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Information Management Division

EMA SPOR User Registration Manual
For RMS and OMS users

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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 the EMA Account Management Portal.

This document provides information on roles available and how to reach EMA Account Management Portal.

2. New Users

User account can be created directly by accessing EMA Account Management and follow a detailed explanation provided on the website.

For registered users, please go to section 3.

2.1. Account creation from the SPOR web landing

Users who do not have access to any of the Agency's systems can follow the steps described below to access EMA Account Management portal. After the registration, you will be able to request user roles that allow you to export, create and update RMS and OMS data.

Navigate to http://spor.ema.europa.eu/sporwi. The SPOR home page appears.

Figure 1. SPOR home page
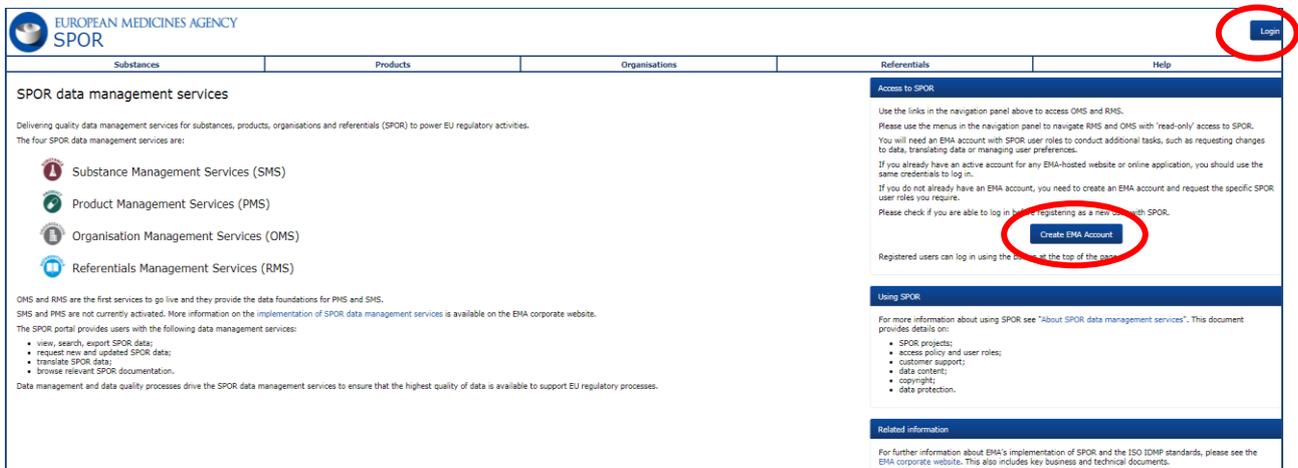
Alternatively, the user can click on Organisations or Referentials tab. Login and registration is available also from there.

