EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA SPOR user registration

Overview for external users

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An agency of the European Union

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- Update authentication questions

Policy violation

NCA required action

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SPOR services – definition

- SPOR services for both OMS and RMS help build the database content and keep it up-to-date
- Guest (anonymous) users can only view the data
- The SPOR services for registered users are:
  - Request new data
  - Request a change to data
  - Download
  - Authorise users (super users only)

SPOR user roles

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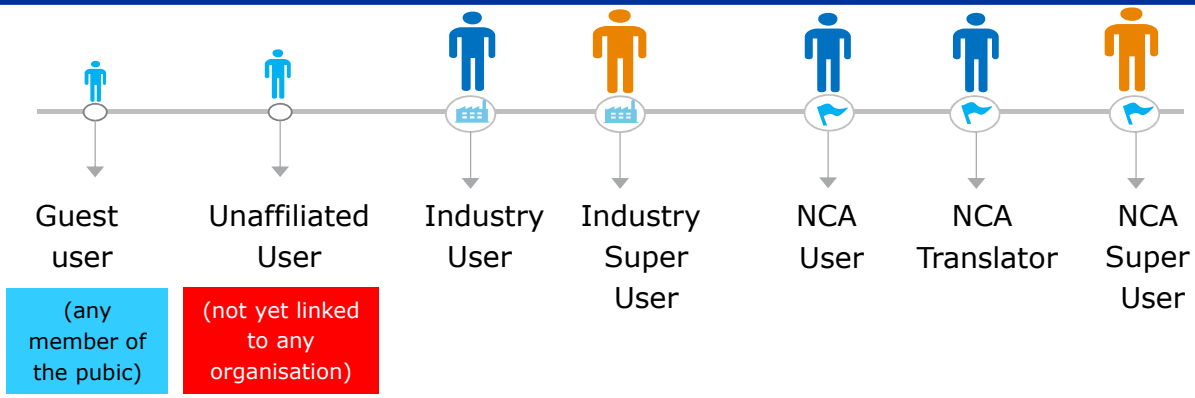

- Industry super users will authorise industry users
- Industry User can be pharma or non-pharma
- NCA super users will authorise NCA users
- There is no limit for number of SPOR users or super users per organisation

SPOR user roles vs. functionality

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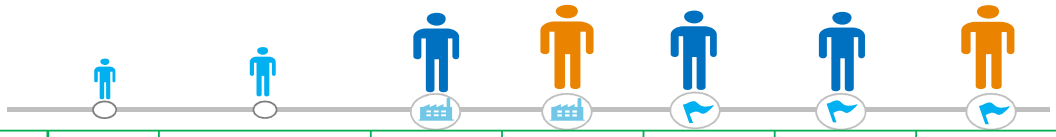

	Guest user	Unaffiliated user	Industry User	Industry Super User	NCA User	NCA Translator	NCA Super User
Login	Not required	Login required	Login required	Login required	Login required	Login required	Login required
View Public data	Yes	Yes	Yes	Yes	Yes	Yes	Yes
View Restricted data	No	No	No	No	Yes	Yes	Yes
Search data	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Download data	No	Yes	Yes	Yes	Yes	Yes	Yes
Submit Change Request (CRs)	No	Can submit CRs in OMS for a new org. (1 pending request at a time)	Yes	Yes	Yes	Yes	Yes
Translations	No	No	No	No	No	Yes	No
Permission to authorise users	No	No	No	Can authorise Industry Users	No	No	Can authorise NCA users

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Link to SPOR web user interface

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

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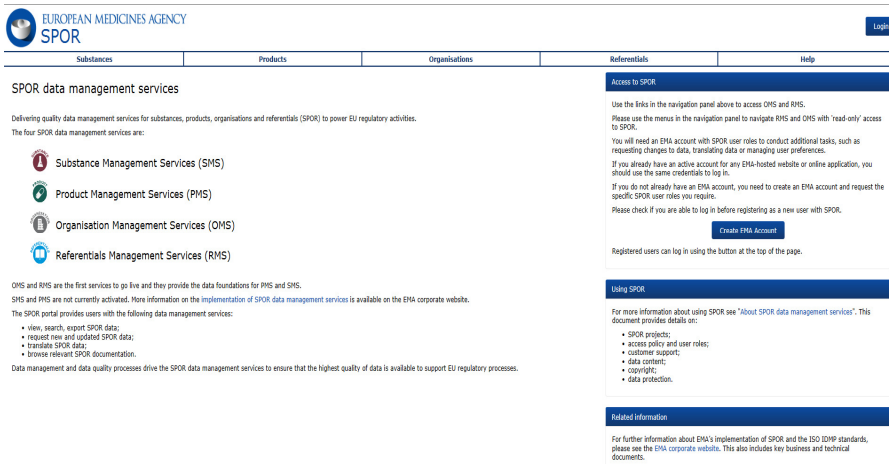
Access to SPOR services – web landing



- Continue to OMS as guest user *(Public info only, no user preferences)*
- **Register** if you are a new user
- **Login** if you are a registered user
- View Help (User manual) and details for Customer support *(across all domains of SPOR)*

