



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

02 October 2018 version 2  
EMA/307181/2017  
Information Management Division

## On-boarding of users to SPOR data services



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## 1. Purpose of this document

This document is intended to provide both guidance and information for stakeholders who are supporting the implementation of the SPOR programme and for all stakeholders who are using RMS and OMS data management services. The information applies to both human and veterinary stakeholders; however, there may be different impacts experienced by NCAs and industry stakeholders depending how these data services are used and in which business process (eAF, IRIS portal, EV user registration).

This document will be reviewed periodically for accuracy.

## 2. Executive summary

Referential and organisation master data services are accessible through the [SPOR portal](#). Any member of the public can view and search RMS lists of terms<sup>1</sup> and the OMS dictionary<sup>2</sup> as a guest user without having to log in. To benefit from full access to these data services (e.g. request changes to the master data held in SPOR), stakeholders are invited to **register** their **SPOR Users**, starting with Super Users who can authorise further users from the same organisation. EMA recommends that each organisation should have **at least two** registered SPOR **Super Users**. An organisation can have **multiple** SPOR Industry **Users**. Registration of users is through the [EMA Account Management portal](#) (a central point to manage access to EMA systems).

The registration of SPOR users is predominantly driven by the business process using the referential and/or organisation master data. The organisation in question should decide, depending on their circumstances (e.g. business process using the master data, organisational structures, etc.), how many users they need to register in SPOR. There may also be other parts of business operations which will benefit from access to data services, if not immediately but in the future, as the SPOR services will eventually support a wider range of EMA business processes and EU-wide regulatory activities. Any additional usage of the SPOR master data will be communicated by the related business process owner.

This document starts with a brief introduction to the type of SPOR roles users can request, highlighting the role of the Super User and what companies should take into consideration when setting up user populations. The scenarios provided in this document may help you to consider the best options for your own organisations.

## 3. Access to SPOR data services and overview of SPOR user roles

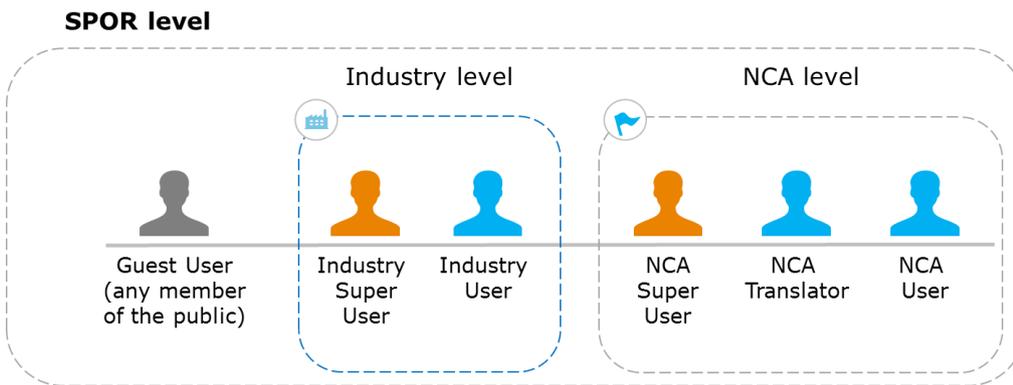
Users can access SPOR data services directly online through the [SPOR portal](#). Any member of the public (as a guest user) can view and search RMS lists and the OMS dictionary without having to log in. In order to **request changes** and **updates** to the organisation or referential data, **users must** be registered with the [EMA Account Management portal](#) and **have a relevant SPOR user role** assigned (*either* Industry *or* NCA role, but not both). In other words all users will need to be affiliated with a specific industry or NCA organisation in the Account Management portal. The SPOR services user types and system permissions are briefly explained below.

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<sup>1</sup> Lists of terms (controlled vocabularies) to describe attributes of products, e.g. lists of dosage forms, units of measurement and routes of administration

<sup>2</sup> OMS dictionary – is a list of organisations with associated physical locations

**Figure 1.** SPOR user roles



**Guest User** – A user who does not require login credentials (username and password) to access the SPOR portal and view/search RMS lists and OMS dictionary.

