.

6.1. XCOMP registration for organisations with a Production profile

1. With the launch of the new EudraVigilance Veterinary platform, all organisation that were already registered in Production environment that will need Webtrader access to XCOMP, should raise a [Service Desk](#) request for their organisation to be created in XCOMP environment and a routing ID assigned. Same process applies to new organisations. The newly created XCOMP Organisation ID will be provided by the ServiceDesk team once the accesses are granted.

Important note: Only those organisations that already had a Gateway connectivity to XCOMP, will automatically get the Organisations created and routing IDs assigned.

2. When the main RP has completed their registration of a new organisation in the EudraVigilance Veterinary Production system (i.e. when a RP role has been approved), access to XCOMP test system will be automatically granted for all Web Trader users, assigning the same permissions as the approved for Production system for that organisation. If a user has a trusted deputy role in the EudraVigilance Veterinary Production system, they will automatically be given the same role in the XCOMP system.

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 confirmation by the EMA Gateway Support team.

6.2. Managing an EV VET XCOMP organisation profile

Disabling of a XCOMP profile:

When the main 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.

6.3. IT system Vendors registration with EV VET XCOMP

Access to IT system for Vendors is not allowed. In the case that a Vendors needs to access the XCOMP Test system, this need to be handled through the registered organisations that the Vendor is providing the service.

Annex 1 – EV VET Production roles

To change a role in a profile, please remove all the roles you have (see section 3.6.) and then request the role again.

EV VET Base Roles	
EV VET NCA Responsible	Request this role, if you work for an NCA/Veterinary 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 VET MAH Responsible	Request this role, if you work for a pharmaceutical company and you are the main Responsible Person. This role allows you to grant and revoke access to users and manage the organisation hierarchy. This role grants you full access. *MAH affiliate must request RP role for affiliate organisation*
EV VET NCA Trusted Deputy	Request this role, if you work for an NCA/Veterinary Regulatory Agency and you are supporting the main responsible person 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 VET NCA Responsible person.
EV VET MAH Trusted Deputy	Request this role, if you work for a pharmaceutical company and you are supporting the main responsible person 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 VET MAH Responsible person.
EV VET NCA/MAH AER Browse	Request this role, if you need only access to AER messages. Please note, this role will be rejected, if your organisation does not have an EV VET MAH Responsible person.
EV VET NCA/MAH AER Browse & Send	Request this role if you need to perform queries, create and send AERs, receive safety messages, store the safety messages locally and generate acknowledgement messages. Please note, this role will be rejected, if your organisation does not have an EV VET MAH Responsible person.
BI EVVET NCA Dashboards	This role allows the NCA users to access predefined reports and dashboards.
BI EVVET NCA Answers	This role allows the NCA users to create ad-hoc reports.
BI EVVET MAH Dashboards	This role allows the MAH users to access predefined reports and dashboards.