EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management

On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services

Version 4

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Summary of changes

Following the publication of version 3 in February 2021, the content of this document was amended to:

- include information relevant to the Product Management Service (PMS) roles throughout the document;
- Update section 2. Executive summary;
- Update section 3. Access to SPOR data services and overview of user roles;
- Figure 1: OMS and RMS user roles' was amended;
- Figure 2: PMS user roles' added as new;
- Table 4: User roles versus permissions in PMS (available to industry stakeholders) updated;
- Table 6: Figure 6: User role versus permissions in PMS (available to NCA stakeholders) updated;
- Update to section 4: Role of Super/Admin User;
- Update to Figure 7: Approval of industry users

Editorial changes are not included in this summary.

1. Purpose of this document

This document is intended to provide guidance and information for stakeholders supporting the implementation of the Substance, Product, Organisation and Referentials (SPOR) master data programme and for all stakeholders who are using the Substance Management Service (SMS), Product Management Service (PMS), Organisation Management Service (OMS) and Referentials Management Service (RMS).

The information applies to human and veterinary stakeholders; there may however be different impacts experienced by national competent authority (NCA) and industry stakeholders, depending on how these data services are used and in which business process (eAF, IRIS portal, EudraVigilance user registration).

This document will be reviewed periodically for accuracy.

2. Executive summary

RMS and OMS are accessible through the SPOR portal. Any member of the public can view and search RMS lists of terms[1] and the OMS dictionary[2] as a guest user without having to log in.

SMS will follow the same principles of RMS and OMS accessibility. Dedicated information on SMS accessibility is envisaged to be made available at later stage.

PMS is accessible through the SPOR application programming interface (API) and Product User Interface (PUI) hosted in the Product Lifecycle Medicinal (PLM) Portal for read-only purposes. Registered users can view, search and download/export medicinal product data in accordance with the user rights assigned to the **user roles** below reported. Upon the deploying of additional functionalities in PMS, users will also be able to submit and amend medicinal product data.

To benefit from the full access to the various data services (e.g. request changes to the master data held in SPOR, extract medicinal product data, submit medicinal product data etc.), users should register through the EMA Account Management portal [a central point to manage access to the European Medicines Agency's (EMA's) systems] with the required user role, starting with the following:

- **RMS/OMS: Industry Super Users or NCA Super Users** named "Super User" in this document
- **PMS: IRIS / PLM Industry Admin or IRIS / PLM NCA Admin** named "Admin User" in this document

The above roles can authorise or revoke additional users from the same organisation.

- EMA recommends that **each organisation should have at least two registered Super/Admin Users**.
- **Multiple user roles** can be assigned to the **same user** of the **same organisation** (e.g. a user affiliated to organisation ABC can have the role of Administrator user, as well as a 'Qualified User' **or** a 'User'.)

This document starts with a brief introduction to the type of SPOR roles users can request, highlighting the role of the Super User and Qualified Users 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 organisation.

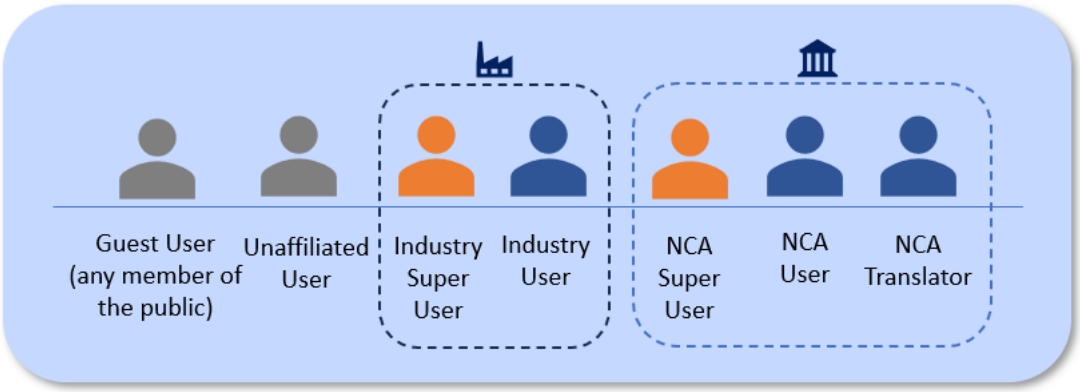
[1] Lists of terms (controlled vocabularies) to describe attributes of products, e.g. lists of dosage forms, units of measurement and routes of administration
[2] OMS dictionary – is a list of organisations with associated physical locations

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

Users can access **OMS** and **RMS** directly online through the SPOR portal or programmatically via 'Rest API' services. Any member of the public can browse and search RMS lists and terms, as well as the contents of the OMS dictionary, as a guest user without the need to log in.

In order **to request new changes** and **updates** to the **organisation** or **referential** data, users must be registered with the EMA Account Management portal (IAM) and have a relevant user role assigned (*either* Industry *or* NCA role, but not both). In other words, all registered users will need to be affiliated with a specific industry or NCA organisation in the Account Management portal.

Figure 1: OMS and RMS user roles



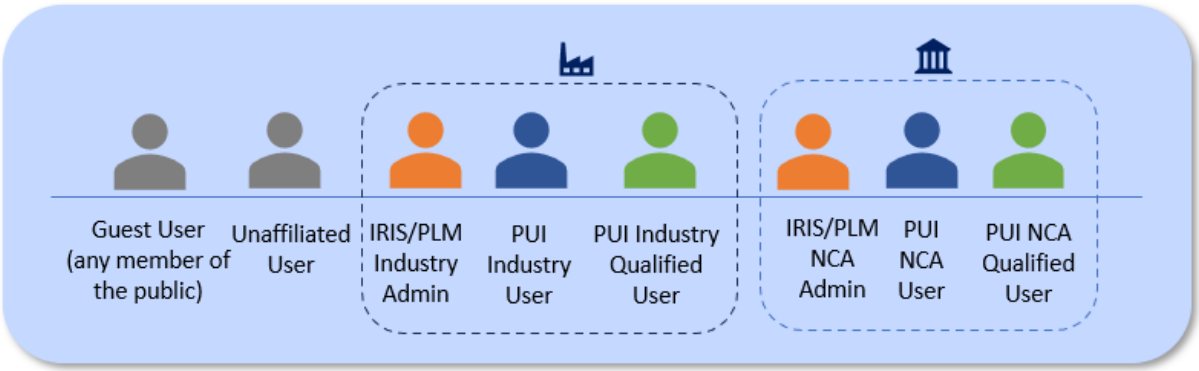
PMS is accessible through the SPOR application programming interface (API) and Product User Interface (PUI) hosted in the Product Lifecycle Medicinal (PLM) Portal for read-only purposes. Registered users can view, search and download/export medicinal product data in accordance with the user rights assigned to the **user roles** below reported. Upon the deploying of additional functionalities in PMS, users will also be able to submit and amend medicinal product data.

To download/export, submit and amend medicinal **product data** users must be registered with IAM and have the relevant user role assigned (*either* as an industry *or* NCA, but not both).

PMS is not yet publicly accessible. A limited data set of PMS will be made publicly accessible via API and PUI based on the agreements reflected in EU IG Chapter 5 and its Annex A.

For further information related to the PMS registration process please refer to EU IG Chapter 1 available on the EMA website and PMS PUI registration process guideline available on the PLM portal.