**Unaffiliated User** (this role is **temporary** and it supports SPOR user registration) - A logged-in user who self-registered in the EMA Account Management Portal but is not yet linked to any organisation. In OMS only, they will be able to submit change requests to register a new organisation, limited to one pending request at a time. Once the new organisation is registered in the OMS, the user can be affiliated with this organisation and request a relevant SPOR role.

**Industry Super User** - A logged-in user that can approve other users’ requests for access to SPOR on behalf of an organisation they are affiliated with. This user role also includes the revocation of these roles should the user no longer represent their organisation. They can view, search, download or submit change requests for RMS lists and the OMS dictionary.

**Industry User** - A logged-in user who represents an industry organisation and who has been approved by the Super User of that organisation *i.e.* is affiliated to an industry organisation. They can view, search, download and submit change requests to RMS lists and the OMS dictionary.

Note: approving/revoking access to SPOR through the EMA Account Management portal is the only aspect that differentiates a Super User from a User (see the table below).

**Figure 2.** User role versus permissions in SPOR (available to industry stakeholders)

Permissions	Guest User	Industry User	Industry Super User
Login to SPOR	Login not required	Login required	Login required
View, search SPOR data	Yes	Yes	Yes
Download SPOR data	<b>No</b>	Yes	Yes
Submit a Change Request (CR) to SPOR data	<b>No</b>	Yes	Yes
Grant/revoke access to SPOR in the Account Management Portal	<b>No</b>	<b>No</b>	<b>Yes</b>

**NCA Super User** – This is a logged-in user who works for an NCA (or an organisation acting as a regulatory authority) and is responsible for approving access to SPOR for other users on behalf of their organisation. This user role also includes the revocation of these roles should the user no longer represent their organisation. They can view, search, download or submit change requests for RMS lists and the OMS dictionary.

**NCA User** - A logged-in user who works for an NCA (or an organisation acting as a regulatory authority) that has been approved by the NCA Super User to have access to SPOR. They can view, search, download and submit change requests to RMS lists and the OMS dictionary.

**NCA Translator** - A logged-in user affiliated to an NCA. If the user is requesting a Translator role, they must also specify the language for which they will be providing translations, in addition to their organisation’s name. Having an NCA User or Super User role is not sufficient to do translations in RMS.

**Figure 3.** User role versus permissions in SPOR (available to NCA stakeholders)

	Guest User	NCA User	NCA Translator	NCA Super User
Login to SPOR	Login not required	Login required	Login required	Login required
View, search RMS/OMS data	Yes	Yes	Yes	Yes
Download RMS/OMS data	<b>No</b>	Yes	Yes	Yes
Submit a Change Request (CR) to RMS/OMS data	<b>No</b>	Yes	Yes	Yes
Perform translations in RMS	<b>No</b>	<b>No</b>	<b>Yes</b>	<b>No</b>
Grant/revoke access to SPOR in the Account Management Portal	<b>No</b>	<b>No</b>	<b>No</b>	<b>Yes</b>

## 4. Role of the Industry Super User

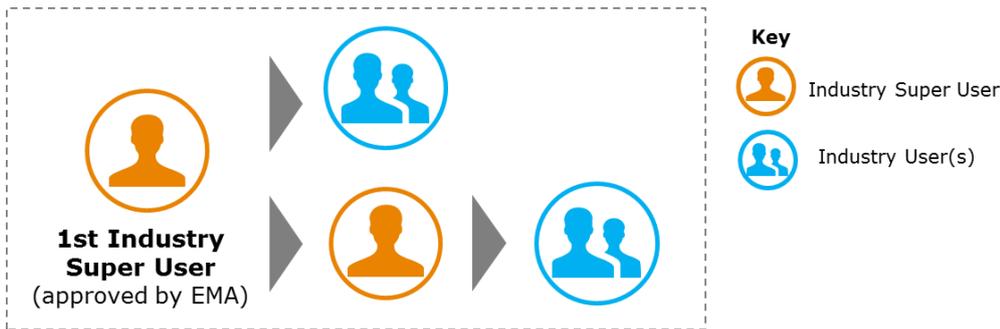
It is important to note that the **EMA will approve the 1st Industry Super User** of an organisation and the requestor will have to submit a document<sup>3</sup> that validates their authority to represent that organisation. In the absence of such proof, the request will be rejected by EMA. Follow this [guidance](#) to apply for the **first SPOR Industry Super User**.