Figure 2. OMS home page (RMS home page has the same look)
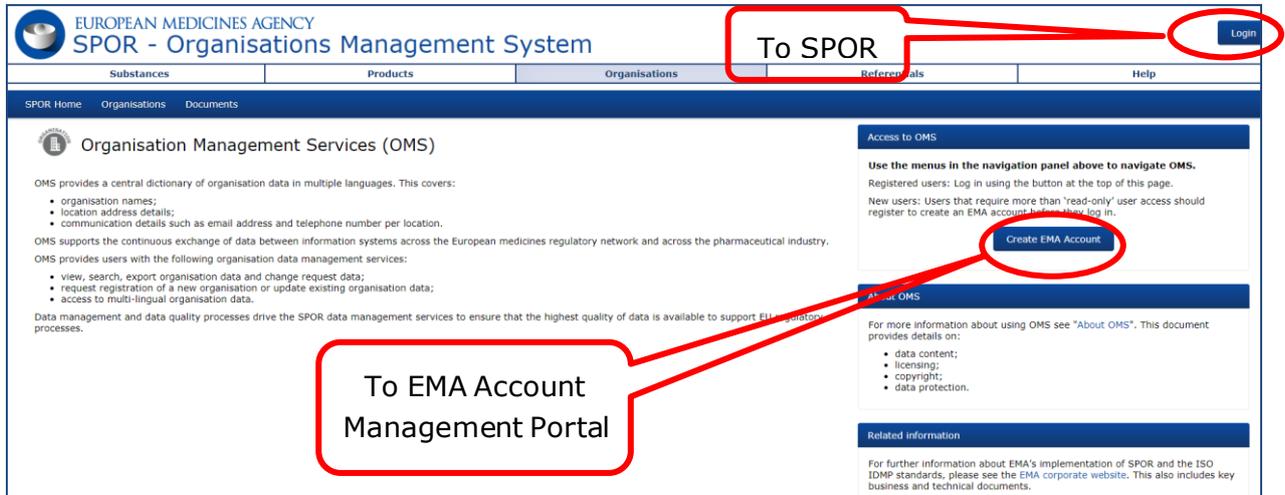
Figure 3. Create EMA account from the SPOR home page
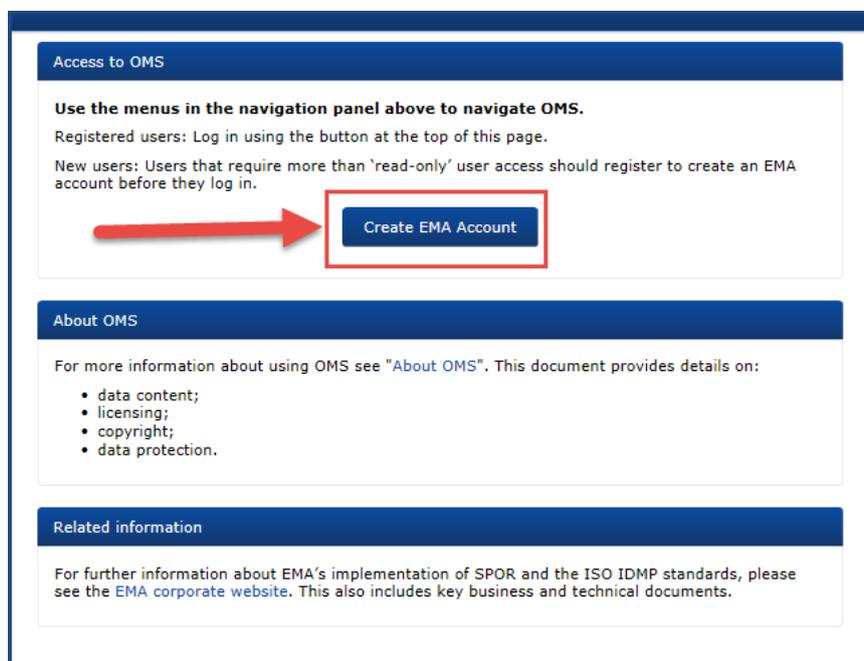
After clicking on "Create EMA Account" you will be directed to the EMA account management.

3. 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 the EMA Account Management Portal.

The username and password are the same for these systems, the SPOR portal and the EMA Account Management Portal.

- Registered users can already login with the EMA username/password from the SPOR web page; they can access to SPOR interface as Unaffiliated user

- In order to use SPOR services, the user needs to request a SPOR user role in EMA Account Management Portal first, accessed through the "Create EMA account" button

- If the user does not remember whether they already have an EMA account, they should attempt to login the EMA account management before initiating the self-registration process.

- If you already have an account but do not remember username or password you can recover it by selecting Forgot password? or Forgot username?

- There is a validator on e-mail address to prevent creation of duplicate EMA profiles during self-registration. If you are creating an account and you receive message the e-mail address is already in use, it means that you have an EMA account and should not register again. If you do not remember your credentials, please use the "Forgot username" or "Forgot Password" links to retrieve your details.

