EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Referentials Management Services (RMS) and Organisations Management Services (OMS) – industry on-boarding plan

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1. Launch of Referential Management Service (RMS) and Organisations Management Services (OMS)

The **Referential Management Services** (RMS) and **Organisation Management Services** (OMS) were **deployed to production in June 2017.** They are compliant with IDMP standards ISO11239 and ISO11240. Their scope includes data content, functional capabilities, and a range of services:

- **a single source of Referentials data**, including updated lists from EUTCT[1]. Flat lists have been re-structured to comply fully with ISO data elements, lists have been migrated from EUTCT, and new lists defined to support OMS;
- **a single list of organisations and their physical locations to be used as a reference and to support regulatory activities** (also known as the 'organisation dictionary'). The number of organisations defined in OMS dictionary is increasing daily;
- **Referential and organisation data is accessible via the SPOR web portal[2] and programmatically** via an application programming interface (API);
- **a new process** is in place for industry and National Competent Authorities (NCAs) to register and update both organisation and referential data;
- a specialised team of **EMA Data Stewards** has been established to oversee management of data and to provide support to stakeholders. The overall objective of data stewards will be to apply consistent data quality rules and standards.

The launch of RMS and OMS did not change immediately any regulatory submission processes. EMA has been consulting stakeholders on the benefits of using SPOR services. In future we expect SPOR master data will support regulatory submissions in systems such as the electronic application forms (eAF) and the Common European Single Submission Portal (CESSP)[4]. RMS is integrated already with eAF and OMS integration is planned for December 2017. A minimum period of 6 months will be allowed before the use of RMS and OMS becomes mandatory in any given regulatory procedure.

The SPOR programme is working closely with the eAF team and will provide in advance communications about any changes to the eSubmissions process.

EMA are now inviting NCAs and Industry stakeholders to register their RMS and OMS users, starting with Super Users who can authorise further users from the same organisation.

However, **the timetable is different for different stakeholders.**

National Competent Authorities:

- NCAs registration of SPOR users started in June 2017.

Industry stakeholders:

- are invited to begin registering their **Super Users from 15 December 2017** and **Users from January 2018**.

[1] EUTCT - the European Union Telematics Controlled Terms (EUTCT) System.
[2] SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above).
[4] Integration between SPOR and Telematics systems/applications is subject to availability of resources at EMA and NCAs.

2. Overview of RMS and OMS

2.1. RMS core functionality and services

RMS replaces EUTCT (EU Telematics Controlled Terms) as the central repository and provider of Referentials data for the EU medicines regulatory network (EMRN). RMS includes the following lists of controlled terms:

- lists migrated from EUTCT;
- new lists required for OMS;
- EDQM lists and Units of Measurement (U&M) lists (*these are ISO IDMP standard lists*);
- EudraVigilance lists;

Note: *Substance-related lists remain in EUTCT until the Substance Management Services (SMS) is delivered. Therefore EUTCT should be used only for browsing and downloading the Substances-related lists.*

RMS data can be accessed directly via the RMS web portal (compatible with web browsers Internet Explorer version 10 and above and Chrome version 58 and above), or programmatically via the application programing interface (API). The process for industry to request access to SPOR API will be published on the SPOR portal by the end of November 2017.

Users can perform simple or advanced searches for referentials, view lists and terms, export data and browse translations (and provide translations in the case of NCA users only). They can also set preferences to personalise their RMS experience:

- subscribe to receive notifications of changes to terms and lists;
- tag subsets of referential terms;
- save frequently used searches.

Users can submit change requests for the creation of a new list/term, or request updates of already existing lists/terms. In addition, change requests may be submitted to request deletion of terms.

For more information on RMS functionality please see the **RMS web user manual** published on the SPOR portal. This is available from the 'Documents' tab of the RMS web portal. It includes step-by-step instructions on using the RMS web interface.

2.2. OMS core functionality and services

OMS is a new service that EMA is implementing for the EU medicines regulatory network. OMS will provide a central source of organisation data (OMS dictionary) that consists of lists of organisations with associated physical locations to be used as a reference and in support of EU regulatory activities. The initial content of the OMS dictionary derives from Telematics systems, *i.e.* xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems. Inclusion of data in the OMS dictionary has been divided into sets (see Figure 1. below). EMA will inform stakeholders once each data set has been included in the OMS dictionary.