The requestor's organisation Super User will approve any subsequent Super User or User access requests (see Figure 4). Follow this [guidance](#) to apply for **subsequent SPOR Industry Super User or Industry User** access.

*Note:* It is important to verify that the organisation has a Super User before submitting a request for subsequent SPOR industry Super User or Industry User access. If the organisation does not have one the request will be pending in the registration portal.

<sup>3</sup> SPOR User Affiliation Template Letter - available to download from the documents section on the OMS portal

**Figure 4.** Approval of industry users

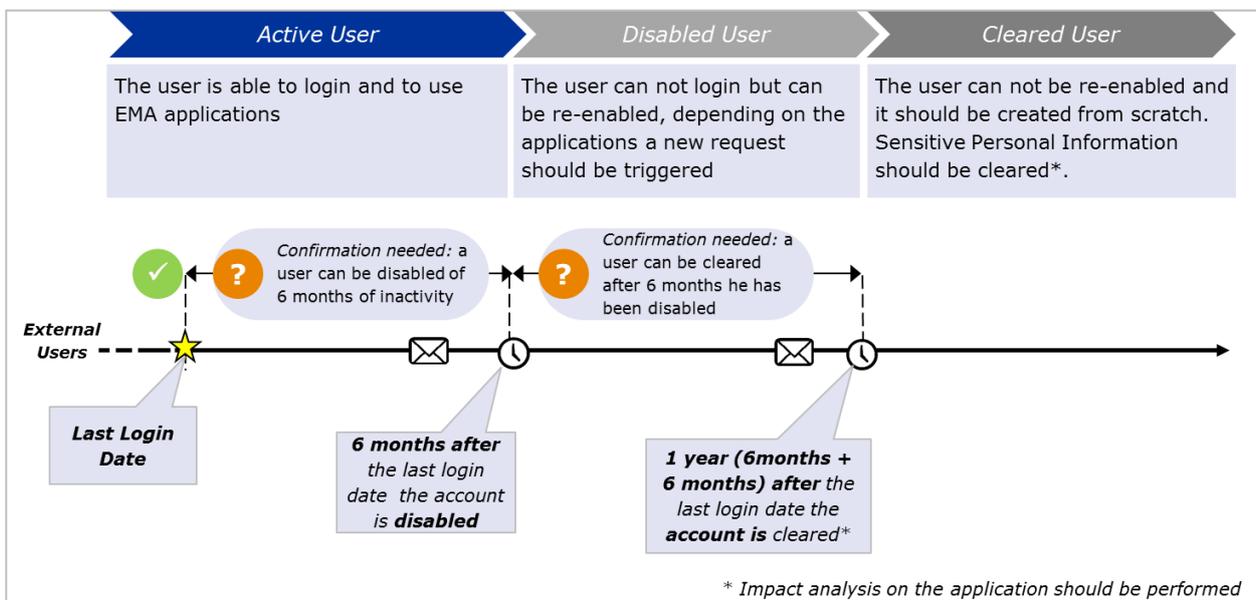


**Summary of Super User accountabilities:**

- approval and verification of access for their organisation’s users, EMA will **not** check;
- confirmation that all users indeed belong to the organisation before granting access;
- ensuring that there are a sufficient number of SPOR Super Users and Users for their organisation;
- as soon as they are informed that a Super User or User has left their organisation, the Super User must deactivate their SPOR access;
- Approving and revoking access to SPOR is through the EMA Account Management portal.

In addition, the EMA account management project implemented a process by which a **user** who has been **inactive for 6 months** will be disabled (subject to confirmation from a user). The process is outlined in the Figure 5 below.

