EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

EMA SPOR User Registration Manual

For RMS and OMS users

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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1. Purpose of this document

SPOR is a centralised EU master data service covering **S**ubstance, **P**roduct, **O**rganisation and **R**eferential in relation to medicines. Each of these domains is accessible through the common SPOR web portal.

The SPOR system provides users with services that enable them to contribute to the content of the database – they can request new data, request a change to current data and they can download content. In order to access these services, the users need to be registered for one or more user roles. The user registration and provisioning of the SPOR roles is managed through an identity and access management tool called IAM (IIQ).

This document provides step-by-step instruction how to register in IAM (IIQ) and how to apply for SPOR user roles.

2. SPOR user roles

An individual will have a single account created in IAM (IIQ). A user can have more than one SPOR role provided they do not contravene the permission policies (see section 7). The user will need to submit new SPOR role requests (either for the same role or a different role) if a different organisation (as defined in OMS) needs to be represented.

2.1. User roles and authorisation process flow

Users who do not have access to any of the Agency's systems need to self-register and create EMA account. They can then request SPOR user roles for their account.

Users with an EMA account (for details see below) can request SPOR roles that will be added to their current permissions.

The user roles and authorisation process flow is described below. For SPOR user role definitions, read section 2.2.

Figure 1. Diagram of user roles in OMS/RMS

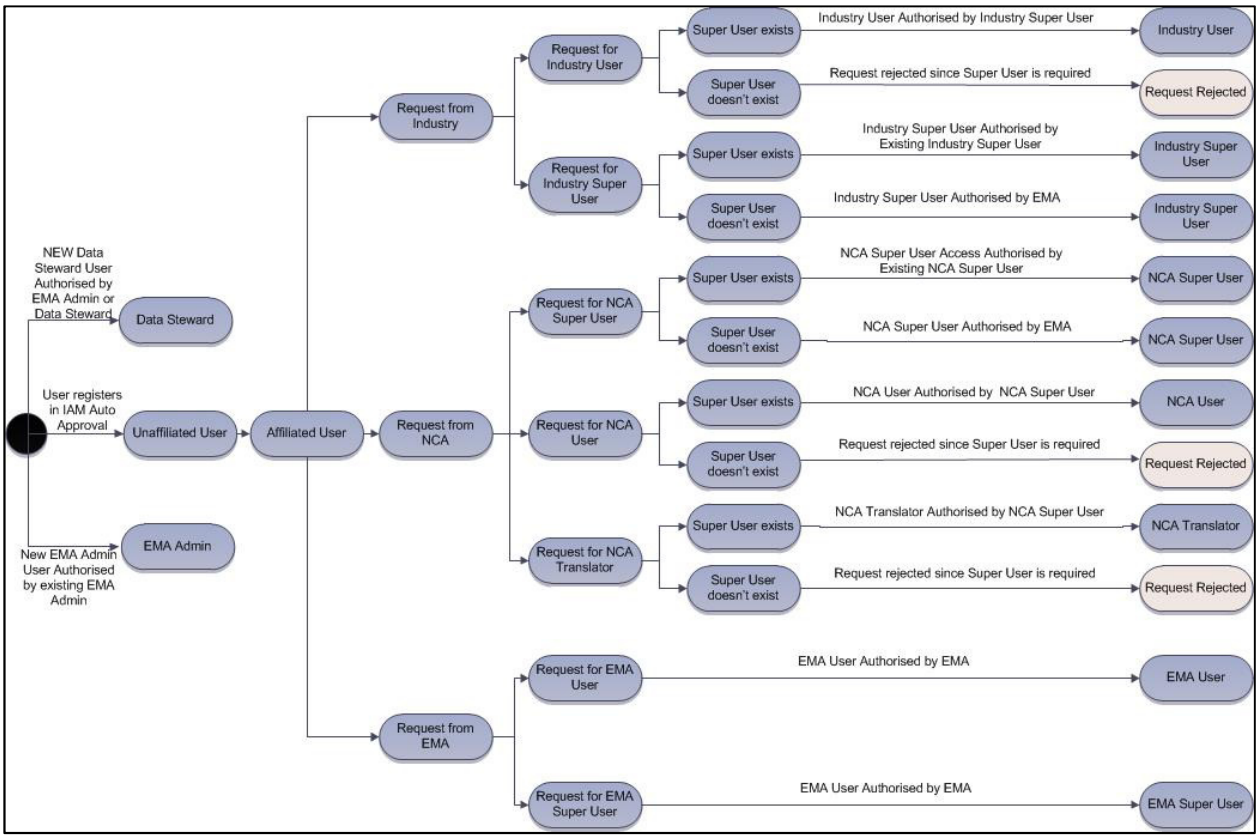
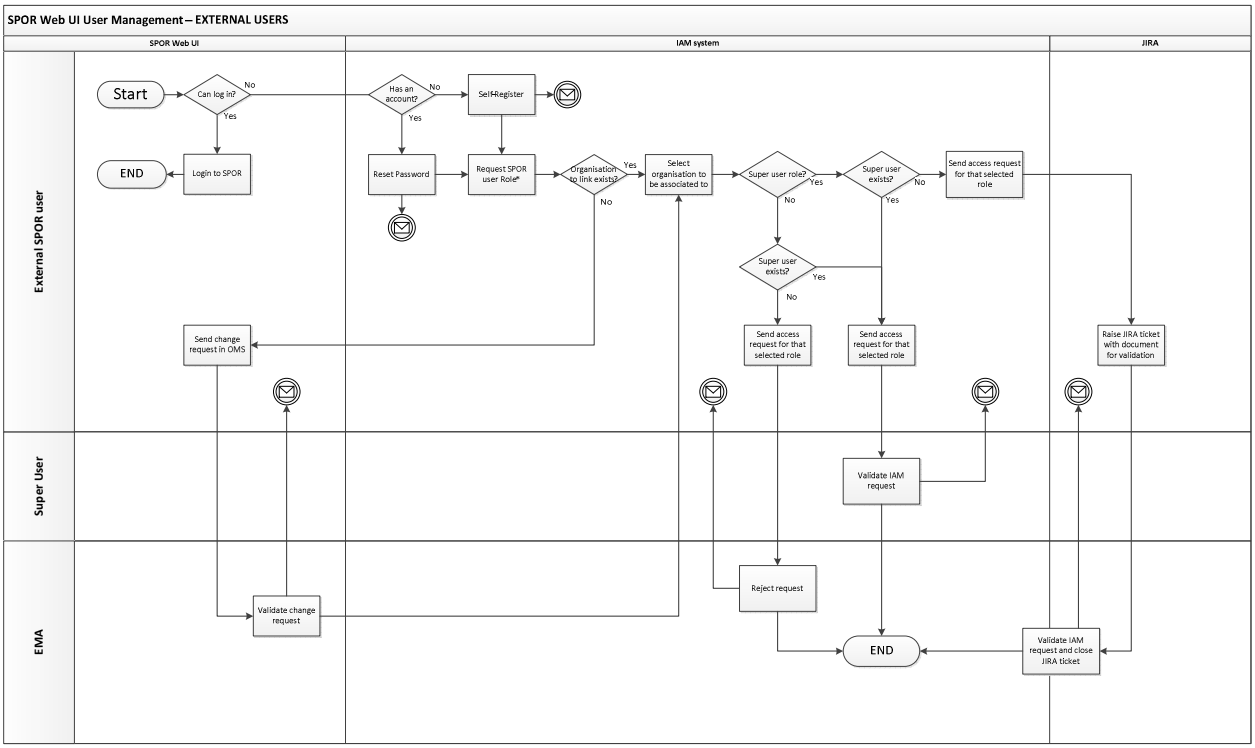


Figure 2. User access authorisation for external users – process flow



2.2. SPOR user roles – description and access rights

Role Name	Description
Data Steward	SPOR role that allows to validate change requests and use master data management functionality in Informatica IDQ and IDD; you should have this role if you are responsible for any of the following: • managing the data cleansing, standardisation and match rules • profiling data within IDQ • validating change requests for new/amended SPOR data • resolving potential master record merges raised by the match process within IDD. • approve external users to become SPOR super users for an organisation Only EMA personnel or persons working on behalf of EMA will be provided with this role
EMA User	SPOR role that allows you to view (only your own), download data (RMS: all lists & OMS: all content) and submit change requests; you can have this role if you are EMA staff or a person working on behalf of EMA
EMA Super User	SPOR role that allows you to view (only your own), download data (RMS: all lists & OMS: all content) and submit change requests; you can have this role if you are EMA staff or a person working on behalf of EMA You can also approve EMA user role requests in IAM.
EMA Admin	You should have this role only if you work in IT Infrastructure and Operations Department and if you are responsible to administer MDM and configure functions

Role Name	Description
	within MDM; encapsulates Data Steward role. You can have this role if you are EMA staff or a person working on behalf of EMA.
Guest User	Any user (registered or not) who accesses the publicly available information on the SPOR Portal Website without logging in
Unaffiliated User	A logged in user who has self-registered via the IAM platform but is not yet linked to any organisation. They will be able to view the same information as a Guest User, but will also be able to export that information. For OMS only, they will be able to submit change requests for a new organisation, limited to one pending request at a time.
Industry User	You should request for this role only if you represent an industry organisation; it allows you to view (only your own), download data (RMS: some lists & OMS: all content) and submit change requests on behalf of your organisation within the SPOR applications. This role will be approved by the super user of your organisation. Please verify your organisation has a super user before submitting this request in IAM. If your organisation does not have a super user, the request will be rejected by EMA.
NCA User	You should request this only if you work on behalf of a national competent authority or an organisation acting as a regulatory authority; it allows you to view (RMS: everyone's & OMS: only your own), download data (RMS: all lists & OMS: all content) and submit change requests on behalf of your organisation within the SPOR applications. This role will be approved by the super user of your organisation. Please verify your organisation has a super user before submitting this request in IAM. If your organisation does not have a super user, the request will be rejected by EMA.
Industry Super User	You should request this only if you work on behalf of an industry organisation and if you are the main representative of your organisations; it allows you to view (RMS: some lists & OMS: all content), download data (RMS: some lists & OMS: all content) and submit change requests on behalf of your organisation within the SPOR applications; You will be accountable for approving other users to access SPOR on behalf of your organisation in IAM and ensuring that only the right users have the SPOR roles against the same organisation This includes the revocation of these roles when the user should no longer represent your organisation. In order for this role to be approved, you have to submit a document showing you are authorised to represent your organisation through the EMA Service desk tool (JIRA): http://servicedesk.ema.europa.eu/ You are able to access the Service Desk application using the same username and password received when registering in IAM. In case you do not submit the document in JIRA, your request will be rejected by EMA.

Role Name	Description
NCA Super User	You should request this only if you work on behalf of a national competent authority or an organisation acting as a regulatory authority and if you are the main representative of your organisations; it allows you to view (RMS: everyone's & OMS: only your own), download data (RMS: all lists & OMS: all content) and submit change requests on behalf of your organisation within the SPOR applications; You will be accountable for approving other users to access SPOR on behalf of your organisation in IAM and ensuring that only the right users have the SPOR roles against the same organisation This includes the revocation of these roles when the user should no longer represent your organisation. In order for this role to be approved, you have to submit a document showing you are authorised to represent your organisation through the EMA Service desk tool (JIRA): http://servicedesk.ema.europa.eu/ You are able to access the Service Desk application using the same username and password received when registering in IAM. In case you do not submit the document in JIRA, your request will be rejected by EMA.

3. New Users

3.1. Account creation from the SPOR web landing

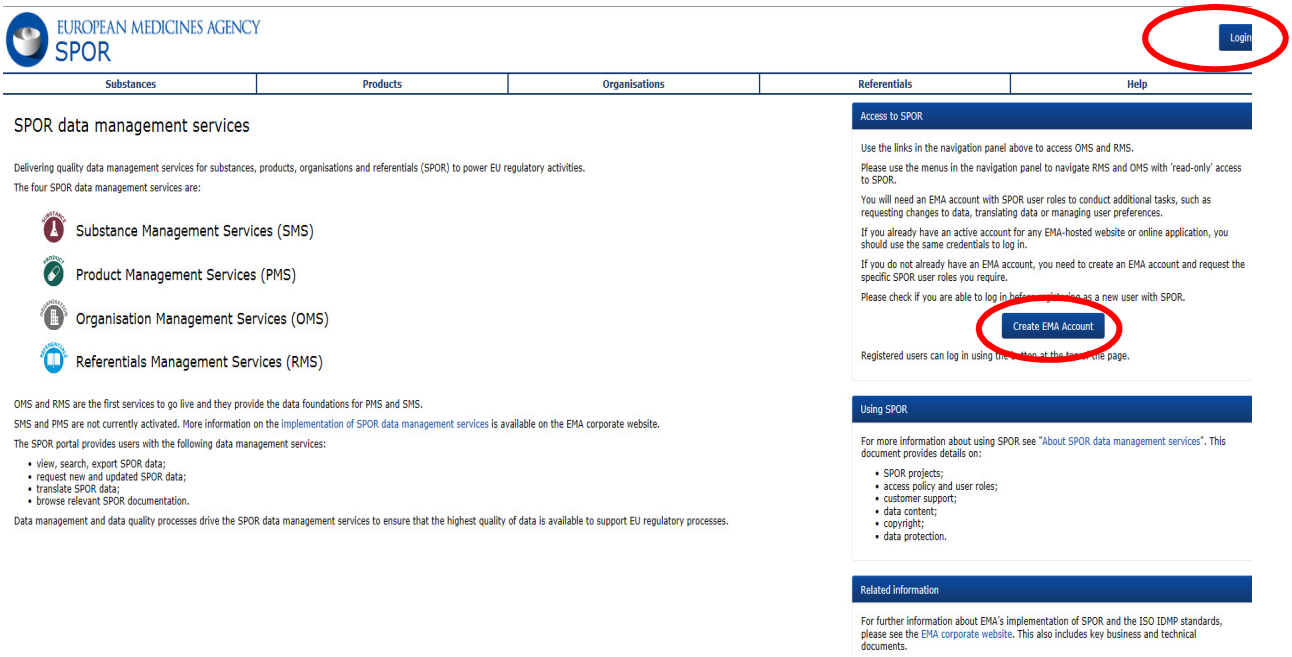
Users who do not have access to any of the Agency's systems should follow the steps described below. After the registration, they will be able to request user roles as per the process in *Fig. 2*.

For registered users, please go to chapter 4.

Navigate to http://spor.ema.europa.eu/sporwi

The SPOR home page appears. Registered users can log in here and new users can register.

Figure 3. SPOR home page



Alternatively, the user can click on Organisations or Referentials tab. Log in and registration is available also from there.

Figure 4. OMS home page (RMS home page has the same look)

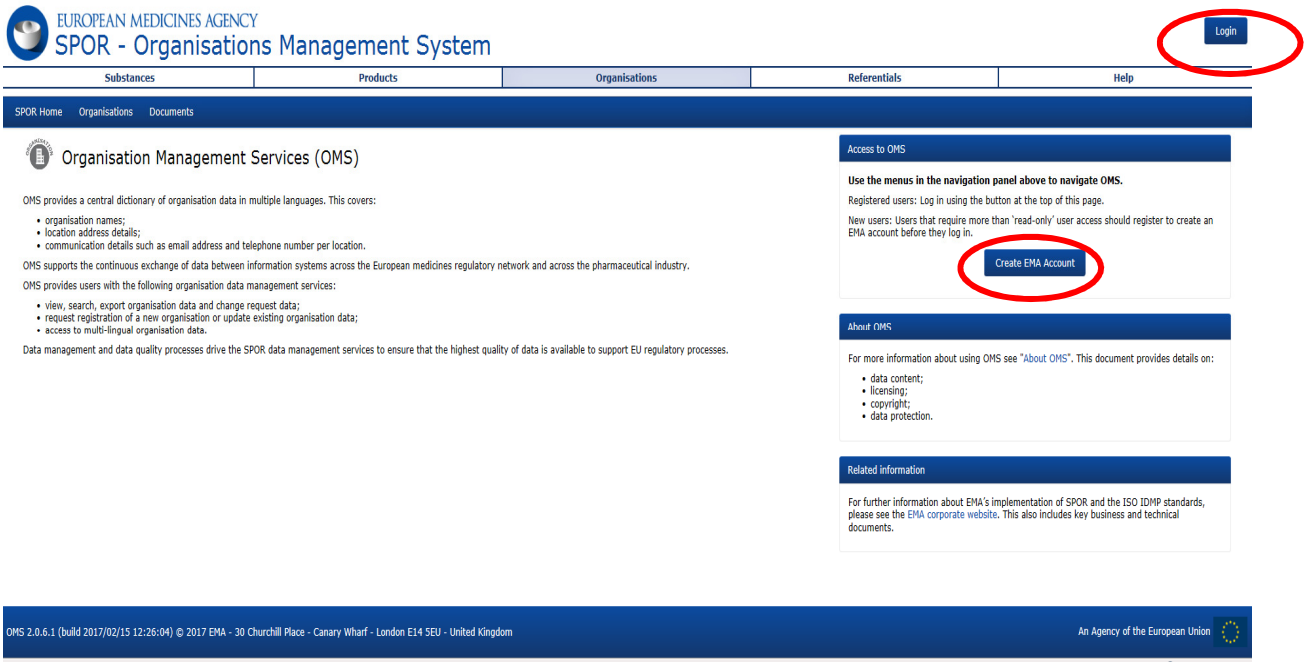
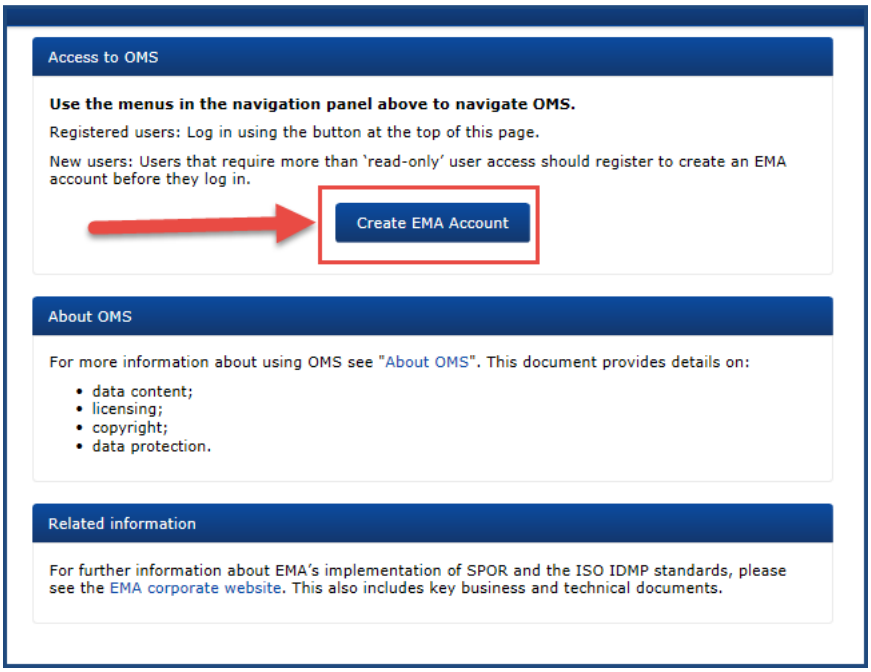


Figure 5. Create EMA account from the SPOR home page

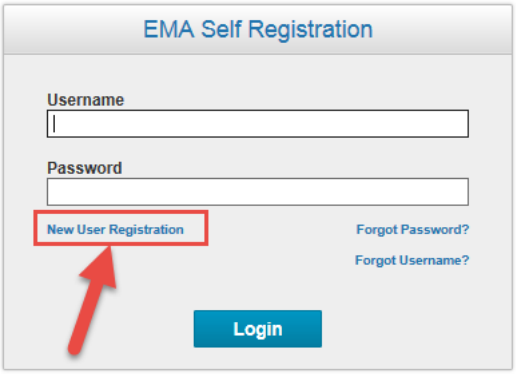


After clicking on "Create EMA Account", the following screen appears – click on "New User Registration".