Organisation data will be structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems, *e.g.* xEVMPD or EudraGMDP organisation IDs. The Location_ID will be unique and will not change even after moving the location under another organisation (if this happens within the same jurisdiction). In the OMS there will be no differentiation between organisations created in the context of a human medicinal product versus a veterinary medicinal product. OMS will not define which role(s) the organisation performs since this depends on the context in which the data will be used, *e.g.* in theory an organisation can act as an MAH (Marketing Authorisation Holder) in the context of one medicinal product but as a sponsor or manufacturer for another medicinal product.

Organisations are categorised by **Type:** 'Industry', 'Regulatory authority', 'Educational institution', 'Health care', *etc*. or by **Size**: SME as 'Micro', 'Small' or 'Medium'.

OMS data can be accessed directly via the OMS web portal (compatible with web browsers Internet Explorer version 10 and above and Chrome version 58 and above), or programmatically via the application programing interface (API). The process for industry to request access to SPOR API will be published on the SPOR portal by the end of November 2017.

Users will be able to search for organisations and locations and view details of organisations and locations. The search is based on exact character matching. This applies to all search fields. For example, if searching for "Székesfehérvár", special characters "é" and "á" will need to be used. Once the search is run, default sort order will be Organisation ID, Organisation Name, and then Country.

Search is a starting point for the user to request changes to the organisation data. The following options are available:

- if the user is not able to find the requested organisation – defined by name in a given country – they can request **creation of a new organisation;**
- if the organisation is found, but the required location is not found, the requestor needs to submit a request to **add a new location to the existing organisation;**
- alternatively, a user locates an existing organisation and location, but determines that the **organisation and/or location need to be changed**.

In OMS the preferred language is English. Organisation and location details can also be entered in other EEA official languages but the system will supplement the English address data with the transcription into the local language(s) where possible. For organisation names, multiple names can be stored in the form of alternative names, which can be in other languages (non-English) as well.

For more information on OMS functionality please see the **OMS web user manual**. This is available from the 'Documents' tab of the OMS web portal. It includes step-by-step instructions on using the OMS web interface.

Figure 1. Data sets to be included in the OMS dictionary

Data sets for the OMS Content
Data set 1: Marketing Authorisation Holders (MAHs): Human (H) + Veterinary (V) Centrally Authorised Products (CAPs) and Human (H) Nationally Authorised Products (NAPs); • Marketing Authorisation Applicants (MAAs): (H+V) CAPs; • Maximum Residue Limit (MRL) applicants (Veterinary).

Data sets for the OMS Content
Data set 2: • Sponsors (H) CAPs and NAPs.
Data set 3: • Manufacturers (H+V) CAPs.
Data set 4: Manufacturers (H+V) NAPs.
Additional Organisation data will be published in the future and the prioritisation of its inclusion in the dictionary will be defined at a later stage: • Veterinary MAHs for NAPs; • Contract Research Organisations (CROs); • Clinical trials sites; • Academia; • Hospitals; • Wholesale distributers; • MAA/MAH and manufacturers in the context of herbal and homeopathic medicinal products or compassionate use medicinal products; • QPPV (Qualified Person for Pharmacovigilance).

2.3. RMS and OMS Service Level Agreements (SLAs)

RMS and OMS SLAs are indicative and set up based on experience. SPOR Data Stewards aim to validate RMS requests within 2-5 working days and approve it within 1-2 months (depending on the list).

As for the OMS standard requests, these aim to be approved within 5 working days.

