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Information Management Division

EudraVigilance Registration Frequently Asked Questions

Information on creating and maintaining EV user accounts using IAM2

Glossary

Acronym	Definition
CS	Commercial Sponsor. A profile in the EudraVigilance registration system
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EV	EudraVigilance
HQ	Headquarter. A profile in the EudraVigilance registration system
NCA	National Competent Authority of a Member State in the EEA
NCS	Non-Commercial Sponsor. A profile in the EudraVigilance registration system
OMS	Organizations Management Services
EU QPPV	The super administrator for the MAH HQ profiles. It usually coincides with the main QPPV in the Pharmacovigilance department of a company, but it is not necessarily that same person.
RP	Responsible Person. The person responsible for maintaining Commercial Sponsor and Non-Commercial Sponsor EudraVigilance profiles in the EV registration system.
SPOR	Substance, Products, Organizations and Referential management services
TD	Trusted Deputy for a profile in EudraVigilance

Introduction

This document addresses questions received from stakeholders as a part of the launch of the new EudraVigilance Registration System, which went live on 26 July 2018.

The document summarises questions received through the Agency's service desk and as part of the support webinars organised by the EMA.

The document is regularly updated and should be consulted as a first reference before contacting the Agency's service desk.





1. Questions for all user groups

Ref.	Question	Answer
1.1	Where do I need to register an organization?	Please go to EMA Account portal - https://register.ema.europa.eu , and request the role of "SPOR Unaffiliated". The system automatically grants it. After that, please register your organization in the SPOR portal/organizations
1.2	Where do I need to register an Affiliate?	Affiliates are legal entity organizations. You need to follow the same steps as for creating a new organization. Once the organization has an active RP associated with it, the EU QPPV/RP of the HQ profile needs to request a merge via EMA service desk . The request needs to be done on an official headed paper from the HQ organization, adding all the necessary information for the merge: organization name and ID of the profiles to become affiliates, and organization name and ID of the profile to become or remain as HQ, and signed by the responsible person for the profile(s) to be merged. Please note that we need this information for both XCOMP and Production, if your organization has profiles in both environments. This Service Desk ticket needs to be addressed to the EMA technical team.
1.3	What is an Affiliate and when do I need to create it?	An affiliate is a legal entity with physical presence and registered by an NCA. You do not need to create it, unless you wish to have it under a hierarchy sitting "underneath" a particular HQ. We recommend keeping profiles as simple as possible, with the least number of affiliates and virtual affiliates as possible. If you are managing a global company represented in EV via a HQ profile, and then want to have subsidiaries or acquired companies under it, then you would need to affiliate them.



Ref.	Question	Answer
1.4	What is a Virtual affiliate and when do I need to create it?	<p>Virtual affiliates are profiles existing only in EudraVigilance restricted area.</p> <p>They are created for third party service providers or additional transmission modes. If the case is an organization that has been acquired by another or national branches of a global company, then these are considered affiliates.</p> <p>The responsible person for the HQ is the same responsible person for the Virtual Affiliates</p> <p>To create and manage a virtual affiliate, please check the EV Registration User Manual uploaded in the EudraVigilance Registration Webpage</p>
1.5	How do I request a role for a Virtual Affiliate?	<p>Users need to request an EV Contributor role to the HQ of the organization that has created the Virtual affiliate.</p> <p>The Trusted Deputy (TD)/QPPV will then be able to select the users from their EV restricted area to add them to the virtual affiliate profile.</p>
1.6	How do I remove an EV profile (HQ and affiliate)	<p>The QPPV or TD of the HQ organization profile needs to login to their profile via EMA Account Management portal and revoke all roles of the users of that affiliate. This can be done via EV Admin role Tab, found on the main dashboard.</p> <p>The QPPV/TD of the HQ organization profile needs to ensure no active products are linked to the affiliate they wish to remove. If so, please transfer or nullify the products.</p> <p>The QPPV/TD of the HQ organization profile needs to raise an EMA service desk ticket to the gateway team requesting the removal of the transmission mode connection, adding the IDs, in XCOMP and Production.</p> <p>If the profile belongs to an organization that no longer exists, please raise a ticket via SPOR and request to remove the organization from OMS.</p>
1.7	How do I add an EU QPPV/RP role?	<p>You need to ensure the organization profile does not have an active EU QPPV/RP role already. If so, the former EU QPPV/RP needs to be removed in advance, including any base role of the new QPPV/RP, in advance. The request will be approved by EMA.</p> <p>Only then the new QPPV/RP can request the role. Once they request it via EMA Account Management portal, they need to follow the instructions as per document "Change of qualified person for pharmacovigilance and responsible person for EudraVigilance".</p> <p>PLEASE NOTE: SPOR Super User Industry role is needed if you need to raise a change request in SPOR, and it is approved by the SPOR team. This relates to changes of organization.</p>