Figure 2: PMS user roles



Guest User: A user who does not require login credentials (username and password) to access the SPOR portal/SPOR API/PMS PUI. Guest users will be able to access data classified as 'public' (i.e. not commercially sensitive); this includes medicinal product data available in the Summary of medicinal Product Characteristics (SmPC).

Unaffiliated User *(this role is **temporary,** and it supports SPOR portal user registration):* A logged-in user who self-registered in IAM but is not yet linked to any organisation. The Unaffiliated user is able to view the same information as a Guest User but will also be able to export that information. 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 (RMS/OMS) or IRIS / PLM Industry Admin (PMS): A logged-in user that can approve (through IAM) 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. Industry super user can submit change requests in OMS. Users with this role can receive the PMS API credentials. For further information please refer to EU IG Chapter 1.

Industry User (RMS/OMS) or PUI Industry User (PMS PUI): A logged-in user who represents an industry organisation and who has been approved by the Super User or Admin User of that organisation; i.e. is affiliated to an industry organisation. Industry user can submit change requests in OMS. Users with this role can access PMS PUI but not PMS API.

PUI Industry Qualified User (PMS PUI): this role is available for PMS PUI user registration only. A logged-in user who represents an industry organisation and who has been approved by the Admin User of that organisation; i.e. is affiliated to an industry organisation. User with this assigned role will be able to access and handle the full PMS data set in accordance with permission shown in Figure 4 and as reported in Annex A to Chapter 5. Users with this role can access PMS PUI but not PMS API.

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

Figure 3: User roles versus permissions in RMS/OMS (available to industry stakeholders)

Permissions	Guest User	*Unaffiliated user (temporary role)*	Industry User	Industry Super User
Login to SPOR	not required	required	required	required
View, search RMS/OMS	yes[3]	yes	yes	yes
Download/export RMS/OMS/ data	no	yes	yes	yes

Permissions	Guest User	*Unaffiliated user (temporary role)*	Industry User	Industry Super User
Submit a Change Request (CR) to RMS/OMS data	no	yes, in OMS only	yes	yes
Grant/revoke access to SPOR in the Account Management Portal	no	no	no	yes

Figure 4: User roles versus permissions in PMS (available to industry stakeholders)

Permissions	Guest User	*Unaffiliated user (temporary role)*	IRIS / PLM Industry Admin	PUI Industry User	PUI Qualified Industry User
Login to SPOR	not required	required	required	required	required
View Product	yes[3]	yes	no	yes	yes
Search Product	yes[3]	yes	no	yes	yes
Edit Product	no	no	no	yes	yes
Edit Products in Bulk	no	no	no	no	yes
Clone Product	no	no	no	no	yes
Compare Products	no	no	no	yes	yes
Compare Product Versions	no	no	no	yes	yes
Export Product	no	yes	no	yes	yes
Create Product	no	no	no	no	yes
Delete Draft Product	no	no	no	no	yes
Nullify Product	no	no	no	no	yes
Transfer Product Ownership	no	no	no	no	yes
Grant/revoke access to SPOR API in the Account	no	no	yes	no	no

[3] Public data only

Permissions	Guest User	*Unaffiliated user (temporary role)*	IRIS / PLM Industry Admin	PUI Industry User	PUI Qualified Industry User
Management Portal					

NCA Super User (RMS/OMS) or IRIS / PLM NCA Admin (PMS): This is a logged-in user who works for a national competent authority (NCA) or an organisation acting as a regulatory authority and is responsible for approving access (through IAM) to SPOR/SPOR API 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. Users with this role can receive the PMS API credentials. For further information please refer to EU IG Chapter 1.

NCA User (RMS/OMS) or PUI NCA User (PMS PUI): 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 or Admin User to have access to SPOR/SPOR API. Users with this role can access PMS PUI but not PMS API.

PUI NCA Qualified User (PMS PUI): this role is available for PMS PUI user registration only. A logged-in user who represents an NCA or an organisation acting as a regulatory authority who has been approved by the Admin User of that organisation; i.e. is affiliated to an NCA/regulatory authority organisation. User with this assigned role will be able to access and handle the full PMS data set in accordance with permission shown in Figure 6 and as reported in Annex A to Chapter 5. Users with this role can access PMS PUI but not PMS API.

Note: the PUI NCA Qualified User role will not be available at the time of the PMS go live (31 May 2024). NCA can request the regular PUI NCA User to access the full PMS product data set available.

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

Figure 5: User role versus permissions in RMS/OMS (available to NCA stakeholders)

Permissions	Guest User	*Unaffiliated user (temporary role)*	NCA User	NCA Translator	NCA Super User
Login to SPOR	not required	required	required	required	required
View, search RMS/OMS data	yes	yes	yes	yes	yes
Download RMS/OMS data	no	yes	yes	yes	yes
Submit a Change Request (CR) to RMS/OMS data	no	yes, in OMS only	yes	yes	yes
Perform translations in RMS	no	no	no	yes	no

Permissions	Guest User	*Unaffiliated user (temporary role)*	NCA User	NCA Translator	NCA Super User
Grant/revoke access to SPOR in the Account Management Portal	no	no	no	no	yes

Figure 6: User role versus permissions in PMS (available to NCA stakeholders)

Description	Guest User	*Unaffiliated user (temporary role)*	IRIS / PUI NCA Admin	PUI NCA User	PUI NCA Qualified User
Login to SPOR	required	not required	required	required	required
View Product	yes	yes	no	yes	yes
Search Product	yes	yes	no	yes	yes
Edit Product	no	no	no	no	yes
Edit Products in Bulk	no	no	no	no	yes
Clone Product	no	no	no	no	no
Compare Products	no	yes	no	yes	yes
Compare Product Versions	no	yes	no	yes	yes
Export Product	no	yes	no	yes	yes
Create Product	no	no	no	no	no
Delete Draft Product	no	no	no	no	no
Nullify Product	no	no	no	no	yes
Transfer Product Ownership	no	no	no	no	yes

Description	Guest User	*Unaffiliated user (temporary role)*	IRIS / PUI NCA Admin	PUI NCA User	PUI NCA Qualified User
Grant/revoke access to SPOR API in the Account Management Portal	no	no	yes	no	no

4. Role of Super/ Admin User

It is important to note that the **EMA will approve the 1st Super/Admin User (including Industry or NCA Super users** as well as **IRIS / PUI Industry Admin or IRIS / PUI NCA Admin)** of an organisation and the requestor will have to submit a document named Letter of affiliation that validates their authority to represent that organisation.

This document is also available to download from the document section of OMS portal.