- If you have an account and don't login within a period of 6 months your account will be disabled. If your account is locked or disabled, you can reactivate your account by selecting Forgot password? link.

4. Login

- Go to http://spor.ema.europa.eu/sporwi

Figure 4. Login from the SPOR/OMS/RMS home page
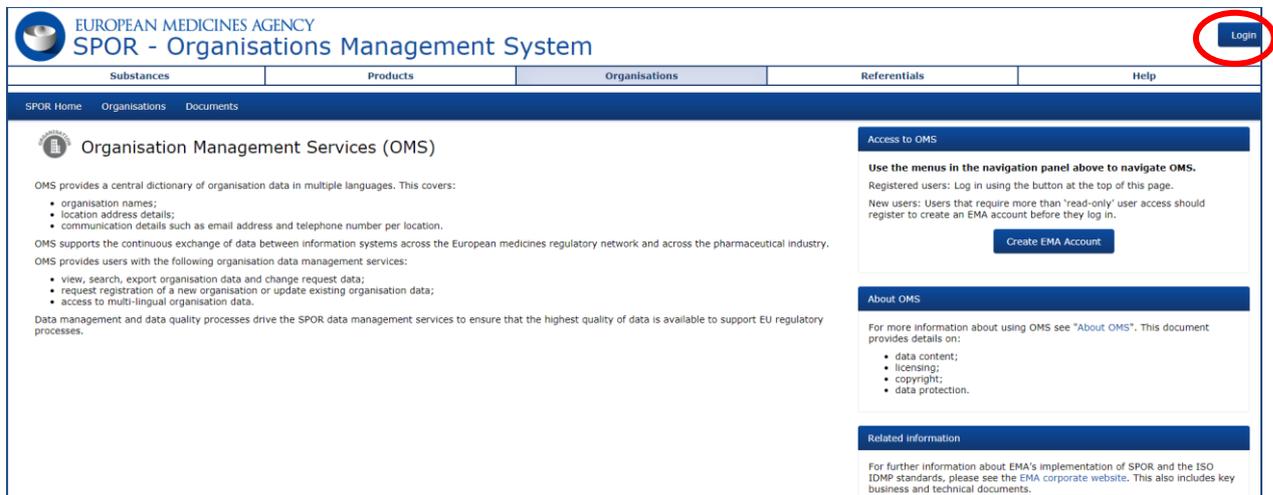
- After clicking on "Login", the following screen appears – login with your EMA system username and password

Figure 5. Login page for registered users
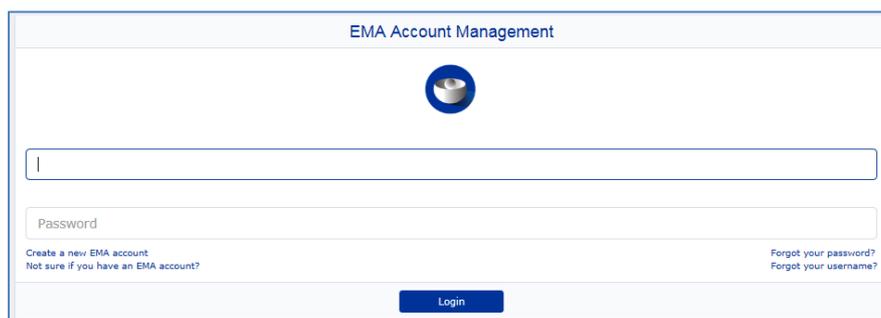
5. SPOR user roles

An individual will have a single account created in the EMA Account Management Portal. A user can have more than one SPOR role. 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.

The EMA Account Management Portal homepage is a user interface for managing access to SPOR as well as other EMA systems. It appears once the user registration process or security question setting process is completed.

All SPOR roles are organisation-specific.

