SPOR – Registrering av firmaadresse i OMS

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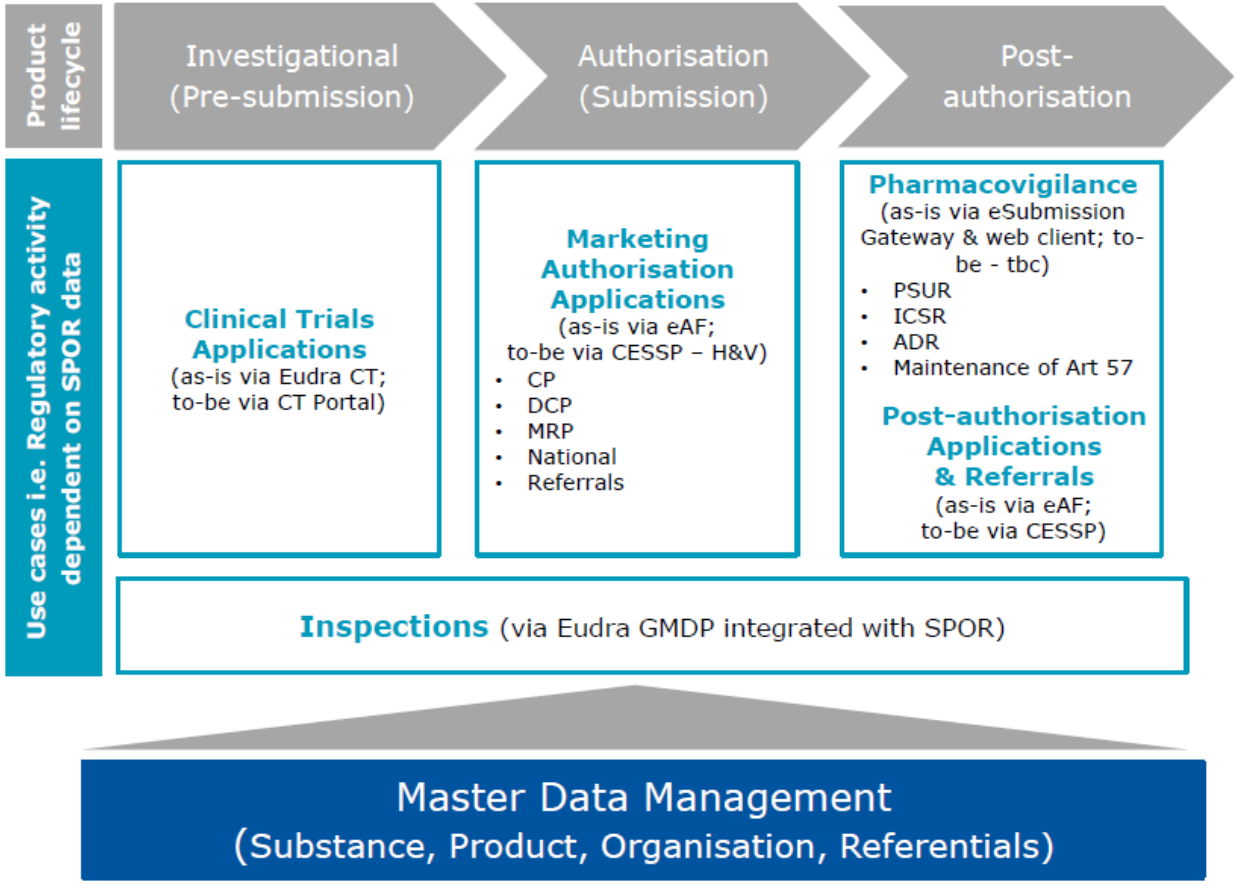
Statens legemiddelverk

Hva er SPOR?

- Prosjektprogram i EMA/HMA 2016-201?
- Skal lage «Data management services» for «masterdata» → **Legemiddeldata**

Bruk av SPOR i regulatoriske aktiviteter



eHealth

Falsified Medicines

Future EU initiatives that will depend on SPOR data

OMS – Adresseregister

- Oppbygning
  - ORG-ID
  - LOC-ID
- Organisasjonstype
  - Industry
  - Health care
  - Regulatory Authority
- Koder fra kilde
  - Organisation & Location IDs
  - xEVMPD EV_Codes
  - EudraGMDP numbers
  - DUNS numbers
  - GS1 numbers
- Ingen informasjon om kontaktperson, e-post eller detaljert rolle