Ref.	Question	Answer
1.8	How do I remove an EU QPPV/RP role?	<p>EU QPPV/RP roles should be removed on their last day of work at that organization. There are 2 ways to remove the role:</p> <p>a) Roles can be removed by TDs of the organization, or the EU QPPV/RP themselves, by going to EMA Account Management portal> EV Role admin tab.</p> <p>b) Roles can be removed by the user by going to EMA Account Management portal> manage my access> remove role.</p> <p>Once on the page, select the role to be removed (only one request at a time) and go to review, then submit. The role removal request will be sent to EMA for approval and you will need to add the request id for role removal in the change of QPPV/RP ticket. EMA will review the request, approval the removal and confirm to the ticket requester so that the new EU QPPV/RP can request the vacant role.</p>
1.9	How do I add users?	<p>Users are no longer added by EMA. This is now a self-managed process by the user.</p> <p>Go to EMA Account Management portal> manage access> Add access. Search for the required role and go to review.</p> <p>In review, you submit the request (only one role at a time) and then a form pops up. You need to select the right organization and then finally submit the request.</p> <p>QPPV/RP/TDs will approve your request.</p>
1.10	What is the role I need to Request for Article 57?	The user needs "EV Browse or Browse and Send MPR".
1.11	What roles do I need for CIOMS download?	The user will need EV ICSR browse or EV ICSR Browse and Send + EVDAS scientific roles.
1.12	What role do I need to create an organization in OMS?	You need to request the SPOR unaffiliated role via EMA Account Management portal . The role is automatically granted by the system.
1.13	How many Trusted Deputies can my organization have?	As many as the organization considers necessary. There are no limits in the system. All Trusted Deputies of the same EV profile have the same administrator rights.

Ref.	Question	Answer
1.14	Why is my role request automatically rejected?	<p>There are different possible scenarios:</p> <ol style="list-style-type: none"> 1. There is an existing active QPPV in the system for your profile. They will need to have their role removed before you request a new one. 2. You have already a base role. (See question 1.15). Please remove your roles before requesting new ones. 3. Your organization profile does not have an active EU QPPV/RP. Please speak with your organization to ensure one is appointed and activated in the system.
1.15	What are a base and a supplementary role?	<p>Supplementary roles: EV MAH Additional QPPV (the one needed for QPPV Code, only for HQ MAH profiles) L2B access and EVDAS access.</p> <p>Base role: They are the non-supplementary roles.</p> <p>Base roles are mutually exclusive. The user cannot have more than 1 base role. Whichever role is requested, the user needs to first remove their existing roles (base and supplementary) then request the new base one and once approved, request again the supplementary role.</p>
1.16	How do I change my role in EV?	<p>First, you will need to request the removal of all your roles for that profile by logging into EMA Account Management portal> manage access> Remove access.</p> <p>Search for the required role and go to review, submit and confirm. The role will automatically be rejected. If you have more than one role assigned to that particular profile, please repeat the above process. You can only remove one role at a time.</p> <p>Then please log into EMA Account Management portal> manage my access> add role, select the role you wish to have (only one role at a time can be selected).</p> <p>Go to review, search for the organization you wish to have the role for, and submit the form. This request will go to your TD or EU QPPV/RP for approval.</p>
1.17	Who approves my request?	<p>If you requested an EU QPPV role, your request will be approved by EMA, after you have informed us via the Service Desk Portal and sending all necessary documents to us (See question 1.7).</p> <p>For any other user, your TD , RP or EU QPPV will approve your role(s) via EMA Account platform.</p>
1.18	I am the EU QPPV/RP/TD for HQ and cannot have access to my affiliates' profiles and/or users. What can I do?	<p>The hierarchy in EV is connected with OMS. Some affiliate profiles for legacy organizations will not be linked to the same OMS ID.</p> <p>This is why we recommend that EU QPPV/RP/TD who needs to access their Affiliate profiles, must have a TD or RP role in those affiliate profiles by requesting the relevant role for the relevant affiliate organization via EMA Account Management portal.</p>