5.1. SPOR user roles – description and access rights

Role Name	Description
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 within MDM; encapsulates Data Steward role. Only EMA personnel or persons working on behalf of EMA will be provided with this role.
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 Super User	SPOR role that allows you to view data, download data (RMS: all lists & OMS: all content) and submit and view change requests. You can also approve EMA user role requests in the EMA Account Management Portal. 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 data, download data (RMS: all lists & OMS: all content) and submit and view change requests. Only EMA personnel or persons working on behalf of EMA will be provided with this role.
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 EMA Account Management. It allows you to view data, download data (OMS: all content) and submit and view change requests on behalf of your organisation within the SPOR applications.
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 the EMA Account Management Portal and ensuring that only the right users have the SPOR roles against the same organisation - This

Role Name	Description
	includes the revocation of these roles when the user should no longer represent your organisation. For this role to be approved, you have to submit a document showing you are authorised to represent your organisation through the EMA Account Management Portal: https://register.ema.europa.eu/ **Note:** For the first super user the requester's e-mail should be a work e-mail from the same organisation on behalf of which the user is requesting the user access. The EMA will refuse requests coming from Gmail, Yahoo and similar private addresses.
Industry User	You should request for this role only if you represent an industry organisation; it allows you to view data, download data (RMS: some lists & OMS: all content) and submit and view 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 the EMA Account Management Portal. If your organisation does not have a super user, the request will be automatically rejected.
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 the EMA Account Management Portal 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. For this role to be approved, you have to submit a document showing you are authorised to represent your organisation through the EMA Account Management Portal: https://register.ema.europa.eu/ **Note:** For the first super user the requester's e-mail should be a work e-mail from the same organisation on behalf of which the user is requesting the user access. The EMA will refuse requests coming from Gmail, Yahoo and similar private addresses.
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 & **Error! Hyperlink reference not valid.** 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 the EMA

Role Name	Description
	Account Management Portal. If your organisation does not have a super user, the request will be automatically rejected.

5.2. 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 can request SPOR roles that will be added to their current permissions.

If users want, they can be users and superusers. However, it is not mandatory from OMS prospective as anyone who is logged in and has self-registered via the EMA Account Management (unaffiliated user) can create any type of change request in OMS for any organisation.

The user roles are described below. For SPOR user role definitions, read section **Error! Reference source not found.**

For further information on authorisation process flow please access EMA account management.

