EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

RMS & OMS – Industry on-boarding to SPOR Webinar with Industry Change Liaisons

Webinar 04 October 2017

Agenda

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- RMS & OMS related milestones
- eAF-OMS integration
- Overview of SPOR user roles and process flow for requesting a SPOR role
  - Overview of SPOR user roles
  - Role of the Industry Super User
  - Managing user populations by a company (different scenarios)
  - Registering 1st Industry Super User
  - Registering Additional Industry Super Users
  - Add Organisations & Attach Documents
- SPOR Help & Support
- Upcoming communications/events
- Key Messages & Actions

NOTE:

Slide deck updated since 04/10/2017

Minor updates on slides: 4, 5, 6, 13, 14, 28, 32.

RMS & OMS related milestones

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RMS & OMS milestones

Q4 2017			Q1 2018		
Oct	Nov	Dec	Jan	Feb	Mar

- RMS & OMS Release 2.2 *(16 Oct 2017)*
- RMS & OMS Release 2.3 (*date tbc*)
- **eAF integration with OMS** (already integrated with RMS) MA application, Renewals, Variations for Human and Veterinary (*planned 15 Dec 2017*)

Expansion of the OMS dictionary. EMA will inform stakeholders once each data set has been included in the dictionary.

Requesting SPOR roles

Industry start requesting *Industry Super Users* roles

Industry start requesting *Industry Users* roles
(Note: *Industry Super Users* must exist first)

Impacts on eAF

As is: Industry requests Referential term via mdms@ema.europa.eu

Change 1. Industry **can start** requesting Referential terms and updates via the **RMS portal** (aka submit a change request). SPOR user role is required.

As is: Industry enters manually Organisation data in eAF

Change 2. Industry **can start** requesting organisation and updates to organisation data for **MAHs human + veterinary CAPs, MAAs human + veterinary CAPs** via the **OMS portal**. SPOR user role is required.

As-is: Industry requesting Substances via mdms@ema.europa.eu

Change 3. January - Industry **start** requesting **Substance** via EMA Service Desk portal (**SPOR user role is NOT required**). Please stop using mdms@ema.europa.eu

RMS & OMS Related Milestones

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- EMA Data Stewards continue working to expand the content of the OMS dictionary *(OMS dictionary provides a list of organisations with associated locations).*
- OMS & RMS release **2.2 is live**; scope includes **functionality enhancements** and **bug fixes**:

  RMS: EDQM deltas, improved subscriptions.

  OMS: Web portal functionality (CRs, improved export) and data management.
- **OMS & RMS release 2.3**, planned for **December 2017**, will address the OMS UAT from September 2017.
- **Process** to access SPOR application programming interface (**API)** to support your API development will be communicated in November 2017.
- **eAF integration with OMS** is planned for **15 December 2017.**
  - RMS is integrated already with eAF via the Backward Compatible API.
- EMA will invite Industry to begin registering their Super Users and Users in December 2017, and commence use of RMS and OMS.
  - This aligns with eAF release v1.22.0.0 going live 15 December 2017.

eAF-OMS integration

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- OMS will be integrated in all four forms, for all address fields, in the eAF release v1.22.0.0 going live 15 December 2017.
- The use of OMS in the eAF will be initially optional. However, applicants are strongly recommended to perform a search in the form to familiarise themselves with the use of OMS and to ensure they are familiar with the process before any mandatory use:
  1. If the address is not found it is possible to clear the address and provide the details using free text fields as previously.
  2. If the address/location is not found, the user is advised to follow the new OMS process to request that a new organisation is added.
  3. If the address/location is not correct, the user is advised to follow the new OMS process to request updates to organisation/location data.
- **Please observe the OMS guidance on which types of addresses are available**, *e.g.* please avoid submitting OMS change requests to Manufacturer addresses until this OMS dataset is publicly available.

eAF-OMS integration – mock up

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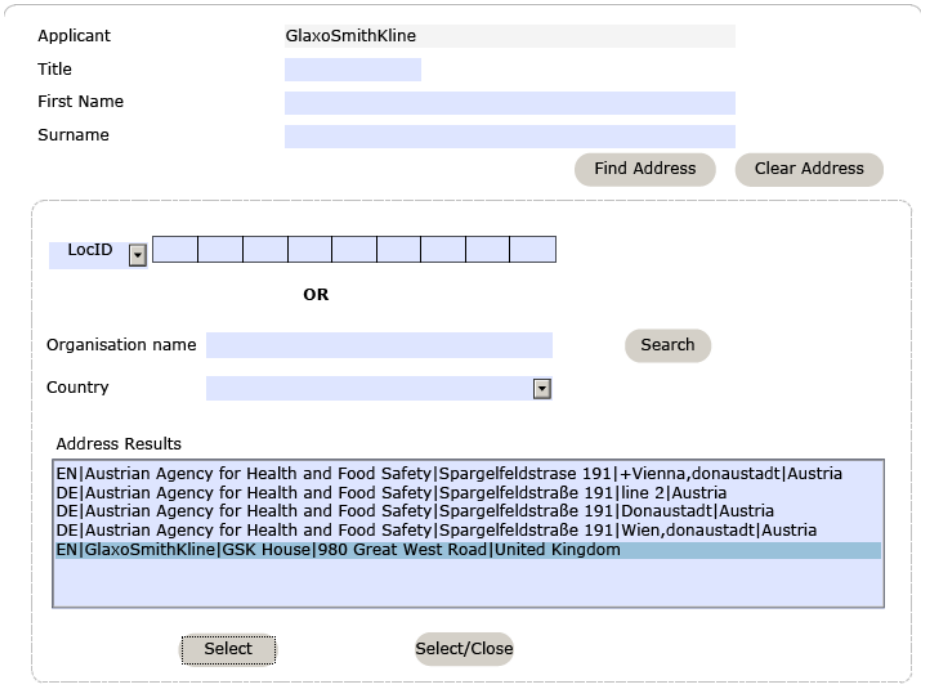
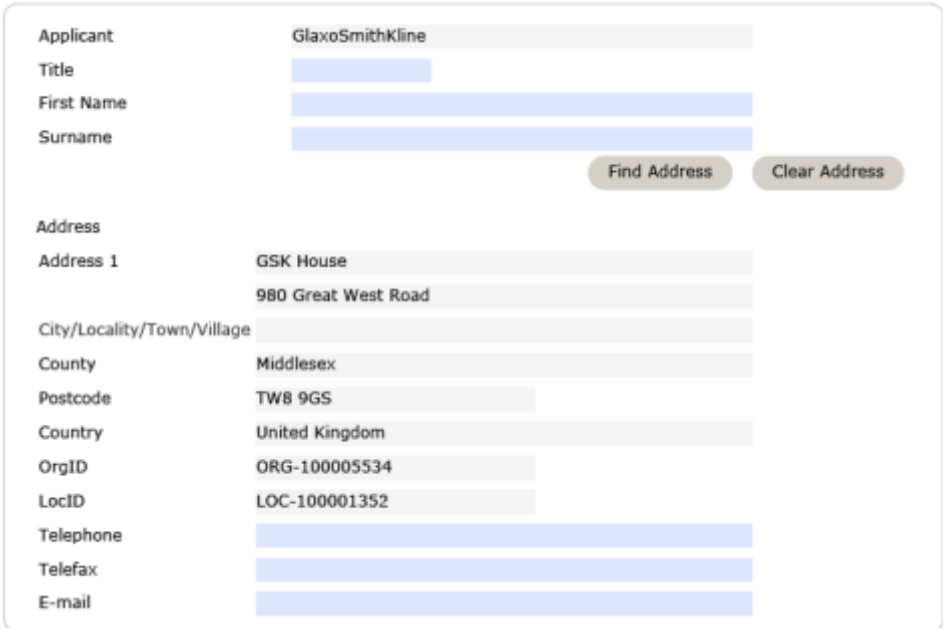