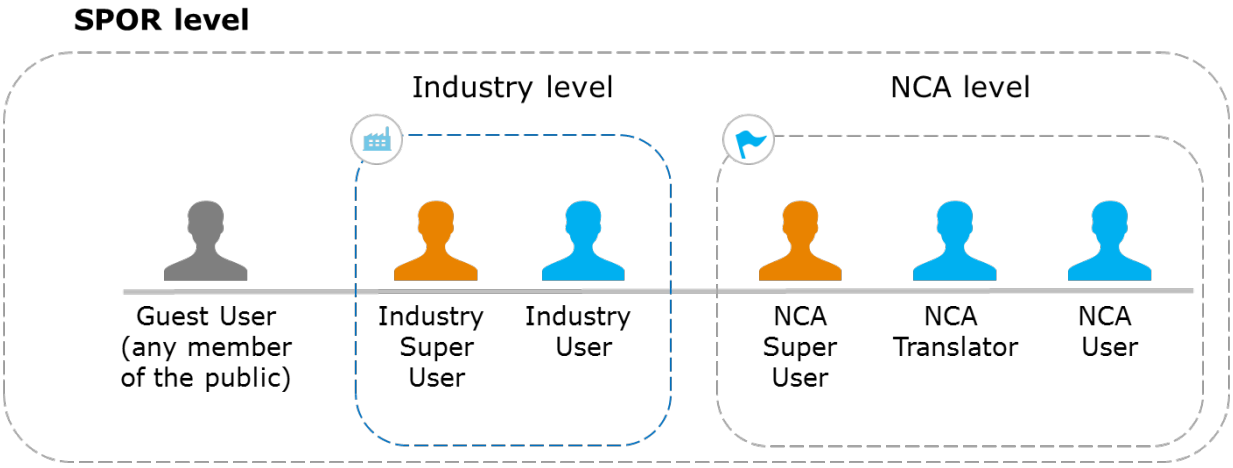
In future the SLAs will be reviewed as these are new services where the workload still needs to be verified.

More information about SPOR service levels is included in the “SPOR Service Level Agreements” document available from either the RMS web portal or OMS web portal under the ‘Documents’ tab.

3. SPOR user roles

Referential and organisation data is accessible via the SPOR web portal. Any member of the public (as a guest user) can view and search publically-available data (RMS: public lists, OMS: all content) without having to login. In order to request changes and updates to existing organisation or referential data, users must be registered with the EMA Account Management portal (a central point to manage access to EMA systems, including SPOR) and have a relevant SPOR user role(s). These users will need to be affiliated to a specific industry or NCA organisation. The user types are illustrated in Figure 2. and explained briefly below.

Figure 2. SPOR user roles



Guest User – a user who does not require login credentials (username and password) to access the SPOR portal. They can view and search publically available data (RMS public lists; OMS all content).

Industry Super User – is a logged-in user that can approve on behalf of their own organisation other users' requests for access to SPOR. A Super User needs to ensure that the correct users are assigned SPOR roles in their organisation. This user role also includes the revocation of these roles should the user no longer represent their organisation. Approval of users is done via the EMA Account Management portal.

It is important to note that the **first Super User** of an organisation will have to submit documents that validate their authority to represent that organisation. In the absence of such proof, the request will be rejected by EMA. Submission of such documents needs to be via the EMA Service Desk portal[1].

In terms of access to SPOR functionality, Industry Super Users have the same access as a standard Industry User who can view, search, download public data (RMS – public lists; OMS – all content), and submit change requests.

When the first Super User does not find the organisation available in the EMA Account Management portal, they should request 'unaffiliated user role' before attempting to submit a change request in OMS to add this organisation. The provision of this unaffiliated user role is automatic at the time of the request.

Industry User – is a logged-in user who represents an industry organisation and who has been approved by the Super User of that organisation, *i.e.* affiliated or linked to an industry organisation. A request for an Industry User role must be submitted via the EMA Account Management portal[2]. In terms of functionality, an Industry User may view and download public data (RMS public lists; OMS all content). They can also submit change requests on behalf of the organisation to which they are affiliated. It is important to verify that your organisation has a Super User **before** submitting a request via EMA Account Management portal. If your organisation does not have one, the request will be rejected by EMA.

[1] Online EMA Service Desk for Information Technology (IT) systems.
[2] Central point to manage access to EMA systems, including SPOR.

NCA Super User – this is a logged-in user who works for a NCA (or an organisation acting as a regulatory authority) and is responsible on behalf of their organisation for approving access to SPOR for other users. A NCA Super User will need to ensure that only the right users are assigned SPOR roles against their organisation. This user role also includes the revocation of these roles should the user no longer represent their organisation. In terms of SPOR, a Super User is a standard user who can view, search, download data, or submit change requests. Approval of users is done via the EMA Account Management portal.

NCA User - is a logged-in user who works for a National Competent Authority (NCA) or an organisation acting as a regulatory authority and has been approved by the NCA Super User to have access to SPOR. An NCA User will be able to view/download public and restricted data and request changes to RMS and OMS data by submitting a change request on behalf of their organisation. This role will be approved by the NCA Super User of the organisation via the EMA Account Management portal.
It is important to verify that the organisation has a Super User before submitting a request via the EMA Account Management portal. If the organisation does not have one then EMA will reject the request.