In the absence of such proof, the request will be rejected. 'How to request the 1st SPOR Industry Super User role' document should be followed to apply for the **first Super User.**

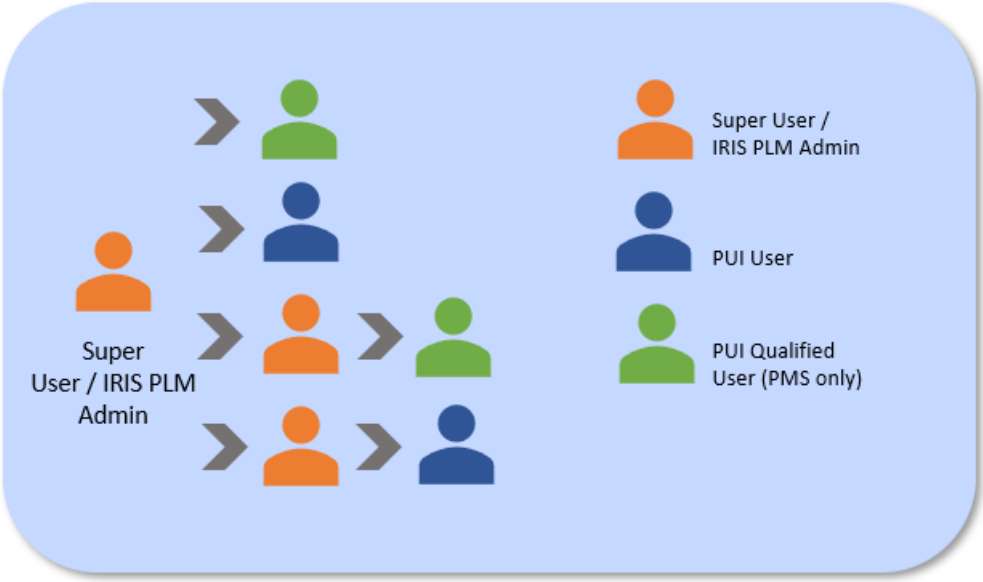
The requestor's organisation Super User will approve any subsequent Super/Admin User/Qualified user/ User access request. The guidance provided in the 'Requests for subsequent SPOR Industry Super User or Industry User access' document should be followed to apply for **subsequent Super User or User** access.

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

It is advisable to read the guidance in conjunction with the 'SPOR User Registration Manual'.

Note: The role IRIS / PLM Industry Admin and IRIS / PLM NCA Admin refers to the previously named IRIS / eAF Industry Admin and IRIS / eAF Competent Authority Admin respectively. Users having this role granted prior the date of PMS go live (31 May 2024) will see their role name updated in their IAM account management platform and do not need to request it again.

Figure 7: Approval of industry users



Note: same process applies to PMS Admin roles.

Summary of Super User accountabilities:

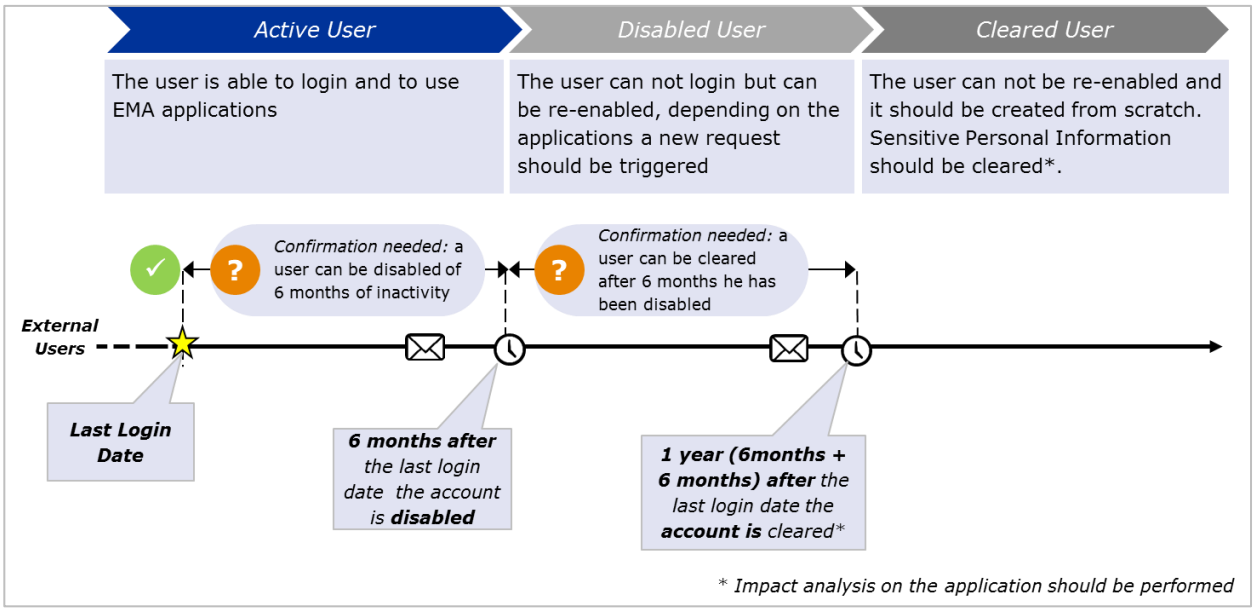
- approval and verification of access for their organisation's users, EMA will **not** check;
- confirmation that all users indeed belong to the organisation before granting access;
- ensuring that there are a sufficient number of Super Users and Users for their organisation;
- as soon as they are informed 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 registered **user** who has been **inactive for 6 months** will be disabled. Users whose access will be disabled will be notified 3 weeks, 1 week and 1 day before their user account will become disabled and asked to log on. If this is not done, the account is disabled.

Once the account is automatically disabled after 6 months of inactivity, the user can **re-activate** the account by using use the "Forgot Password?" process. By re-setting the password, the account will be re-activated and a notification sent to the relevant email address.

The process is outlined in Figure 8 below.

Figure 8: 'Identity cleansing and accuracy – leaver'



5. Managing user populations by company

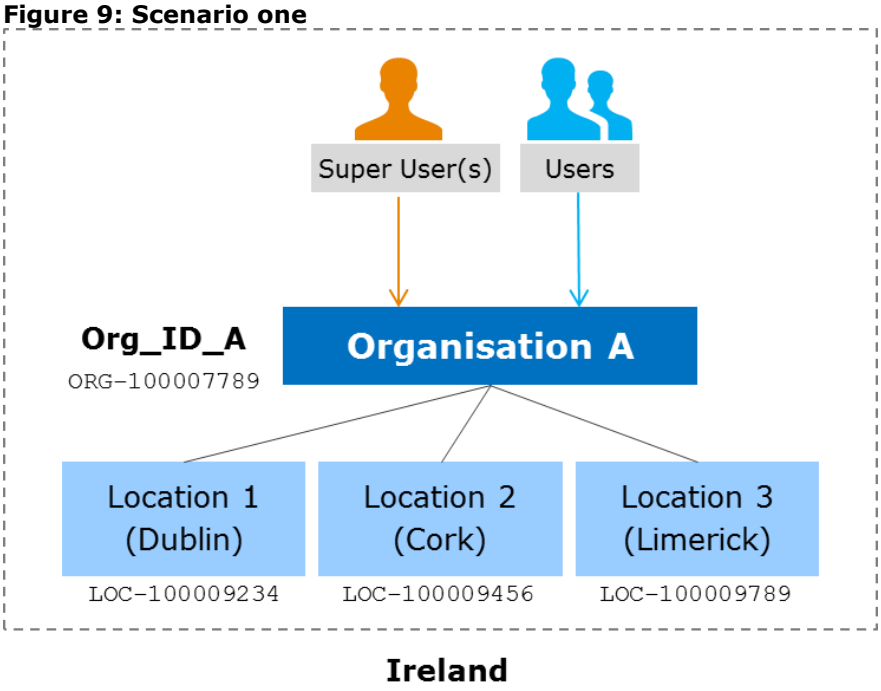
Organisation should decide on their SPOR user population. EMA recommends that each organisation should have **at least two** registered **Super Users** to grant and revoke access to SPOR. An organisation can have **multiple Industry Users**. Such user population can be driven by several factors, for 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 9: Scenario one

