EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR (RMS & OMS) communication update

Update to SPOR TF, 22 June 2018

Update on R & O user on-boarding

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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)

Reported to SPOR TF in March 2018

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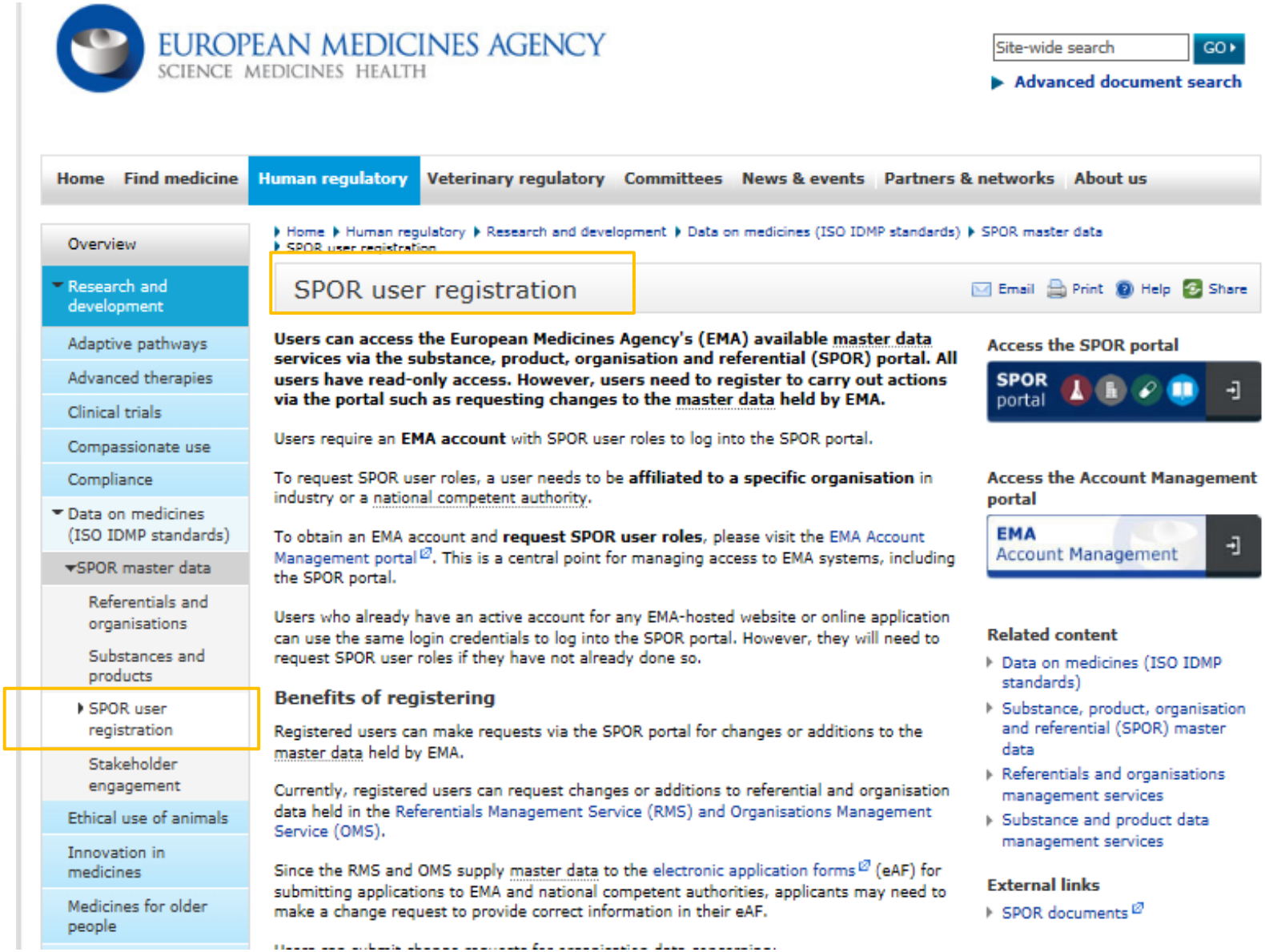
Most frequent issues related to SPOR user registration:

- 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

SPOR user registration on EMA web



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)

OMS & RMS support / guidance

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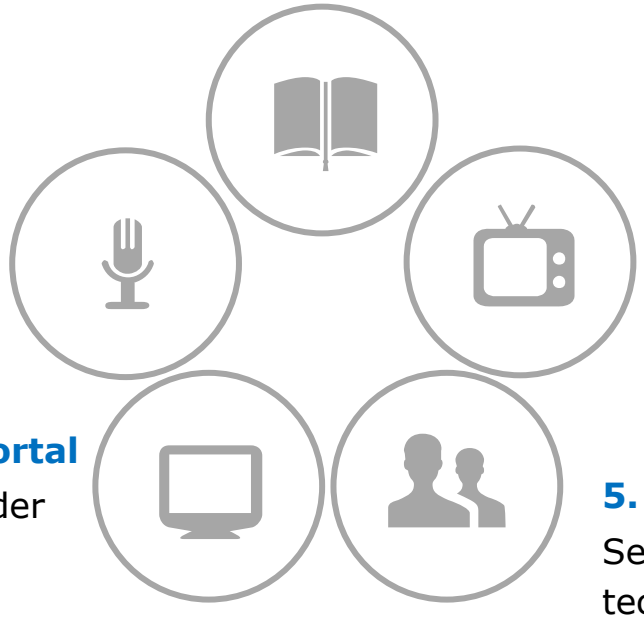
1. Reference documents accessible from the SPOR portal

- 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!