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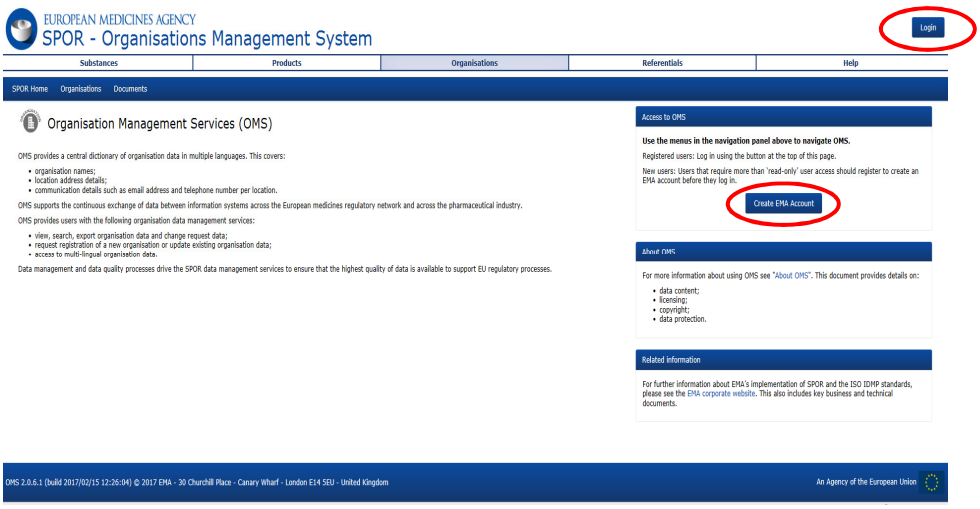
SPOR Log In – with your SPOR log-in details



- Screen available for a guest OMS user before logging in
- The user is able to select from the menu options
- Help option is domain sensitive (here for OMS)
- Register new user – click on "Create EMA Account"
- Alternatively, go to https://register.ema.europa.eu

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Access to SPOR roles is managed through the Identity and Access Management tool called **IIQ**

- New users
- EMA registered users

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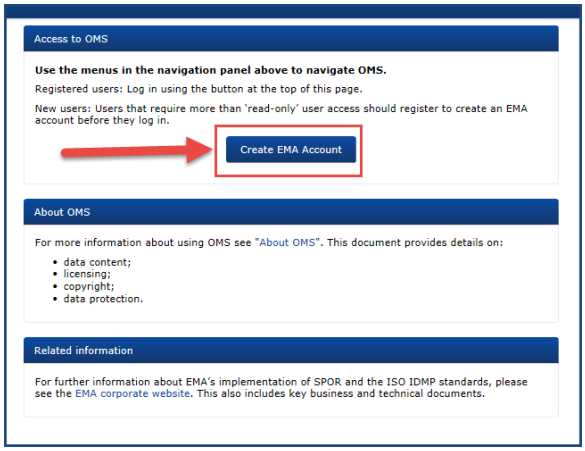
New (non-registered) SPOR users

- Need to request access to EMA systems, i.e. username and password
- This is done through the identity and access management (IAM) tool called IIQ
- After access approval, they can request SPOR user roles
- Click on "Create EMA account" on either the SPOR home page of OMS home page



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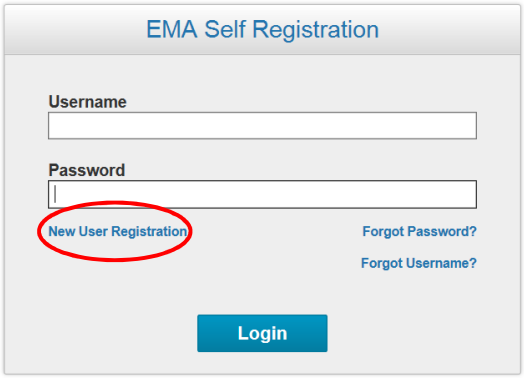
Register

- The self-registration web landing page appears
- New users => click on the New User Registration link
- The self-registration form is displayed



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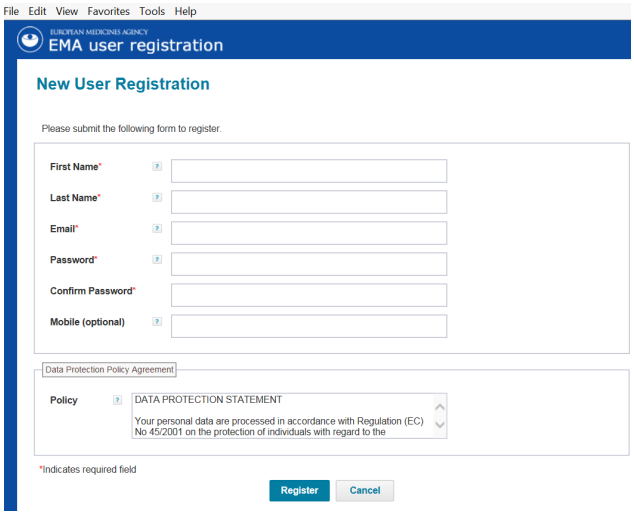
New user registration 1/2

- Mandatory fields:
  - First name
  - Last name
  - E-mail – format validation in place
  - Password
  - Confirm password
- Optional field – (mobile) phone
  - Second point of contact - strongly recommended for cases when e-mail does not work/changes
- Read the Data protection policy agreement
- Click "Register"



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New user registration 2/2

- The system can recognise e-mail addresses to prevent creation of duplicate entries
- In case the e-mail address is already registered, the user is prompted to use a different e-mail

The email you have chosen is already in use. Please choose a different email.

- Or the user should go back to the landing page and choose "forgot password?" option
- Password has some mandatory 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)

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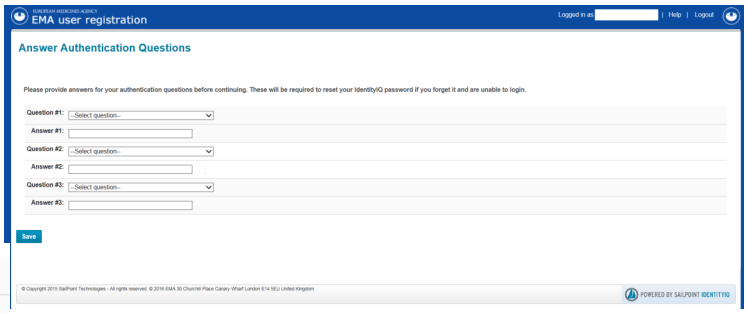
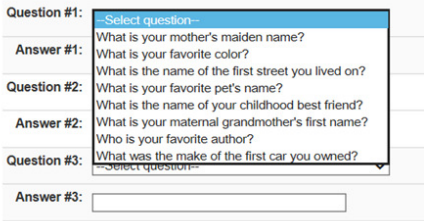
Authentication questions 1/2