NCA Translator – is a logged-in user affiliated to a NCA. If the user is requesting the role of a NCA Translator they must also specify the language for which they will be providing translations, in addition to their organisation's name. Having a NCA User role is not sufficient to allow a user to perform translations; the specific role of NCA Translator must be requested via the EMA Account Management portal.

For more information about SPOR user roles please refer to the SPOR user registration manual, which is available from either the RMS web portal or OMS web portal under the 'Documents' tab.

3.1. SPOR user roles and functionality

Each role allows users to perform a set of tasks. A summary of SPOR user roles and their access to functionality is shown below in Figure 3.

For more comprehensive information on OMS and RMS functionalities please refer to the RMS web user manual and OMS web user manual, which are available from either the RMS web portal or OMS web portal under the 'Documents' tab.

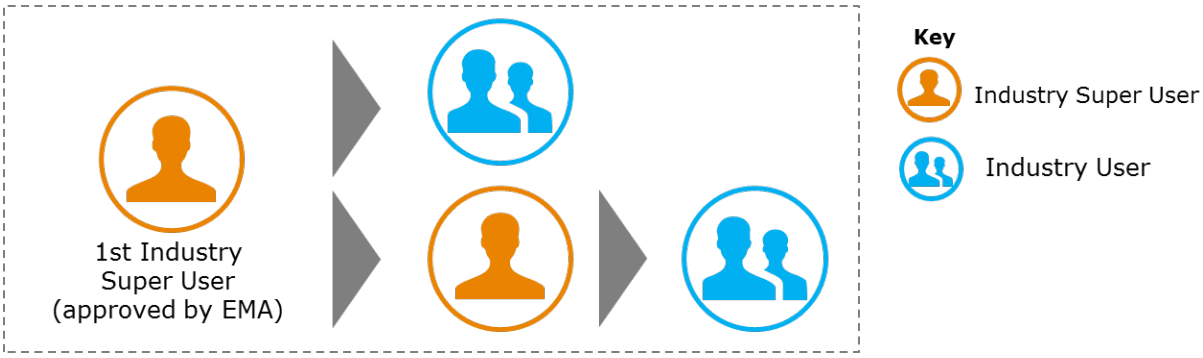
Figure 3. SPOR user roles and functionality

	Guest User	Industry Super User	Industry User	NCA User	NCA Translator	NCA Super User
Login	Login not required	Login required	Login required	Login required	Login required	Login required
View Public data	Yes	Yes	Yes	Yes	Yes	Yes
View Restricted data	No	No	No	Yes	Yes	Yes
Search data	Yes	Yes	Yes	Yes	Yes	Yes
Download data	No	Yes	Yes	Yes	Yes	Yes
Submit Change Request (CR)	No	Yes	Yes	Yes	Yes	Yes

	Guest User	Industry Super User	Industry User	NCA User	NCA Translator	NCA Super User
Translations	No	No	No	No	Yes	No
Permission to authorise users	No	**Can authorise Industry Users**	No	No	No	**Can authorise NCA Users**

3.2. Role of the Industry Super Users

For each industry organisation, EMA will approve the first Industry Super User. Any subsequent Super User or User access requests will be approved by the Super User of the requestor's organisation. Super Users are accountable on behalf of their organisations for approving roles and EMA will **not** check.



Super User accountabilities are:

- approve and verify access for the Users in their organisation;
- confirm that the Users indeed belong to the organisation before granting them access;
- ensure there are a sufficient number of SPOR Super Users (at least two recommended) and Users per organisation;
- once the Super User or User leaves the organisation, the Super User needs to inactivate their SPOR access in the EMA Account Management Portal.

4. Managing user populations by company

In the EMA Account Management portal, an account can have *either* Industry *or* NCA user roles, but not both. Once an account with EMA is verified, requests for access to SPOR roles (Industry Super User, Industry User) can be made for multiple organisations.

Managing multiple organisations as a Super User requires multiple Industry Super User roles with the correct organisation affiliations. Users will need to submit individual access requests for each of their roles.

Each of the Industry User access requests will be approved by the respective Super User of the organisation for which the role is requested (unless it is the first Super User for this organisation, in which case EMA would approve).

It is recommended that each organisation should have at least two registered Industry Super Users. An organisation can also have multiple Industry Users. An industry company may have different subsidiary organisations, each with its own organisation ID.