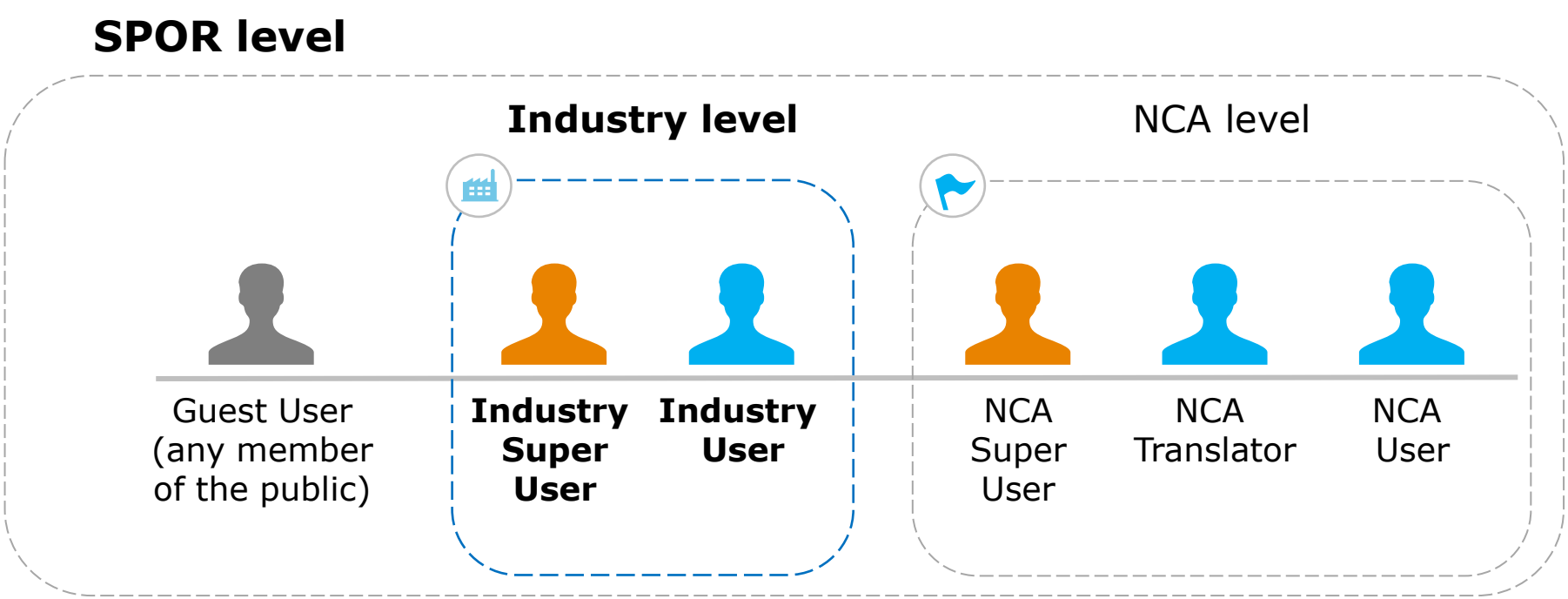


Overview of SPOR user roles and process flow for user registration

SPOR User Roles 1/2

- **Referential** and **Organisation data** is **accessible** via the **SPOR web portal** and programmatically via an **API** (application programming interface).
- Anybody (registered or not) can go to the SPOR web portal to view and search publically-available data (RMS: public lists, OMS: all content).
- SPOR provides users with services that enable them to request changes and updates to existing organisation or referential data.
- In order to access these services (request changes and updates to data), users must be registered with the EMA Account Management portal and have a SPOR user role(s).

SPOR User Roles 2/2



- **Guest User** (with basic access)
- **Super Users** and **Users** are roles that are organisation–specific, *i.e.* these users are granted their access rights on behalf of a specific organisation *(User is affiliated to a specific Industry organisation or NCA)*

SPOR user roles & functionality

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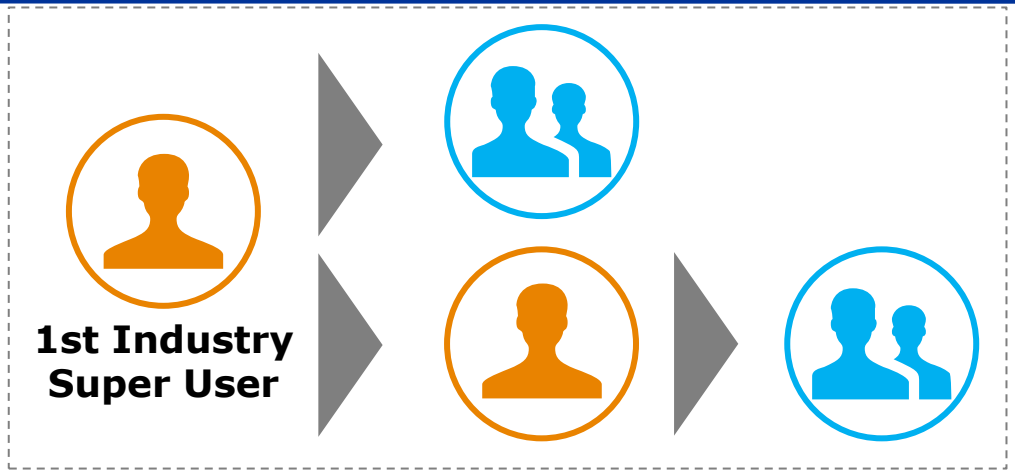
	Guest User	Industry Super User	Industry User	NCA User	NCA Translator	NCA Super User
Login	Not required	Login required	Login required	Login required	Login required	Login required
View Public data	Yes	Yes	Yes	Yes	Yes	Yes
View Restricted data	No	No	No	Yes	Yes	Yes
Search data	Yes	Yes	Yes	Yes	Yes	Yes
Download data	No	Yes	Yes	Yes	Yes	Yes
Submit Change Requests (CRs)	No	Yes	Yes	Yes	Yes	Yes
Translations	No	n/a	n/a	No	Yes	No
Permission to authorise users	No	Yes – can authorise Industry Users	No	No	No	Yes – can authorise NCA Users

Role of the Industry Super User



Key

Industry Super User

Industry User

- 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.**
- Super Users are accountable on behalf of their organisations for approving roles. 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 and Users per organisation.
  - Once the Super User or User leaves the organisation, the Super User needs to inactivate their access in the EMA Account Management Portal (*process to be confirmed*).