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





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

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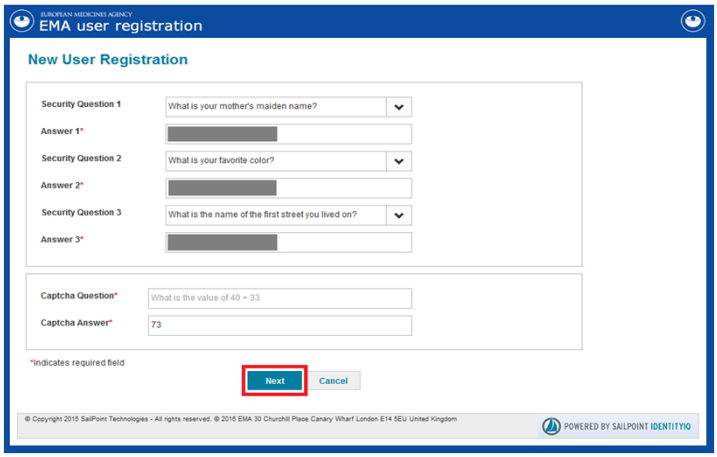
Authentication questions 2/2

- After saving, a captcha question (anti-robot precaution) appears
- Answer the captcha question
- Click 'Next' to go to the registration confirmation page
- an e-mail with an authorisation token is sent to the e-mail address provided



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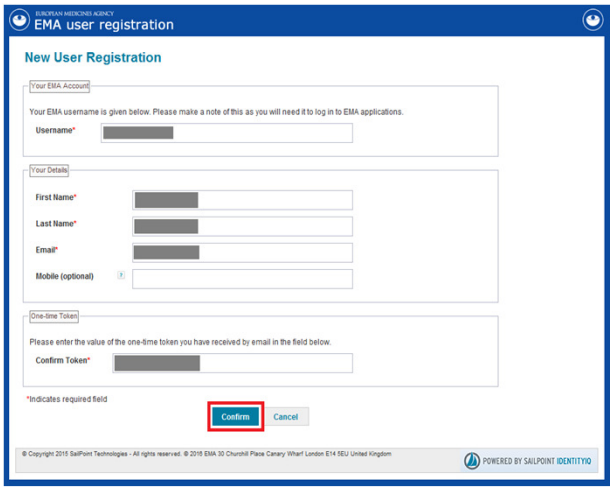
Confirm registration

- Make sure the data in the 'Your details' section is correct
- Under the 'One-time token' section, in the 'Confirm token' field, input the code you received in an email that was sent to you as part of the previous step
- Click "confirm"
- This creates new IdentityIQ account
- A confirmation e-mail of a successful registration is sent



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Registered users 1/2

- Many NCA users have already access to one or more EMA systems:
  - Eudralink, EudraCT Secure, 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 IIQ
- The username and password are the same for the SPOR portal and to the IIQ
- Log in with the EMA username/password from the SPOR web page => access to SPOR interface as non-affiliated user
- In order to use SPOR services, the user needs to request a SPOR user role in IIQ first, accessed through the "Create EMA account" button

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Registered users 2/2

- 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 IIQ yet i.e. answers to authentication questions

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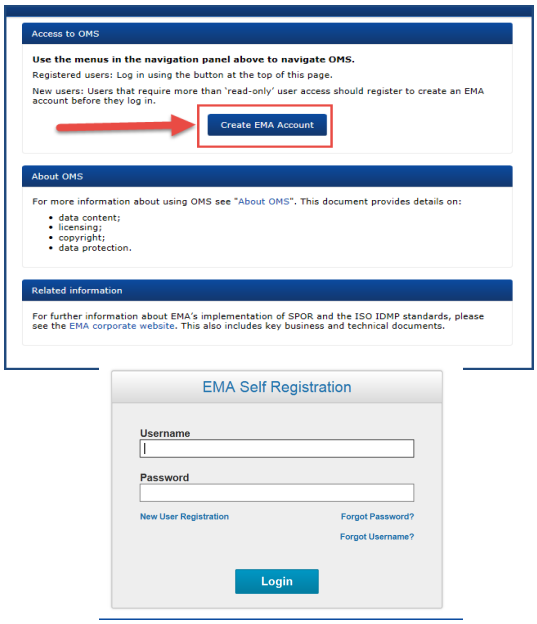
Registered users – requesting SPOR roles

- Go to "Create EMA account"*
- Enter your EMA account login and password
- This will bring you to set up the IIQ account authentication questions
- After that, the EMA user registration dashboard is displayed to request SPOR roles
- For more details and next steps see above for non-registered user

**even if you are not creating a new account*



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EMA user registration dashboard – SPOR roles

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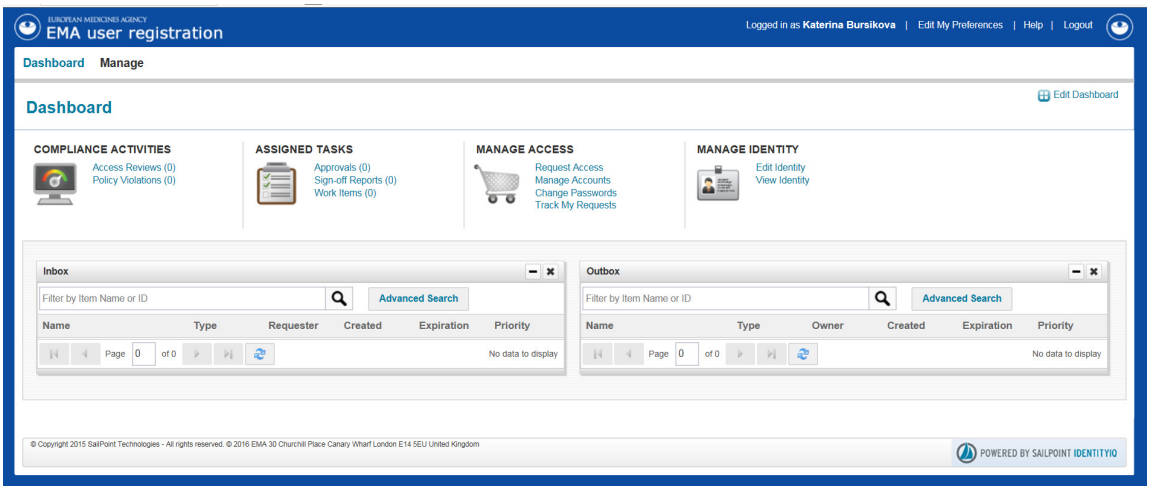
EMA user registration dashboard 1/2