3.2. Self-registration

This interface is also used to log in and request forgotten username or password for registered users.

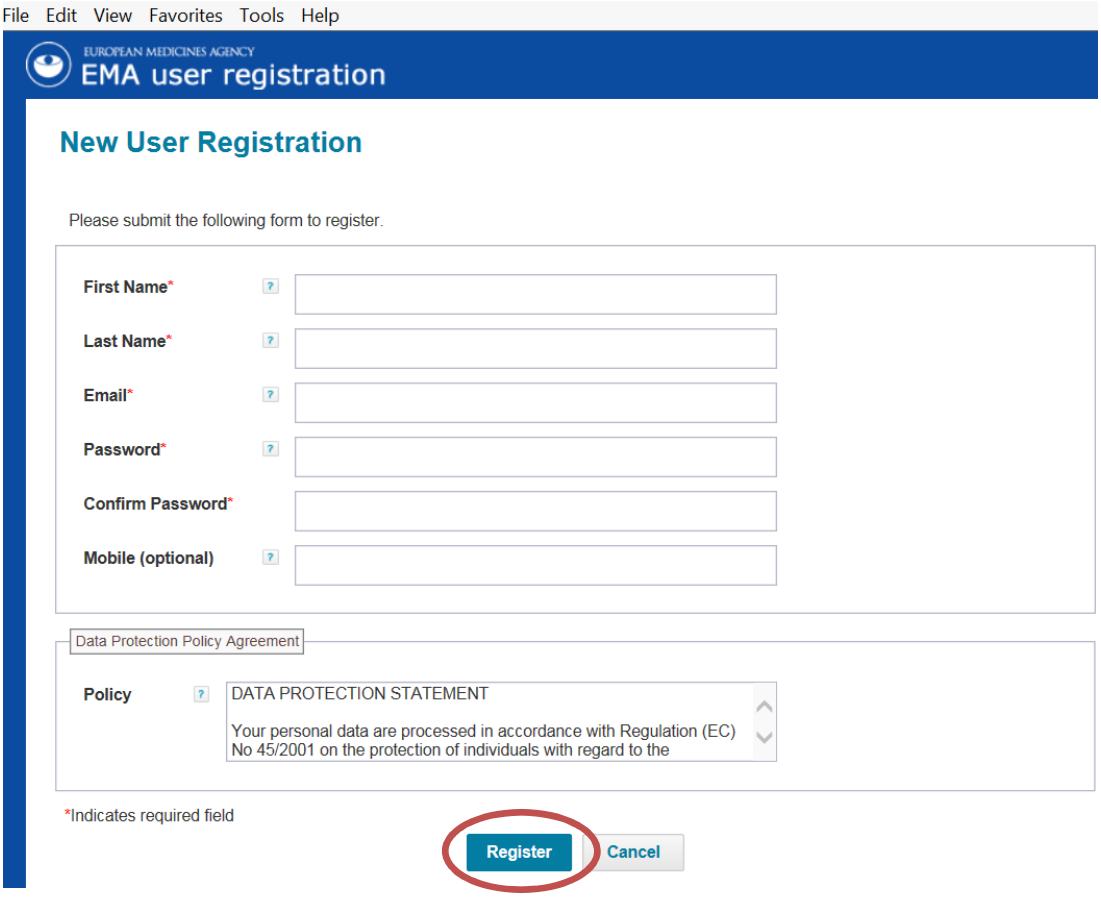
Figure 6. IAM (IIQ) Log in/new user registration/forgot password/forgot username screen



The next screen is the self-registration form.

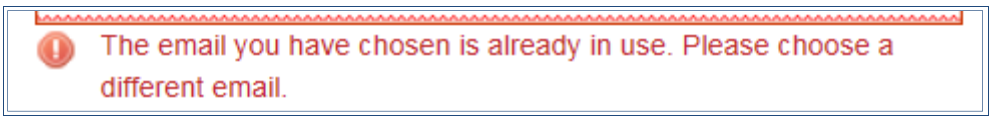
- Mandatory fields are marked by a red asterisk
- Optional field – mobile phone (landline number can be provided too), strongly recommended for cases when e-mail does not work/changes
- Read the Data protection policy agreement
- Click on "Register"

Figure 7. Self-registration form from IAM (IIQ)



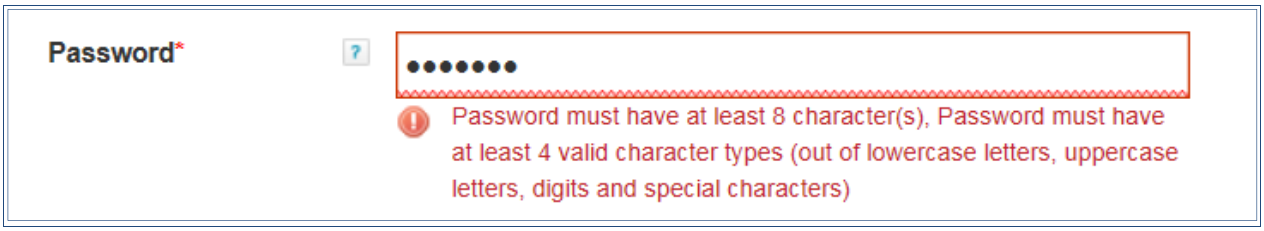
- The system can recognise e-mail addresses to prevent creation of duplicate user entries
- In case the e-mail address is already registered, as shown in *fig. 8.*, the user is prompted to use a different e-mail

Figure 8. E-mail already in use



- Or the user should go back to the landing page and choose "forgot password?" option
- The password has some mandatory requirements – see *fig. 9*

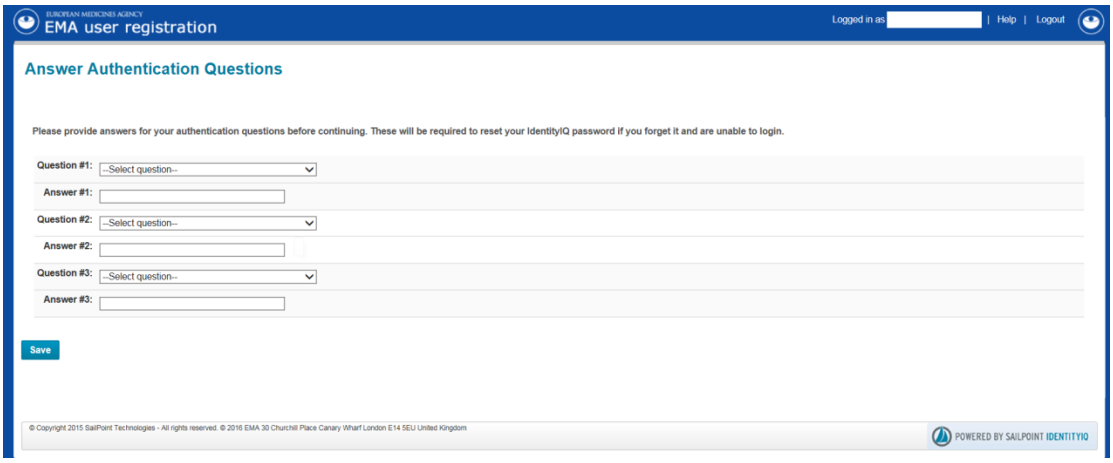
Figure 9. Password requirements



3.3. Authentication questions

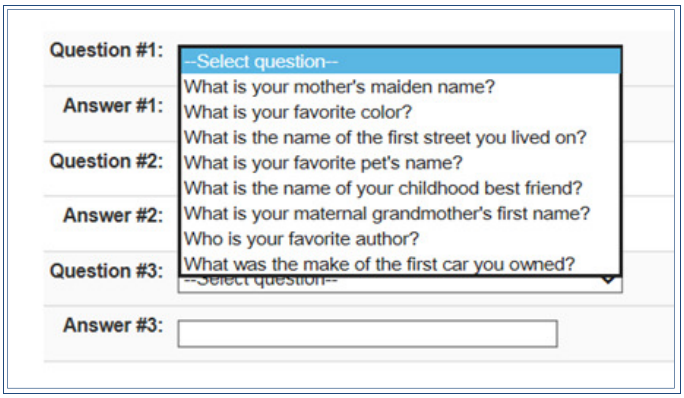
In order to be able to re-set forgotten passwords, the user is prompted to set up authentication questions.

Figure 10. Authentication questions page



- The same list of questions are provided for Q1, Q2 and Q3
- The user must choose 3 different questions
- Save

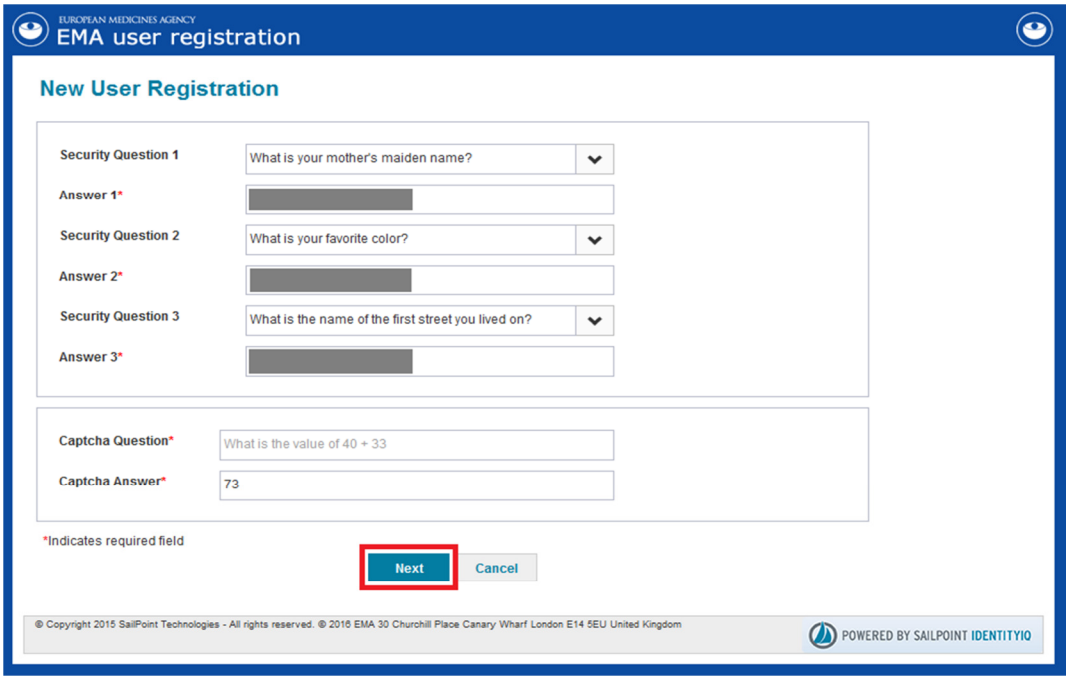
Figure 11. Authentication questions options



After saving, a captcha question (anti-robot precaution) appears

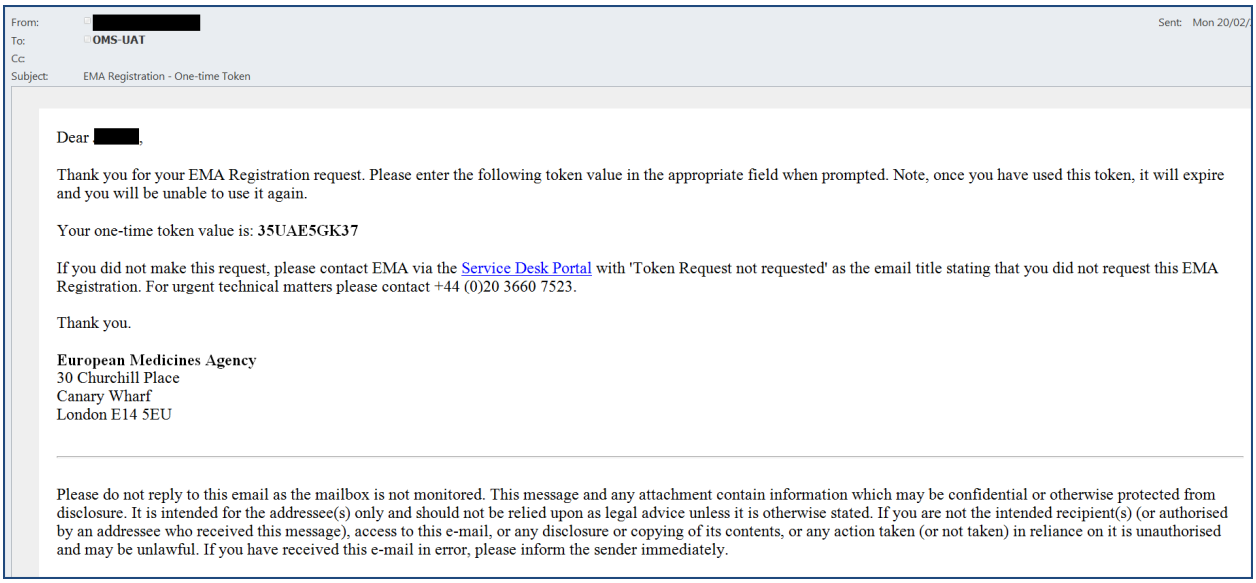
- Answer the captcha question (normally an arithmetic calculation)
- Click 'Next' to go to the registration confirmation page

Figure 12. Captcha questions



- an e-mail with an authorisation token is sent to the e-mail address provided
- Go to section 3.4 to confirm registration

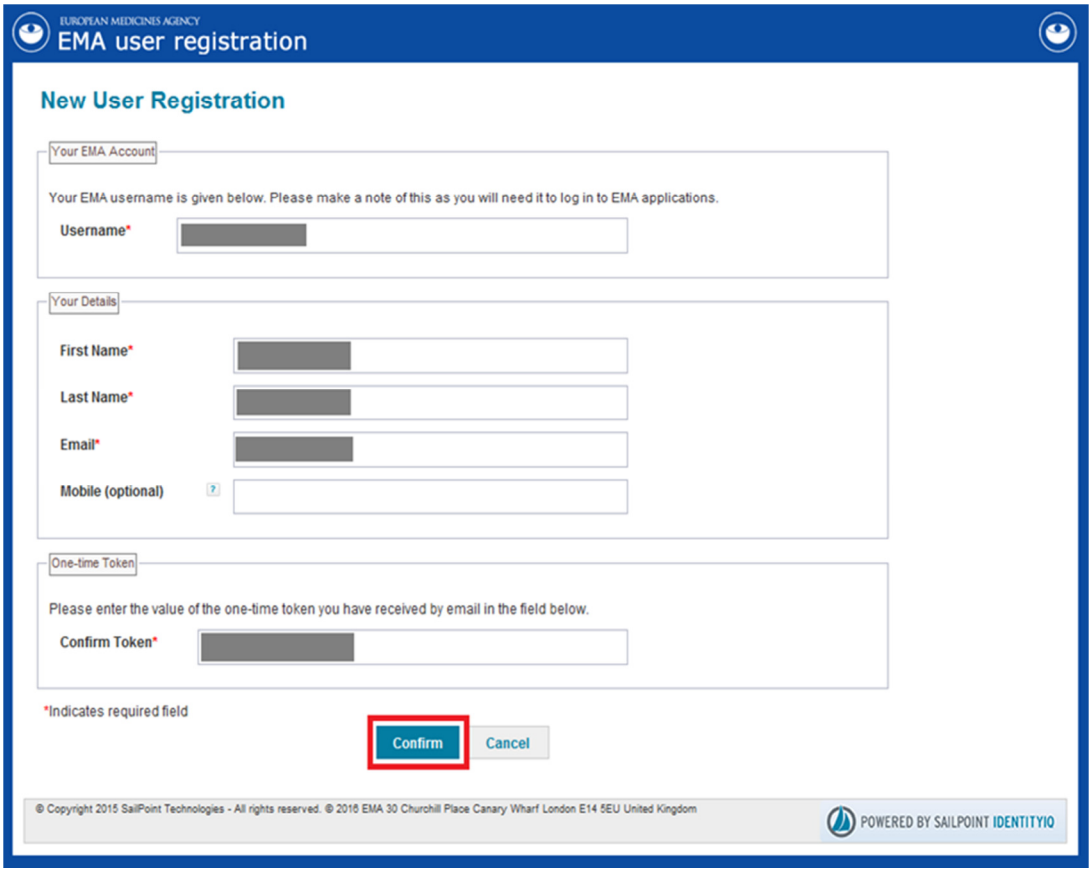
Figure 13. Authorisation token e-mail example



3.4. Confirm registration

- The user needs to make sure the data in the 'Your Details' section is correct – see *fig. 14*
- The code received in the email that was sent previously (see *fig. 13*) needs to be inserted in the 'One-time token' section, in the 'Confirm token' field

Figure 14. Confirmation of the user registration



- Click "confirm"
- This creates new IAM (IIQ) account
- A confirmation e-mail of a successful registration is sent *(fig 15)*

Figure 15. Registration successful – confirmation e-mail example

From: admin@example.com
To: [redacted]
Cc:
Subject: EMA Registration - Your registration request has been processed
Sent: Mon 20/02

Dear [redacted].