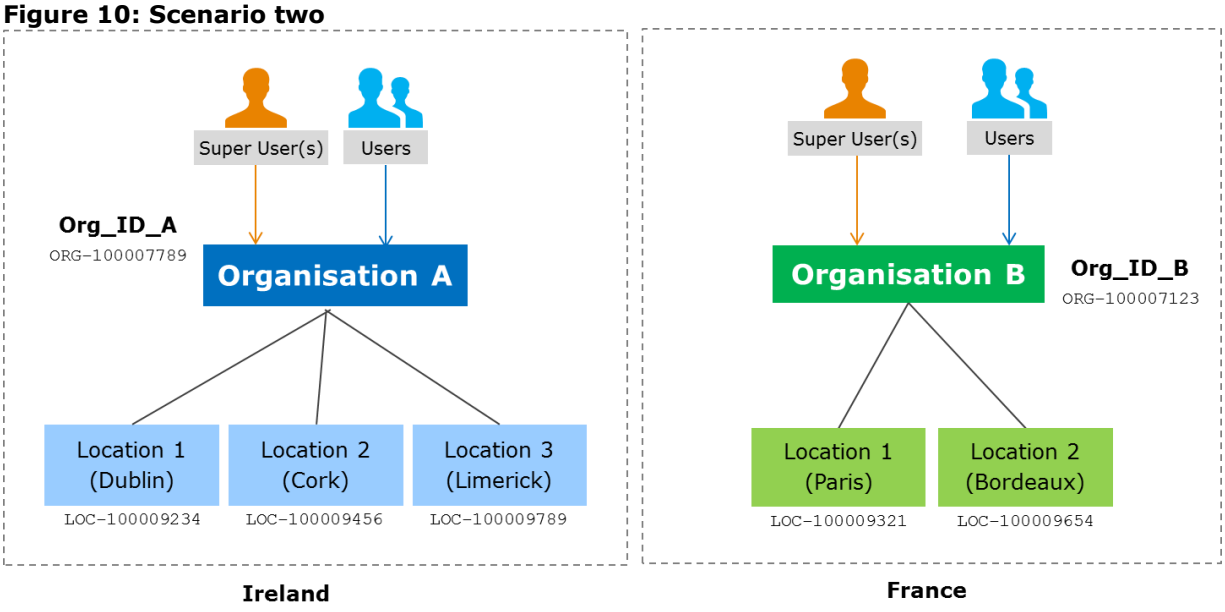


If you are registered already with the EMA Account Management portal, then you can submit requests for Industry User or Industry Super User roles affiliated to a specific organisation. In this example the Industry organisation called 'Organisation A' is identified uniquely by a combination of its Name,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

Figure 10: Scenario two



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

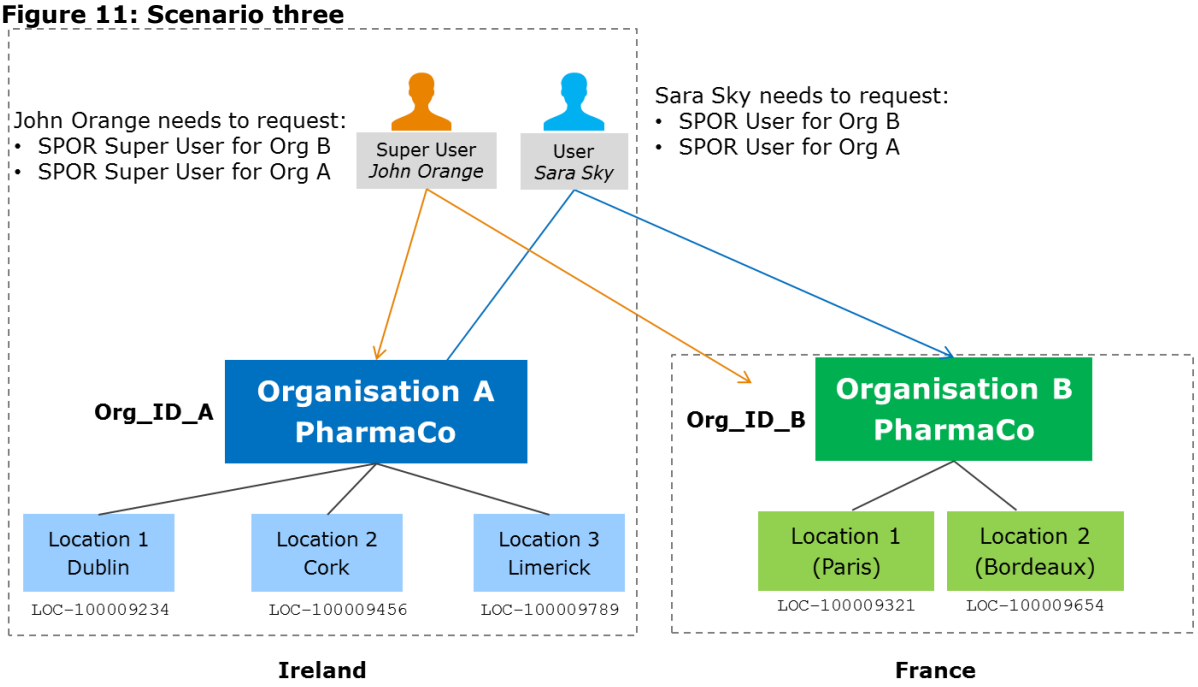
Remember that organisations are identified uniquely by their Name, Country, and Organisation ID. Managing access to user roles require each organisation to appoint people to the *Industry Super User* role. Once they have their first *Industry Super User* then this first super user can approve other requests 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 organisation – shown here as 'Organisation A' and 'Organisation B'.

The first *Industry Super User* at 'Organisation A' in Ireland can grant access to other *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 11: Scenario three



Note: *the name of Organisation_A* is *the same as the name of Organisation_B.*

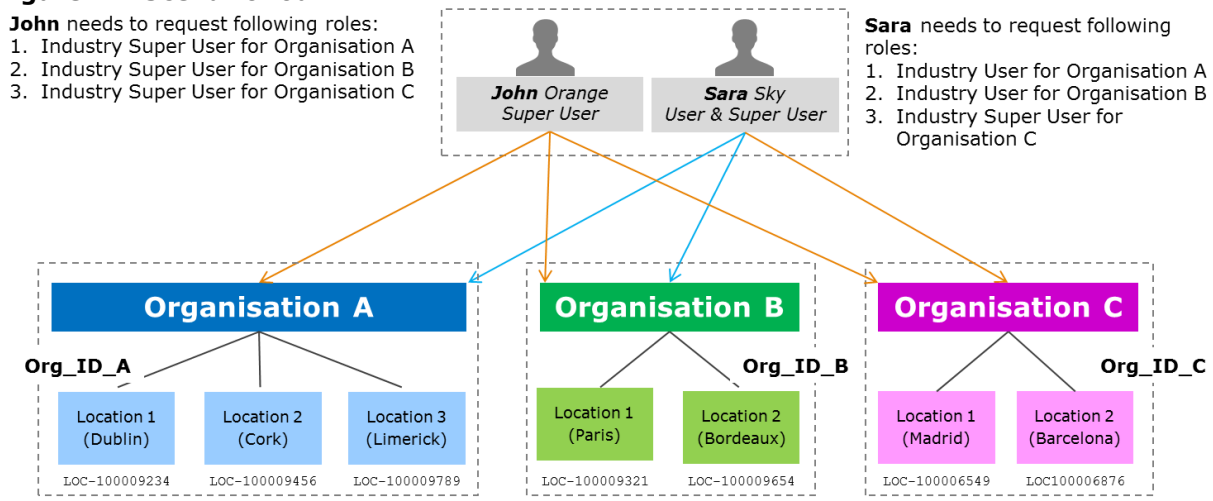
A company may decide to have the same EMA-registered users (*Industry Super User* and *Industry User)* with access for more than one related organisation.