Managing user populations by a company 1/2

- In the EMA Account Management portal, an account can have either Industry or NCA user roles, but not both.
- Once an account with the 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.)
- Each organisation should have at least two registered *Industry Super Users*. An organisation can also have multiple *Industry Users.*

Managing user populations by a company 2/2

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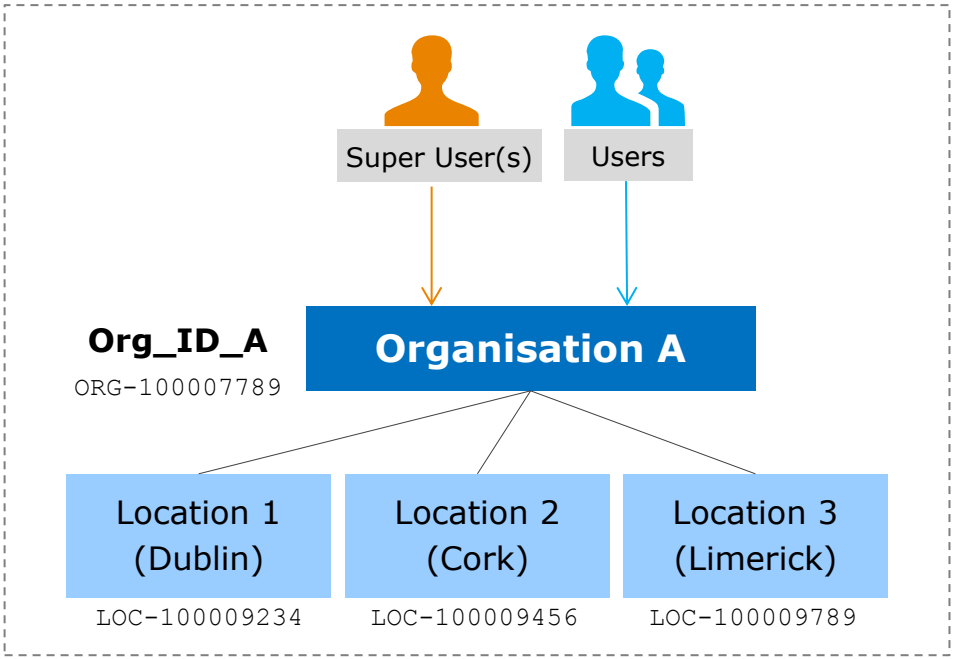
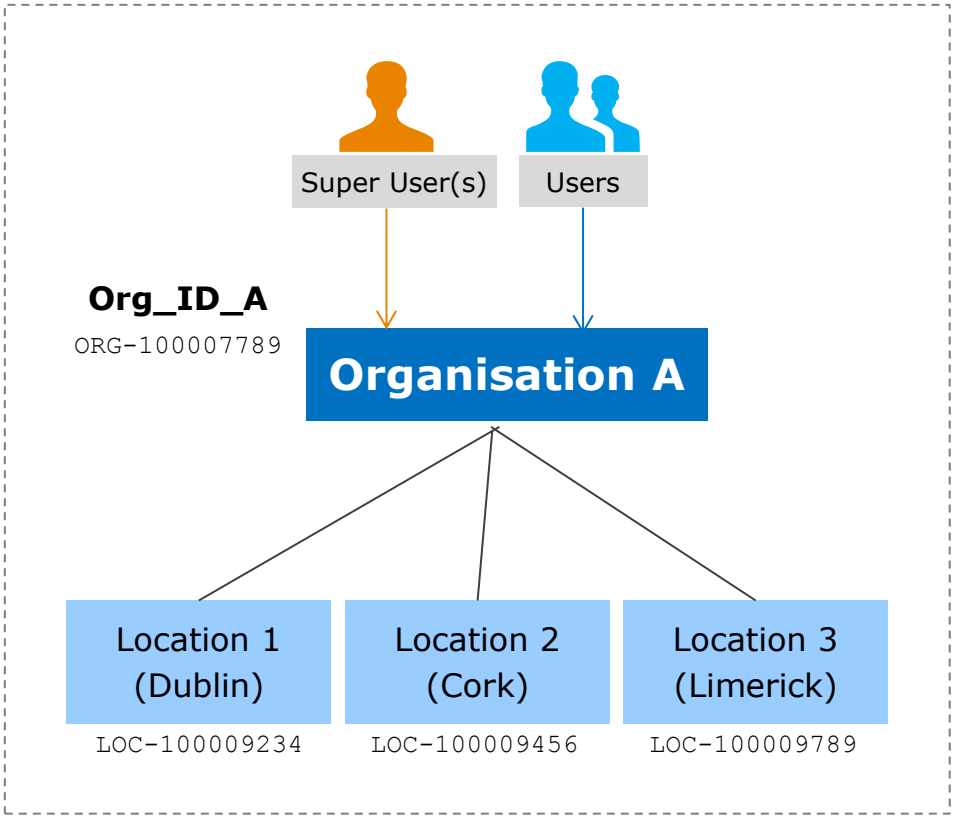
- An industry company may have different subsidiary organisations, each with its own organisation ID.
- Company structures and hierarchies are not defined in OMS – for example, there is no recognition of HQ or Affiliates.
- The population of SPOR Industry Users and Industry Super Users for an organisation 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 scenarios (*see slides 15 – 18*).