Congratulations. You have successfully registered an account with European Medicines Agency Self Registration service.

The Username for your EMA account is: [redacted]

If you did not make this request, please contact EMA via the Service Desk Portal with 'EMA Registration not requested' as the email title stating that you did not request this EMA Registration. For urgent technical matters please contact +44 (0)20 3660 7523.

Thank you.

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU

Please do not reply to this email as the mailbox is not monitored. This message and any attachment contain information which may be confidential or otherwise protected from disclosure. It is intended for the addressee(s) only and should not be relied upon as legal advice unless it is otherwise stated. If you are not the intended recipient(s) (or authorised by an addressee who received this message), access to this e-mail, or any disclosure or copying of its contents, or any action taken (or not taken) in reliance on it is unauthorised and may be unlawful. If you have received this e-mail in error, please inform the sender immediately.

- The user registration dashboard appears (see *fig. 18*)

4. Registered Users

Many users have already access to one or more EMA systems:

EudraLink, EudraCT Secure, IT Service Desk portal (JIRA), MMSe, MMD, EVDAS, EudraPortal, EudraGMP, Paediatrics, BI Dashboard, EUTCT, CorpGXP, EPITT or PSUR. These users don't have to self-register in IMA(IIQ).

The username and password are the same for these systems, the SPOR portal and to the IIQ.

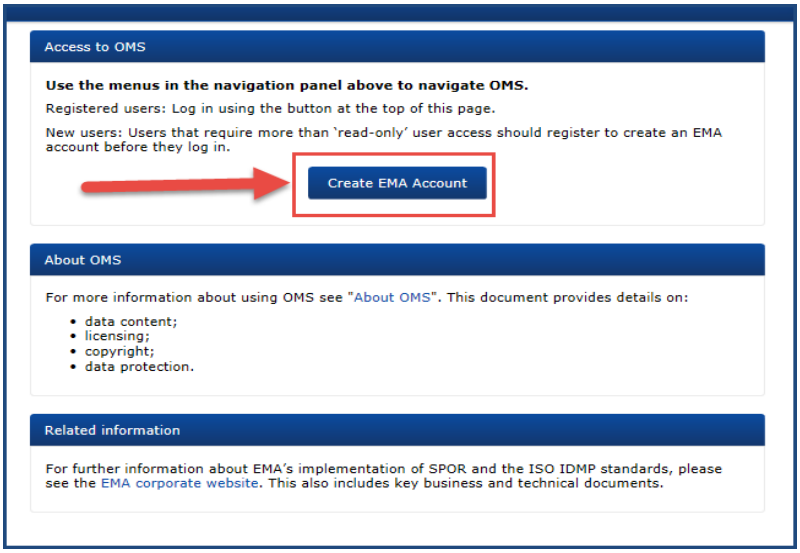
- Registered users can already log-in with the EMA username/password from the SPOR web page; they can access to SPOR interface as registered but non-affiliated user
- In order to use SPOR services, the user needs to request a SPOR user role in IAM(IIQ) first, accessed through the "Create EMA account" button
- If the user does not remember whether they already possess an EMA account, they should attempt to log in IIQ before initiating the self-registration process
- There is a validator on e-mail address to prevent creation of duplicate EMA profiles during self-registration
- If the users know they have an account but don't remember the password, they need to send a request to the EMA IT Service Desk to re-set it for them (http://servicedesk.ema.europa.eu)
- There is no option to re-set the password directly from the SPOR/IIQ webpage for already registered EMA account users who have not completed their SPOR user profile in IAM (IIQ) yet i.e. have not set up answers to authentication questions

4.1. Log In

- Go to "Create EMA account"[1]

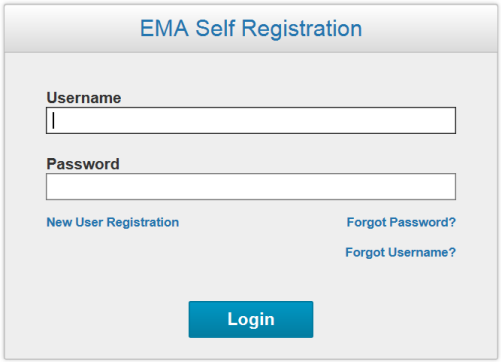
[1] *Even if you are not creating a new account*

Figure 16. Create EMA account from the SPOR/OMS/RMS home page



- After clicking on "Create EMA Account", the following screen appears – log in with your EMA system username and password

Figure 17. Log-in page for registered users



- This will bring you to set up the IIQ account authentication questions
- From there, please proceed the same way as the new users (see 3.3 and 3.4 above)
- After that, the EMA user registration dashboard is displayed to request SPOR roles

5. IAM (IIQ) user registration dashboard

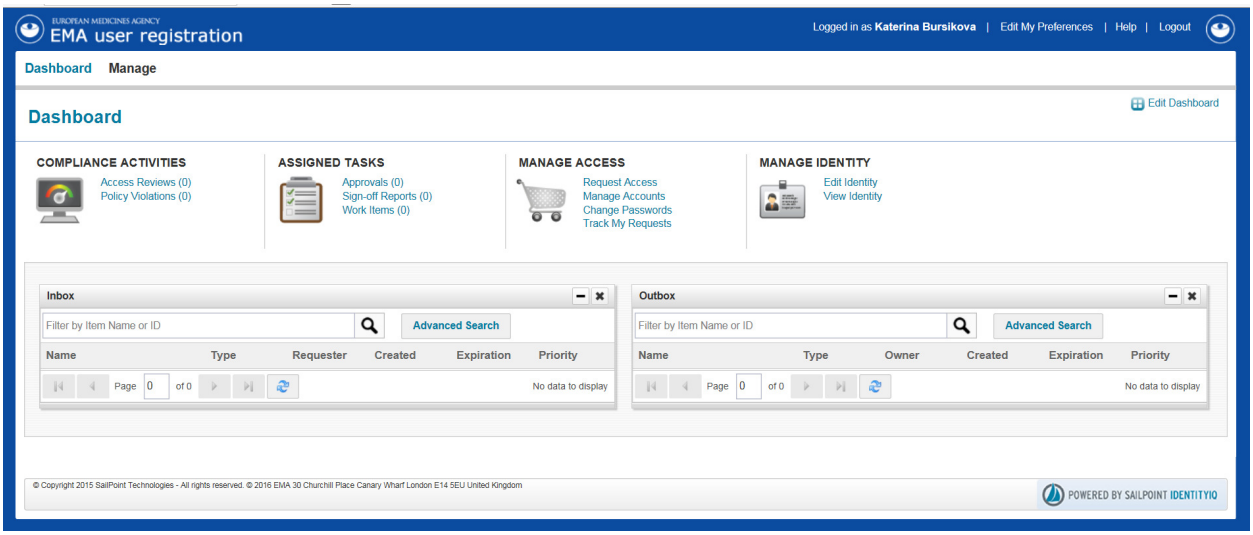
The user registration dashboard is a user interface for managing access to SPOR as well as other EMA systems. It appears once the user registration process or IAM (IIQ) authentication question setting process is completed.

The user can request, view and manage:

- Access rights
- Account information
- Password changes
- Task management
- Identity information
- User profile preferences

All SPOR roles are organisation-specific.

Figure 18. EMA user registration dashboard



Please note that in order to obtain SPOR user role access, **there must be a super user in the requestor's organisation** (on super user access please see below in 5.2). If there is none, the EMA will reject the request in IIQ and will ask the user to

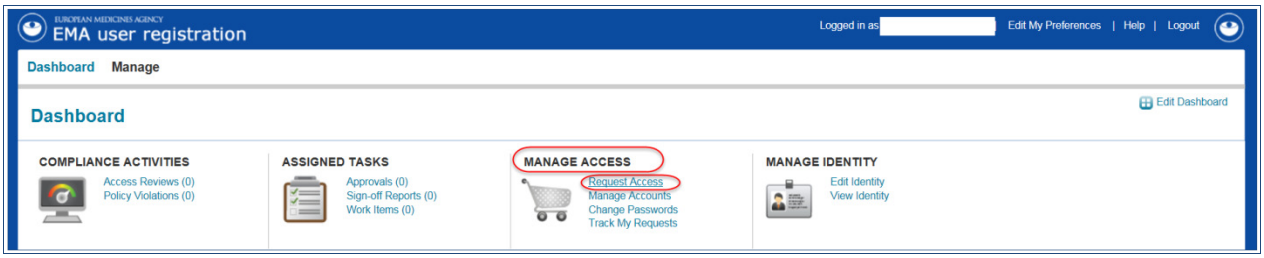
- either resubmit another request to become a super user
- or ensure another user with super user role exists before submitting the same request

5.1. SPOR user access request for industry and NCA users

- SPOR user role will allow the user to view, download or export data and to submit change requests in OMS and RMS
- In RMS, the users can also manage term translations (NCAs only), tagging and subscription services
- The process to request access is the same for industry users and NCA users

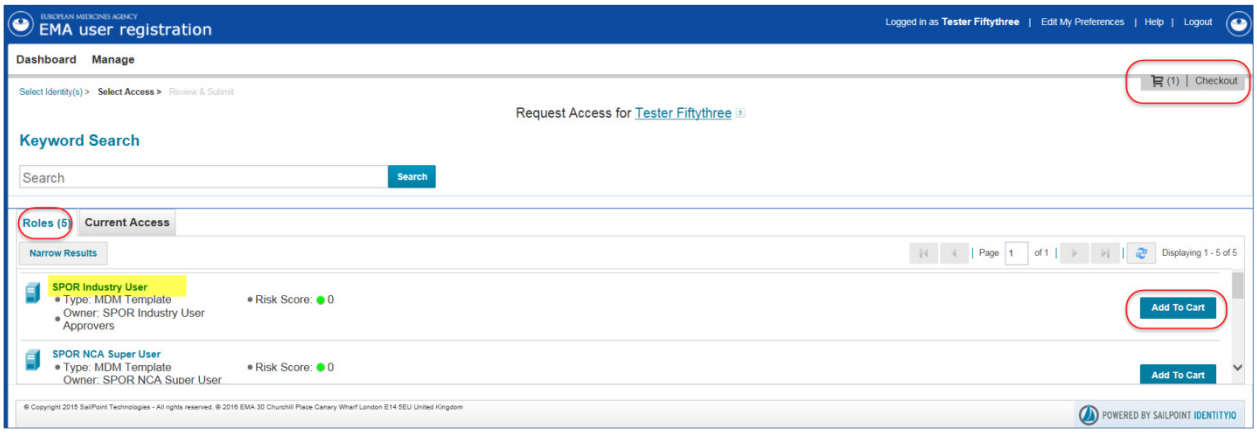
- One person can only have either industry or NCA user access
- On the EMA user registration dashboard, in the "Manage Access" section, select "Request Access"

Figure 19. Manage access



- The user will see possible roles they can choose.

Figure 20. Selection of roles – Industry/NCA user



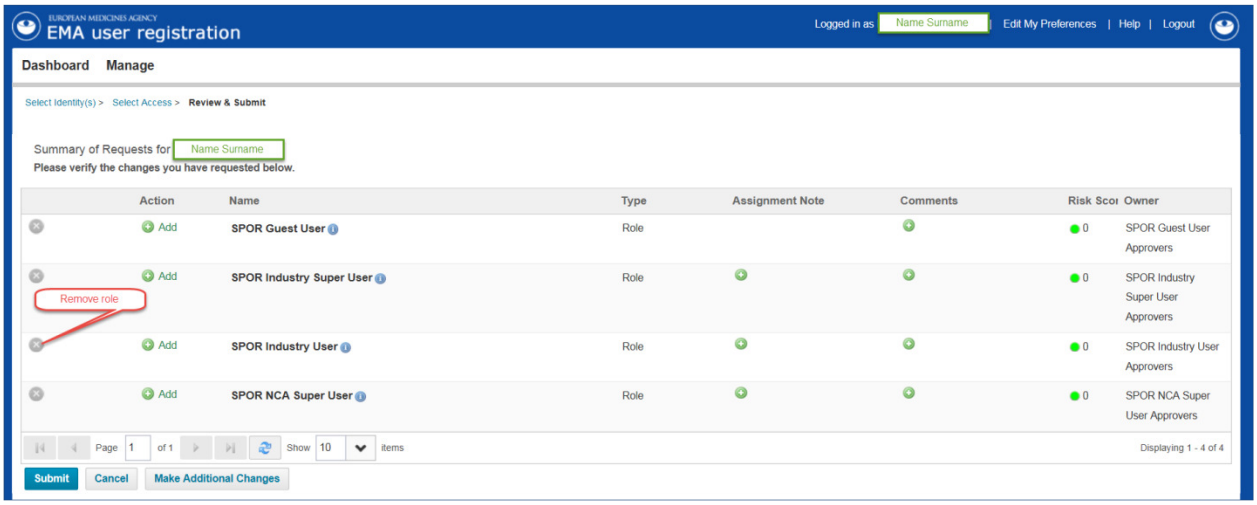
- Select add to cart for the required role[2]
- Once selected, go to checkout

Checkout page appears (see *fig. 21*)

- The user can make additional changes on this screen, e.g. remove role or add assignment note or comments
- Click on "submit"

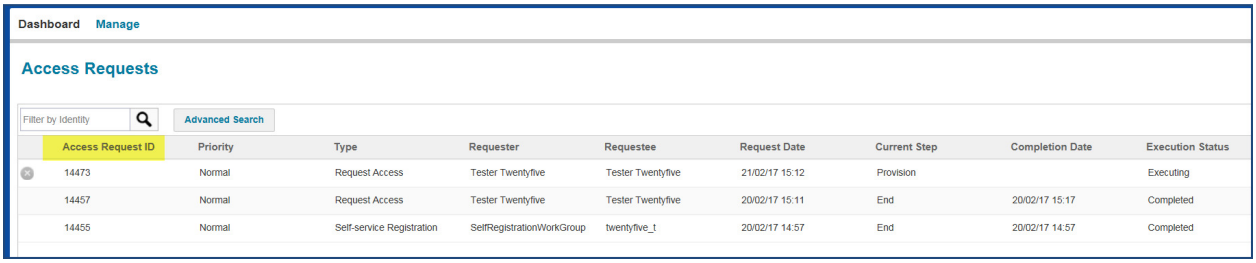
[2] *The choice of roles will expand when more systems are served by IAM (IIA) – IIQ is not SPOR-specific*

Figure 21. Selection of roles – checkout page



- The requestor receives an e-mail that the request has been submitted
- The requests for super user access are approved/rejected by the super user of the requestor's organisation
- The request IDs are listed under "track my requests"

Figure 22. Track my requests



5.2. SPOR super user access request

- The super user role is the first user role to be requested on behalf of any organisation
- To request a super user role for an organisation, the user needs to follow all the steps in 5.1 apart from the role requested, which is Industry or NCA Super User
- The process is the same for industry users and NCA users
- One person can only have either Industry or NCA super user access