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 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 12: Scenario four



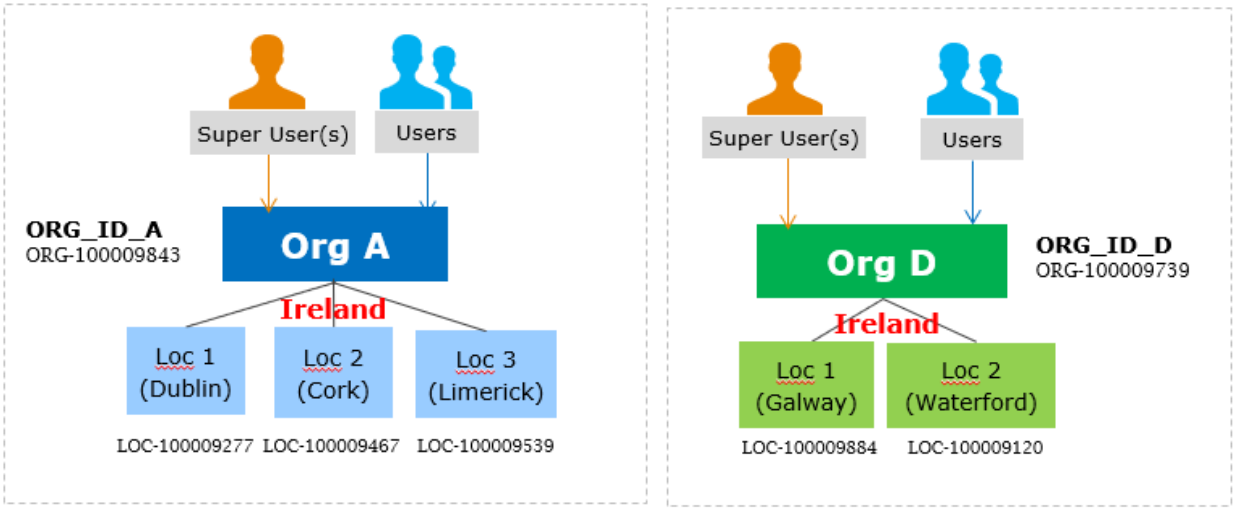
Note: *the name of Organisation A could be the same as the name of Organisation B or Organisation C*

This example illustrates possible arrangements for a third party to manage user roles on behalf of industry organisation. 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 user roles. These could be related organisation within the same global company, or separate organisation in separate companies. OMS does not capture or manage organisation hierarchies.

5.5. Scenario 5 – multiple organisation, different companies

Figure 13: Scenario five



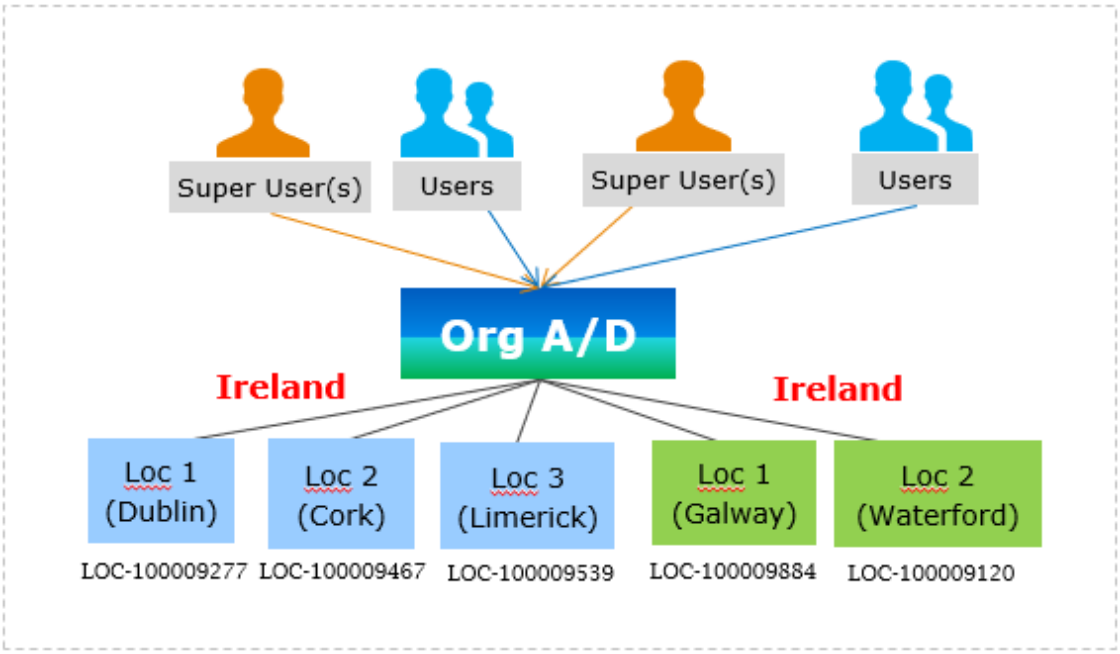
This scenario is similar to the example describe in section 5.1. The only difference is that there are two organisations in this scenario belonging to two different parent companies. Each organisation is identified uniquely by a combination of its Name, Organisation ID, and Country.

As mentioned in section 5.1, to manage the access to user roles require 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 5 illustrates how a company can grant access to *Industry Super Users* and *Industry Users* for their specific organisation – shown here as 'Organisation A' and 'Organisation D'.