Figure 6. Diagram of user roles in OMS/RMS
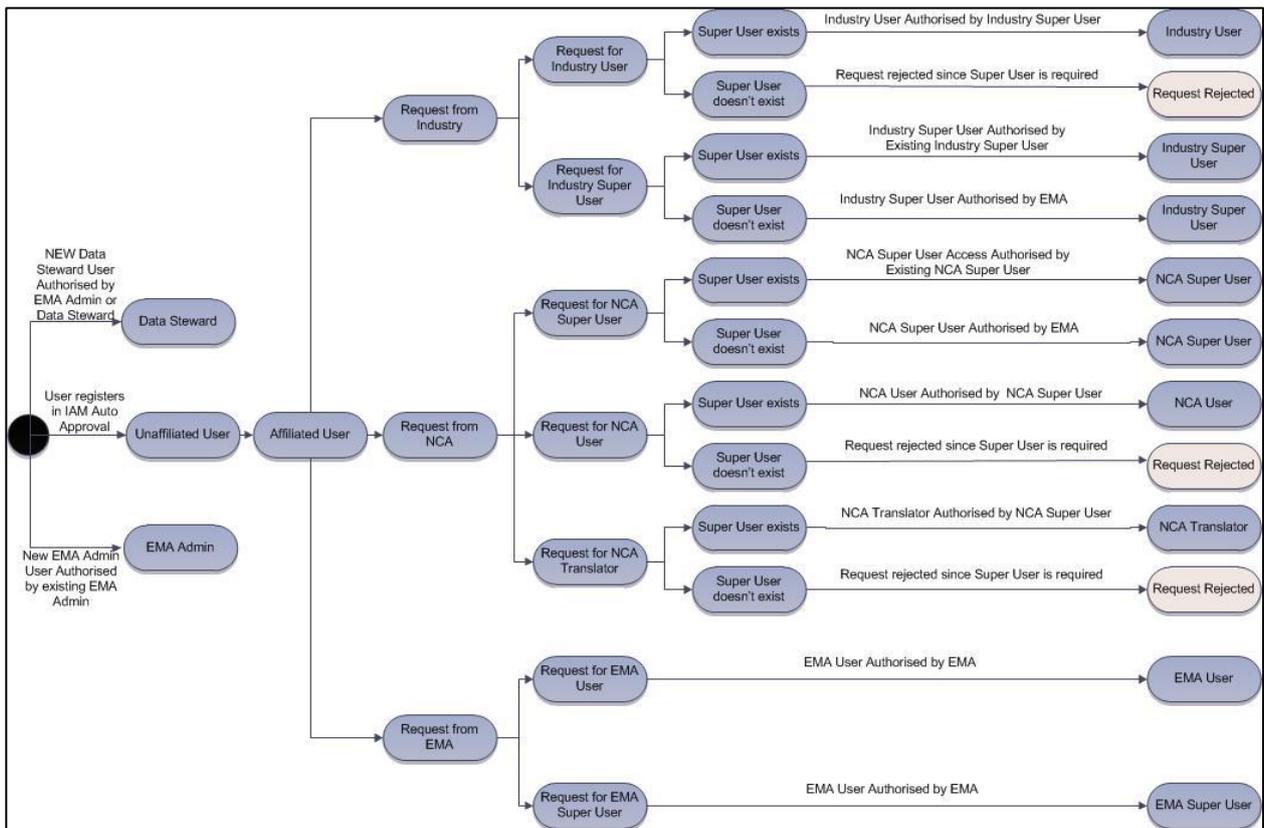
5.3. SPOR Super User access request for industry and NCA users

- The Super User role is the <u>first user role</u> 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 <u>How to request access</u>

- The process is the same, apart from the role requested, which is Industry or NCA Super User

- One person can only have either Industry or NCA Super User access

- In case a user needs a role on behalf of a <u>different organisation,</u> a new request needs to be 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

Please note that a work e-mail is required to request the first SPOR Super User role. E-mail should be from the same organisation on behalf of which the user is requesting the SPOR Super User access

For the first (of a certain organisation) SPOR Super User role requests using personal e-mails, such as gmail, yahoo and similar addresses, the access will be rejected by EMA IT Service Desk

We advise against using generic (i.e. info@) and private (i.e. gmail or yahoo) e-mail addresses due to security reasons. To create an account only personal e-mail address must be used e.g. name.surname@domain.com

The role is organisation specific and if the user leaves the organisation, the Super User has the responsibility to revoke the access

5.3.1. First Super User approval by the EMA IT Service Desk

The <u>first</u> 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 and analyse the required document submitted via in the EMA Account Management Portal

When the Super User access is granted, the user will receive a confirmation e-mail and the role will appear also on the EMA Account Management Portal Home page

5.3.2. Super User responsibilities

The Super User has an <u>obligation to manage/maintain access</u> for the users in their organisation

- The Super User approves and grants access for the users of their organisation

- The Super User needs to confirm that the users indeed belong to the organisation before granting the access

- It is in the responsibility of the Super User to make sure that enough SPOR (Super) Users are active in the organisation

- Once a User/Super User leaves the organisation, the Super User needs to inactivate their access in the EMA Account Management Portal

- Access on behalf of an organisation is in the responsibility of the Super User(s) and the EMA will not check

- In case the organisation has appointed multiple Super Users, the approval is required only by one Super User

5.3.3. Document submission for Super User authorisation on the EMA Account Management 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 document that confirms that they represent the organisation selected in the request – use the template available on the EMA Account Management portal or on SPOR web portal

In case you do not submit the document in EMA Account Management portal, your request will be rejected.