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EMA user registration dashboard 2/2

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

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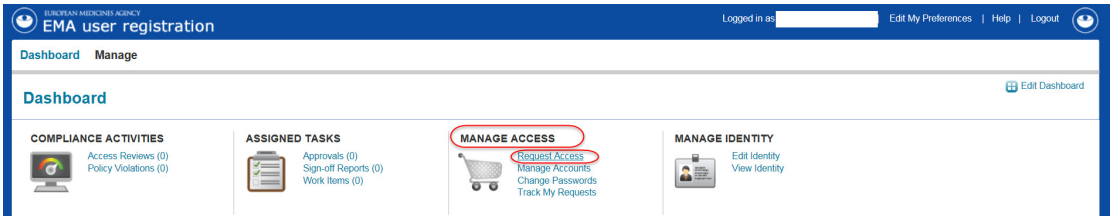
SPOR access request

- Choose Manage access tab
- Click on Request access



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Selection of roles 1/3

- The user will see possible roles they can choose from => add to cart
- SPOR users can view, download or export data and submit change requests in OMS and RMS
- For RMS, the users can also manage term translations, tagging and subscription services
- The choice of roles will expand when more systems are served by IIQ (IIQ is not SPOR-specific)
- <u>NCA specific roles:</u>
  - NCA super user
  - NCA user
  - NCA translator (for RMS)

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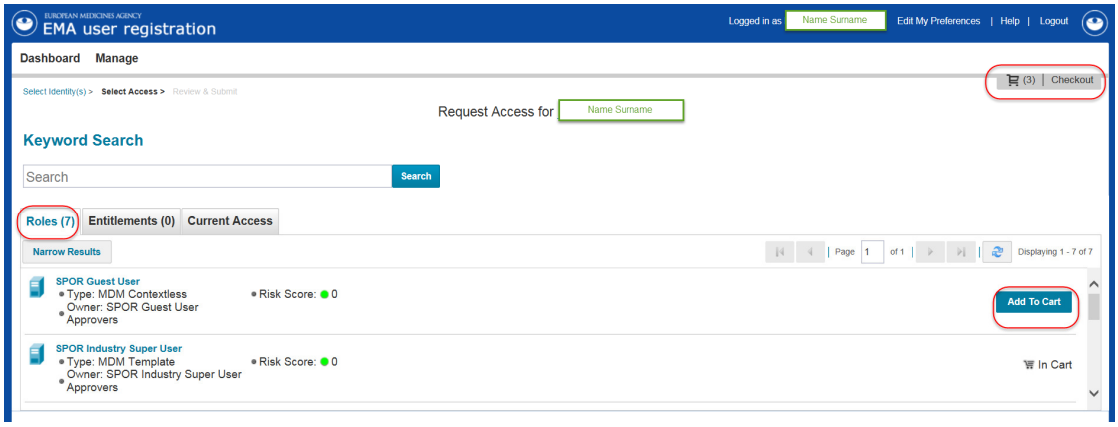
Selection of roles 2/3



- Once selected, go to checkout

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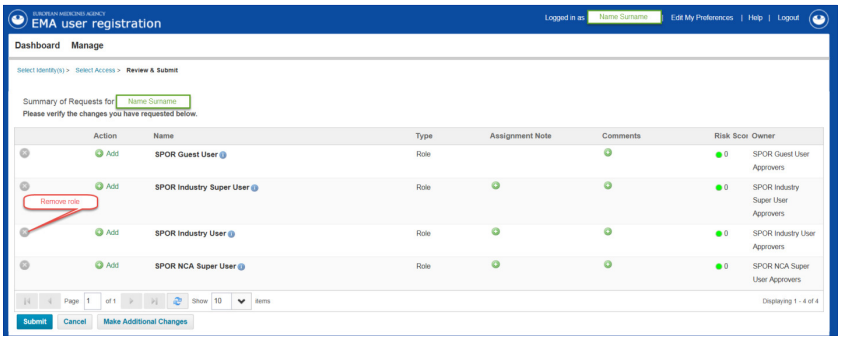
Selection of roles 3/3

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



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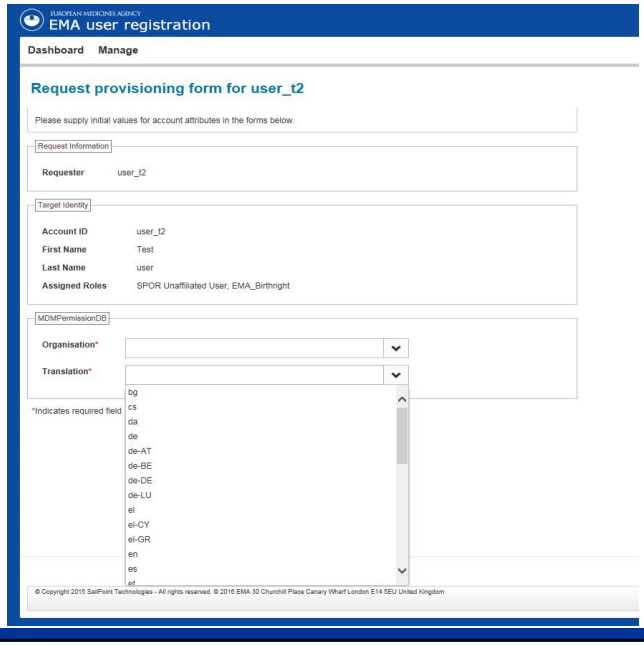
NCA translators