5.6. Scenario 6 - merge of multiple organisations, different companies

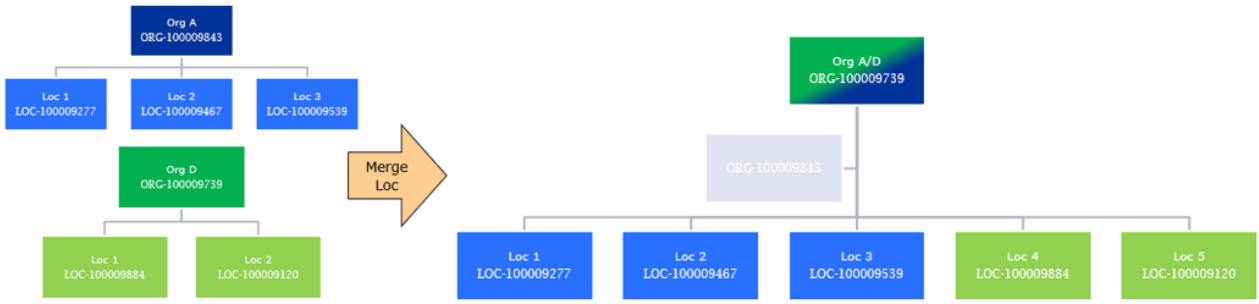
Figure 14: Scenario six



This example illustrates the possibility for two organisations 'Organisation A' and 'Organisation D' (showed in the scenario 5) belonging to two different parent companies to be merged into one organisation 'Organisation A/D'. Each organisation is identified uniquely by a combination of its Name, Organisation ID, and Country. Once merged, the 'Organisation A/D' is identified uniquely by a combination of its Name, Organisation ID and Country referring to one of the two organisations. However, both initial IDs are maintained in the system. In OMS, once 'Organisation A' is merged to 'Organisation D', the lowest in ORG ID value will be displayed and the highest is *hidden.* The other ORG ID of 'Organisation A' can however still be used to retrieve the current Organisation ID (i.e. 'Organisation D') while searching in OMS portal (Figure 15). IAM will intercept the merged organisation in OMS. After the two organisations are merged, both organisations are still visible in IAM; the **non**-surviving organisation display name is marked as MERGED. Access can still be requested for both organisations. User assigned to both organisations retain their access (no changes).

In this example ORG-100009739 has been merged with ORG-100009843 and ORG-100009739 is the *surviving* organisation.

Figure 15: Visibility of OMS ORG IDs following merge



The 'Organisation A/D' will share the Industry User or Industry Super User roles initially affiliated to the two organisations. Once merged, the process to grant access is the same specified in section 5.1 of this document.

This scenario applies in case of acquisition of an entire organisation.

6. User Access to Product Information in PMS

Access to medicinal product data is determined by the organisation which is selected as the owner organisation of the medicinal product in PMS (refer to Product Management Service -Chapter 2: Data elements for the electronic submission of information on medicinal products for human use).

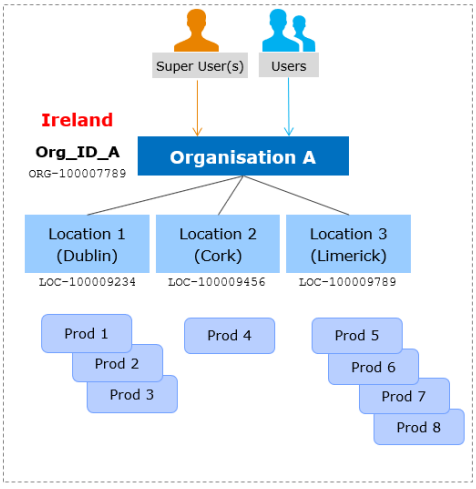
Users affiliated to an organisation, which is also selected as MAH of one or more products in PMS, have access to information of all medicinal products for which this organisation is selected, and are able to conduct different activities permitted by its role type as referred in section 3 of this guide.

Single organisation may be selected as MAH for multiple products. Therefore, a user affiliated to an organisation, which is MAH to multiple products, will have access to the product information of all these products.

Figures below illustrate the previously described scenarios and access to medicinal product information in PMS:

6.1. Scenario 1 - single organisation

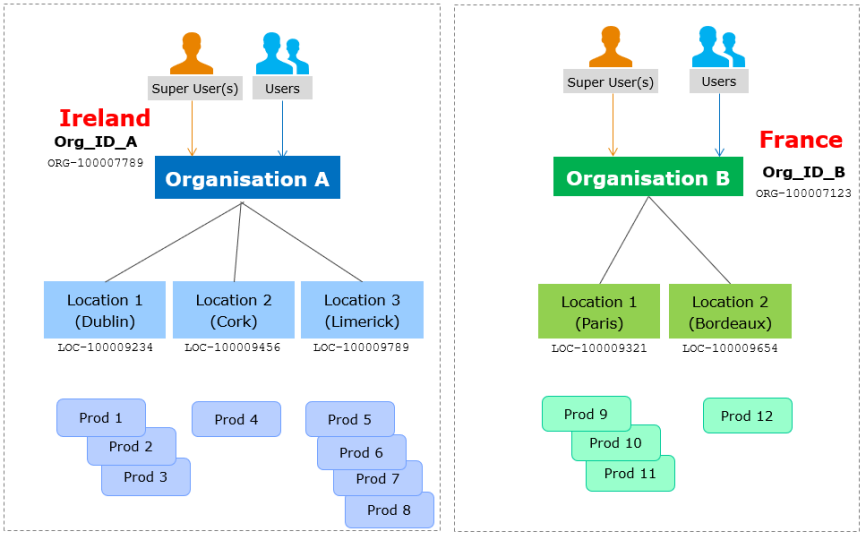
Figure 16: Scenario one



Users affiliated to 'Organisation A' will have access to all medicinal products registered under the same organisation selected as MAH in PMS.

6.2. Scenario 2 - multiple organisations, same company

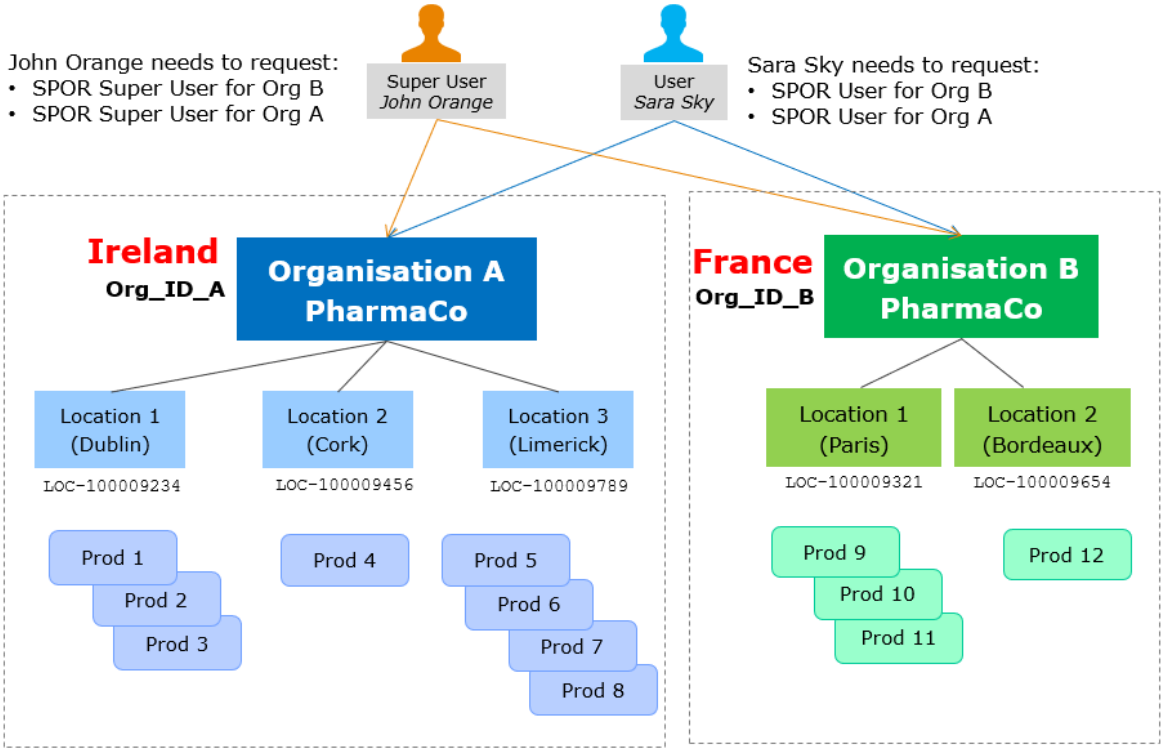
Figure 17: Scenario two



Users affiliated to 'Organisation A' will have access to all medicinal products registered under the same organisation selected as MAH in PMS but not to products in which 'Organisation B' has been selected as MAH, regardless that 'Organisation A' and 'Organisation B' belong to the same parent company or headquarter.