Figure 7. SPOR Super User Affiliation Template Letter on SPOR portal

5.4. 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 Registration Portal homepage, click on Manage My Access

Please note that in order to obtain SPOR User role access, **there must be a Super User in the requestor's organisation**. If there is none, the system will reject the request 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

Further guidance on how to request Super user role can be found How to request access

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5.5. Affiliation to an organisation – OMS search

The Industry (Super) User and NCA (Super) User are roles that are <u>organisation-specific, i.e. the users are granted their access rights on behalf of a specific organisation.</u>

Upon requesting this role in EMA Account Management portal, the user needs to select the organisation from a dropdown list by inserting the Organisation ID from OMS.

The organisation ID can be found on the OMS website*:*

- Navigate to http://spor.ema.europa.eu/omswi/#/

- No login needed

- Enter part of the organisation name

Figure 8. Search for organisation ID on the OMS website
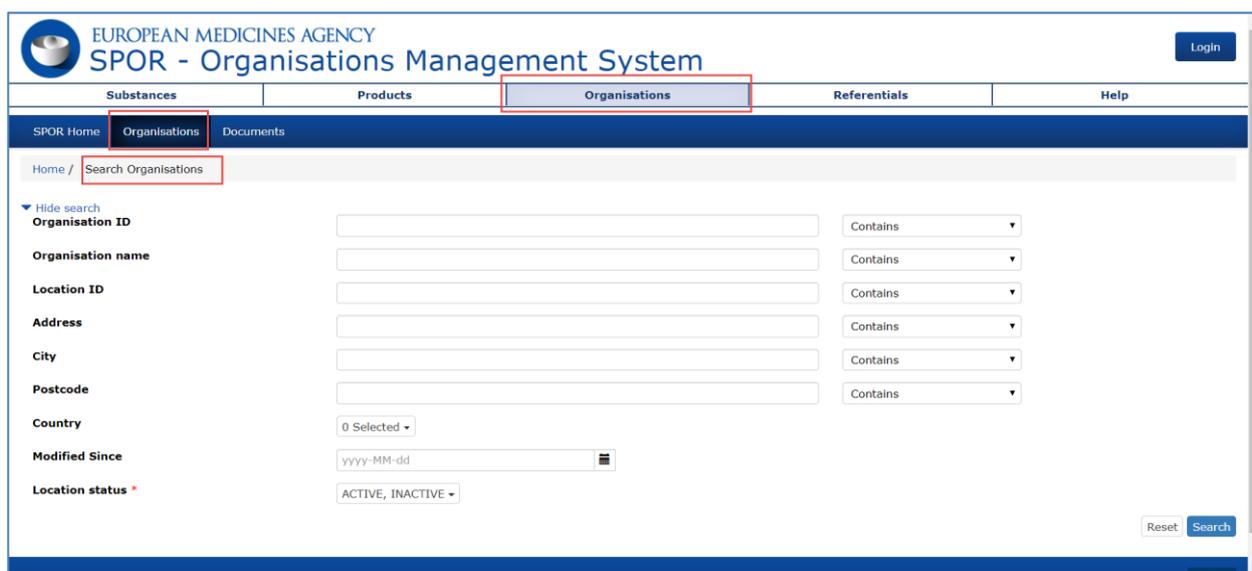
- The search results include all <u>locations</u> that are associated to organisations that match the entered organisation name

- For each returned location the name and ID of the parent organisation is shown

Figure 9. Search results for organisation ID on the OMS website

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	🔍

- Paste the organisation ID in the organisation field in the organisation affiliation form on EMA Account Management Portal.

- Select an organisation from the drop-down list, on the "Organisation" field, by clicking on the drop-down arrow on the right

- 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.