User registration – Scenario 1

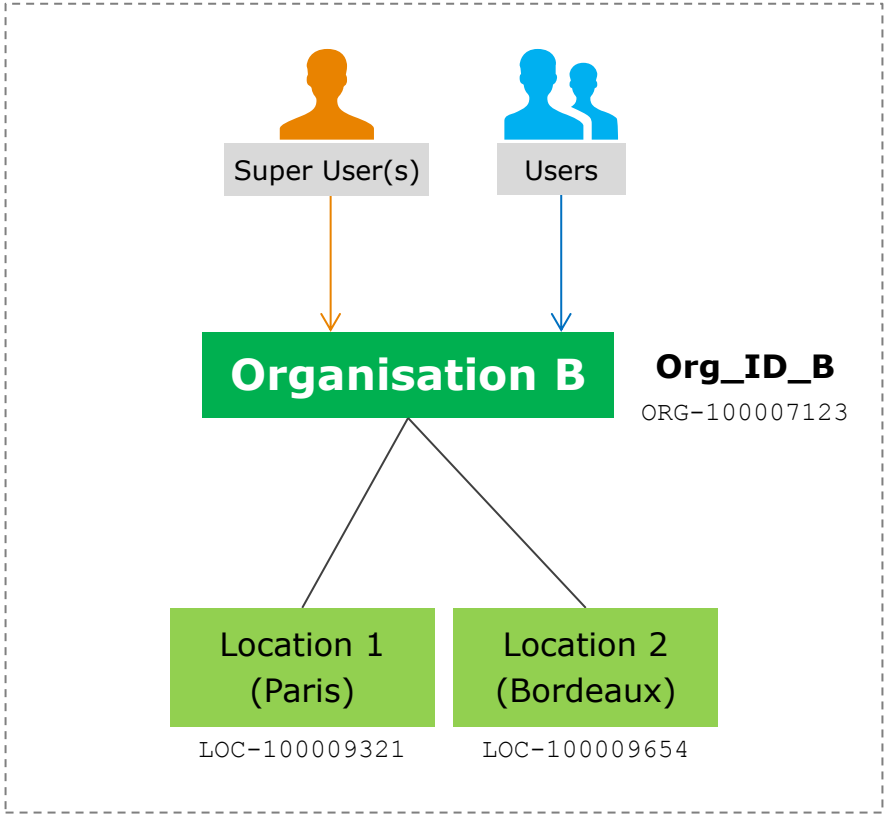


Ireland

User registration – Scenario 2



Ireland

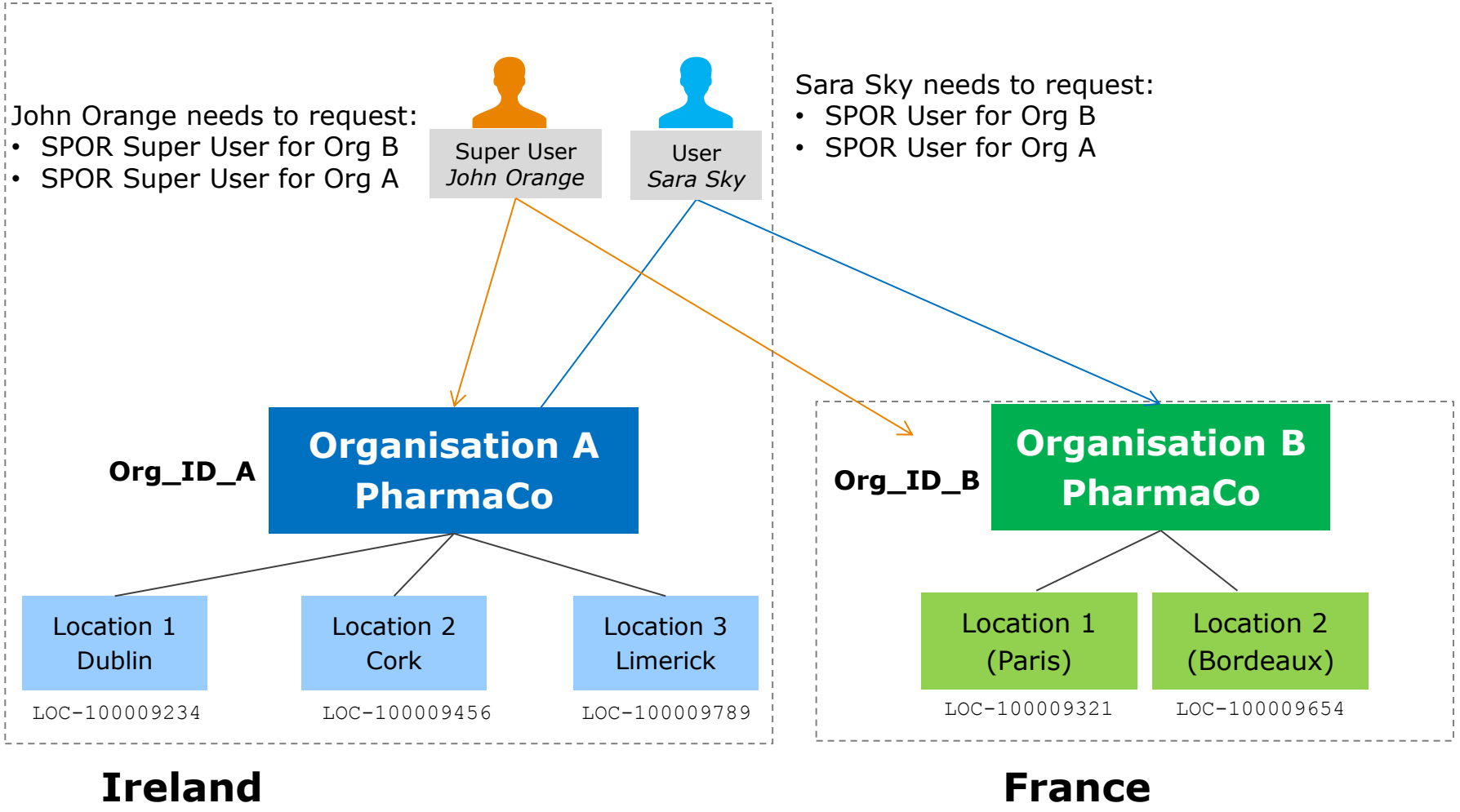


France

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

User registration – Scenario 3

Shared Industry Users and Super Users for Multinational Companies



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

User registration – Scenario 4

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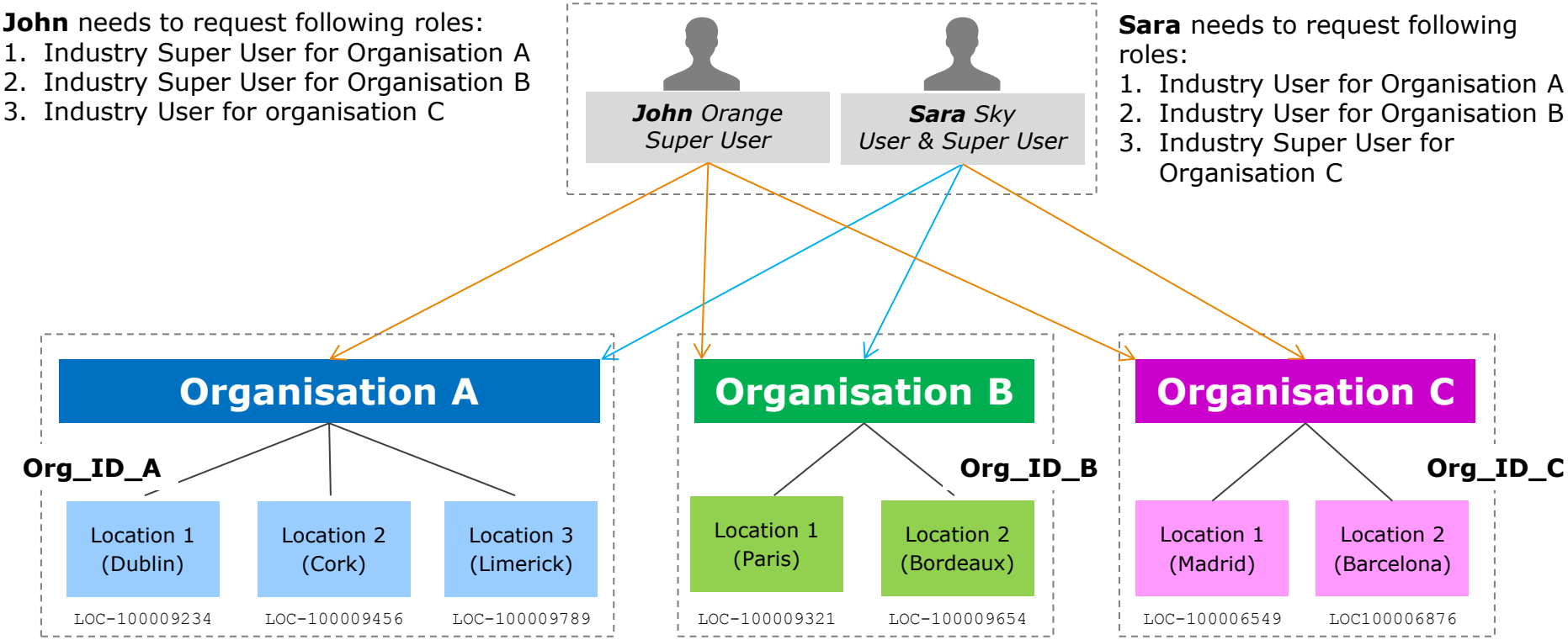
Third Party/Service Provider/Consultancy