6.3. Scenario 3 - shared Industry Super Users and Industry Users for multinational companies

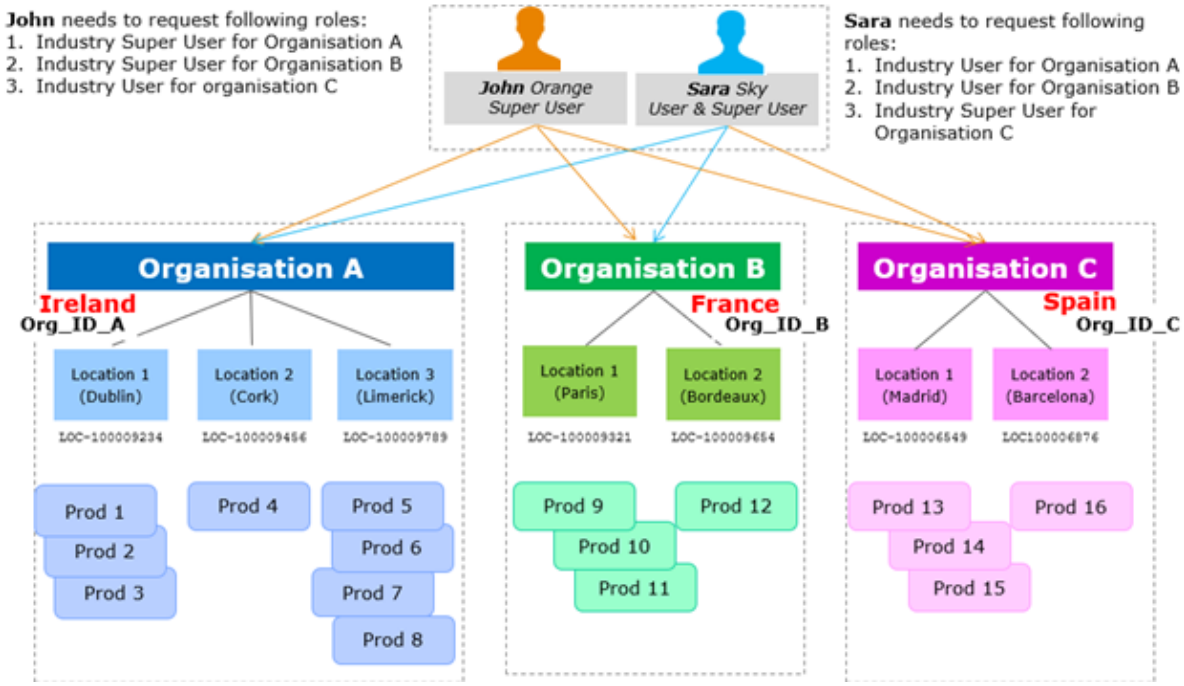
Figure 18: Scenario three



Users may be shared across organisations belonging to the same parent company. In this example, users are affiliated to 'Organisation A' and 'Organisation B' and will have access to all medicinal products registered under those organisations selected as MAH in PMS.

6.4. Scenario 4 - third party service providers

Figure 19: Scenario four



This example illustrates possible arrangements for third-party users to get access and manage medicinal product data (and other SPOR user activities) on behalf of industry organisations. Similarly to previously described scenarios, third party users shared across organisations will have access to medicinal product data in which this organisation is selected as MAH.

6.5. Scenario 5 – updated Industry Super User and User access following transfer between multiple organisations, different companies

Figure 20: Scenario five – Before the transfer of the product ownership

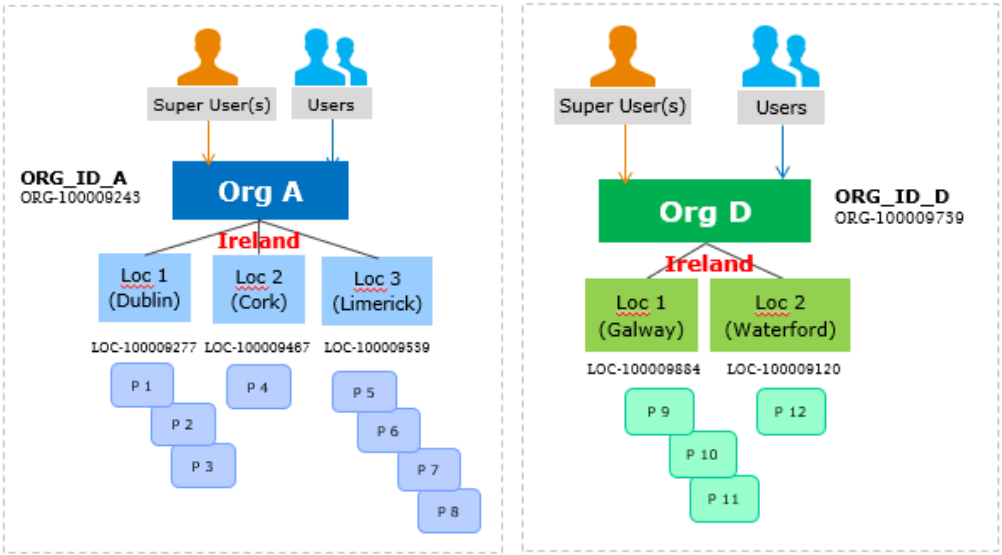
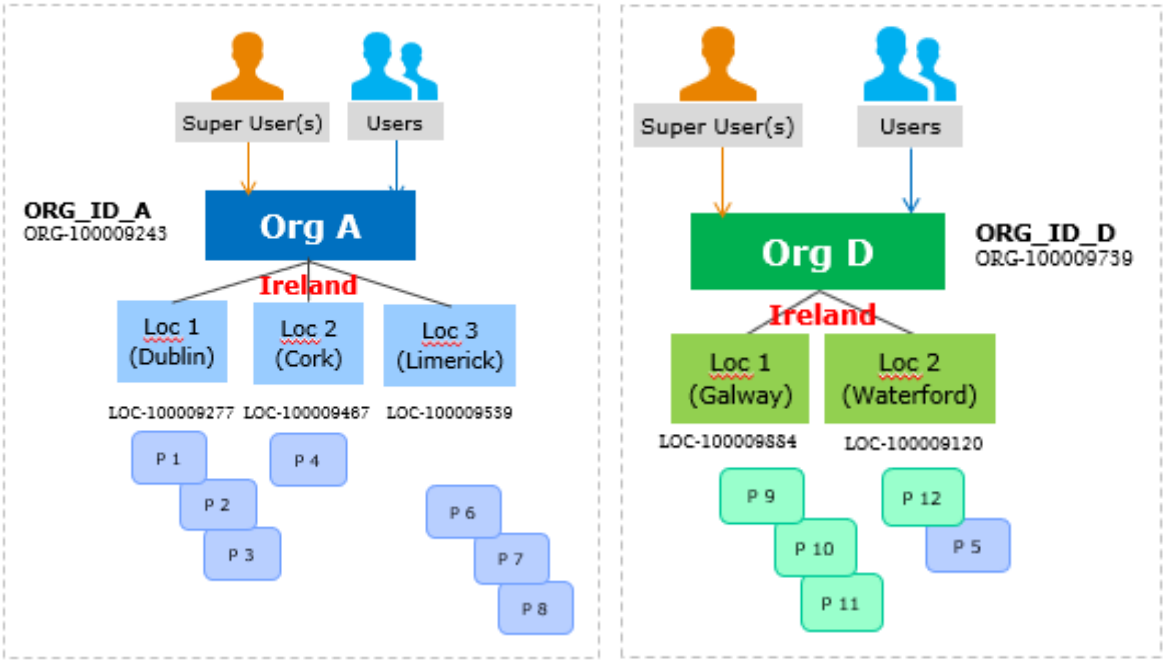