Ref.	Question	Answer
1.19	How do I obtain EV Post functionality?	If you have EU QPPV or Trusted Deputy roles, it is included in your access. Otherwise, please request a browse and send role, which will be approved by your QPPV/RP/TD.
1.20	Can a QPPV of a MAH HQ profile based outside the EU?	No. QPPVs must be based within the European Union.
1.21	Can a RP of a CS/NCS profile based outside the EU?	Yes. You will need to provide forms A and B, which you can find in the EV Registration Webpage
1.22	Can a MAH HQ profile have legal address outside EU?	No. MAH legal address in their profile must be within the European Union.
1.23	Can a CS/NCS profile have legal address outside EU?	Yes, as long as they have a valid Legal representative within the European Union.
1.24	Where do I change the address or information related to my organization?	You will need to create a change request in SPOR .
1.25	Where do I change the address or information related to QPPV?	This can only be done via the EV restricted area. The email address of the QPPV must be edited from EMA Account Management portal > Identity > Edit Identity.
1.26	How do I contact the EudraVigilance Registration Team?	Via the EMA Service Desk
1.27	How can I ask for further support?	For general questions, you can contact AskEMA For specific technical questions, raise an EMA Service Desk ticket You can also call EMA Service desk on 020 3660 7523 if you are unable to log into the service desk portal.
1.28	I cannot submit Safety reports/changes to the Medicinal Product. Why is that?	Verify that in the EV Restricted Area you have the correct transmission mode enabled. For doing this, you first need to login in the EV Restricted Area as a QPPV/Responsible Person/Trusted Deputy on behalf of the organization sending the transmission. If you are a legacy organization, you will see either gateway or webtrader. If the transmission mode is blank, it means a third party service provider is doing the transmissions. If you are a new organization created after 26 July 2018, you will see webtrader or gateway, it will never be blank. For third party service providers you will need to create a Virtual Affiliate.


Ref.	Question	Answer
1.29	How can I set up the Transmission mode of my organisation?	<p>If your organization profile was active before 26 July 2018, your transmission mode is already set up.</p> <p>If your organization profile was activated after 26 July 2018, when the first person (EU QPPV/RP) logs into their EV restricted area, they will have webtrader assigned as default. They will need to modify to gateway, if they wish to have this second transmission mode.</p> <p>In addition, the EU QPPV/RP in their new organization></p> <p>Approve first user request, need to add the information of: OMS ID and type of transmission, so that EMA can connect this organization profile. If you are using gateway, you will have to include the encryption and connectivity forms for both Production and if relevant XCOMP.</p> <p>You will find the templates in the EV Registration Webpage.</p> <p>If you are creating a Virtual Affiliate, you can set it up directly via EV Restricted area and then raise a EMA Service Desk ticket to the gateway team (this is the transmission technical team for both webtrader and gateway). You will need to add type of transmission (webtrader or gateway), organization ID and organization name. If you are using gateway, you will have to include the encryption and connectivity forms for both Production and if relevant XCOMP.</p> <p>You will find the templates in the EV Registration Webpage.</p>
1.30	How can I change the Transmission mode of my organisation.	<p>Please raise a ticket via the EudraVigilance Service Desk.</p> <p>If you are changing from webtrader to gateway, you will have to include the encryption and connectivity forms for both Production and if relevant XCOMP.</p> <p>You will find the templates in the EV Registration Webpage.</p> <p>Note: <i>please be aware that your gateway software may not support both ICSR and MPR transmission. We recommend that if you are changing to gateway and you do not have an additional webtrader profile set up for MRP transmission, you create a virtual affiliate with webtrader transmission mode for MPRs.</i></p> <p>You will also need to include the organisation ID and organization name for Production and XCOMP (if relevant).</p> <p>If you are changing from Gateway to webtrader please include the organisation ID and organization name for Production XCOMP (if relevant) and Production.</p> <p>There is no additional action required from your side.</p>

Ref.	Question	Answer
1.31	I can't see all my organizations in the drop down menu in the EV restricted area; do I need to create a new EMA Account portal profile?	<p>No. If you can't find all your organizations, go to EMA Account Management portal login page. Select "Forgot my user id" and request your user id for all the emails you may think of you have used to log into any EMA system. It may also be that the convention for your email has changed and your corporate email has been updated, which has triggered a duplicate account in EMA portal.</p> <p>If you identify this, please raise a EMA Service Desk ticket and let us know of your multiple user id and which one you would like to keep. The technical team will merge your accounts.</p> <p>You should then be able to have full access to all your profiles. If this is not the case, please re-open the ticket and let us know, so that the technical team can further investigate your profile(s).</p>
1.32	Why I can't see my roles in EMA Account Portal or some functionalities like EV Role admin tab (for TD/QPPV) do not appear?	The synchronization between EMA Account Portal and EV is still ongoing for some profiles that required further analysis and manual migration. Roles and full functionalities are expected to become available for those users before December 2018.




