



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR (RMS & OMS) communication update

Update to SPOR TF, 22 June 2018





Status of SPOR user registration:

- SPOR Industry Super Users approved - **422** (310 Super Users in March 2018)
- SPOR Industry users approved – **236** (150 users in March 2018)

Status of SPOR API user registration:

- **7** NCAs
- **9** Industry users (4 in March 2018)



Most frequent issues related to SPOR user registration:

- Letter not supplied via EMA Service desk portal (by the 1st Super User)
- User unsure about who can sign the letter
- First user is not requesting 'Super User' role
- Only 1 Super User registered with no back up



Overview

Research and development

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Data on medicines (ISO IDMP standards)

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SPOR user registration

Users can access the European Medicines Agency's (EMA) available master data services via the substance, product, organisation and referential (SPOR) portal. All users have read-only access. However, users need to register to carry out actions via the portal such as requesting changes to the master data held by EMA.

Users require an **EMA account** with SPOR user roles to log into the SPOR portal.

To request SPOR user roles, a user needs to be **affiliated to a specific organisation** in industry or a [national competent authority](#).

To obtain an EMA account and **request SPOR user roles**, please visit the [EMA Account Management portal](#). This is a central point for managing access to EMA systems, including the SPOR portal.

Users who already have an active account for any EMA-hosted website or online application can use the same login credentials to log into the SPOR portal. However, they will need to request SPOR user roles if they have not already done so.

Benefits of registering

Registered users can make requests via the SPOR portal for changes or additions to the master data held by EMA.

Currently, registered users can request changes or additions to referential and organisation data held in the Referentials Management Service (RMS) and Organisations Management Service (OMS).

Since the RMS and OMS supply master data to the [electronic application forms](#) (eAF) for submitting applications to EMA and national competent authorities, applicants may need to make a change request to provide correct information in their eAF.

Users can submit change requests for organisation data via the...

Access the SPOR portal



Access the Account Management portal



Related content

- [▶ Data on medicines \(ISO IDMP standards\)](#)
- [▶ Substance, product, organisation and referential \(SPOR\) master data](#)
- [▶ Referentials and organisations management services](#)
- [▶ Substance and product data management services](#)

External links

- [▶ SPOR documents](#)



Upcoming webinars in June & September

- 27 June: “O” data in eAF, CESP (for industry and NCA)
 - Recording will be published
 - 2 supporting documents (PDF format) based on the content of the slide decks being produced
- 25 September: OMS data quality (for industry stakeholders)
- 26 September: OMS data quality, (for NCAs)

1. Reference documents accessible from the [SPOR portal](#)

- OMS / RMS web user manuals
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- Change Request (CR) Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)

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

3. EMA corporate [website](#) also includes SPOR related information, documents and material from webinars.



2. Training videos

OMS training videos available to view on the [@emainfo](#) channel

4. EMA Account Management Portal

To create a new EMA account in order to obtain access to EMA systems (including SPOR). To request SPOR user role.

[Account Management Portal.](#)

5. EMA Service Desk Portal

Service requests, issues, requests for technical support shall be submitted through the

[Service Desk Portal.](#)



Thank you!