Onboarding of SPOR users

OMS – Adresseregister

Page 1 of 1 Showing 20 of 7 results

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status	Modified	Actions
ORG-100006934	Norwegian Food Safety Authority	Norway	LOC-100011841	Oslo	Adamstua	0454	ACTIVE	2018-03-22T18:00:33	
ORG-100003936	Norwegian Medicines Agency	Norway	LOC-100000056	Oslo	Stroemsveien 96	0663	INACTIVE	2018-06-18T16:46:20	
ORG-100003936	Norwegian Medicines Agency	Norway	LOC-100012463	Oslo	Grensesvingen 26	0663	ACTIVE	2018-06-12T15:48:24	
ORG-100003936	Norwegian Medicines Agency	Norway	LOC-100000055	Oslo	Sven Oftedals Vei 8	0950	INACTIVE	2018-06-18T16:42:27	

Organisation Details

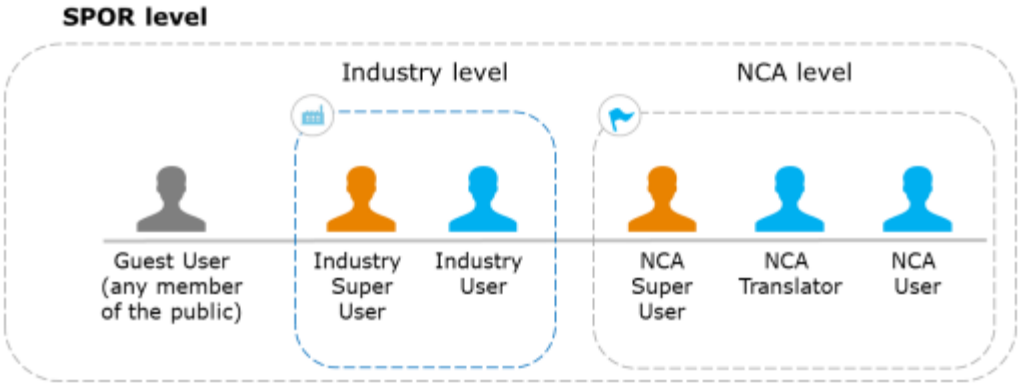
Organisation ID:	ORG-100003936
Organisation Name:	Norwegian Medicines Agency
Alternative Name:	NO - Statens legemiddelverk
Acronym:	NOMA
Status:	ACTIVE
Organisation Type:	EEA National Competent authority Regulatory Authority

Location Details

Location ID:	LOC-100012463
Address:	Grensesvingen 26 Oslo 0663 Norway
Last Modified Date:	2018-06-12T15:48:24
Status:	ACTIVE

Hvordan ta i bruk OMS?

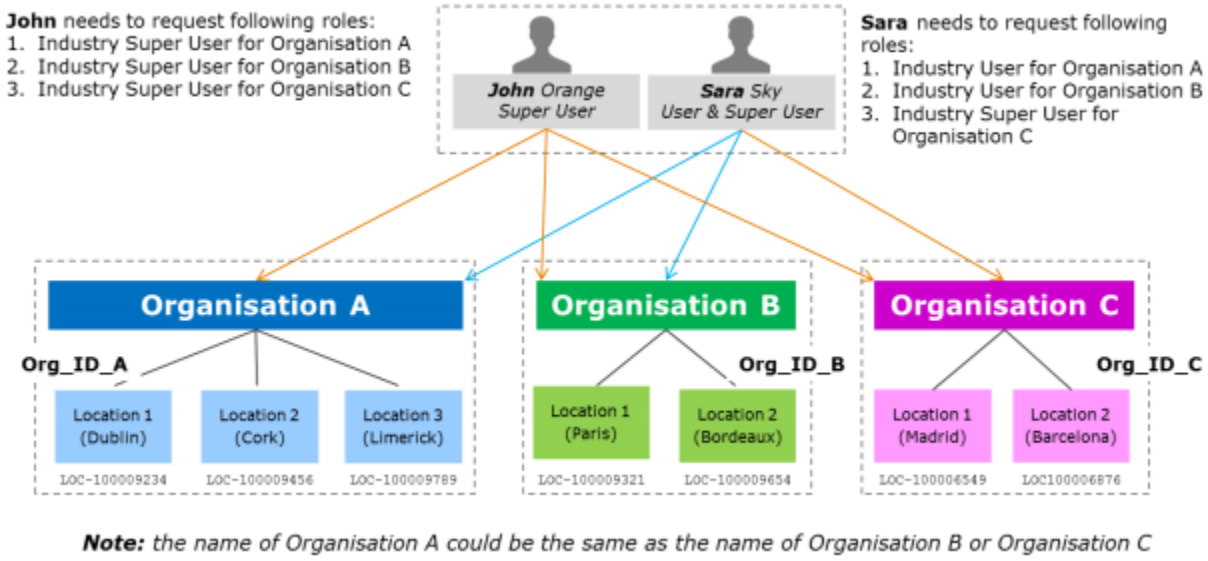
- Alle kan søke og lese i OMS
- For å be om ny eller endret oppføring, må du ha en bruker (personlig)
- Bruksanvisning på https://spor.ema.europa.eu/sporwi/



https://spor.ema.europa.eu/omswi/#/viewDocuments

Hvordan ta i bruk OMS?