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



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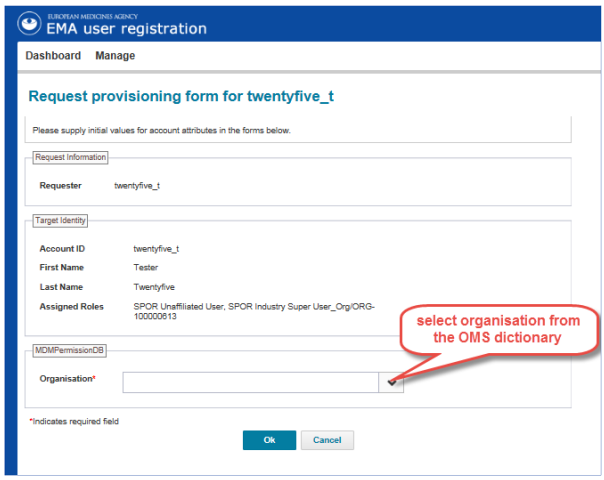
User affiliation to an organisation 1/2

- The industry users and NCA users are roles that are organisation-specific
- The user needs to select the organisation from the dropdown displayed on the screen by inserting the Organisation ID from OMS
- Click on the 'Ok' button
- A message that the request was submitted successfully comes up on the screen, with request ID



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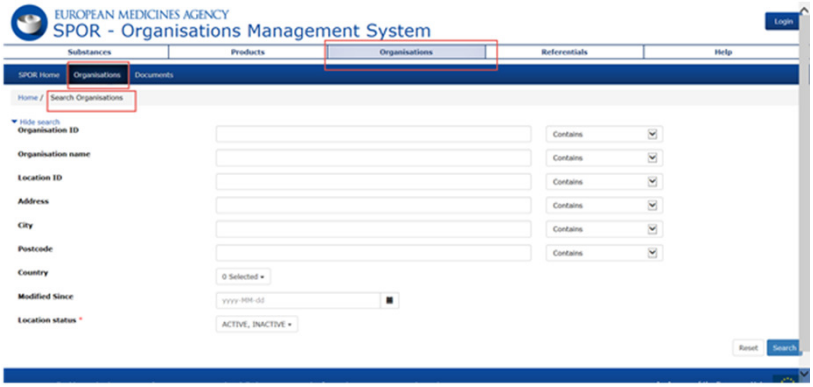
Search OMS for Organisation ID on the OMS website

- No log in needed
- Enter part of the organisation name
- 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



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User affiliation to an organisation 2/2

- All NCAs should appear in the list now
- For most of the roles the access request ID which is automatically generated by IIQ is irrelevant and can be ignored
- However, the first user requiring super user access should take note of the request ID as it will be required to submit supporting documentation through the EMA Service Desk (JIRA)
  - This process will be applicable to NCAs from October 2017 (from June 2017 to October 2017 no documents will be required in order to facilitate user onboarding)
  - Industry will start using SPOR services in October 2017
- This process is explained in detail in the SPOR user registration manual

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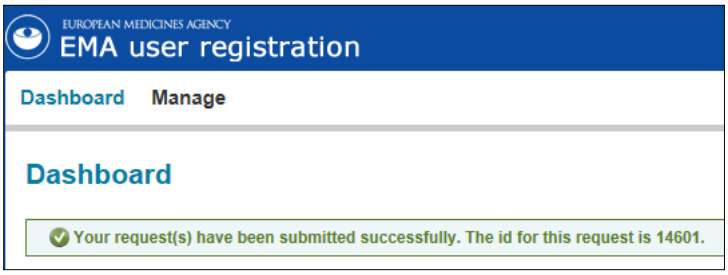
Request submission confirmation message

- After a request for a SPOR role is submitted, a separate e-mail confirming the submission of the request with the request ID is also sent to the user



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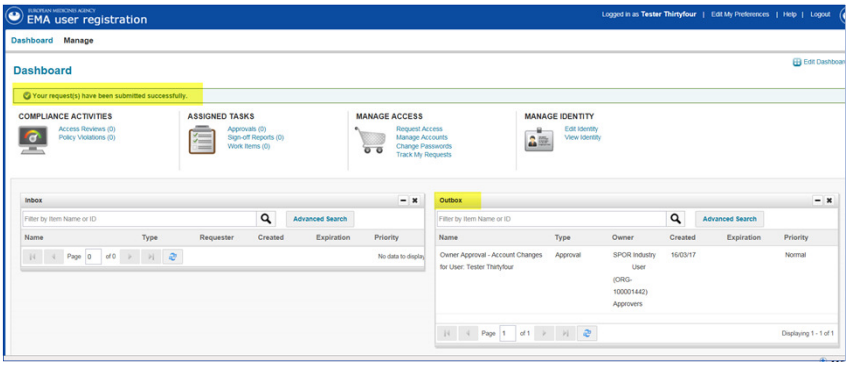
Request submitted successfully

- The request appears in the user's IIQ profile outbox on the dashboard
- If you need role on behalf of a different organisation, please be aware that you need to submit a new request (not applicable for NCAs)



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Track my requests

The request IDs are listed under "track my requests"

Dashboard Manage

Access Requests

Filter by Identity | Advanced Search

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

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SPOR super user role

- The super user is the first user role to be requested for any organisation
- For NCA user/NCA translator account request, if a super user exists for the affiliated organisation, the access request appears on the IIQ dashboard of the organisation super user that approves/rejects the access
- For NCA user or NCA translator roles, if there is no super user for that organisation, 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
- The super user approves/rejects the access request from the IIQ dashboard
- The requestor receives an e-mail about the outcome