Figure 23. Selection of industry super user role

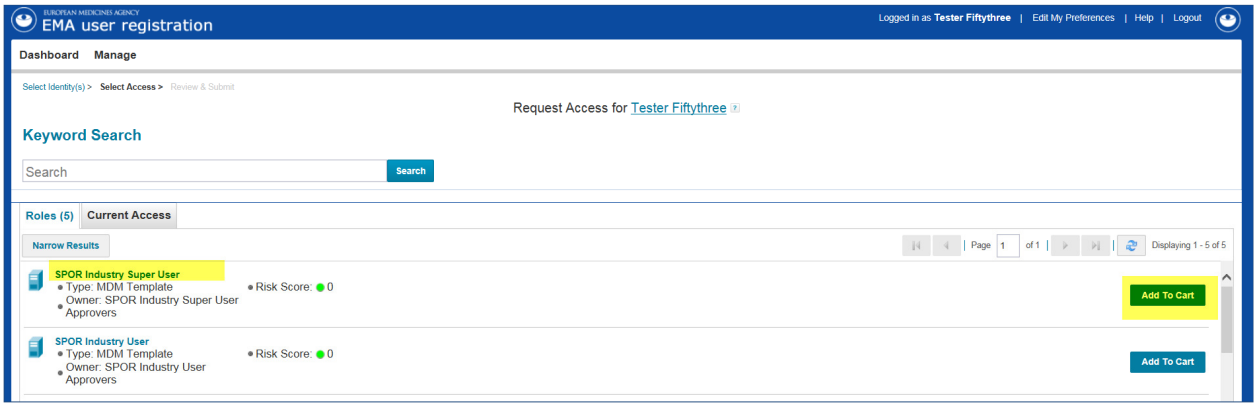
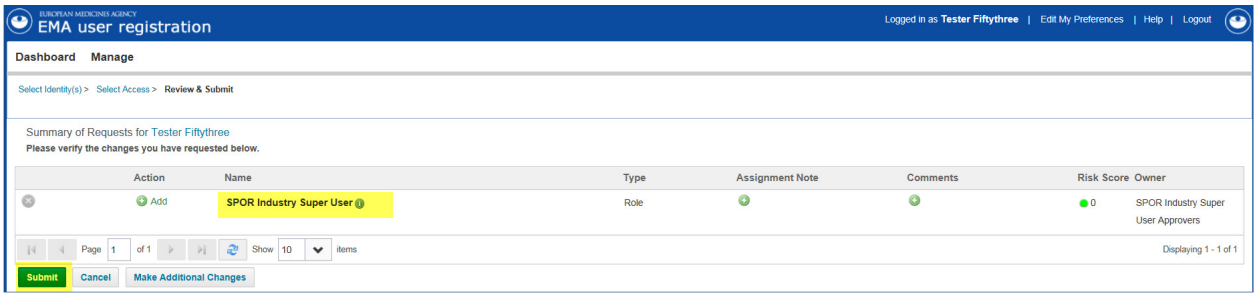
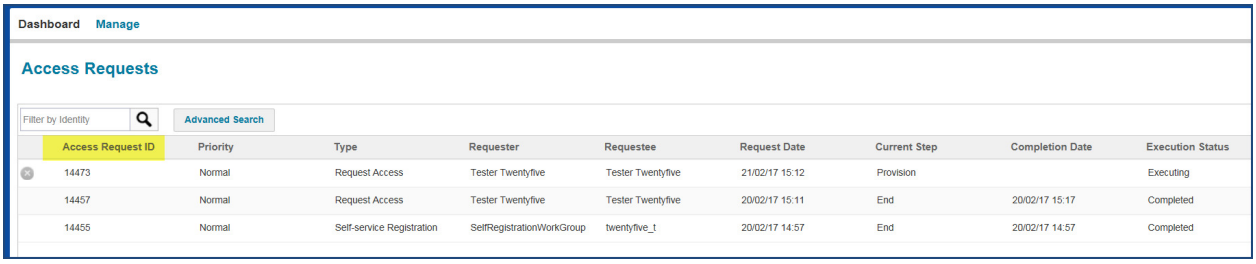


Figure 24. Submit the request for industry super user role



- The requestor receives an e-mail that the request has been submitted
- The requests for the first super user access for a specific organisation are approved/rejected by the EMA IT Service Desk
- Any subsequent super user access requests are approved by the super user of the requestor's organisation
- The request IDs are listed under "track my requests"

Figure 25. Track my requests



5.3. Affiliation to an organisation

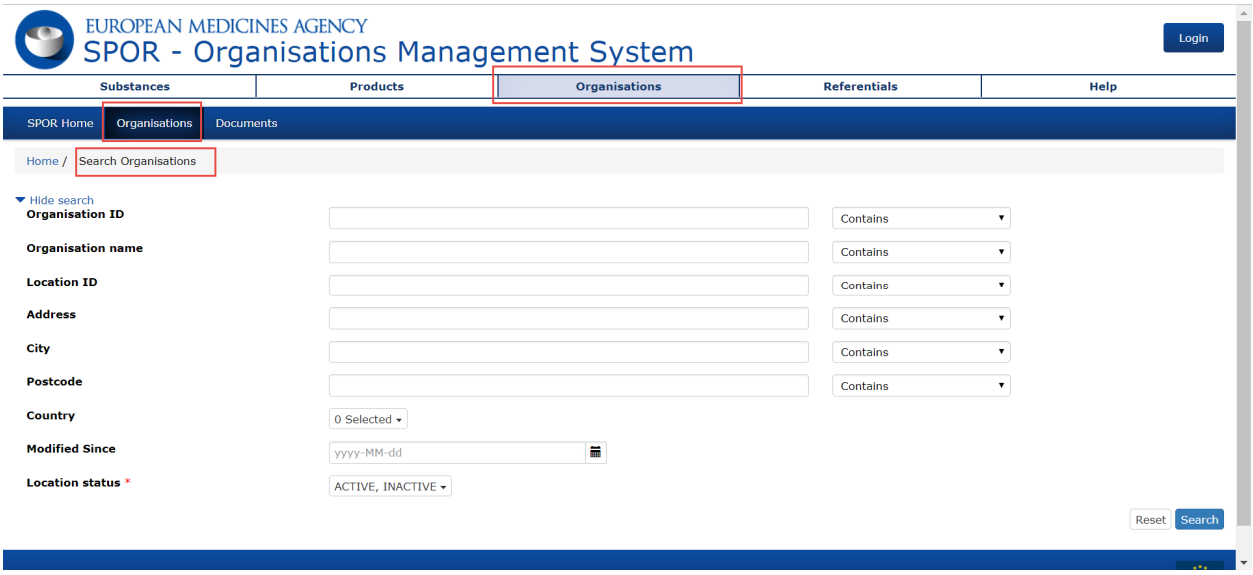
The industry (super) users and NCA (super) users are roles that are organisation-specific, i.e. the users are granted their access rights on behalf of a specific organisation.

The user needs to select the organisation from the dropdown displayed on the screen by inserting the Organisation ID from OMS.

The organisation ID can be found on the OMS website *(fig. 26):*

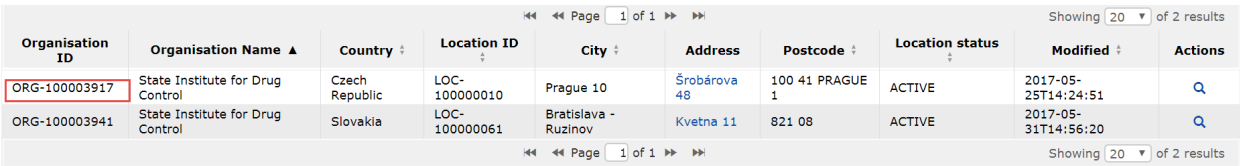
- Navigate to http://spor.ema.europa.eu/omswi/#/
- No log in needed
- Enter part of the organisation name

Figure 26. Search for organisation ID on the OMS website



- The search results include all locations that are associated to organisations that match the entered organisation name
- For each returned location the name and ID of the parent organisation is shown

Figure 27. Search results for organisation ID on the OMS website



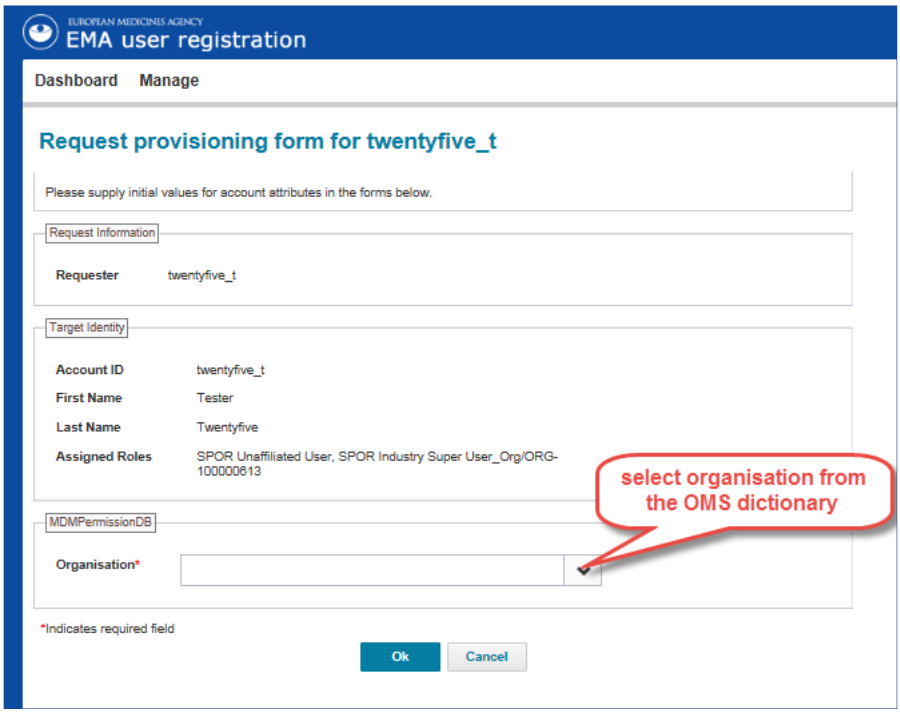
Page 1 of 1 — Showing 20 of 2 results

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100003917	State Institute for Drug Control	Czech Republic	LOC-100000010	Prague 10	Šrobárova 48	100 41 PRAGUE 1	ACTIVE	2017-05-25T14:24:51	
ORG-100003941	State Institute for Drug Control	Slovakia	LOC-100000061	Bratislava - Ruzinov	Kvetna 11	821 08	ACTIVE	2017-05-31T14:56:20	

Page 1 of 1 — Showing 20 of 2 results

- Paste the organisation ID in the organisation field in the organisation affiliation form on the IAM (IIQ) website
- Click on the 'Ok' button

Figure 28. Organisation affiliation

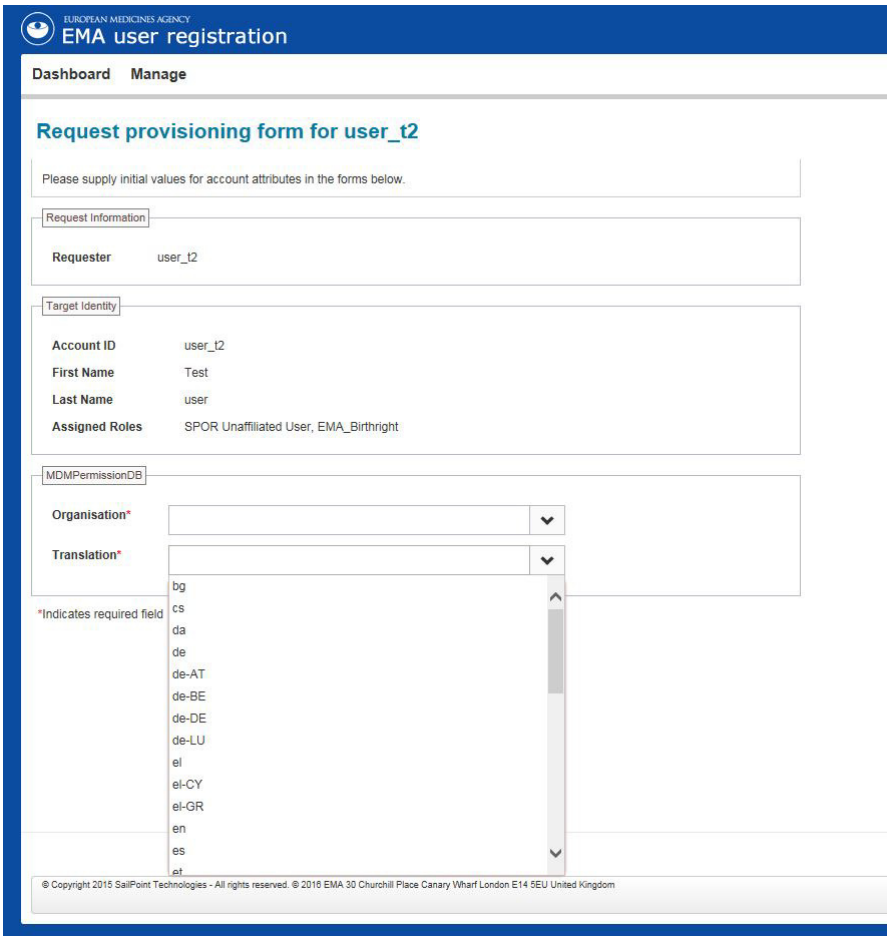


Note applicable from October 2017:

- *In case your organisation does not appear in the list, you need to request the registration of the organisation in OMS at http://spor.ema.europa.eu/omswi/#/.*
- *For most of the roles the request ID which is automatically generated by IAM (IIQ) is irrelevant and can be ignored. However, users requiring NCA or Industry Super User access should take note of this ID as it will be required to submit supporting documentation through the EMA Service Desk (JIRA). This process is explained in detail in section (1.4.2.1 Document submission on the EMA IT Service Desk portal).*

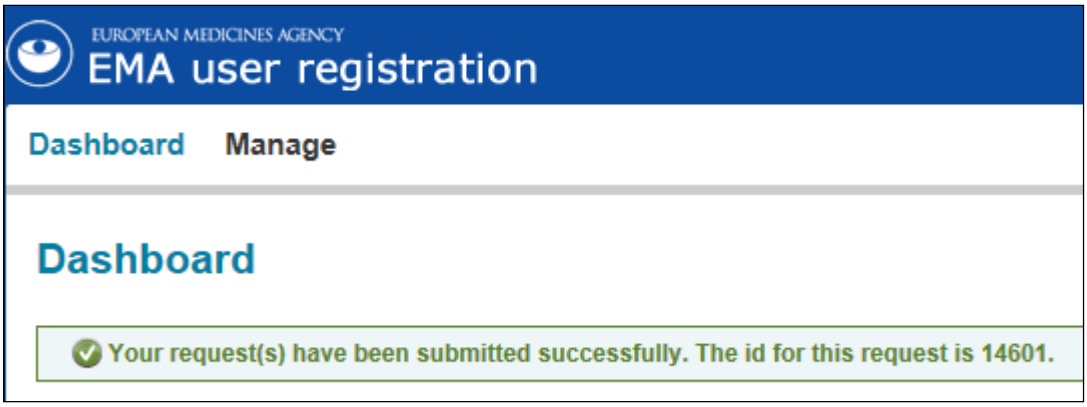
If the user is requesting the role of NCA Translator, in addition to the organisation the user must also specify the language they will be providing translations for.

Figure 29. Choosing a translation language for NCA Translators



A message that the request was submitted successfully comes up on the screen, with request ID

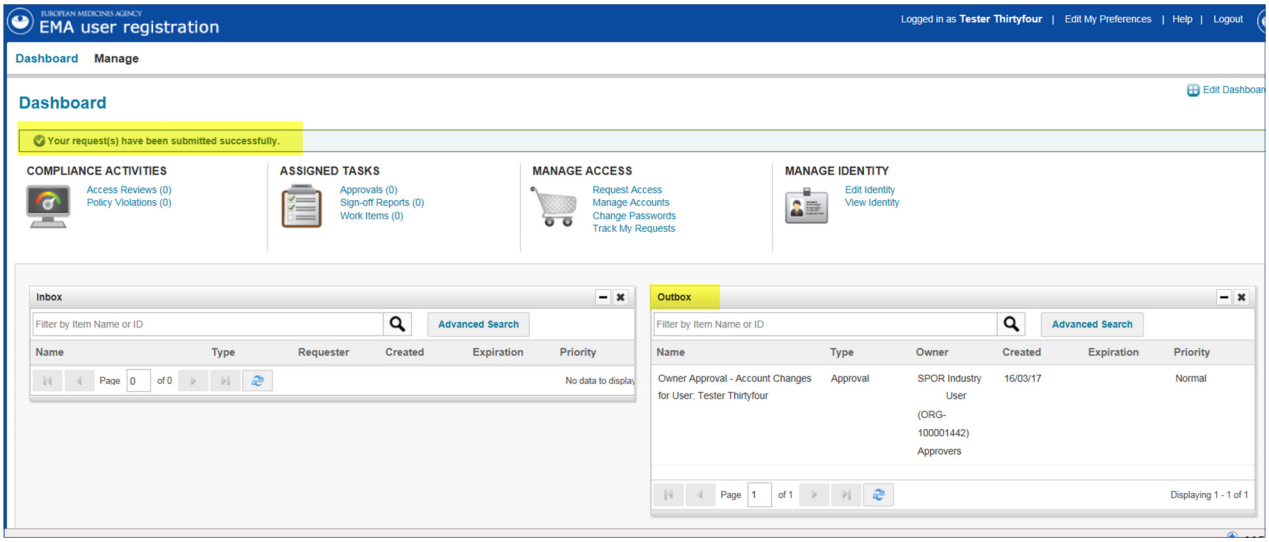
Figure 30. Request submission confirmation message



- A separate e-mail confirming the submission of the request with the request ID is also sent to the user.