2. FAQs for EudraVigilance external users

Ref.	Question	Answer
2.1	How can I register for an EMA Account?	<ol style="list-style-type: none">1. Navigate to the EMA Account Management Portal URL https://register.ema.europa.eu2. First ensure you do not have an account already by checking "Not sure if you have an EMA Account". Your email may have changed or you may have been using EMA systems with other login credentials, which means you already have an active EMA Account portal profile. If you don't:3. Click on "Create a new EMA account" link4. Fill in registration form with all mandatory information5. Setup your challenge questions and answers, input your answer to the challenge question and click 'Next'6. Answer the Captcha Question7. Type in the one-time token that you received in your email inbox8. Click on the "Confirm" button to create a new EMA Account

2.2	During the registration I am getting the following message: "The email you have chosen is already in use". What should I do?	<p>If you are getting a message that your email address is already in use, it means that you have an EMA account and should not register again.</p> <p>This account may already exist if you have used an EMA application in the past. These include: Eudralink, EudraCT Secure, Service Desk portal, MMSe, JIRA, MMD, EVDAS, EUDRAPORTAL, EUDRAGMP, PAEDIATRICS, BI DASHBOARD, EUTCT, CORPGXP, EPITT, PSUR.</p> <p>You can use your EMA account credentials to directly login to the EMA application in question without registering again.</p> <p>However if you have forgotten your credentials you should do one of the following:</p> <ul style="list-style-type: none"> • If you have registered through the EMA Self Registration page in the past and do not remember your credentials, please use the 'Forgot username' and 'Forgot password' links to retrieve your username and reset your password. • In case you have registered through another system in the past and have forgotten your EMA login credentials, you need to contact the Service Desk to reset your password by phone: +44 (0) 20 3660 7523 • After you receive your new credentials please follow the instructions given to setup your challenge questions in the EMA Self Registration portal so that you can retrieve your password autonomously in the future. More details can be found in the Basic External User Guide. • If your EMA account was generated by someone else, you need to contact the Service Desk to obtain your credentials. After you receive your new credentials please follow the instructions given to setup your challenge questions in the EMA Self Registration portal so that you can retrieve your password autonomously in the future.
2.3	I have not received an email with my registration one-time token. What should I do?	<ol style="list-style-type: none"> 1. Please, check that the email you have provided is correct 2. Then, check that the email is not in your Spam Folder 3. If you still cannot find the email please try registering again before contacting the Service Desk by phone: +44 (0) 20 3660 7523


2.4	I have not received a confirmation email after registration. What should I do?	<ol style="list-style-type: none"> 1. Firstly, attempt to login to EMA Account Management Portal on https://register.ema.europa.eu with the password you have set and the username displayed during the self-registration process. 2. Alternatively, if you do not remember your username, use the "Forgot username" link and if you do not remember your password use the "Forgot password" link on the login page. 3. Once you have retrieved your username/password try to login again. 4. If the login is still unsuccessful, your account might not have been created. Please, attempt to register again. 4. Finally, if the registration is still not successful, please contact the Service Desk by phone: +44 (0) 20 3660 7523
2.5	How can I disable my EMA account?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal page on https://register.ema.europa.eu 2. Then, go to the "Manage Access" section located at the top of the Dashboard page and click the "Manage Accounts" link. 3. From the list of Accounts find the account that states 'EMA Account' under the 'Application' Column. 4. Click on the  button located under the "Actions" column 5. Click on the "Confirm" button. The account will be disabled for six months, and then deleted permanently. <p>NOTE: This is to disable EMA account, not to disable roles. To disable roles, please see EMA EudraVigilance Registration Manual</p>
2.6	How to login to EMA Account Management Portal?	<ol style="list-style-type: none"> 1. Navigate to the EMA Account Management Portal URL: https://register.ema.europa.eu 2. Provide EMA credentials in the "Username" and "Password" fields 3. Click on the "Login" button
2.7	Where can I view my user Identity details?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on URL: https://register.ema.europa.eu 2. Click on the 'View Identity' link under the 'Manage Identity' section in your Dashboard page to get to your Identity profile page.
2.8	How can I edit my Identity Details?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal URL: https://register.ema.europa.eu 2. Click on the "Edit Identity" link under the "Manage Identity" section in your Dashboard page to get to your Identity profile page. 3. You are allowed to make changes only to your email address and phone number 4. Once you have made any changes, click on the "Submit" button