Company structures and hierarchies are not defined in OMS – for example, there is no recognition of Headquarters (HQ) or Affiliates.

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

- business needs;
- processes and policies with regard to granting access;
- overall number of products;
- some companies may outsource regulatory affairs to third party service providers;
- each organisation must decide on the numbers of SPOR roles that have access to SPOR on their behalf;
- there can be different approaches. Examples of approaches are shown below.

Figure 4. Scenario 1

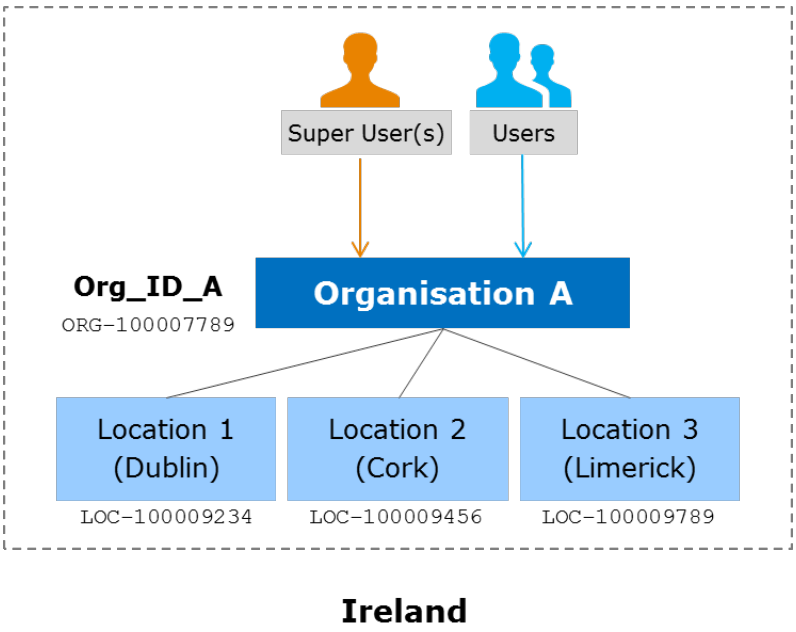
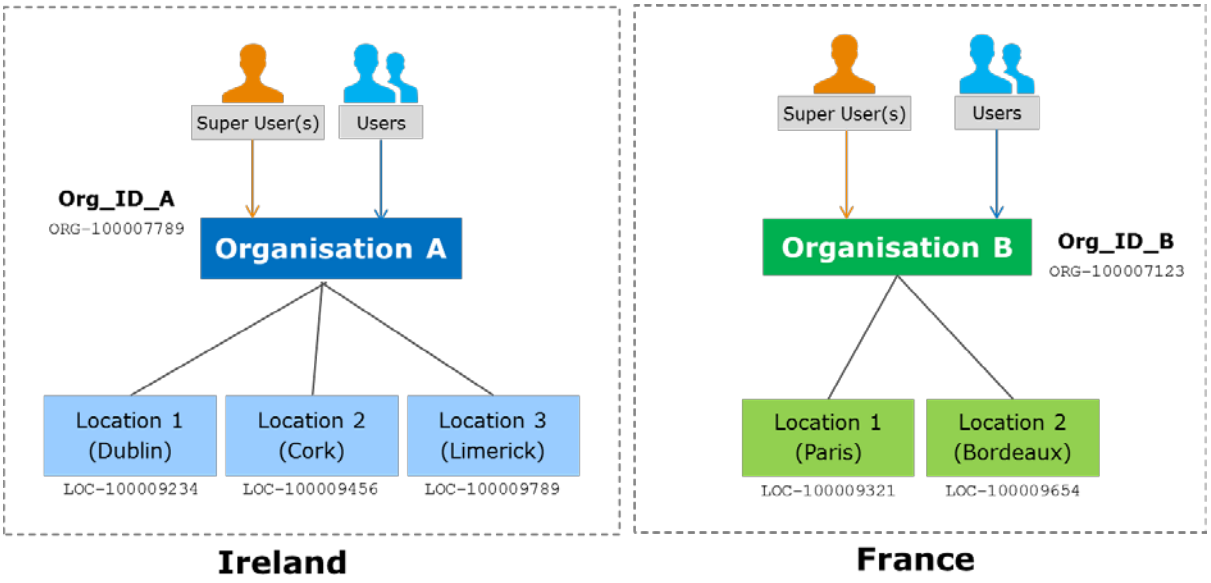
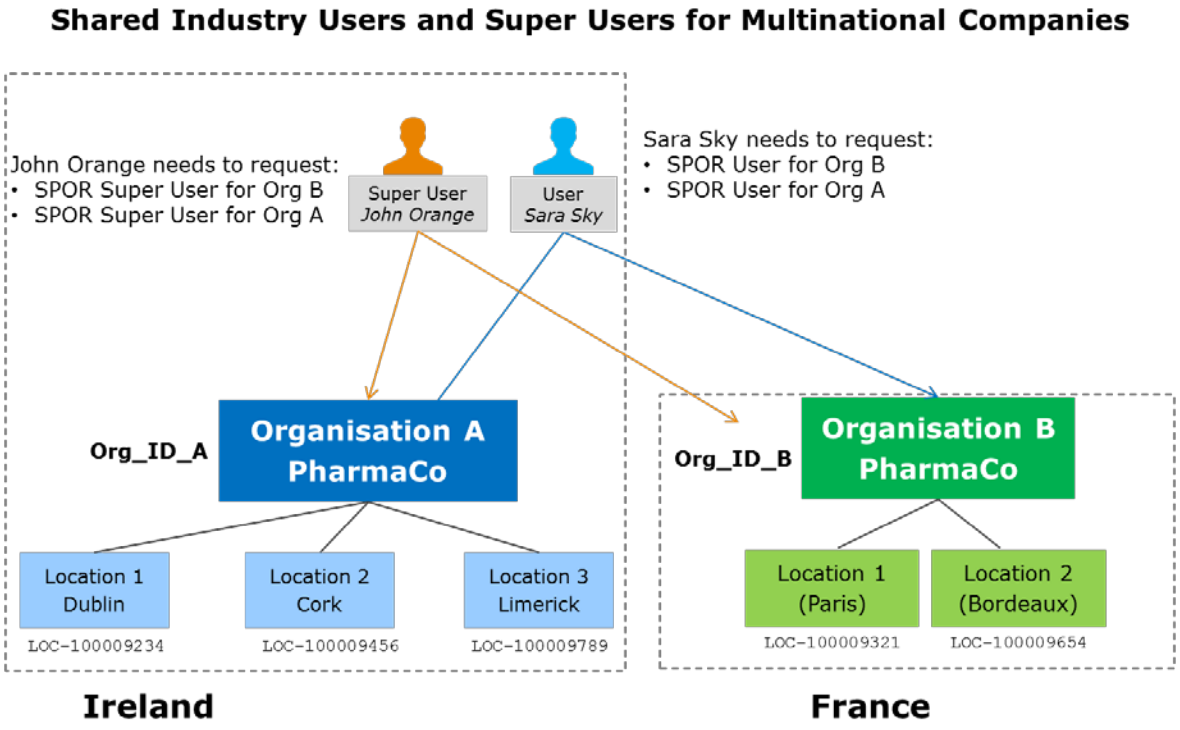