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/#/

Please use the F - OMS Web User Manual for further guidance on how to request a new organisation in OMS Dictionary

- In case a user needs a role on behalf of a different organisation, a new request needs to be submitted

- The requests for user access are approved/rejected by the Super User of the requestor's organisation

6. Multiple SPOR roles

- For industry users, one person can have multiple roles, e.g. representing multiple companies:

    o This can be Industry Super User or Industry User

    o Each user role will be linked to a unique organisation

    o Managing multiple organisations as a Super User requires multiple *Industry Super User* roles with the correct organisation affiliations

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

    o 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, in which case EMA would approve

    o Each organisation should have at least one registered *Industry Super User* (EMA recommends two). An organisation can also have multiple *Industry Users*

- An industry company may have different subsidiary organisations, each with its own organisation ID:

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

    o The population of SPOR Industry Users and Industry Super Users for an organisation is driven by several factors:

- o Business model

- o Pre-existing processes and policies regarding granting access

- o Overall number of products

- o Some companies may outsource regulatory affairs to third party service providers

7. Questions to OMS team

- In case you face any issues trying to register or further guidance is required

- Navigate to EMA Service Desk portal (https://servicedesk.ema.europa.eu); the login page appears

Figure 10. IT Service Desk login page
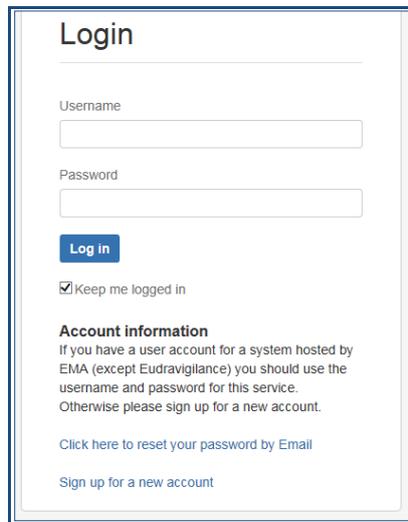
- The login credentials are those for any of the EMA applications, EMA Account Management Portal and SPOR

- If you just self-registered, the credentials are the ones assigned during the self-registration process

- Click on the IT Service Desk link to progress

Figure 11. IT service desk landing page
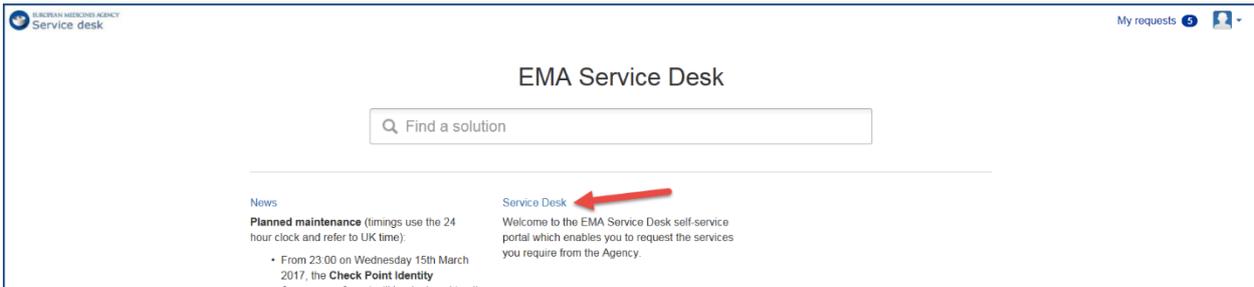
- Select "Ask a Question"

Figure 12. Service Desk question form

- Ensure the name of the user appears under the heading "Raise this request on behalf of". This should be automatically prepopulated by the tool

- Populate Subject using key words, e.g. OMS registration

- For the Type of question please select "Other" from the dropdown list

- Provide a summary of your question under Description

- Upload any relevant documentation or screenshots that may complement your question

- Click on "Create"

- Further information on the SLAs available on the document X - SPOR SLAs on the SPOR portal