2.9	How can I change my existing password?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu. 2. Click on the "Manage Passwords" tab located at the top of the Home page. 3. Press "Change" and repeat the below steps for each application displayed in the list. 4. Type in your current password in the "Current Password" field. 5. Type in the new password in the "New Password" and "Confirm Password" fields. 6. Click on the "Submit" button.
2.10	How can I setup my challenge questions?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Go to the top right corner of your screen 3. Click on your profile name 4. Click on the 'My Preferences' 5. Then click on the 'Edit Authentication Questions' link at the bottom of the page 6. Setup/Update your Authentication Questions 7. Click on the "Save" button
2.11	My EMA account is locked. What should I do?	<p>This applies to all users with an EMA Account profile, regardless of the EMA systems they have access to. There could be 2 reasons:</p> <ol style="list-style-type: none"> 1. You did not login to your account for six months and it was temporarily disabled. Contact Service Desk by phone to have it unlocked - Tel. +44 (0) 20 3660 7523. If it was not used for 12months, your account is deleted and you need to register again. 2. The account is automatically locked after 5 unsuccessful login attempts. Please contact the Service Desk on the number listed above to unlock your account.
2.12	Do I need to register again when I change my employer?	<p>No. You do not have to register again for a new EMA Account. However, please make sure you update your email, so that you are able to recover your username and password. Please also make sure that the access you have to the EMA applications is in line with your new position. In case you have unnecessary access, please request for the role removal. For details on how to do this, please see "How do I request for a role to be removed?"</p>





2.13	How can I request access for an EMA application?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link 3. Click on the "Manage My Access" link located under the "Manage Access" section 4. Use the "search" field to search the application you want to request access for 5. Click on the "Check Mark" button 6. Once identified, click on the "Review" to submit the request 7. If the selected role is specific to an organization, a form will appear prompting you to select the organization 8. Click on the "Ok" button to submit the form
2.14	How can I review the progress of my access request?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link 3. Click on the "Track My Request" link located under the "Manage Access" section 4. From the list of access requests on the screen, click on the request you would like to see in detail. 5. If you need more details, click on the 'View Complete Details' link located on the top left side of the Section that appears in the screen.
2.15	How can I remove a role for my EMA Account?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link 3. Click on the "Manage My Access" link located under the "Manage Access" section 4. Click on the "My Access" tab 5. Use the "search" field to search the application you want to remove access for 6. Once identified, click on the "X" button 7. Click on the "Review" tab to submit the request 8. Click on the "Submit" button

3. FAQ for advanced users with Admin role

Note: This section applies only to users with EU QPPV/RP/TD roles

Ref.	Question	Answer
3.1	How do I grant advanced user rights for a user to the EMA Account?	<ol style="list-style-type: none">1. Login to the EMA Account Management Portal on https://register.ema.europa.eu.2. Click on the "Identity Warehouse" link from the "Identities" section located in the Top Navigation Bar3. Use the "Search" field to search for the user to whom you intend to add more rights4. Click on the user identity you would like to give the capability to5. Click on the 'User Rights' tab6. Select the new capabilities you would like to assign to the user from the "User Capabilities" list on the left side of the "User Rights" page7. Click on the "Save" button to save your changes
3.2	How can I setup a workgroup?	<ol style="list-style-type: none">1. Login to the EMA Account Management Portal on https://register.ema.europa.eu2. Click on the "Setup" link in the Top Navigation Bar and select the "Groups" option in the dropdown menu that appears in the screen3. Click on the 'Workgroups' tab and then click on the "Create Workgroup" button.4. Add a name for the workgroup in the Name field and fill in any other relevant fields.5. In case you would like to give more advanced access rights to this workgroup, go to the "Rights" section and select the capability you would like to add from the "Capabilities" list6. In order to add members in the group go to the Members section at the end of the page. Select the user you would like to add in the dropdown menu and click on the 'Add Member' button.7. Finally, click on the 'Save' button at the end of the page to finalise the group creation.
3.3	I was notified that I have a new approval request. Where can I find it?	<ol style="list-style-type: none">1. Login to the EMA Account Management Portal on https://register.ema.europa.eu2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link3. Click on the "My Dashboard" link located under the Dashboards section4. You can find the approval request item in the Inbox section located in the left side of your Dashboard page.5. Click on it to open the Approval Request page.6. Alternatively, you can go to the "Assigned Tasks" section located in the same left-sided menu and click the "Approvals" link to get the list of all approval requests.