**Figure 5.** “Identity cleansing and accuracy – leaver”



\* Impact analysis on the application should be performed

## 5. Managing user populations by company

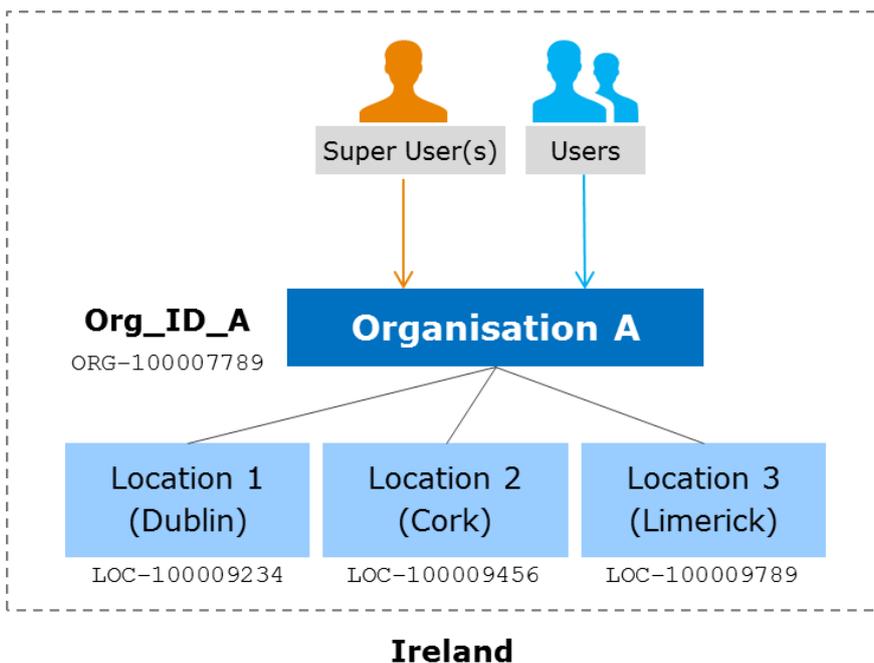
Organisations should decide on their SPOR user population. EMA recommends that each organisation should have **at least two** registered **Super Users** to grant and revoke access to SPOR. An organisation can have **multiple SPOR Industry Users**. Such user population can be driven by several factors, for example:

- business needs;
- size of the organisation;
- processes and policies related to granting access;
- overall number of products;
- some companies may outsource regulatory affairs to third party service providers.

The scenarios provided below may help you to consider the best options for your own organisation(s). Please note that company structures and hierarchies are not defined in OMS – for example, there is no recognition of Headquarters (HQ) or Affiliates.