Figure 5. Scenario 2



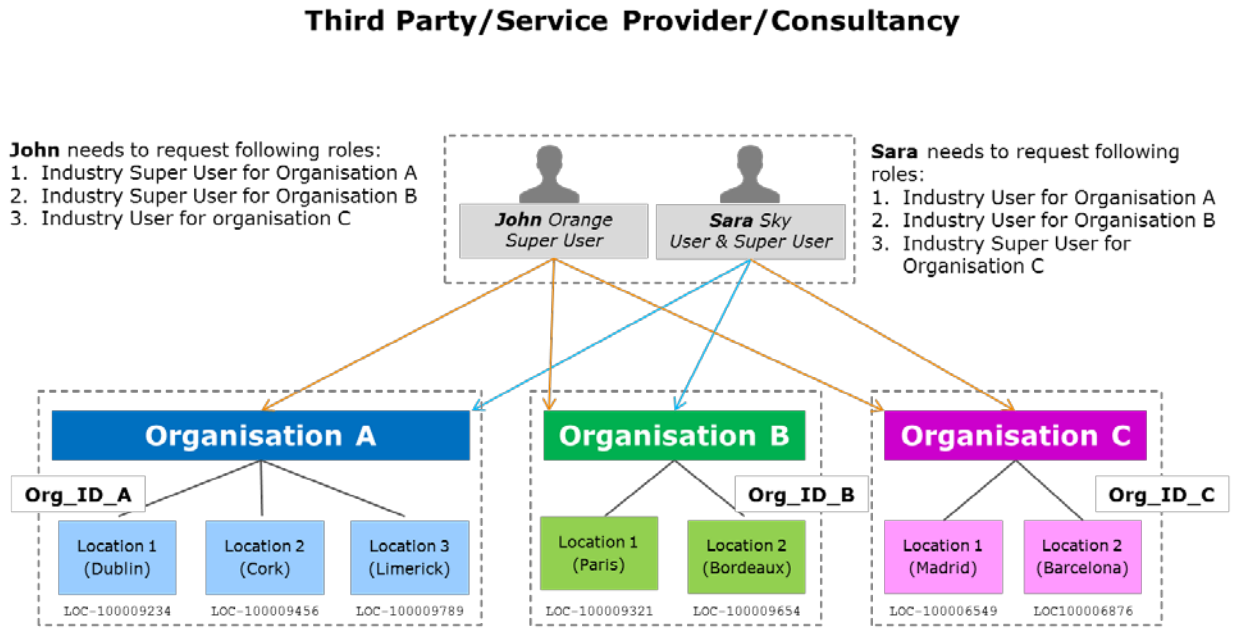
Note: the name of Organisation A can be the same as the name of Organisation B

Figure 6. Scenario 3



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

Figure 7. Scenario 4



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

5. Summary of RMS and OMS milestones and impacts Q4 2017 – Q1 2018

EMA Data Stewards continue working to expand the content of the OMS dictionary (*OMS dictionary – list of organisations with associated locations*). The number of organisations defined in OMS is increasing daily. **EMA will inform stakeholders when additional data sets have been included in the OMS dictionary.**

OMS and RMS release 2.2 went live in October 2017. The scope of this release includes functionality enhancements to RMS and OMS, and some bug fixes. The final OMS and RMS release 2.3 is planned for December 2017, which will address outcomes from OMS user acceptance testing held in September 2017.

Consultation is taking place with the Electronic Application Form (eAF) group to prioritise and plan for eAF integration with OMS (eAF is already integrated with EUTCT/RMS). Integration of eAF with OMS is scheduled to be implemented from December 2017. A **minimum period of 6 months** will be allowed after go-live before the use of RMS and OMS becomes mandatory in any given regulatory procedure.

Changes in the Article 57 submission process are also being discussed with the Article 57 Implementation Working Group (IWG). OMS and RMS integration with Article 57, envisaged initially for the end of 2017, is now planned for Q4 2018 in order to minimise disruption to the ongoing ADR project planned for go-live in November 2017 and also to align with the PMS first release planned for 2018.

5.1. RMS and OMS industry user on-boarding

In June 2017 National Competent Authorities were invited by EMA to register their SPOR users, starting with 'Super Users' who can then authorise the registration of additional users from the same organisation. NCAs were encouraged to start using RMS from June 2017 as the replacement for EUTCT.

Industry stakeholders:

- are invited to begin registering their **Super Users from 15 December 2017** and **Users from January 2018**.

5.2. eAF integration with OMS

OMS will be integrated in all four electronic application forms for all address fields in eAF release v1.22.0.0, planned to go-live on 15 December 2017.

The use of OMS in the eAF will be initially optional, however, applicants are advised to perform a search from within the form to familiarise themselves with the use of OMS and to ensure that they are familiar with the process before its use becomes mandatory.

Two outcomes are possible after searching for an organisation:

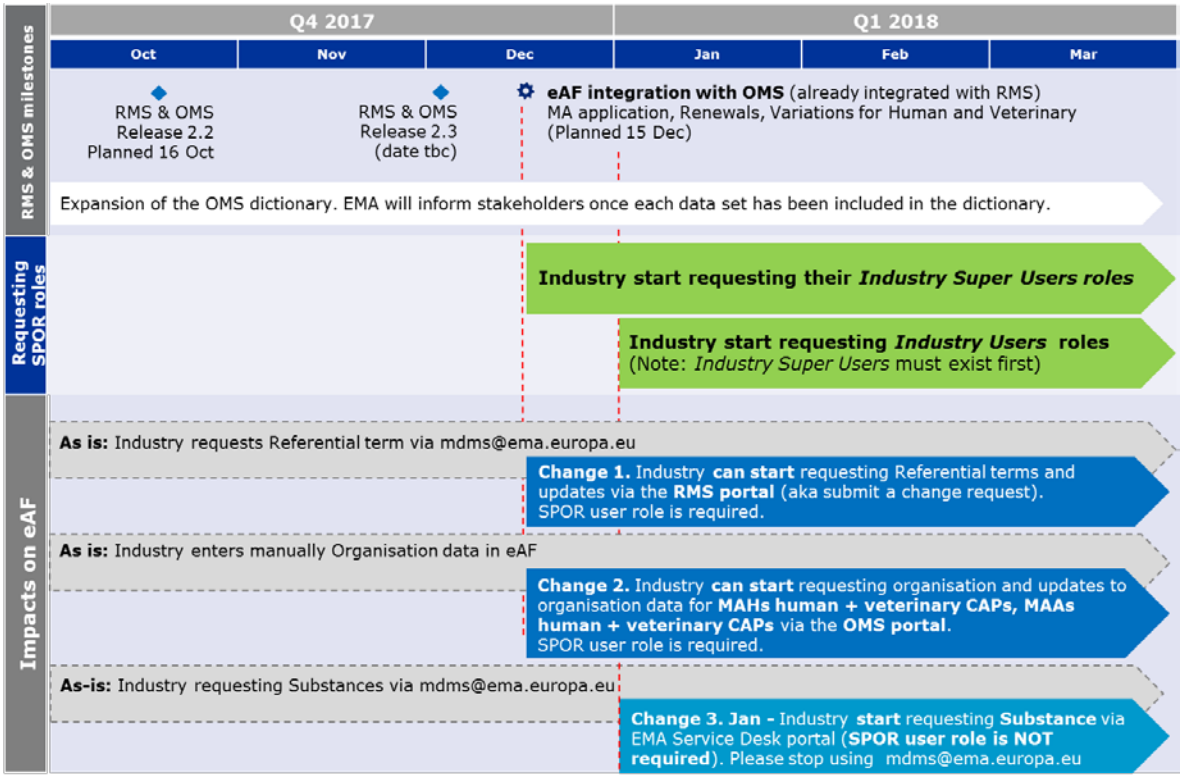
1. If the **address/location is not found or is incorrect**, users can enter manually the address details using free text fields, as previously in the eAF. However, users are advised to follow the OMS process to submit requests for adding or amending organisation data;
2. If the **address/location is correct**, users may proceed using the OMS-provided data.

As of January 2018, in the context of human medicinal products, Marketing Authorisation Holders (MAHs) are expected to be available in the OMS dictionary; stakeholders are asked to start submitting the relevant OMS change requests for new or updated organisations and addresses. This also applies to MAHs for veterinary Centrally Authorised Products (CAPs).

In the context of veterinary medicinal products, MAHs for Nationally Authorised Products (NAPs) will not be included in the initial OMS dictionary content. Before the eAF integration with OMS go-live, EMA will provide further guidance on how these organisations can be included in the OMS.

As publication of Manufacturers in the OMS dictionary is planned to be completed by Q3 2018, stakeholders are asked not to submit OMS change requests for Manufacturer organisations until EMA has communicated that this data set has been added to the dictionary.

Figure 8. RMS and OMS related milestones



6. Key messages and actions for industry stakeholders

- Raise awareness of SPOR amongst your colleagues, especially those involved with regulatory submissions and Referentials data management;
- Review the EMA Account Registration rules and the SPOR documentation (available via the SPOR portal) to understand how they apply to your own organisations;
- Consider how you will appoint Industry Super Users and Industry Users – the scenarios provided above may help you to consider the best options for your own organisations;
- Consult with colleagues, perhaps from related departments and organisations within your own company, to agree how you will authorise and maintain SPOR user roles;
- Industry stakeholders should be ready to start registering their first Industry Super User roles from December 2017 (note: for each industry organisation, EMA will approve the first Super Industry User);
  - any subsequent Super User or User access requests will be approved by the Super User of the requestor's organisation.
- Integration of eAF with OMS is scheduled to go-live on 15 December 2017. (eAF is already integrated with EUTCT/RMS);
- A minimum period of 6 months will be allowed after go-live before the use of RMS and OMS becomes mandatory in any given regulatory procedure.