Ref.	Question	Answer
3.4	How can I ask the requestor for more information?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Then, go to the 'Assigned Tasks' section located in the left-sided menu 3. Click on the 'Approvals' link. 4. Select the relevant request from the list of approval requests. 5. In the "Approval Request" page go to the 'Comments' section and type your comments to initiate a conversation with the requestor. The requestor will then receive an email notification regarding your enquiry.
3.5	How can I approve/reject the request?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Then, go to the "Assigned Tasks" section located in the left-sided menu 3. Click on the "Approvals" link. 4. Select the request you would like to approve/reject from the list of approval requests. 5. Review the item 6. Click on the "Approval Details" and "Details" buttons to get more information about the item 7. Go back to the approval page 8. Click on the "Approve" or "Deny" button as appropriate 9. Finally, click on the "Save" button to submit the approval request.
3.6	How can I delegate the request to another approver?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Then, go to the "Assigned Tasks" section located in the left-sided menu 3. Click on the "Approvals" link. 4. Select the request you would like to delegate from the list of approval requests. 5. Click on the "Actions" dropdown button located below the "Identity + Name" text 6. Select "Forward" option 7. From the popped-up window, select the user you want to delegate the request to 8. Click on the "Forward" button
3.7	What is Access Certification and what is the purpose of it? – Do we have it?	Access Certification is referred to as the activity that Access Reviewers/Business Owners/Line-Managers need to perform where they validate/certify that users have access to the right applications at the right time and that the access is appropriate for their roles at the EMA. Access Certification ensures compliance with audit and information security policies around user access.

Ref.	Question	Answer
3.8	How often is the Access Certification performed?	Business Owners should certify the user access to their application on an annual basis.
3.9	I was notified that I have a new access review request. Where can I find it?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link 3. Click on the "My Dashboard" link located under the Dashboards section 4. You can find the new access review requests in the Inbox section located in the left side of your Dashboard page. 5. Alternatively, you can access all your access review items through the 'Access Reviews' link located on the 'Compliance Activities' section on the top of your Dashboard page.
3.10	How can I approve/reject the access review items?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Open the left-side menu by clicking on the  button located on the left side from the "Home" link 3. Click on the "My Dashboard" link located under the Dashboards section 4. You can find the new access review requests in the Inbox section located in the left side of your Dashboard page. 5. Click on the user identity you would like to review. For each review request item click the 'Approve' () or 'Reject' () button on the left side of the request item. 6. Click on the "Save" button 7. Click on the "Sign off" button at the top of the page.
3.11	How can I delegate the access review of a user?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. You can find the review request item on the Inbox section located in the left side of your Dashboard page. 3. Click on it to open the Access Review page. 4. Click on the user identity you would like to delegate. 5. You can delegate the review of a user's access to another reviewer by clicking on the "Delegate" icon. 6. Select the Recipient 7. Click on the "Delegate" button 8. Then, click on the "Save changes" button

Ref.	Question	Answer
3.12	How can I re-assign the access review items?	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. You can find the review request item on the Inbox section located in the left side of your Dashboard page. Click on it to open the Access Review page. 3. In the access review page, click on the checkbox next to the identity you would like to re-assign. 4. Next, select the 'Reassign' option on the 'Bulk Action' drop down menu located at the bottom of the page. 5. Select the Recipient 6. Click on the "Reassign" button 7. Then, click on the "Save Changes" button
3.13	I have completed my access review but I cannot see the 'sign off' button. What should I do?	<p>Check that your access review Completion status is 100% and there are no outstanding items from other reviewers, if any.</p> <p>Additionally, if there is a challenge period where users can request for their access not to be removed, the reviewer you might have to wait until the end of the challenge period to sign off the review.</p>
3.14	I have completed my access review but the completion status is not 100%.	In the case some review items have been forwarded to other reviewers, these review items might still be outstanding. You can check the progress of access review items forwarded to other Access Reviews at the top of the access review page.
3.15	How can I see the users for a particular organization and their roles	<ol style="list-style-type: none"> 1. Login to the EMA Account Management Portal on https://register.ema.europa.eu 2. Select " EV Role Admin" tab 3. Add the organization name 4. Click on the arrow on the field saying "organization *"once it becomes white. Select the organization 5. Go to the end of the form and click "List roles"