### 5.1. Scenario 1 - single organisation

Figure 6. Scenario one

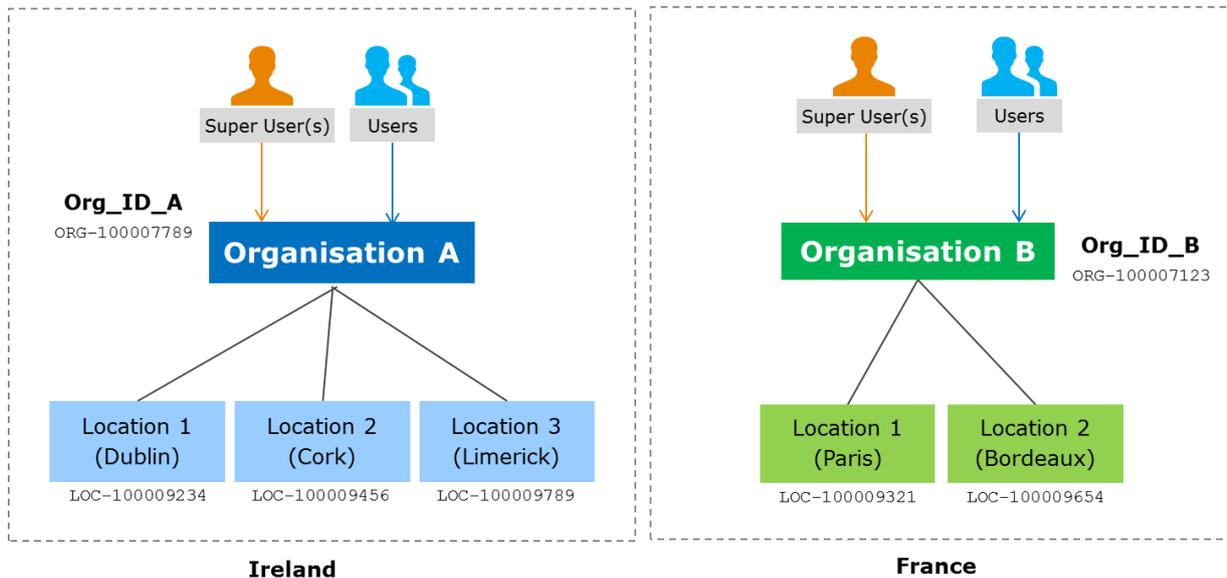


If you are registered already with the EMA Account Management portal then you can submit requests for Industry User or Industry Super User roles affiliated to a specific organisation – in this example the Industry organisation called 'Organisation A' is identified uniquely by a combination of its Name, Organisation ID, and Country.

Once granted, Industry Super User(s) can approve access requests for other Industry Super Users and Industry Users at the same organisation (same Name, same Country, same Organisation ID).

## 5.2. Scenario 2 - multiple organisations, same company

Figure 7. Scenario two



Note: the name of Organisation A can be the same as the name of Organisation B

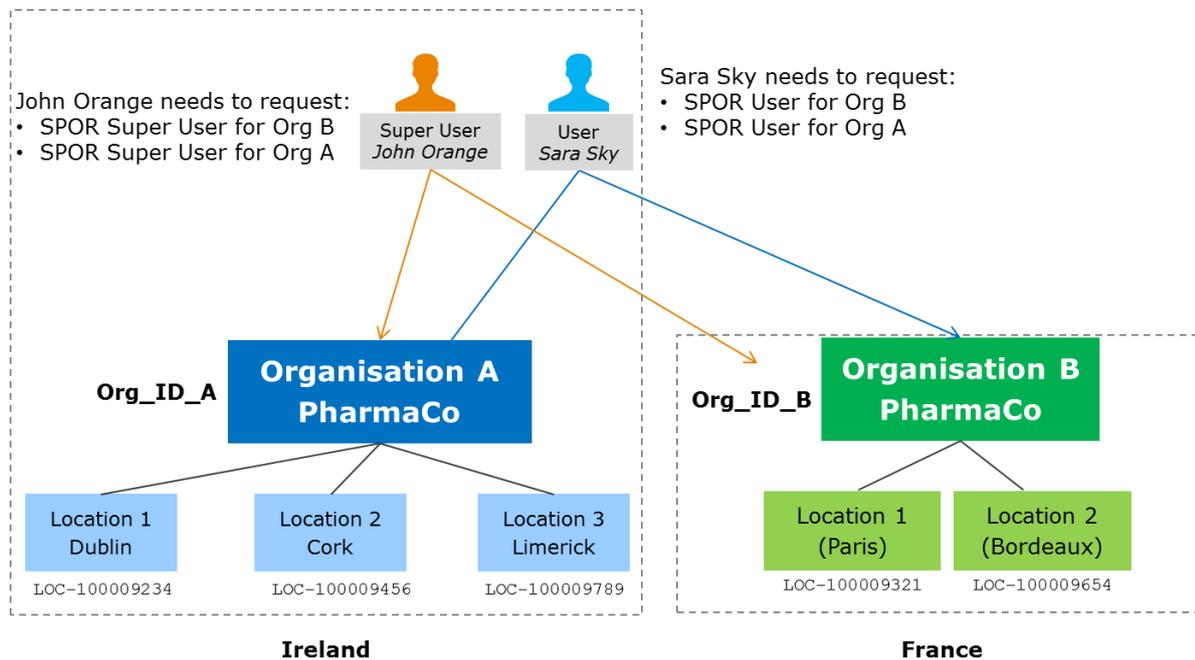
Remember that organisations are identified uniquely by their Name, Country, and Organisation ID. Managing access to SPOR user roles requires each organisation to appoint people to the *Industry Super User* role. Once they have their first *Industry Super User* then this first super user can approve other requests for additional *Industry Super Users* and *Industry Users*.