John needs to request following roles:
1. Industry Super User for Organisation A
2. Industry Super User for Organisation B
3. Industry User for organisation C

Sara needs to request following roles:
1. Industry User for Organisation A
2. Industry User for Organisation B
3. Industry Super User for Organisation C



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

Registering 1st Industry Super User

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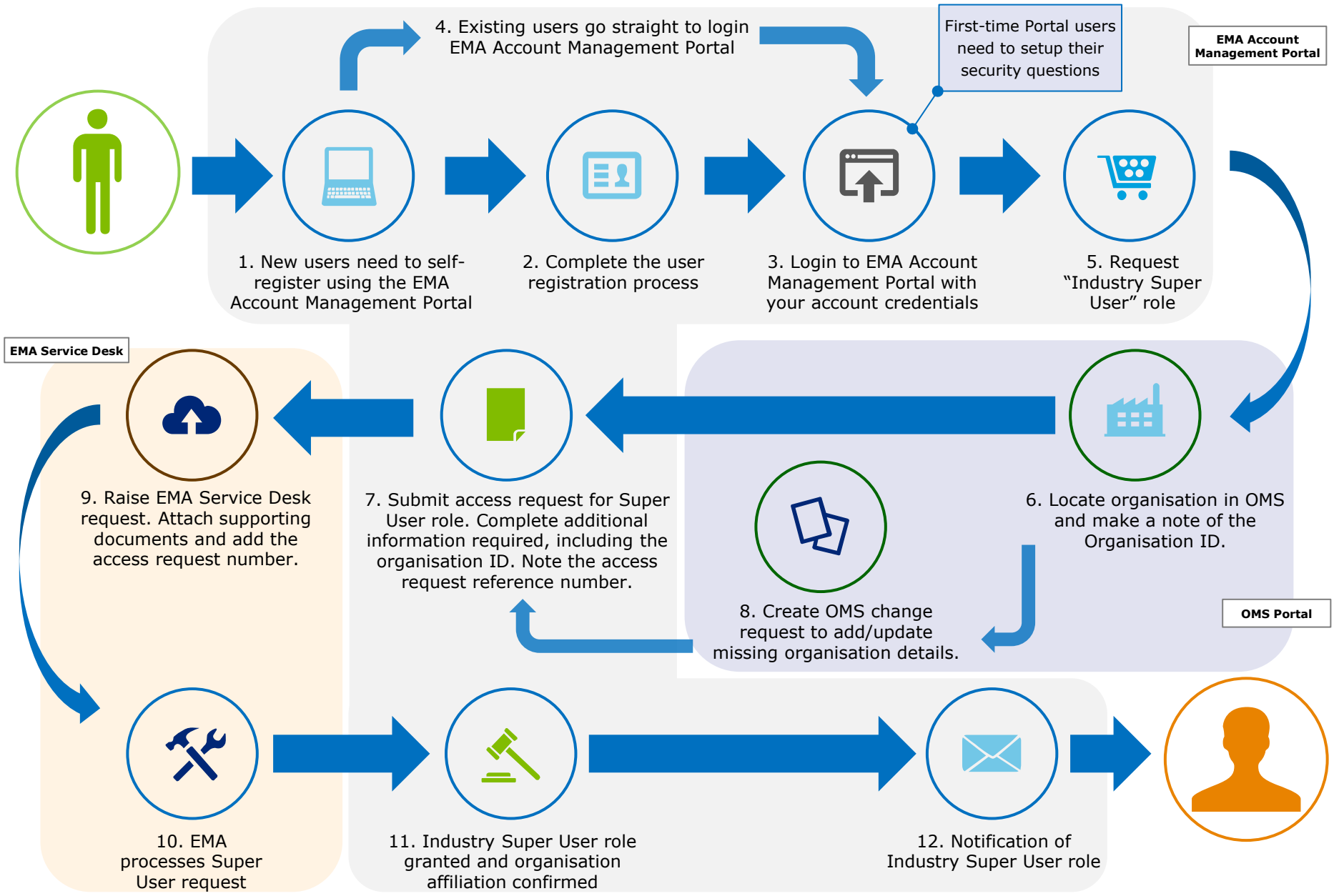

Registering Additional Industry Super Users

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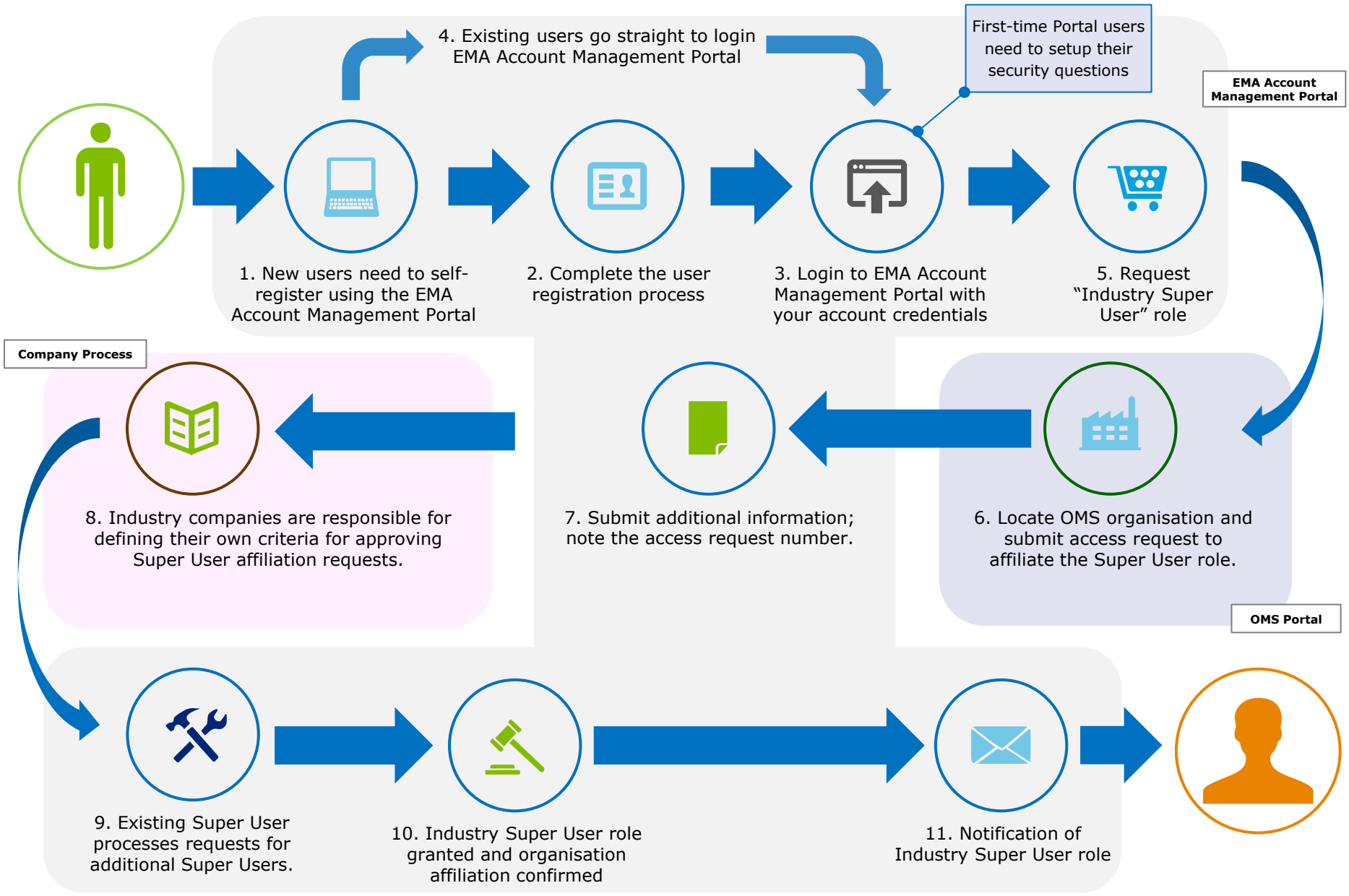