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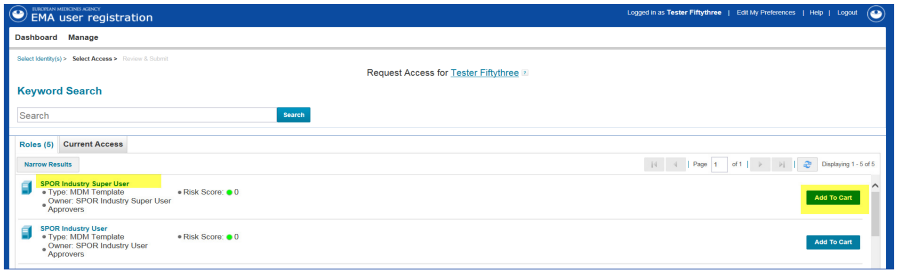
SPOR super user access request 1/2

- To request a super user role for an organisation, the user needs to follow all the steps as described above 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



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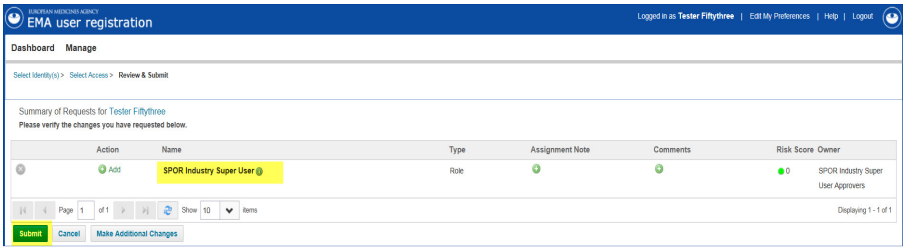
SPOR super user access request 2/2

- Submit the request for the super user role



- The requestor receives an e-mail that the request has been submitted

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SPOR super user role – approval process

- The first super user for each NCA will be approved by EMA IT Service Desk after they select the NCA super user role in the request access tab in IIQ
- From October 2017, the requests for the first super user access will be approved/rejected based on submitted documents
- If the super user access is granted, this role appears also in their IIQ dashboard
- The super user is now able to approve industry/NCA users/NCA translators and other super users for their organisation
- The super user has an obligation to manage/maintain access for the users in their organisation
  - Once a user/super user leaves the NCA, they need 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

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Super user access – multiple 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
- The user/super user can be linked to multiple organisations
- The users will need to submit individual access requests for each of the roles

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Access management

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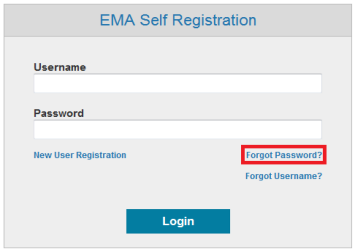
Reset Password – for both SPOR and IIQ

- This applies only for users who self-registered in IIQ or completed their IIQ profile with authentication questions
- Any other password reset requests need to go through the EMA IT Service Desk
- Go to "Create EMA account" on SPOR or OMS webpage
- Alternatively, navigate to https://register.ema.europa.eu/
- In both cases, the EMA self-registration page appears



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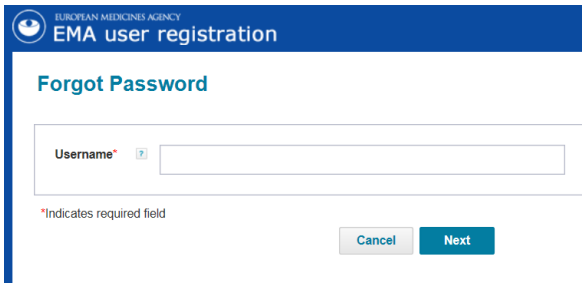
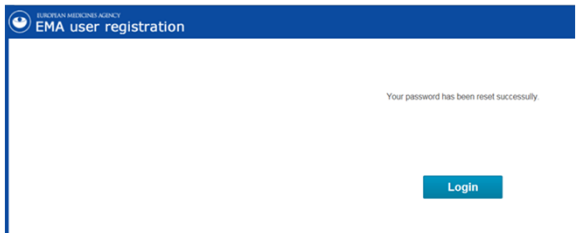
Reset password

- Click on "Forgot Password?"
- Insert username
- The authentication questions appear
- Answer as appropriate
- You will receive one-time token by e-mail
- Insert the token in the form => next





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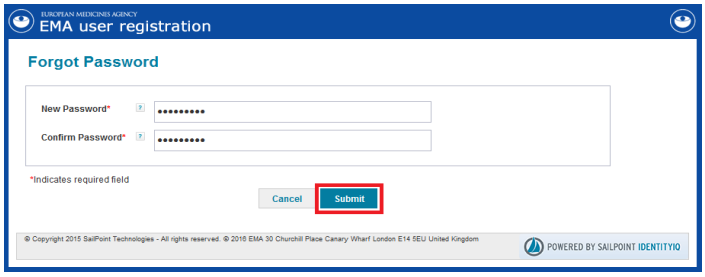
Reset password

- Hover over the red asterisk for password format requirements
- Choose new password and confirm
- Log in as normal



- If the username is incorrect, go back to the landing page and click on "Forgot Username?" link

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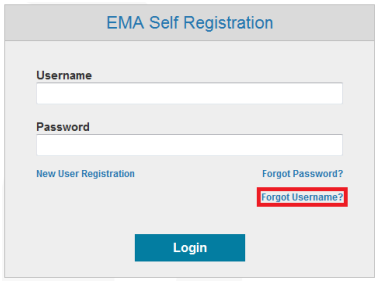
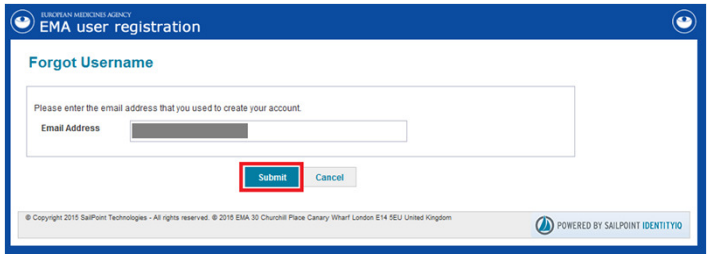
Retrieve forgotten username