Figure 21: Scenario five – After the transfer of the product ownership



This example illustrates the possibility for a location of 'Organisation A' to transfer the ownership of a medicinal product to another location of a different organisation such as 'Organisation D'.

In such scenario, upon completion of the procedure, users affiliated to 'Organisation A' will no longer be able to have access to the medicinal products transferred to 'Organisation D'. Only users affiliated to 'Organisation D' will have access to the transferred medicinal products in PMS.

6.6. Scenario 6 – shared Industry Super Users and Industry Users following merge of multiple organisations, different companies

Figure 22: Scenario six – Before the merge

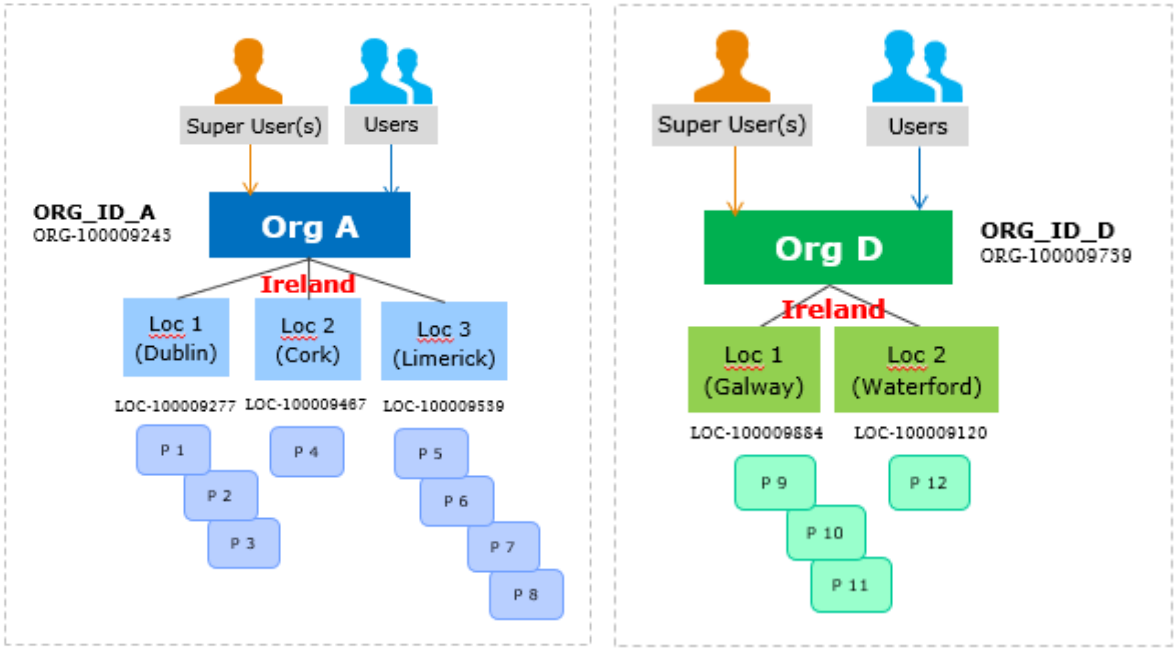
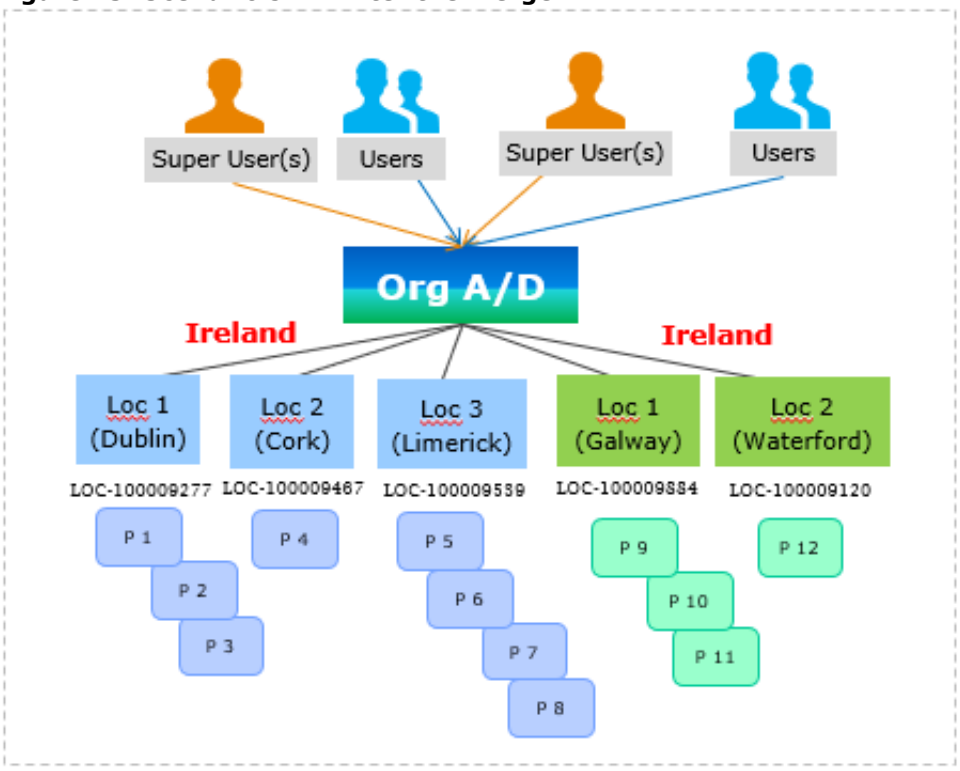


Figure 23: Scenario six – After the merge



In case of a merge of two organisations belonging to two different parent companies into one single organisation, as mentioned in section 5.5., the organisation created as a result of the merge called 'Organisation A/D' will share all users initially affiliated separately to the two different organisations called 'Organisation A' and 'Organisation D'. Users shared across organisations can have access to all medicinal products with the ORG ID in which this organisation is selected as MAH. The ID of 'Organisation A' and the ID of 'Organisation D' will both appear under the same record.

This scenario applies in case of acquisition of an entire organisation.

7. 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 2017-2020 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.