Add Organisations & Attach Documents

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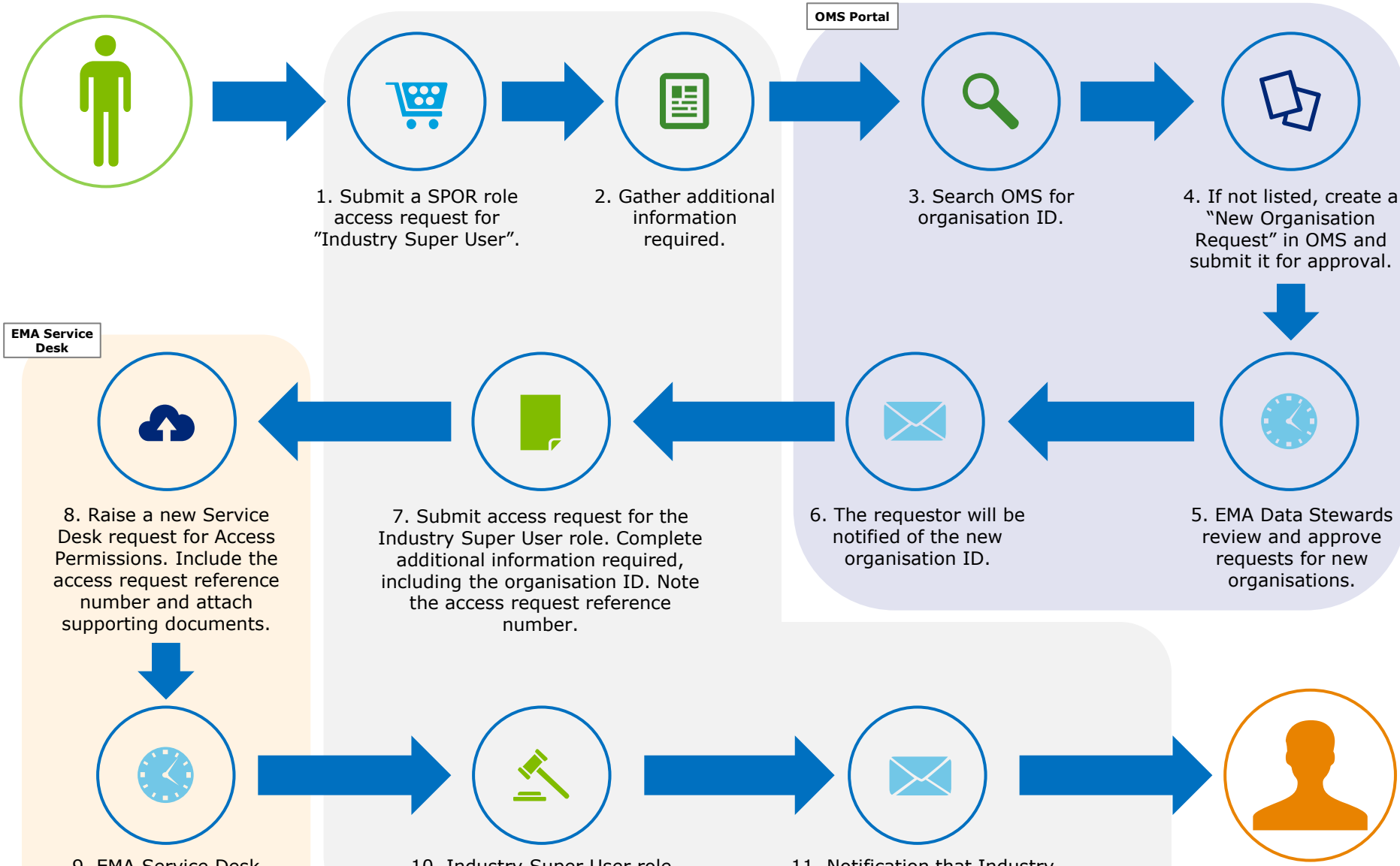
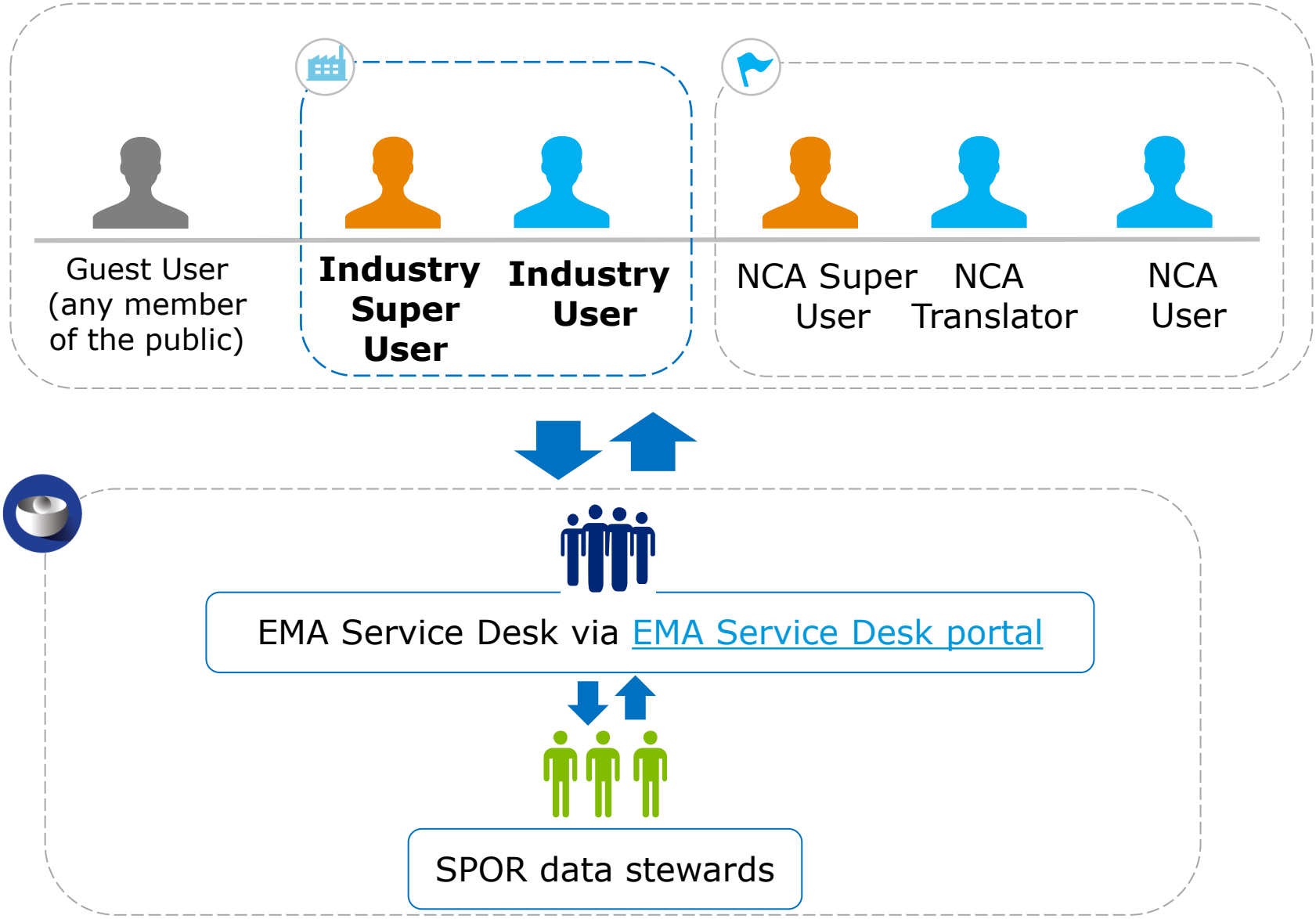