- Navigate to IIQ url: https://register.ema.europa.eu/
- Click the 'Forgot Username?' link
- Enter the email address you used to register in IIQ and click 'Submit'





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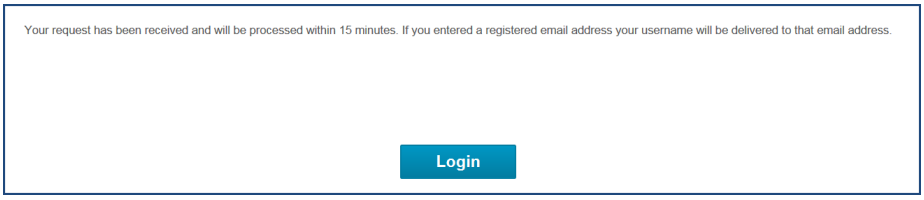
Retrieve forgotten username

- Confirmation of the request is displayed



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

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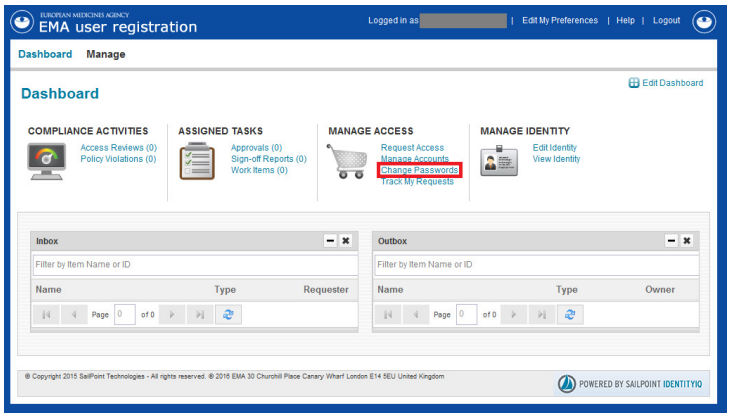
Change Password 1/3

- Log in to your IIQ account on https://register.ema.europa.eu/
- Click on the 'Change passwords' link under the Manage access section on your Dashboard



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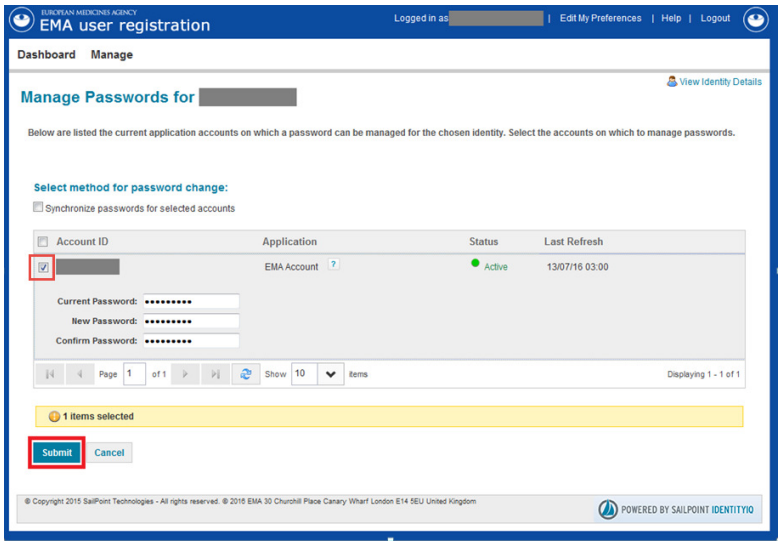
Change Password 2/3

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



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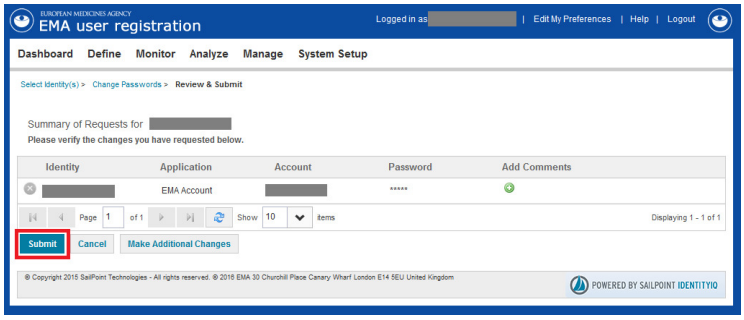
Change Password 3/3

- Click on Submit to finalise the password change



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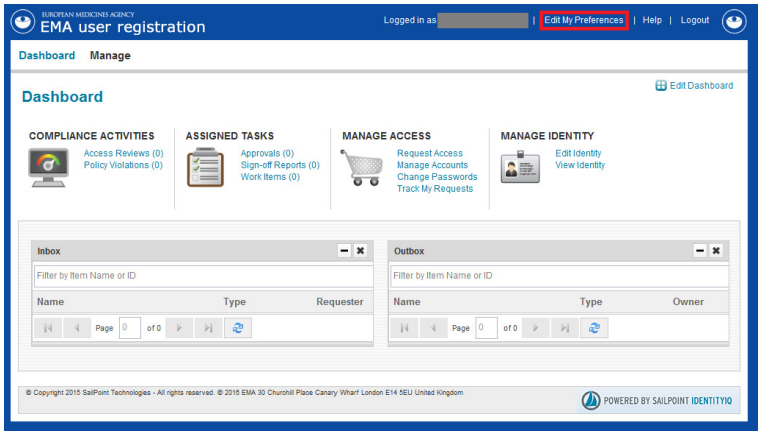
Update authentication questions 1/3

- Log in to your IIQ account on https://register.ema.europa.eu/
- Click on the 'Edit my preferences' link in the top right corner of the IIQ dashboard