- En bruker kan ha flere roller
- En bruker kan ha roller for flere organisasjoner innenfor enten industry/NCA level



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

Hvem kan melde inn endringer?

- Alle registrerte brukere
- Dokumentasjon
  - DUNS/GS1 registration proof

OMS Change Request (CR) stages

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1

Submit OMS Change Request (CR):
- Add Organisation
- Update Organisation
- Add Location
- Update Location
- Update Organisation & Location

Any registered SPOR user can submit a CR for his organisation or any other organisation.
CR should include relevant documentation/ information.

Submit CR → **Validate CR** → **Approve CR**

2 **Validation:** EMA data stewards validate the request (SLA 5 w/d - indicative).
Except for very minor (administrative e.g. spelling mistakes) changes, documentation must be provided in the change request.

If validation criteria are not met:

a) CR On hold – SPOR Data Stewards requested clarification / information.

b) CR rejected – E.g. Organisation/Location already exists, not enough information to validate the request, provided data is not acceptable, etc. See 'OMS Controlled Vocabularies (CVs)' document in OMS portal.

3 **Approved**: Validation criteria were met (relevant info and/or document(s) were provided). Following the approval OMS dictionary will be updated automatically and data will be published.

Status på innhold i OMS

Data sets to be mastered and included in the OMS dictionary	Status of data mastering	Submission of CRs
Data set 2: • EV (EudraVigilance) organisations to support EV user management.	Completed	Users can start submitting change requests (CRs) for data set 2.
Data set 3: • Orphan Designation organisations (supporting S-REPS project).	Completed	Users can start submitting change requests (CRs) for data set 3.
Data set 4: • Sponsors (H) CAPs and NAPs.	Completed	Users are **NOT required** to start submitting change requests (CR) yet
Data set 5: • Manufacturers (H+V) CAPs; • Manufacturers (H+V) NAPs.	Plan to complete by end of Q2 2019	Timing to be communicated in 2019.
Data set 6: • Veterinary MAHs & MAAs for NAPs.	EMA proposes to include the MAHs & MAAs for NAPs Veterinary through the OMS change request process.	From September 2018 users can start submitting OMS change requests for data set 6.

Bruk av OMS i eAF/CESP

- Tilgang til OMS direkte fra eAF/CESP
- Fortsatt mulig å bruke fritekst (frem til Q3 2019)

Summary of milestones & impacts

June 2017 new OMS data services live.
No impact on regulatory submissions at go live.

Free text removed in Q3 2019

OMS dictionary being expanded with additional data

2017 | 2018 | 2019

Dec 2017
OMS & v.1.22 eAF integration - OMS starts supplying organisation master data to eAF (MAA, Variation, Renewal (vet/human).
Use of OMS is initially optional.

Jul 2018
v.1.23 eAF integration - OMS Location (address) versions available in eAF for Variation forms (vet/human).
Use of OMS is still optional.

Q1/2019 (tbc):
CESP & OMS integration go live for Human & Vet MAAs

Q3 planned for CESP to mandate use of OMS data. Selection from OMS only for MAH, MA Applicant, Manufacturer for Initial MA Applications.
eAF Initial MAAs removed. (tbc).

Using OMS data in eAF

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- **Using the Drop down list available to select Org data**
  - Applicants are advised to **familiarise** themselves **with the use of OMS data** and to ensure that they are familiar with the process **before the use of OMS data becomes mandatory.**
  - Applicants are advised to **perform a search** from within the form
  - **What OMS data can be searched on in eAF?**
    - IDs: **Organisation_ID** and **Location_ID**
    - Name: **Organisation name** (Main name and alternative names)
    - **Country**
      - eAF v1.22 Forms allow search only on current version (no historical/previous versions)
      - A change will be implemented in eAF variations form (v1.23), in the present/proposed section, to also allow searching for historical/previous versions in the present section (but not on proposed)
  - **What happens after searching for an organisation?**
    - If the **Organisation name and/or address/location is not found or is incorrect**, users are advised to follow the OMS process to submit requests for adding or amending organisation data before the eAF submission for the following data,
      - Now….
        - MAHs for Human medicinal products CAPs & NAPs, and MAHs for Veterinary CAPs
        - MA Applicants for Human and Veterinary CAPs
      - In addition, from September 2018….
        - MA Applicants and MAHs for Veterinary NAPs
    - If the **Organisation name and address/location are correct**, users may proceed with using the OMS-provided data.