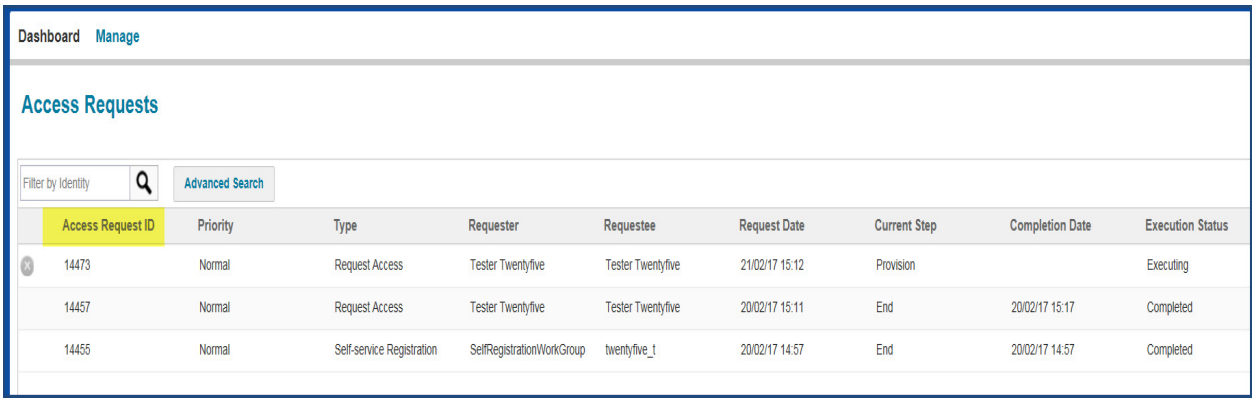
- The request appears in the profile outbox as in *fig. 31 .*

Figure 31. Access request submitted successfully



The request IDs are listed under "track my requests"

Figure 32. Track my requests



Access Request ID	Priority	Type	Requester	Requestee	Request Date	Current Step	Completion Date	Execution Status
14473	Normal	Request Access	Tester Twentyfive	Tester Twentyfive	21/02/17 15:12	Provision		Executing
14457	Normal	Request Access	Tester Twentyfive	Tester Twentyfive	20/02/17 15:11	End	20/02/17 15:17	Completed
14455	Normal	Self-service Registration	SelfRegistrationWorkGroup	twentyfive_t	20/02/17 14:57	End	20/02/17 14:57	Completed

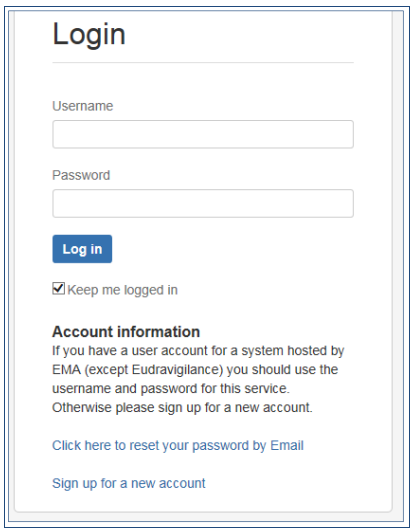
- In case a user needs a role on behalf of a different organisation, they need to submit a new request.

5.4. Document submission for super user authorisation on the EMA IT Service Desk portal

- There is one additional step to request super user access for the **first** super user in an organisation
- In order to support the super user access, the requestor needs to submit a declaration which confirms that they represent the organisation selected in the request – see the template :
    - TO BE INSERTED in October 2017

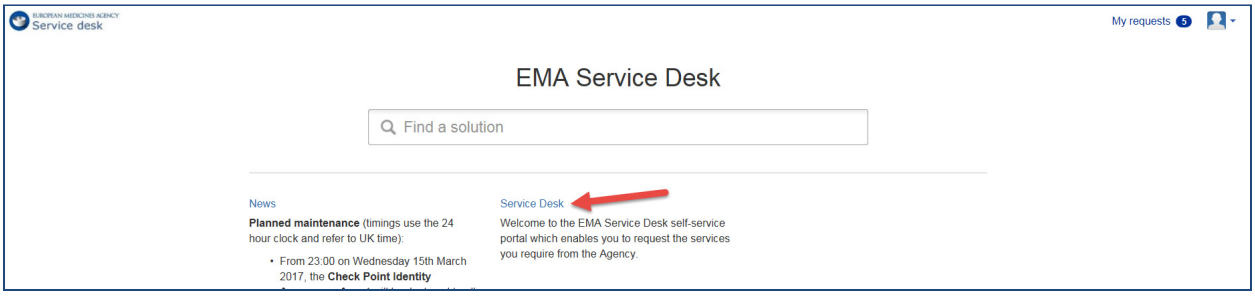
- As the IAM (IIQ) doesn't support submission of documents in the form of attachments, the required document needs to be submitted through the EMA Service Desk (also known as "JIRA") quoting the IAM Request ID number
- Navigate to EMA Service Desk portal (https://servicedesk.ema.europa.eu); the log in page appears

Figure 33. IT Service Desk log in page



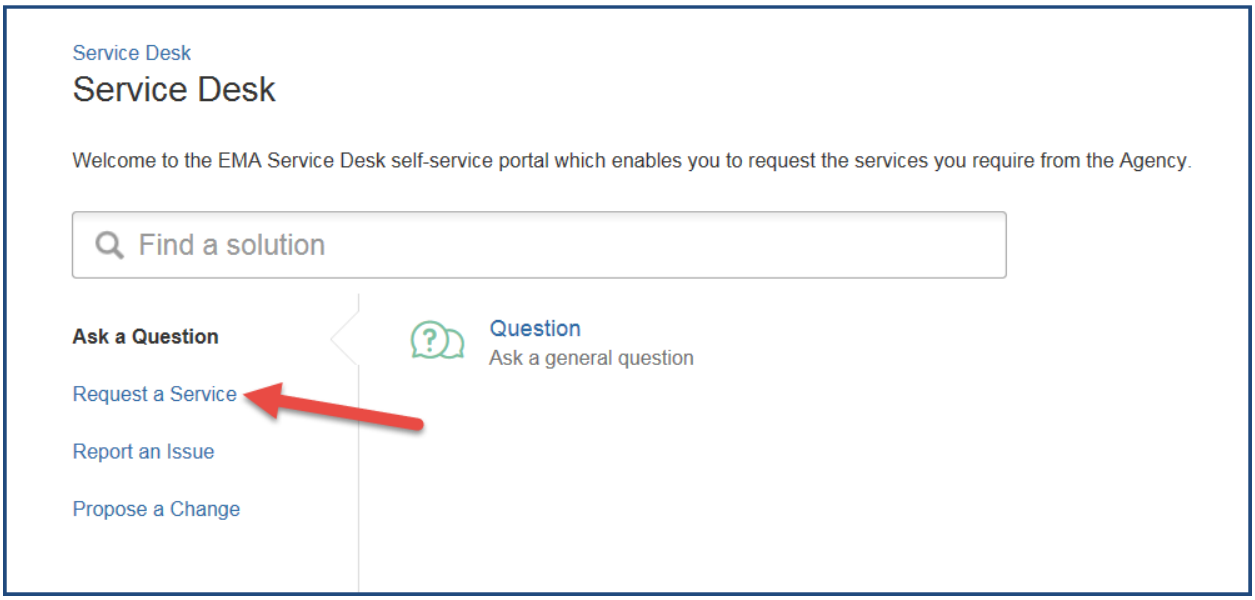
- The log in credentials are those for any of the EMA applications, IAM (IIQ) and SPOR
- If you just self-registered with IAM (IIQ), the credentials are the ones assigned during the self-registration process.
- Click on the IT Service Desk link to progress

Figure 34. IT service desk landing page



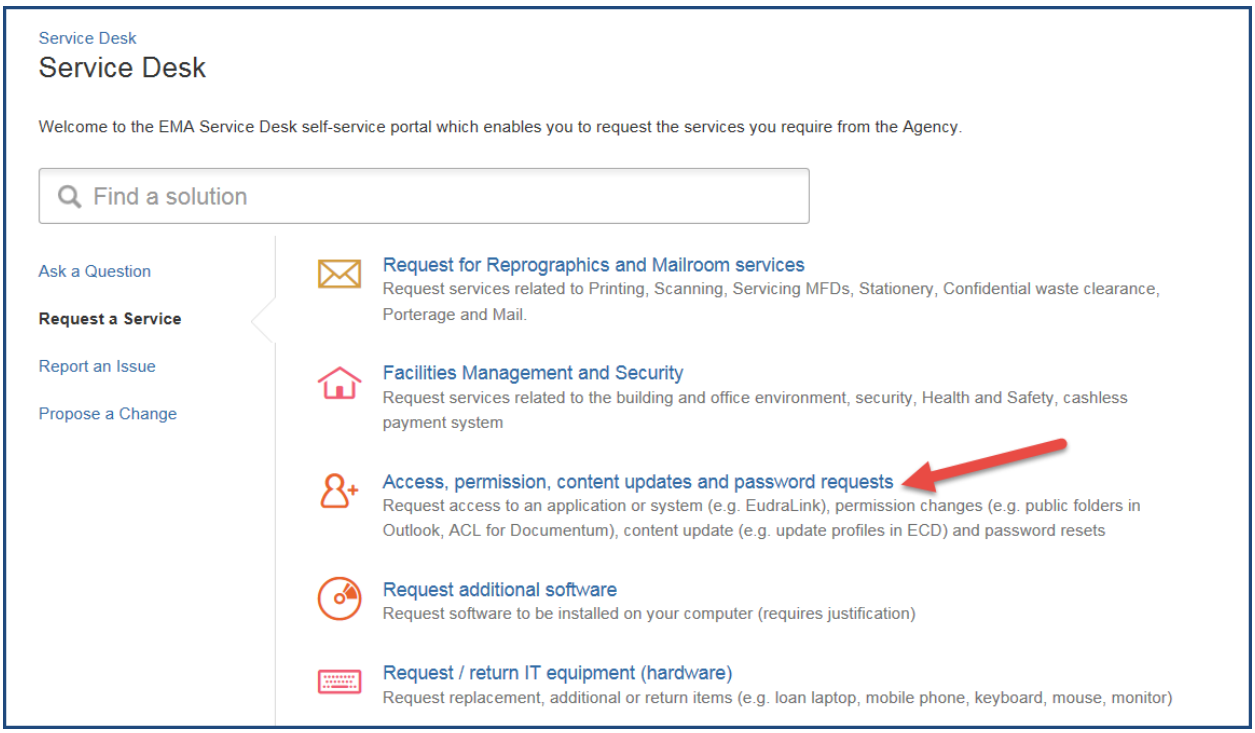
- Select "request a service"

Figure 35. IT Service Desk options



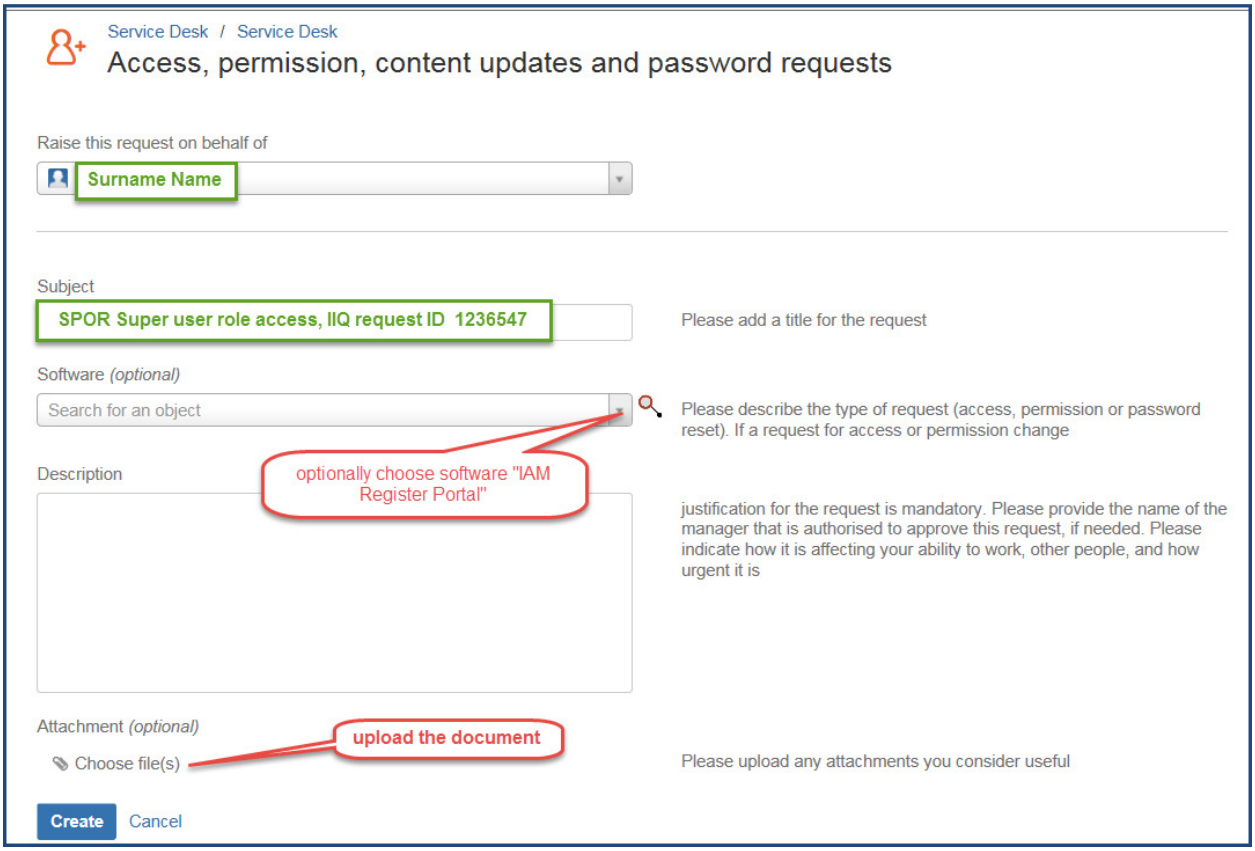
- On the list of services, select the "access, permission, content updates and password requests"

Figure 36. Service options



A form to submit the requested documents opens

Figure 37. Service request form



- Ensure the name of the future Super User appears under the heading "Raise this request on behalf of". This should be automatically prepopulated by the tool.
- "SPOR Super user role access" should be mentioned in the subject together with the IAM (IIQ) request ID number automatically obtained when requesting access in IAM (IIQ), example: "SPOR Super user role access - IIQ request 14601"
- This request ID number can also be found in the users dashboard under "track my requests" as mentioned above or in the email received at the time of request submission
- Optionally, select the software "IAM Register Portal" from the drop-down list under "Software"
- In the description field, state your name and organisation and explain that you are requesting Super User role access
- Upload the "Super User access request form" document, completed with all the necessary information
- Click on "Create"
- The EMA Service Desk approves or rejects the super user request and notifies the requestor of the outcome

6. Multiple SPOR roles

- For industry users, one person can have multiple roles, e.g. representing multiple companies
    - This can be industry super user or industry user
    - Each user role will be linked to a unique organisation
    - Therefore, the user/super user can be linked to multiple organisations
    - The users will need to submit individual access requests for each of the roles
    - Each of the user access request will be approved by the respective super user of the organisation for which the role is requested unless it is a first super user for this organisation

7. Super user access approval process

7.1. First super user approval by the EMA IT Service Desk

- The first super user for each organisation will be approved by EMA IT Service Desk after they select the NCA/industry super user role in the request access tab in IAM (IIQ) and submit the required documents via IT Service Desk portal as described above
- When the super user access is granted, they will receive a confirmation e-mail and this role appears also on their IAM (IIQ) dashboard

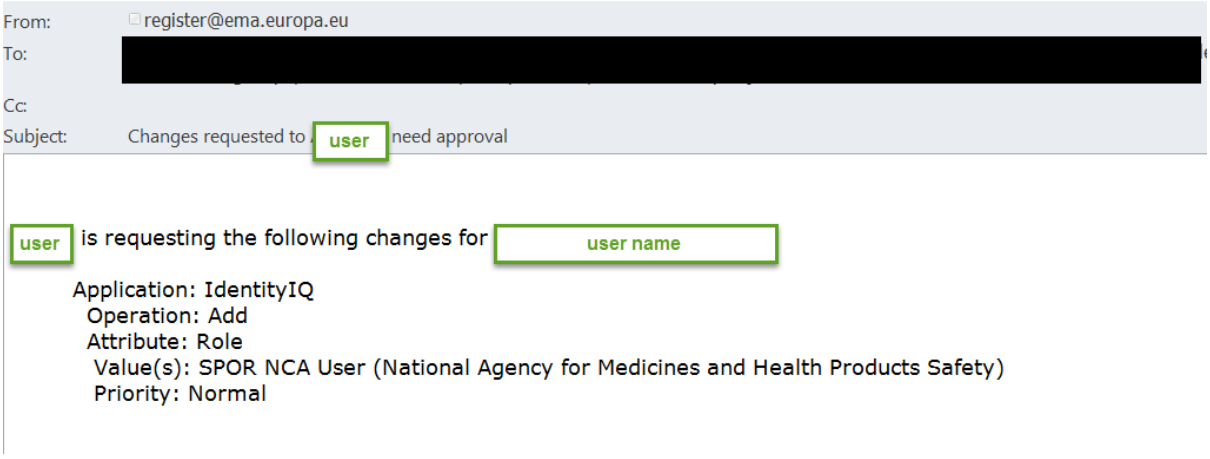
7.2. Access approval by super users within their organisation

The super user approves all roles for SPOR users and all subsequent super users within the same organisation once their own super user access had been granted by the EMA IT Service Desk.