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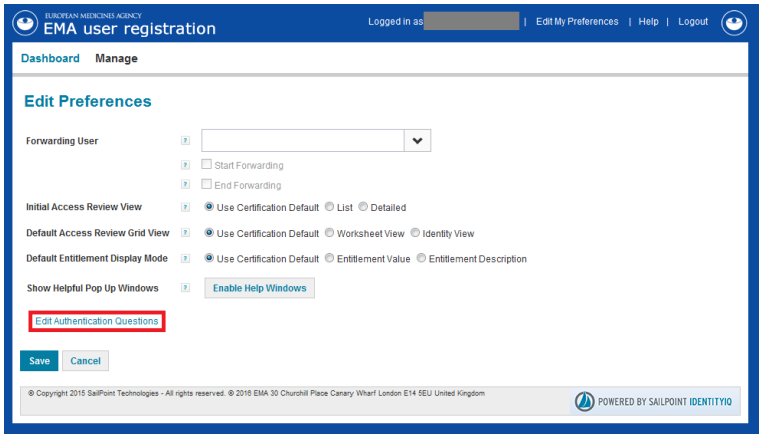
Update authentication questions 2/3

- Click on the 'Edit authentication questions' link
- The authentication question section appears on the screen



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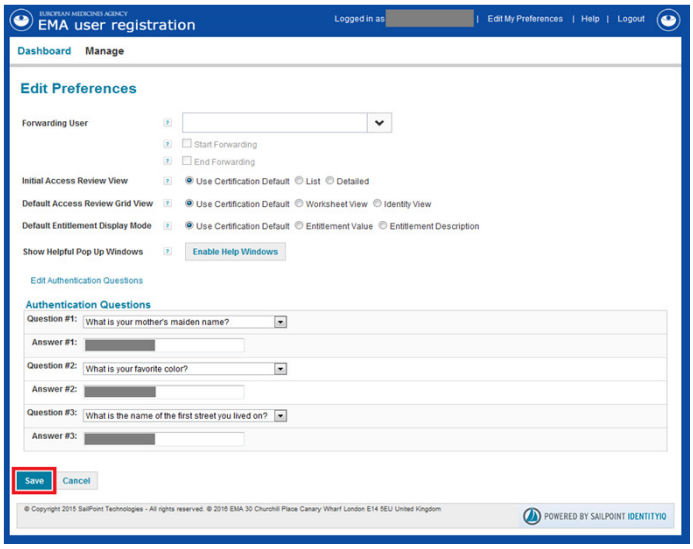
Update authentication questions 3/3

- 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 authentication questions and answers.



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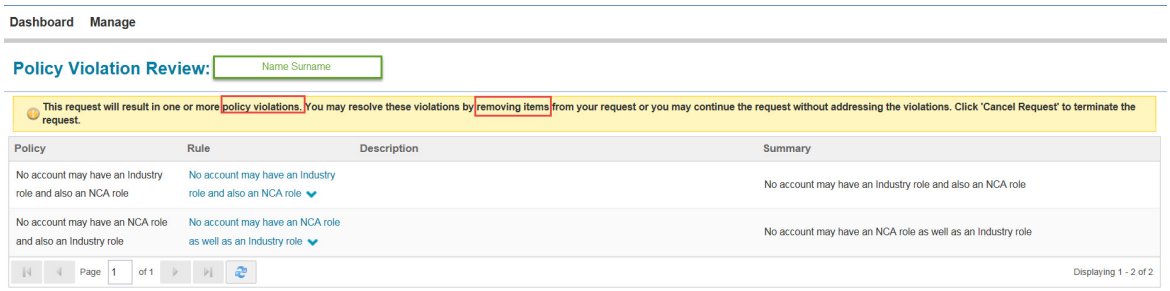
Policy violation

- 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



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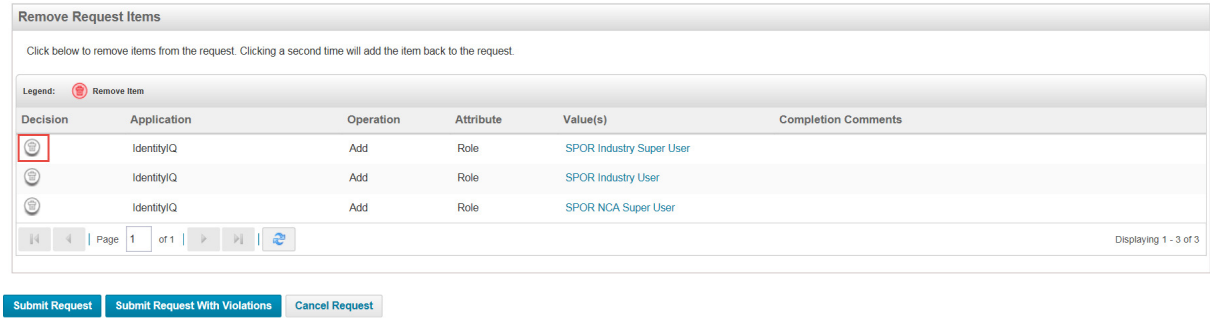
Policy violation – to solve and submit a request

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



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Required action from NCAs as of June 2017

- Please self-register with the EMA if you don't have the access yet
- If you already have an EMA account, please complete your IIQ profile by setting up the authentication questions and affiliate your user role to your NCA
- Apply for super user access in IIQ – the first super user for the NCA (approved by EMA)
- Start approving NCA users, super users and translators
- **Please note the following:**
  - After self registration, request SPOR role without delay
  - Once the SPOR role is approved, the SPOR portal will only have this information on the next day (data refreshed overnight)
  - Don't try to log in SPOR until the next day

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Where do I get more information

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Where do I find more information and out RMS and OMS users?

- SPOR User Registration Manual. It covers SPOR user roles as well as other areas related to user registration and access
  - It will be published on SPOR Portal **Link**

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