What IS mandatory by when?

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"Role"		Content available in OMS	OMS CR submitted from	Mandatory in CESP (only for initial MA application)
Applicants	H CAP	Yes	As off January 2018 - stakeholders can start submitting the relevant OMS change requests.	
	H Non-CAP (MRP, DCP, National)	No plans, we expect many will fall within data set 4 (Sponsors target end Q3 2018)	**As off Q3 2019**	
	V CAP	Yes	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V Non-CAP (MRP, DCP, National)	Content populated via submission of OMS CRs	**As of September 2018** - stakeholders can start submitting the relevant OMS change requests.	
MAH	H CAP	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	6 Month after CESP goes live. (eAF forms will be removed)
	H Non-CAP (MRP, DCP, National)	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V CAP	End of Q4 2017	**As off January 2018** - stakeholders can start submitting the relevant OMS change requests.	
	V Non-CAP (MRP, DCP, National)	Content populated via CRs	**As of September 2018** - stakeholders can start submitting the relevant OMS change requests	
Manufacturers	H CAP	By end of Q2 2019	**As off Q3 2019**	
	V CAP	By end of Q2 2019	**As off Q3 2019**	
	H Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As off Q3 2019**	
	V Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As off Q3 2019**	
Other	Eg. CROs, Billing Orgs., Contact people Organisations, etc	Not planned yet.		

Spørsmål?

- Les om SPOR på nettsidene våre

Følg oss

@legemiddelinfo

legemiddelverket

legemiddelverket.no

Statens legemiddelverk

Expanding the OMS dictionary with data sets

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Data set 1 published in the OMS:
- **MAHs:** (H+V) CAPs & (H) NAPs
- **MAAs:** (H+V) CAPs

Data set 2 by Q2 2018:
- EudraVigilance organisations to support EV user management

Data set 3 by Q2 2018:
- Orphan Designation organisations (supporting IRIS portal)

Data set 4 by Q3:
- Sponsors (H) CAPs and NAPs

Additional Organisation data to be added in future. Its prioritisation will be communicated Q1 2019.

Data set 5 by end of Q2 2019
- Manufacturers: (H+V) CAPs & NAPs

As of January 2018 Registered SPOR users can start submitting OMS change requests (**CRs**) for **Data set 1** to request changes or additions to OMS data:
- **Add Organisation**
- **Update Organisation**
- **Add Location**
- **Update Location**
- **Update Organisation & Location**

Data set 6: Veterinary MAHs & MAAs for NAPs
As of Sep 2018 stakeholders can start submitting OMS change requests for data set 6

EMA will communicate when each data set is added to the OMS dictionary. Until communicated please do not submit the OMS CRs.

Key messages

- **OMS dictionary** (list of organisations with associated physical locations) can be used to **support regulatory business processes**
- OMS content is growing and **data quality** is expected to **improve over time**
- Business owner of the process using OMS data decides how/when to use it and mandates its use. OMS team will work closely with the business process owners
- **eAF will not mandate** the use of **OMS** data, **free text will still be available**
- **CESP will mandate the use of OMS data in the form**. Organisation data will have to be pre-registered in OMS and can be selected in CESP. This is not planned before Q3-2019 for initial MA Applications
- Applicants are advised to **familiarise** themselves **with the use of OMS data** and with the process **before the use of OMS data will be mandated**
- **Applicants and MAHs** are responsible to **register/update organisation data in OMS** before regulatory submissions (e.g. Initial MAA, Var, Renewal)
- **Submission of OMS Change Requests for Veterinary MAH & MAAs for NAPs starts from September 2018**

Key messages

- **Key User Group** is planed to be set up in Q4 2018 – this will be a **forum** to discuss **OMS operational issues**
- Use of OMS data in eAF **-** **a focus group** is in operation for eAF/CESP. This group is composed of representatives from CMDx, regulatory EMA (H+V) and NCAs
- **Informing manufacturers in & outside EEA about OMS implementation**
  - Applicants/MAHs are responsible to ensure manufacturers data needed for the regulatory applications is in OMS

OMS support / guidance

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1. Reference documents accessible from the SPOR portal

- OMS web user manual – guidance on OMS services, e.g. searching, exporting data, requesting CRs
- 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 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.