7.2.1. Approval process

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

Figure 38. Super user e-mail alert for a new SPOR role request

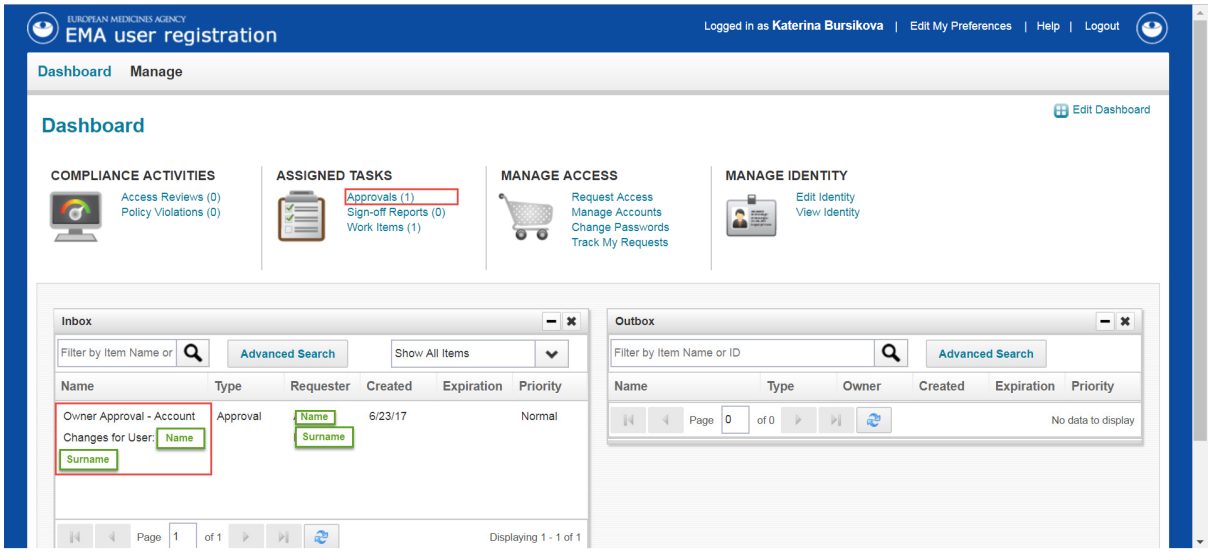


The super user needs to log in to

https://register.ema.europa.eu/

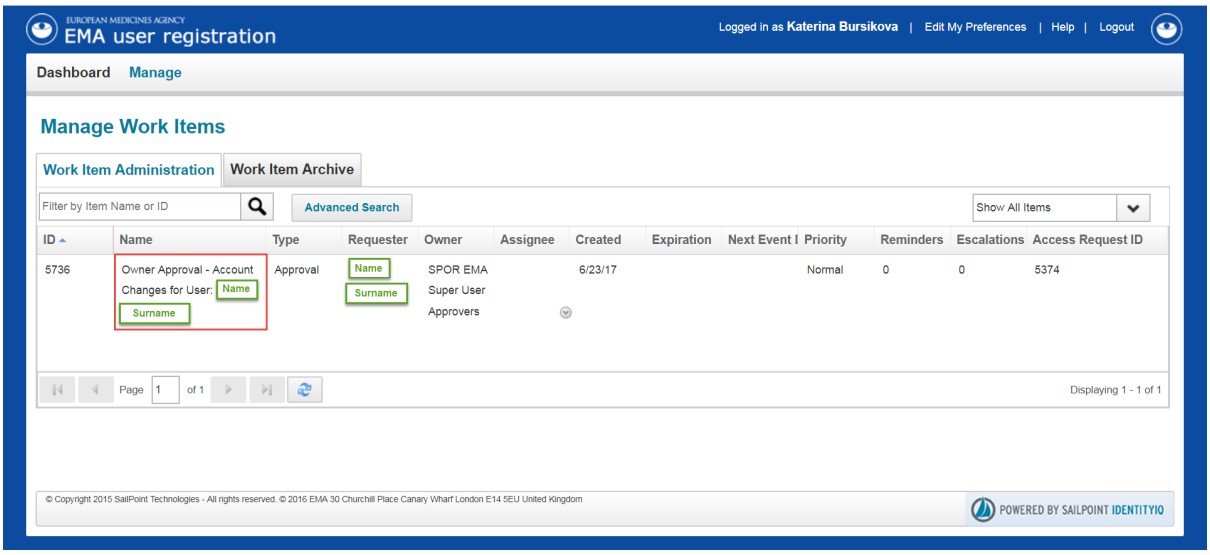
The IAM (IIQ) dashboard appears, with a task to solve under the Assigned tasks – approvals, that also appears in the dashboard inbox

Figure 39. Super user's dashboard with a new access request in the inbox



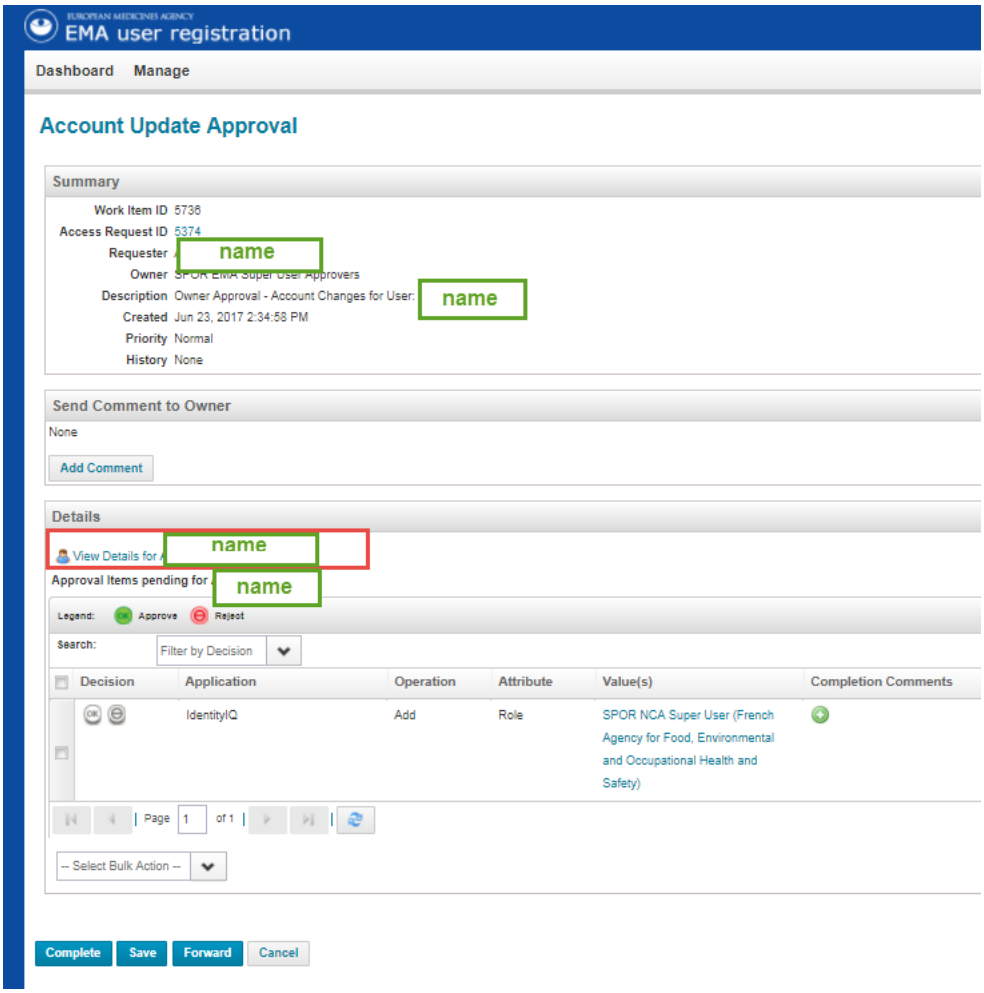
Click on approvals – overview of the request appears

Figure 40. Request overview



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

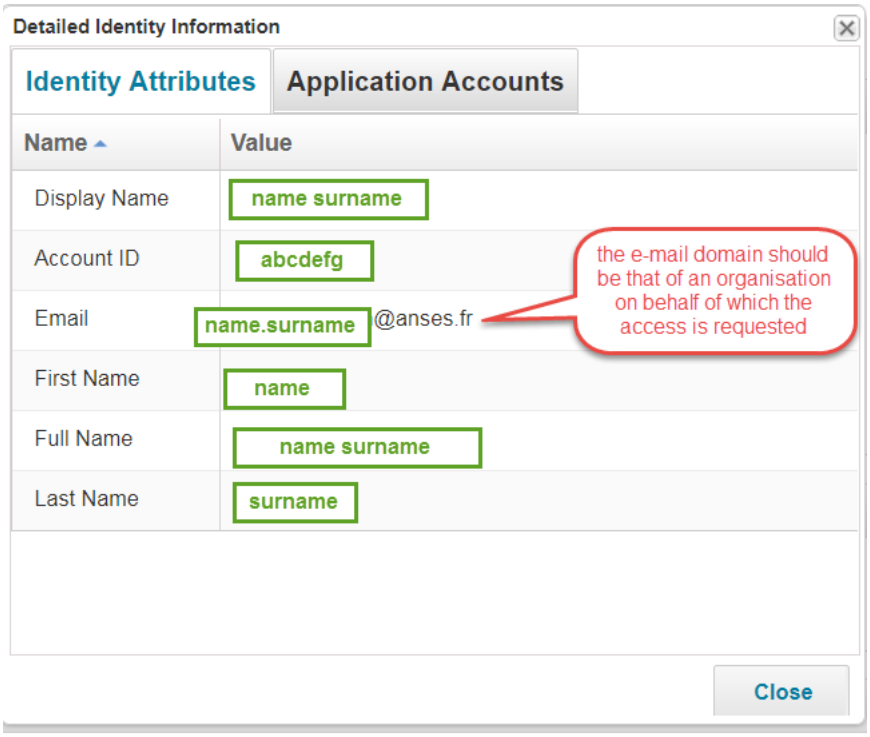
Figure 41. Request approval page



Click on "view details"

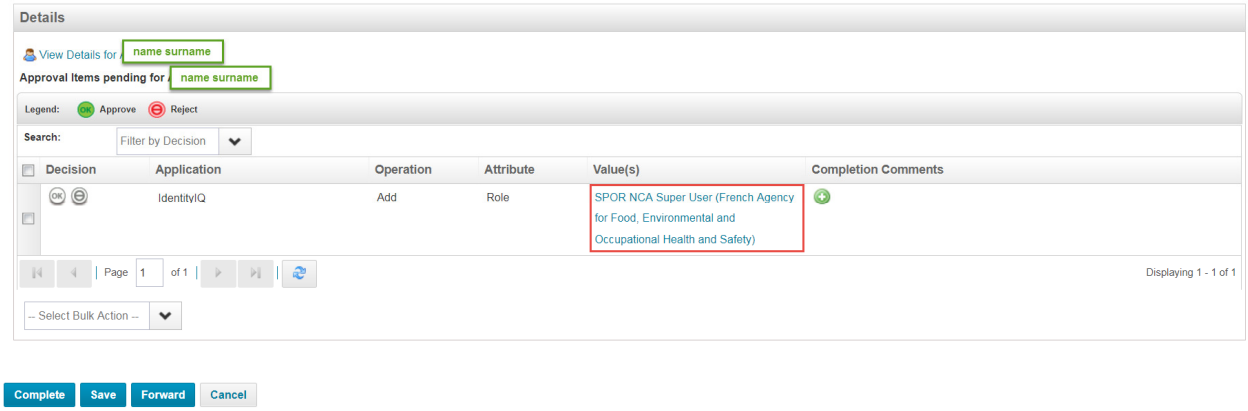
- The details include name and surname of the requestor, their ID and e-mail address
- the e-mail should be a work e-mail from the same organisation on behalf of which the user is requesting the SPOR user access
- no g-mail, yahoo and similar addresses should be used – the role is organisation specific and if the user leaves the organisation, the e-mail address stops working and so does the access
    - requests with private e-mail addresses should be rejected
- after checking the details, close the window and proceed with the approval process on the approval page

Figure 42. View requestor's details



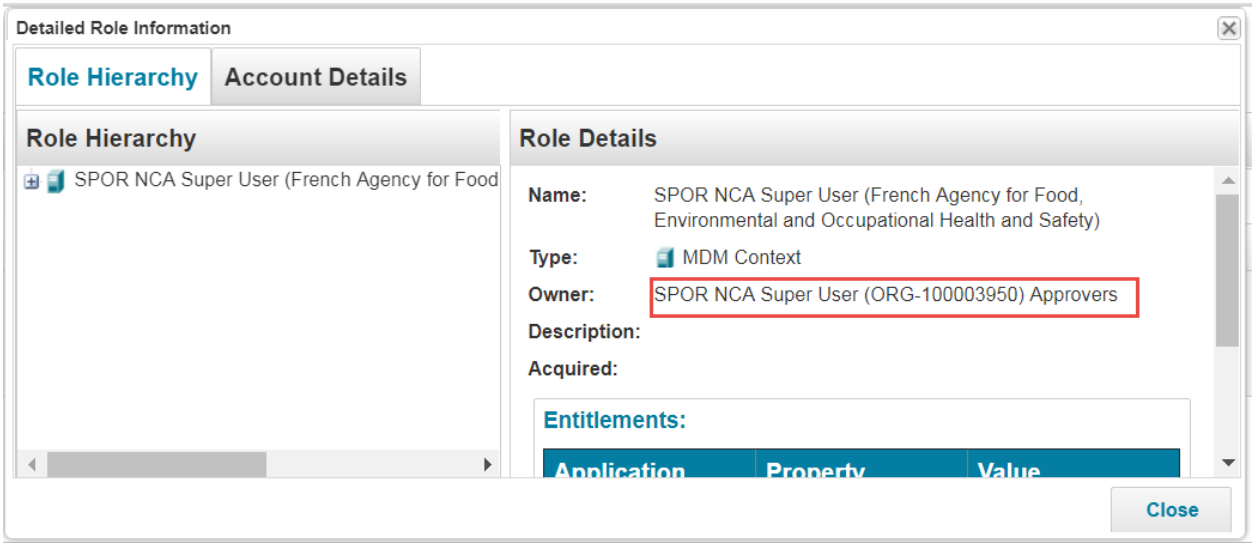
On the approval page, click on the "values" to see the role values and the organisation ID

Figure 43. Role value



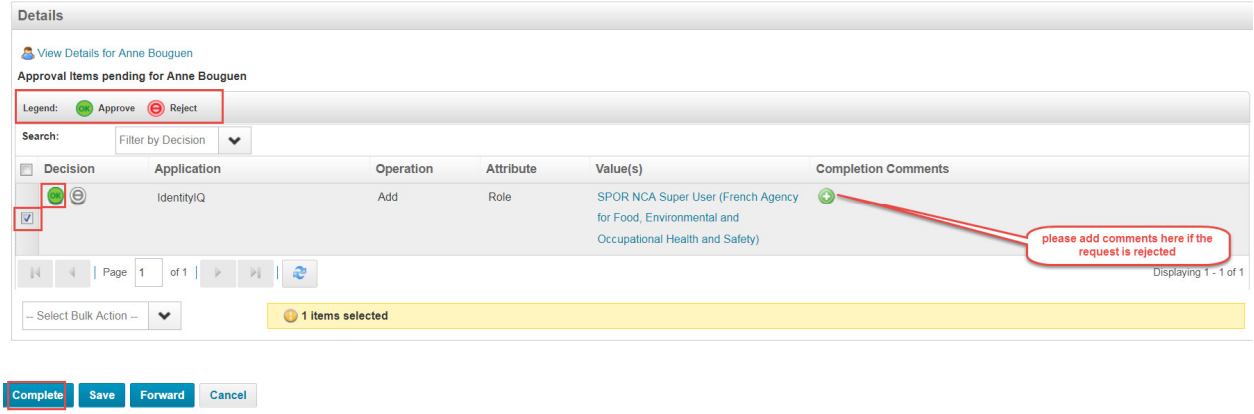
Role details are displayed including the affiliated organisation ID. The organisation must be the same as the organisation of the super user.