SPOR Help & Support 1/2

SPOR stakeholders



SPOR Help & Support 2/2

Tools/self service	When
EMA Account Management portal https://register.ema.europa.eu/	• To create a new EMA account in order to obtain access to EMA systems • To request SPOR user role
EMA Service Desk portal. The online EMA Service Desk for IT systems	• For technical support • Also used when registering 1st industry super user - Raise EMA Service Desk request. Attach supporting documents and add the access request number

E-mails	When
mdms@ema.europa.eu	• For SPOR master data content related questions • In December 2017 we will replace the mdms@ema.europa.eu email address with the EMA Service Desk portal for requesting Substance
SPOR-Change-Liaisons@ema.europa.eu	For SPOR project related questions such as; how SPOR is being implemented? what activities are in the pipeline?

SPOR-related Documents & Information

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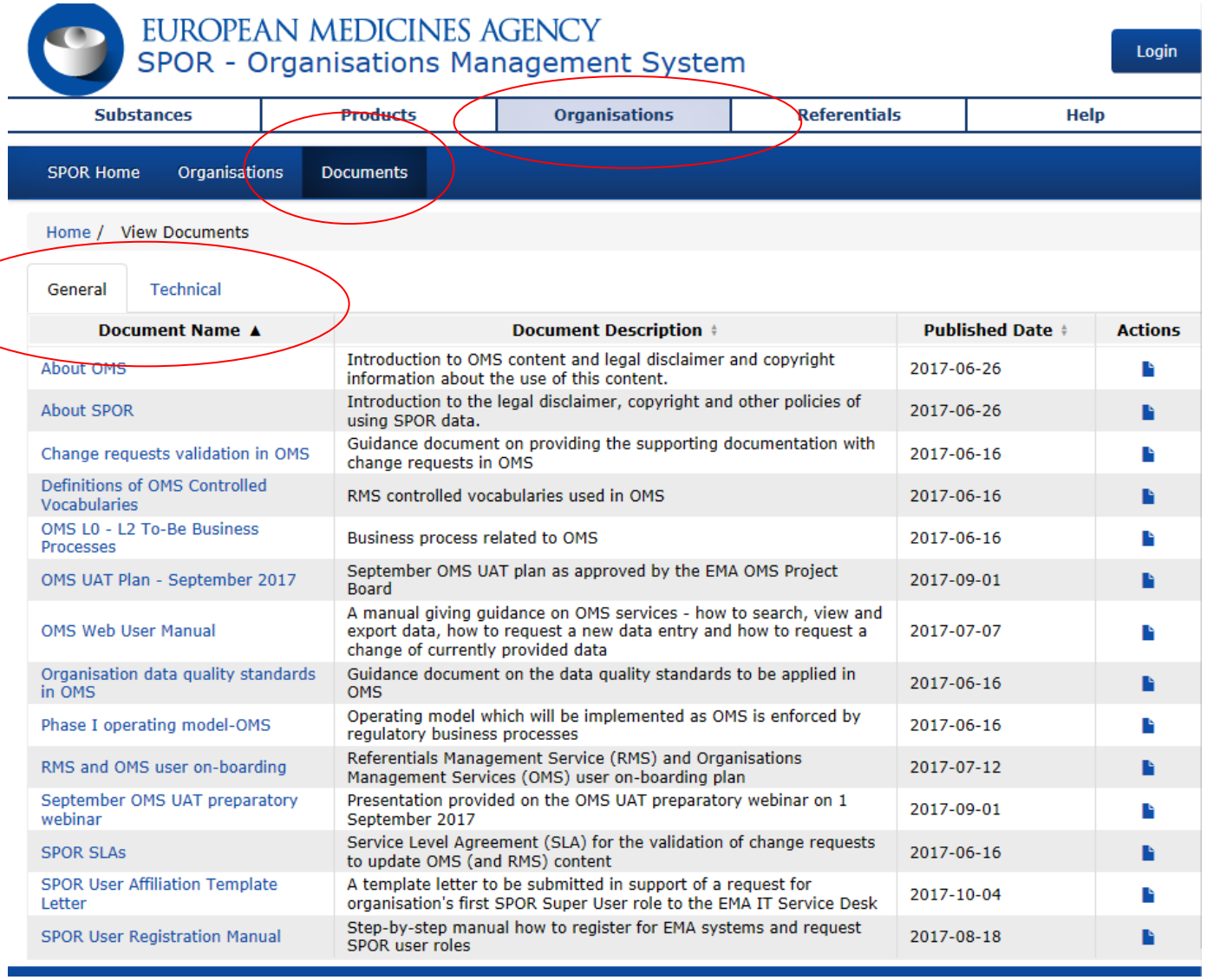