Scenario 2 illustrates how a company can grant access to *Industry Super Users* and *Industry Users* for their specific organisations – shown here as “Organisation A” and “Organisation B”.

The first *Industry Super User* at “Organisation A” in Ireland can grant access to other SPOR *Industry Super Users* and *Industry Users*, but only at “Organisation A”. They have no jurisdiction over SPOR user access at “Organisation B” (and *vice versa*).

### 5.3. Scenario 3 - shared industry Super Users and Industry Users for multinational companies

**Figure 8.** Scenario three



**Note:** the name of Organisation\_A is the same as the name of Organisation\_B.

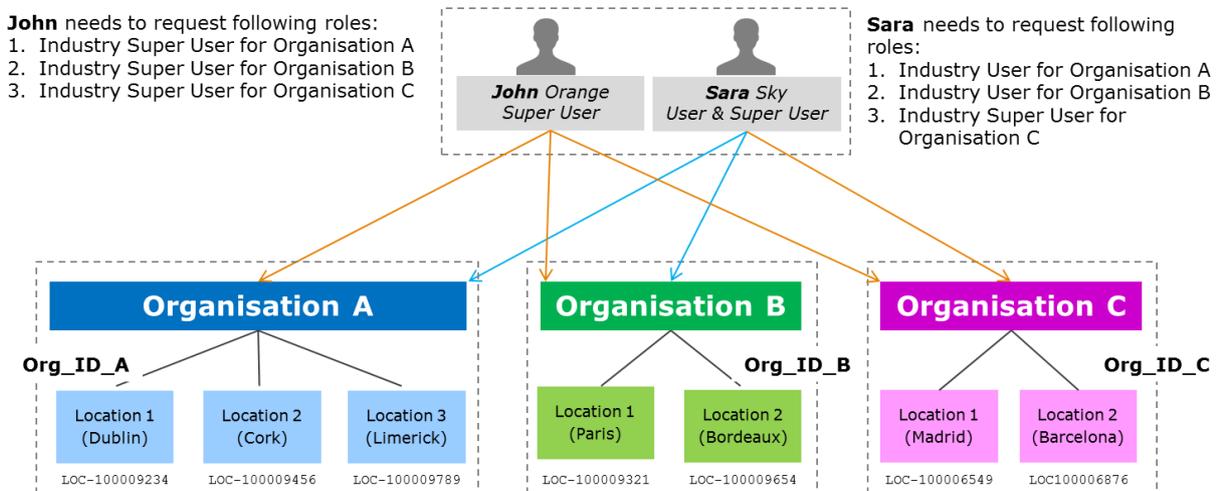
A company may decide to have the same EMA-registered users (*Industry Super User* and *Industry User*) with access for more than one related organisation.

In this example, the users (John Orange and Sara Sky) first need to be registered with the EMA Account Management portal. They need to submit individual requests for SPOR user roles that are affiliated to each organisation.

Once his own access is approved as an *Industry Super User*, John Orange would be able to approve further access requests for both PharmaCo in Ireland and for PharmaCo in France.

## 5.4. Scenario 4 - third party service providers

Figure 9. Scenario four



**Note:** the name of Organisation A could be the same as the name of Organisation B or Organisation C

This example illustrates possible arrangements for a third party to manage SPOR user roles on behalf of industry organisations. John Orange and Sara Sky must be registered and have accounts with the EMA Access Management portal.

Separate access requests need to be submitted for each individual organisation at which they will be managing SPOR user roles. These could be related organisations within the same global company, or separate organisations in separate companies. OMS does not capture or manage organisation hierarchies.

## 6. Where to find related information and documents

A selection of documents produced as part of the SPOR programme development, as well as slide decks from a number of webinars that were held by SPOR team in 2017-2018 are available on the EMA corporate [website](#). These documents are a useful starting point for those who are new to the SPOR programme or are part of the implementation teams.

A comprehensive document related to EMA Account Registration rules is published on the [SPOR portal](#) under the OMS>Documents section.