Figure 44. Role details



- Select the requested role (tick the box)
- Select the approve or reject icon as appropriate
- Click "complete"

Figure 45. Role selection



For approved access – the access is now active and the requestor is notified by an e-mail

For rejected access – please include completion comments to justify rejection of the request

7.2.2. Super user responsibilities

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

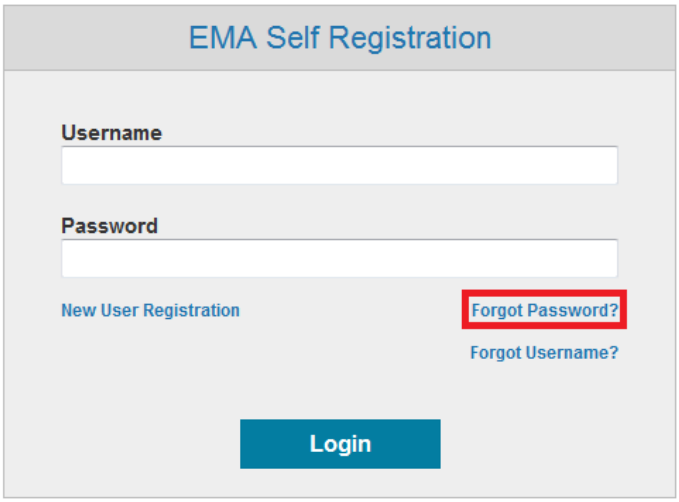
- The super user needs to confirm that the users indeed belong to the organisation
- It is in the responsibility of the super user to make sure that sufficient number of SPOR (super)users is active in the organisation
- Once a user/super user leaves the organisation, the super user needs to inactivate their access in IIQ
- Access on behalf of an organisation is in the responsibility of the super user(s) and the EMA will not check

8. Manage Passwords and Usernames in IAM (IIQ)

8.1. Reset forgotten password in IAM (IIQ)

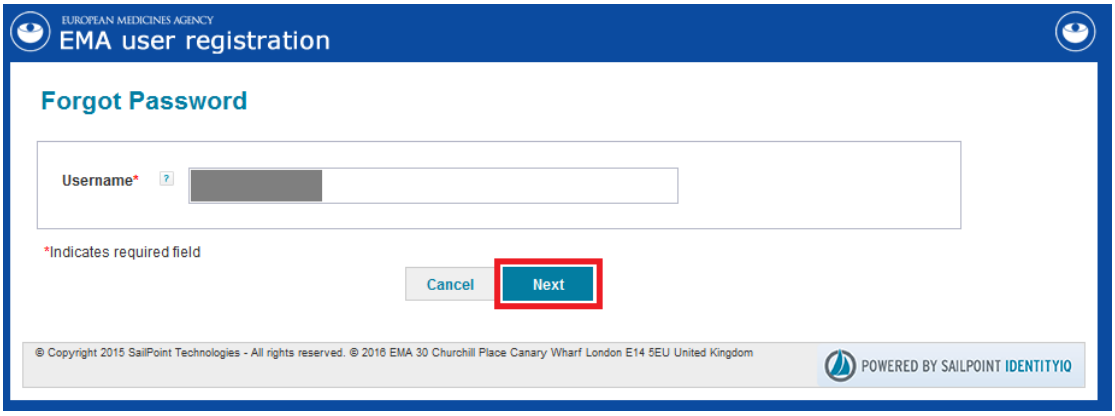
- A forgotten password can be reset in IAM (IIQ) with the help of the authentication questions
- Navigate to IAM (IIQ) url: https://register.ema.europa.eu/
- Or go to "Create EMA account" on SPOR or OMS/RMS webpage
- Click the 'Forgot Password?' link.

Figure 46. IIQ landing page and forgotten password link



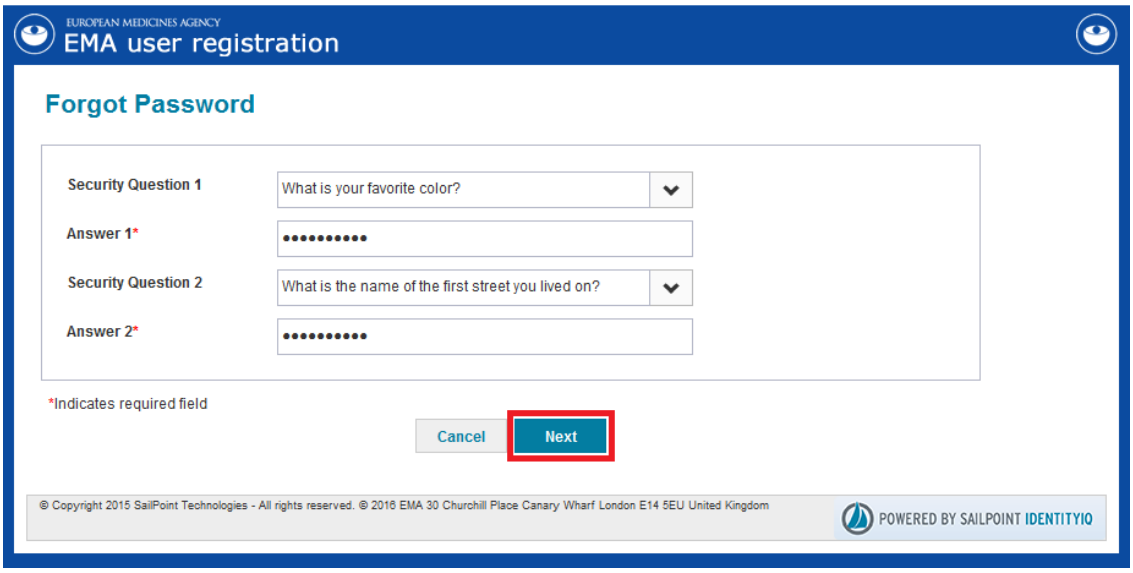
- Input your username in the 'Username' field and click the 'Next' button

Figure 47. Input username to retrieve forgotten password



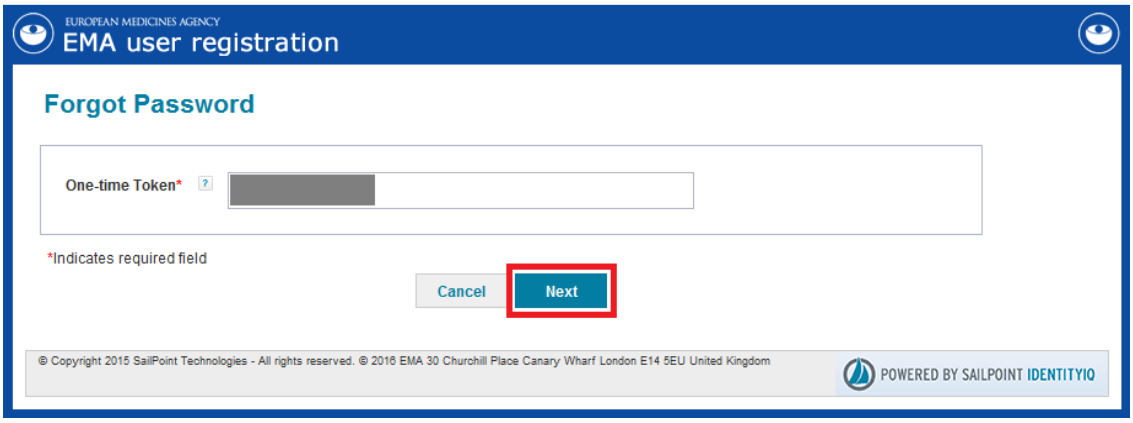
- Select two of the authentication questions and enter the answers you have put during self-registration of when requesting SPOR roles for registered users
- Click on the 'Next' button to go to the next page.

Figure 48. Answering the authentication questions



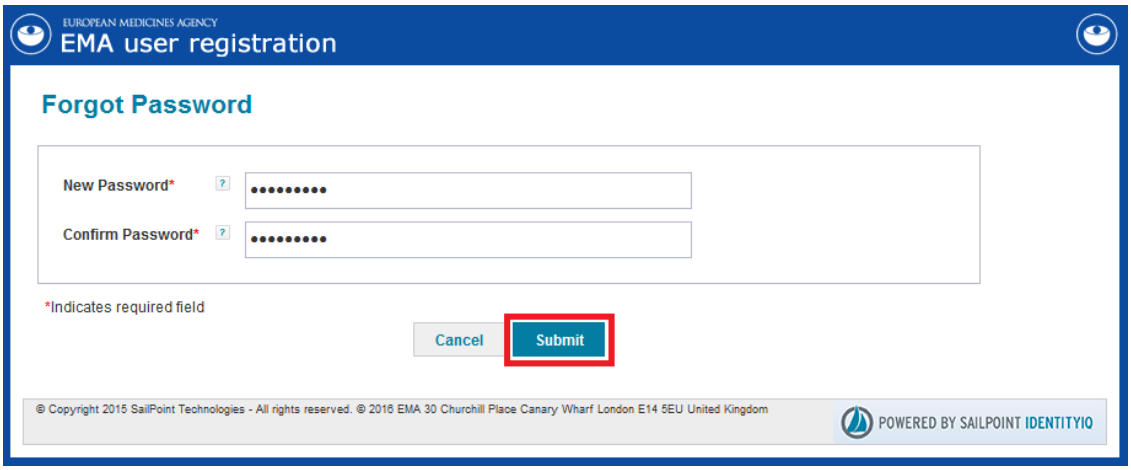
- An e-mail with a registration token is sent to the registered e-mail address
- Input this token in the 'One-time Token' field and click 'Next'.

Figure 49. Insert one-time token



- When choosing your new password, please choose a combination of lower case, upper case, numbers and symbols (hover the red asterisk for guidance)
- Enter your new password in the 'New Password' and 'Confirm Password' boxes and click 'Submit'
- The password is reset

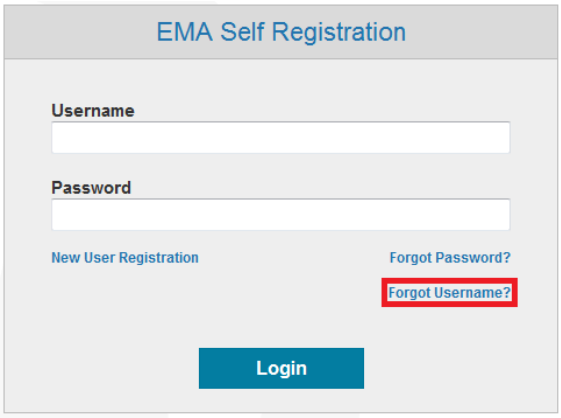
Figure 50. Enter new password



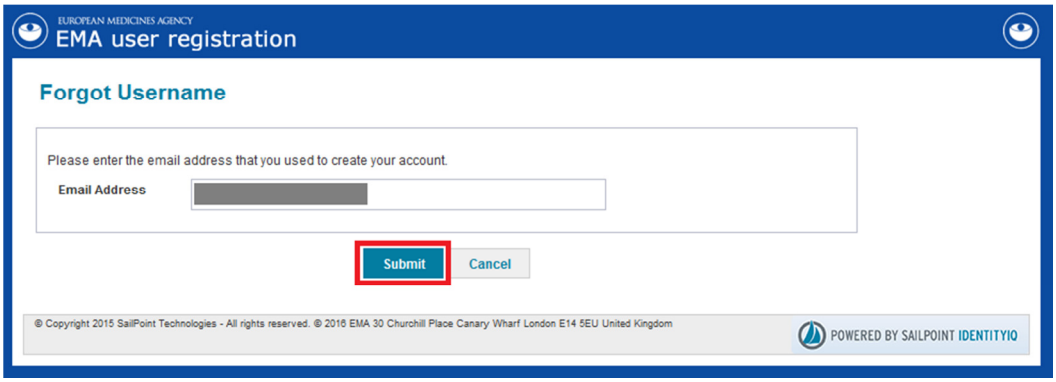
8.2. Retrieve Forgotten Username

- Navigate to IAM (IIQ) url: https://register.ema.europa.eu/
- Click the 'Forgot Username?' link

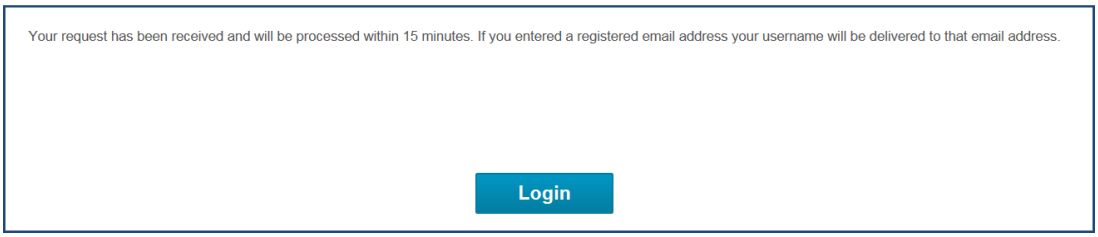
Figure 51. IAM (IIQ) landing page and forgotten username link



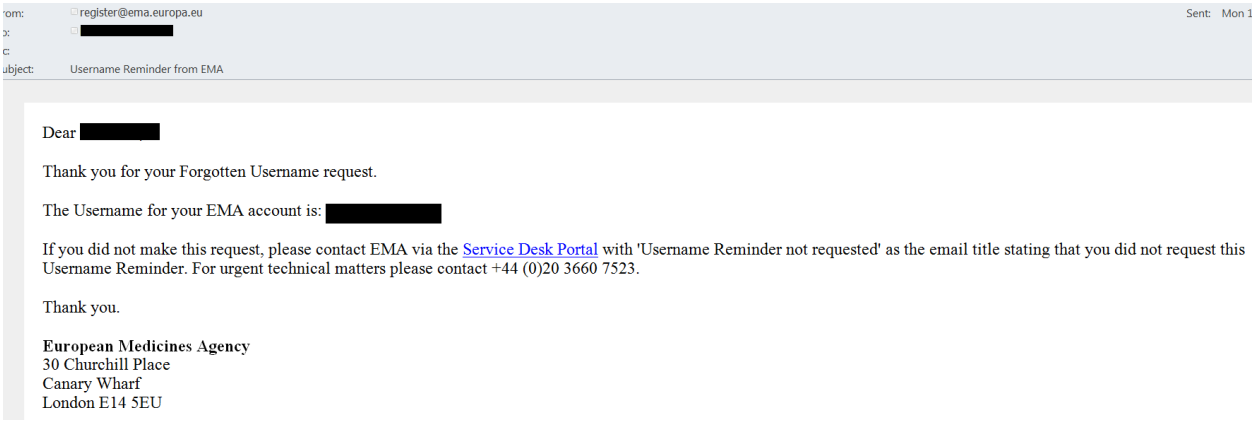
- Enter the email address you used to register in IAM (IIQ) and click 'Submit'



- Confirmation of the request is displayed



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

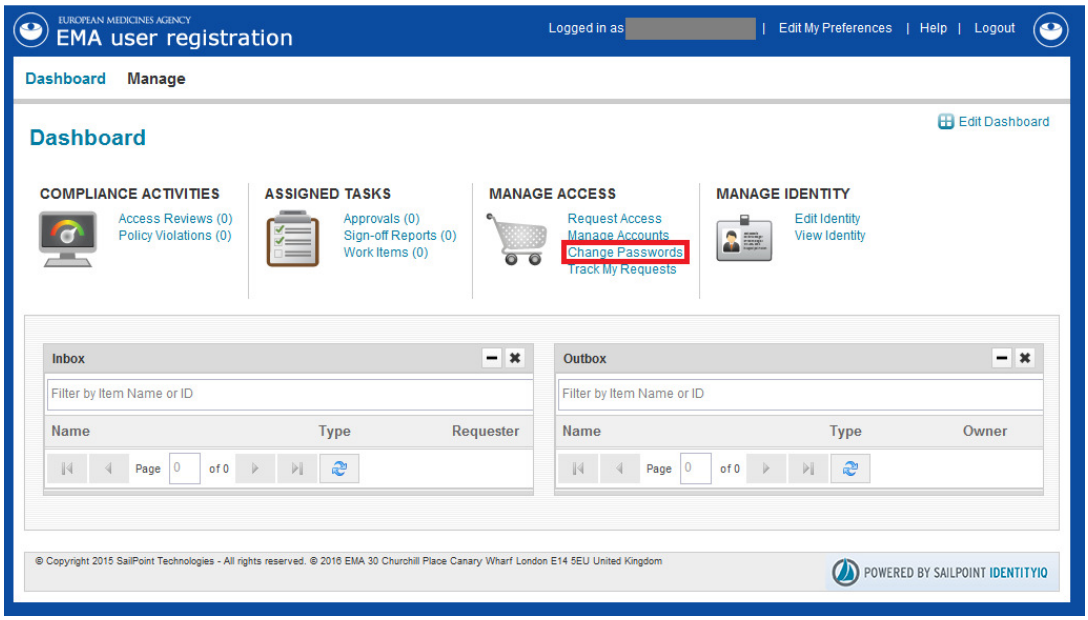


- Log in with your username and password

8.3. Change password in IAM (IIQ)

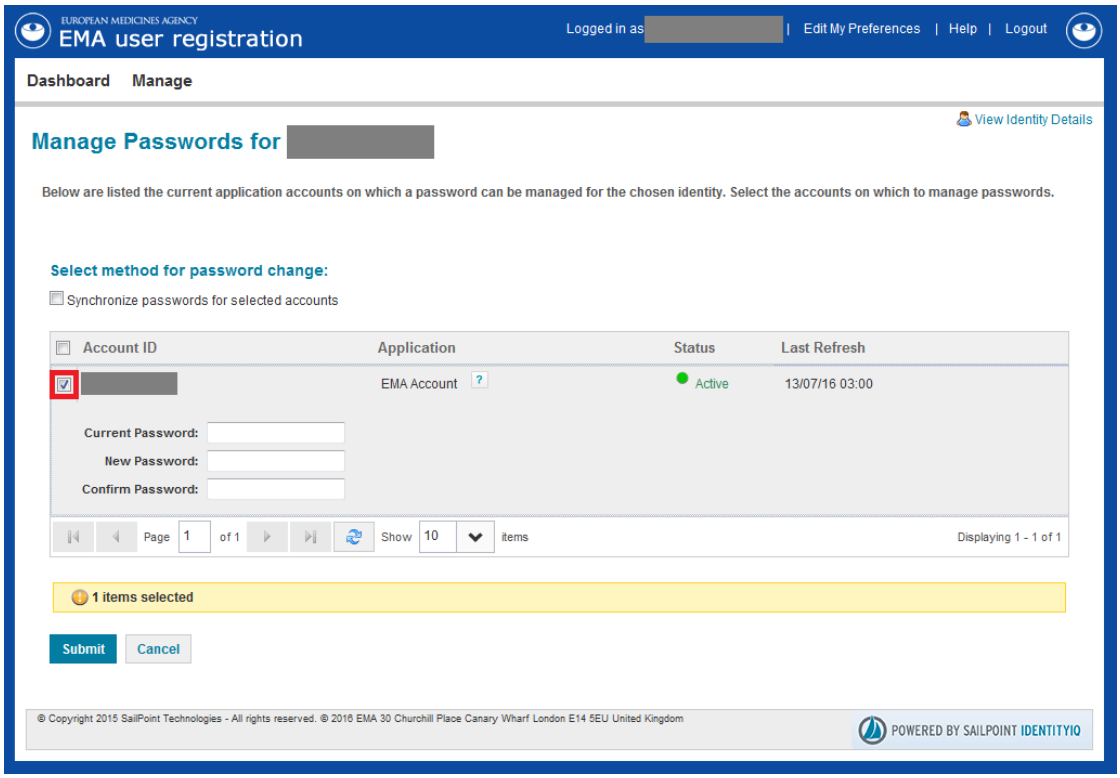
- Log in to IAM (IIQ)
- Click on the 'Change Passwords' link under the Manage Access section on your Dashboard