Document Name ▲	Document Description	Published Date	Actions
About OMS	Introduction to OMS content and legal disclaimer and copyright information about the use of this content.	2017-06-26	
About SPOR	Introduction to the legal disclaimer, copyright and other policies of using SPOR data.	2017-06-26	
Change requests validation in OMS	Guidance document on providing the supporting documentation with change requests in OMS	2017-06-16	
Definitions of OMS Controlled Vocabularies	RMS controlled vocabularies used in OMS	2017-06-16	
OMS L0 - L2 To-Be Business Processes	Business process related to OMS	2017-06-16	
OMS UAT Plan - September 2017	September OMS UAT plan as approved by the EMA OMS Project Board	2017-09-01	
OMS Web User Manual	A manual giving guidance on OMS services - how to search, view and export data, how to request a new data entry and how to request a change of currently provided data	2017-07-07	
Organisation data quality standards in OMS	Guidance document on the data quality standards to be applied in OMS	2017-06-16	
Phase I operating model-OMS	Operating model which will be implemented as OMS is enforced by regulatory business processes	2017-06-16	
RMS and OMS user on-boarding	Referentials Management Service (RMS) and Organisations Management Services (OMS) user on-boarding plan	2017-07-12	
September OMS UAT preparatory webinar	Presentation provided on the OMS UAT preparatory webinar on 1 September 2017	2017-09-01	
SPOR SLAs	Service Level Agreement (SLA) for the validation of change requests to update OMS (and RMS) content	2017-06-16	
SPOR User Affiliation Template Letter	A template letter to be submitted in support of a request for organisation's first SPOR Super User role to the EMA IT Service Desk	2017-10-04	
SPOR User Registration Manual	Step-by-step manual how to register for EMA systems and request SPOR user roles	2017-08-18	

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

Upcoming communications & events

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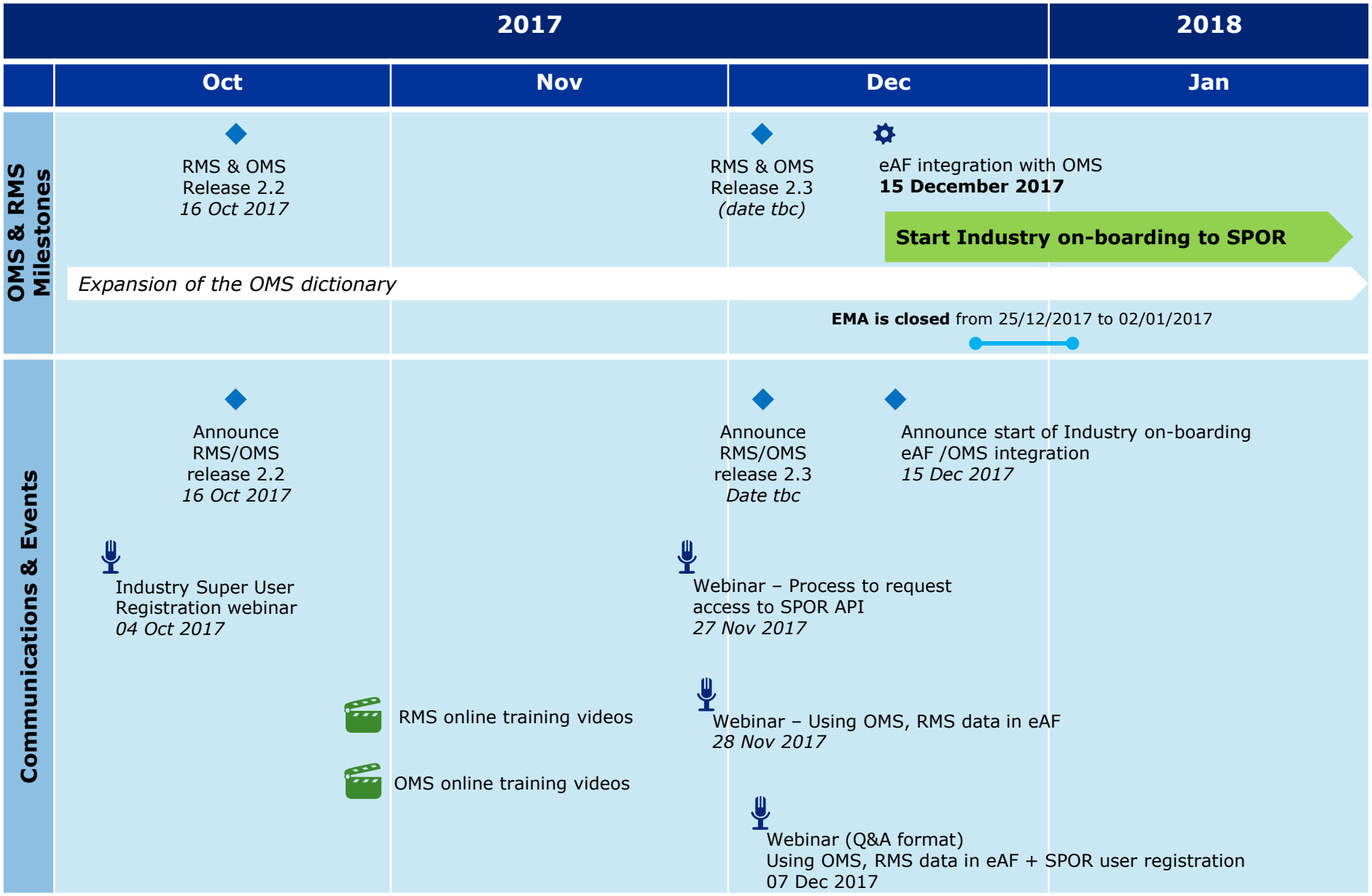

Note: SPOR team is working with eAF stakeholders to align communications

Key Messages & Actions

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1. Raise awareness of SPOR amongst your colleagues, especially those involved with regulatory submissions and reference data management. Training material will be provided that covers key functionality of OMS and RMS.
2. Review the EMA Account Registration rules and the SPOR documentation to understand how they will apply to your own organisations.
3. 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.
4. Consult with colleagues, perhaps from related organisations within your own company, to agree how you will authorise and maintain SPOR user roles.
5. Industry stakeholders should be ready to start registering their first *Industry Super User* roles from **December 2017**.
6. EMA will hold further webinars in future that include eAF + SPOR integration.

Thank You!

Do you have any questions?

Annex

OMS Content Plan Q3 2017 – 2018

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Key

Points at which new organisation data set is published/completed in OMS. Communication will be provided closer to the publication of the data set

As of 16 October OMS have published approximately 26% of organisations (>1500)

OMS go-live
June 2017

RMS & OMS
Release 2.2
16 Oct

NCAs/Regulatory Authorities

Sponsors:
(H) CAPs & NAPs

Manufacturers:
(H+V) NAPs

- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs
- **MRL applicants** (Vet)

Manufacturers:
(H+V) CAPs

Additional Organisation data will be added in future, its prioritisation will be defined at a later stage

Service Levels for SPOR Data Stewards

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- Indicative RMS and OMS SLAs, based on experience.
- RMS requests aimed to be validated within 2-5 working days and approved within 1-2 months.
- OMS standard requests aimed to be approved within 5 working days (target).
- **In future the SLAs will be reviewed as these are new services where the workload still need to be verified.**
- **Service levels will be discussed with stakeholders as SPOR data will be consumed by other systems.**