Figure 52. Change password in IAM (IIQ)



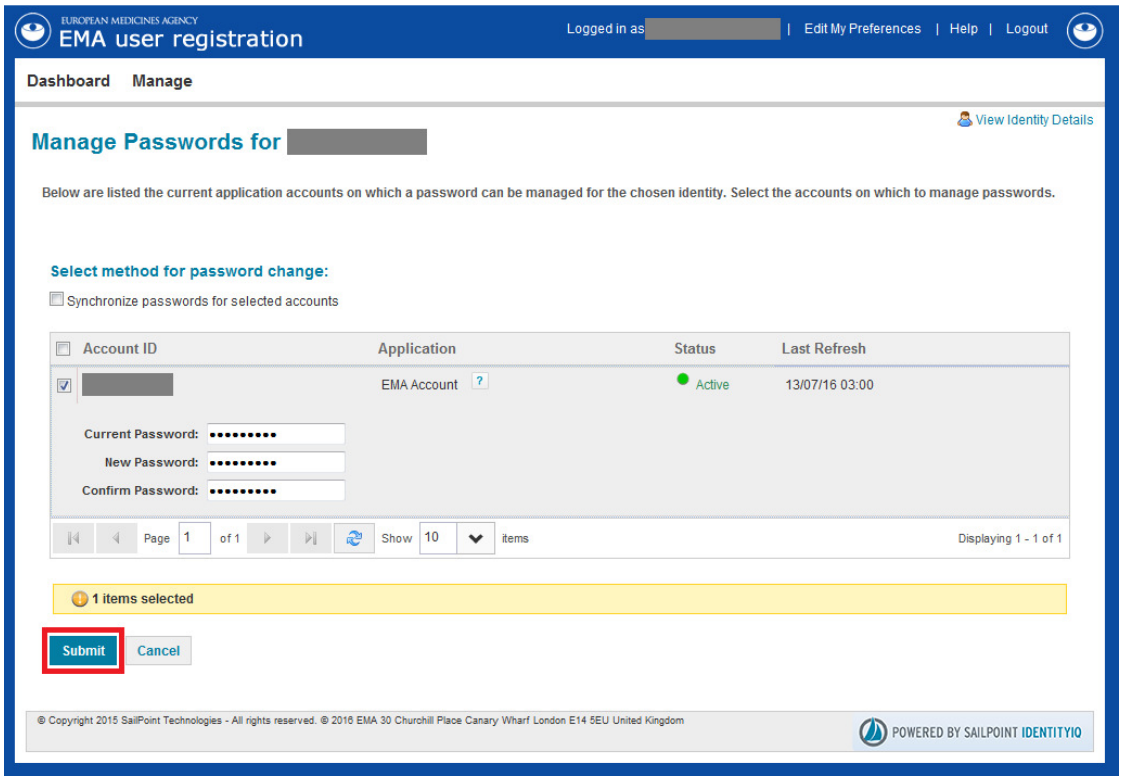
- Select your EMA Account by clicking on the checkbox in front of the account for the EMA Account Application

Figure 53. Manage passwords screen in IAM (IIQ)



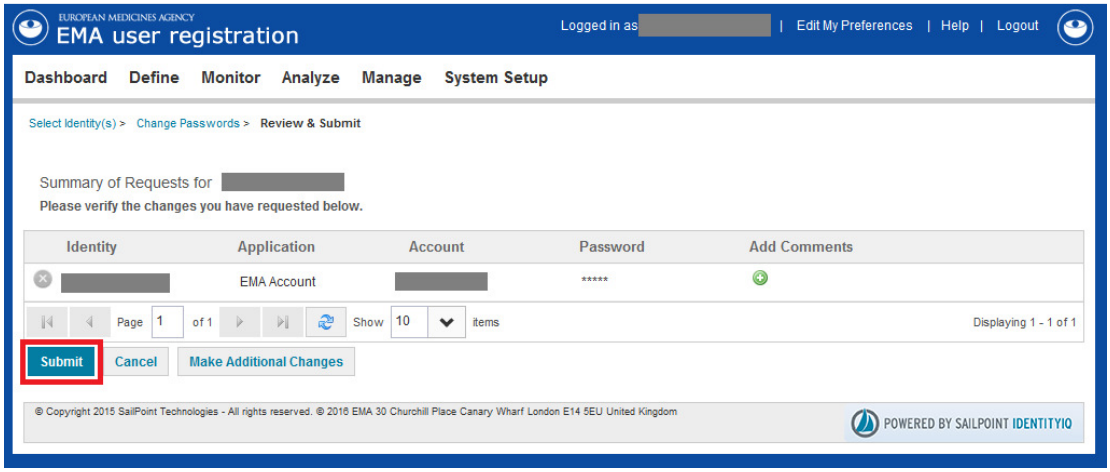
- Type your current password in the 'Current Password' field and the new password in the 'New Password' and 'Confirm Password' fields
- Click the 'Submit' button

Figure 54. New password and submit



- Click the "submit" button on the next page to complete the password change process

Figure 55. Finalise password change



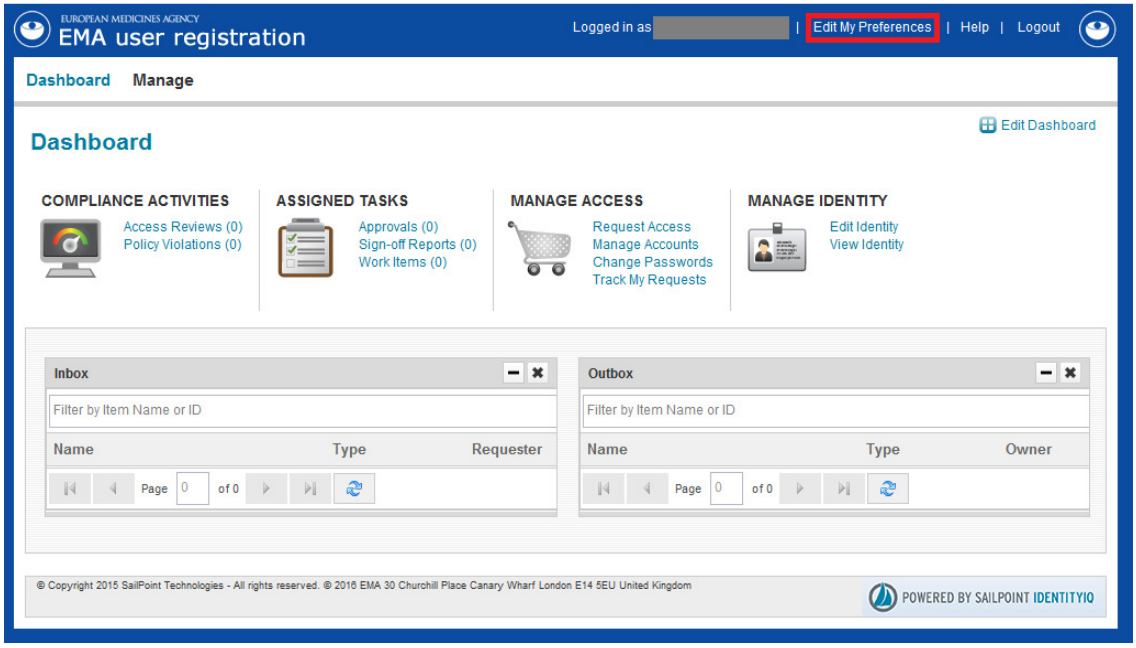
8.4. Update Authentication Questions

In order for the External User to be able to reset his password using the self-service functionality, they need to setup their challenge questions and answers in IAM (IIQ); see above. The questions and answers are populated with the user input during self-registration. In case the user needs to update their challenge questions they should follow the steps below:

- Login to IAM (IIQ) on https://register.ema.europa.eu/

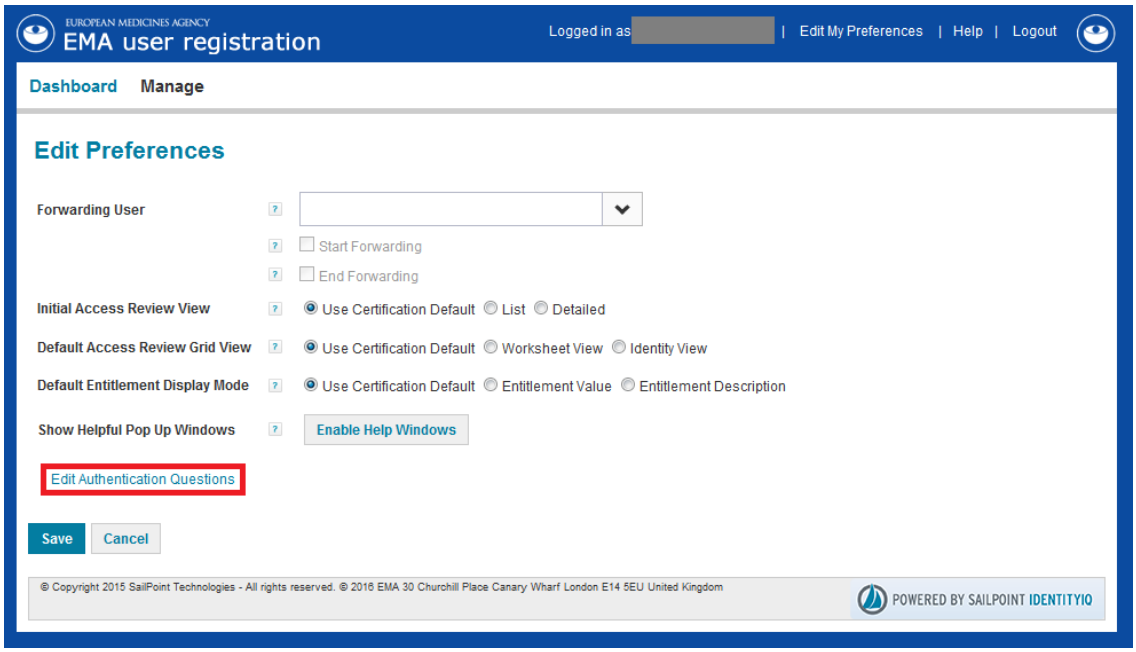
- Click on the 'Edit My Preferences' link in the top right corner of the IAM (IIQ) dashboard

Figure 56. Edit my preferences



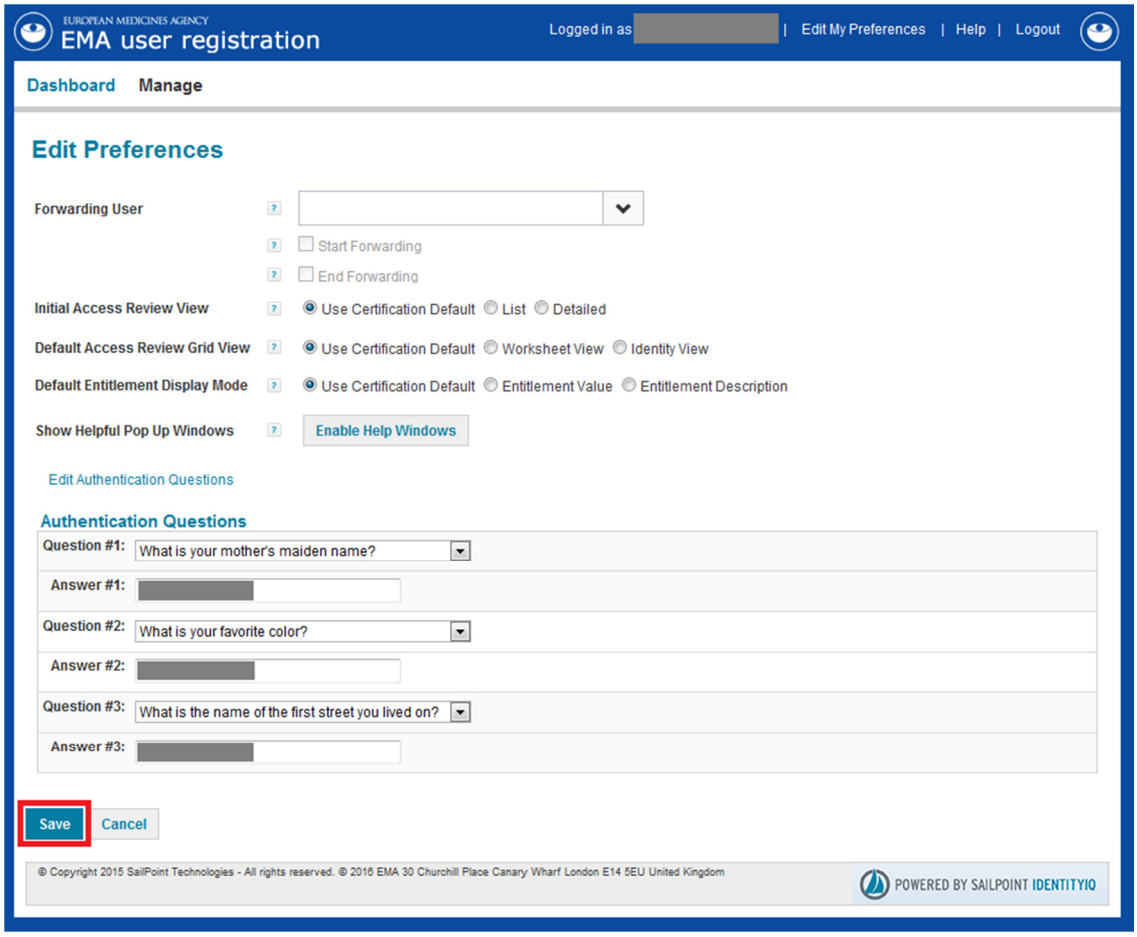
- Click on the 'Edit Authentication Questions' link. The Authentication Question section appears on the screen

Figure 57. Edit authentication questions



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

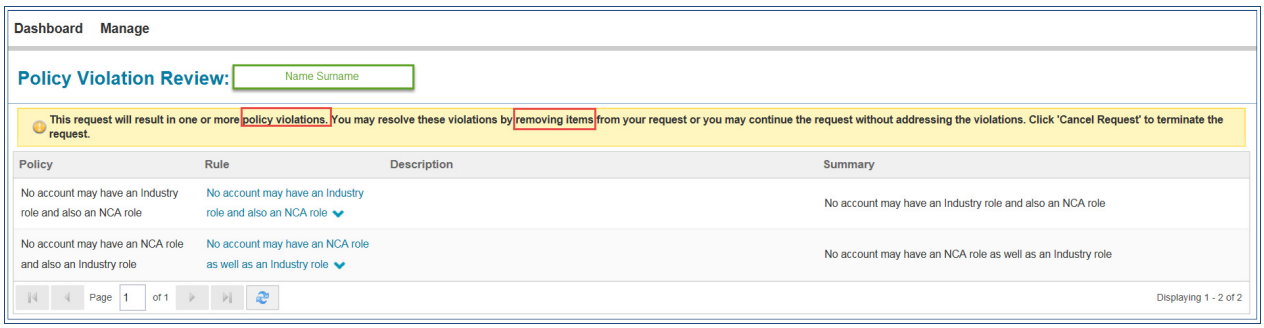
Figure 58. Selecting authentication questions



9. IAM (IIQ) policy violation

- There are policy rules about what types of access can be held by one user; e.g. no account may have an industry and also an NCA role
- If the policy is breached, a warning appears

Figure 59. Policy violation examples



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

- Remove a role to proceed – bin icon
- Or submit the request with violation
- Or cancel request

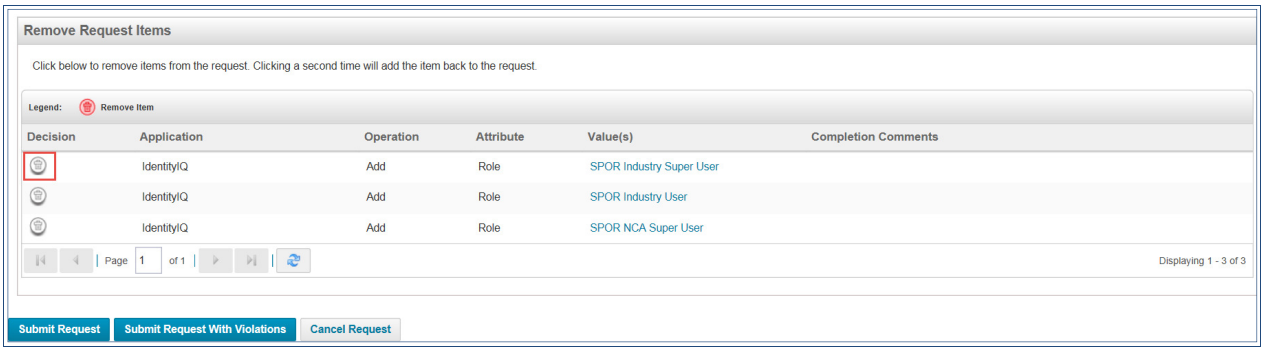



Figure 60. Policy violation solutions