EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Information Management Division

Organisation Management Services (OMS) operating model

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1. Purpose of the document

This document is intended to provide both guidance and information for stakeholders who are supporting the implementation of the SPOR programme and for all stakeholders who will be using RMS data management services. The information applies to both human and veterinary stakeholders; however, there may be different impacts experienced by NCAs and industry stakeholders.

This document is reviewed periodically for accuracy.

2. Executive summary

The use of pharmaceutical and regulatory data can vary between organisations. The data may be stored in different formats using different database systems, applications, or data models. As a result, the same concept may be represented in a variety of different ways. For example, in the context of organisation data, the same organisation name can be entered differently into various databases or applications, *e.g.* "Middle Trade Group Limited" could be entered as "MTG Limited" or "MTG Ltd". The consequence is that data is not consistent and cannot easily be reused.

Organisations Management Services (OMS) is part of the phased implementation of the **SPOR** programme. The goal of SPOR is to deliver services that will centralise the management of pharmaceutical and regulatory data for **Substances**, **Products**, **Organisations**, and **Referentials** (SPOR master data) and **enable** a consistent basis for **reuse** by EMA, NCAs and industry. Benefits of SPOR data are expected to be realised incrementally as all phases of SPOR are delivered, and different business processes use the data.

The key to achieving the goal of SPOR is the **OMS operating model**. It provides a shared understanding of the OMS services by allowing visualisation of the services from a variety of stakeholder perspectives as each significant element of OMS is represented. **People**, **process** and **functional capabilities** are the key underlining components ensuring successful delivery of the service.

The scope of **OMS services** includes data content, new process, functional capabilities and a team of Data Stewards:

- **central repository and provider of organisation master data;**
- **SPOR web portal**[1] and an application programming interface (**API**) through which data can be accessed;
- **a new process** to register and update organisation data;
- **EMA Data Stewards** to manage data, applying consistent data quality rules and providing support to stakeholders.

The use of OMS will become mandatory, although the roll-out will be staggered when a given regulatory business process begins to be supported by OMS data. More detailed information will be provided in advance (by the relevant business owner) of any process changes including transition timelines. The mandating may vary between Human and Veterinary stakeholders depending on the implementation timescales and business processes using the OMS data.

OMS is already integrated with Electronic Application Forms (eAF) and supplying organisation master data to MAA Human, MAA Vet, Renewal and Variation application forms (use of OMS is not mandated

[1] SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above).

yet). IRIS platform to support orphan designation procedures (see here for more information) and EudraVigilance user registration process also started to make use of organisation master data.

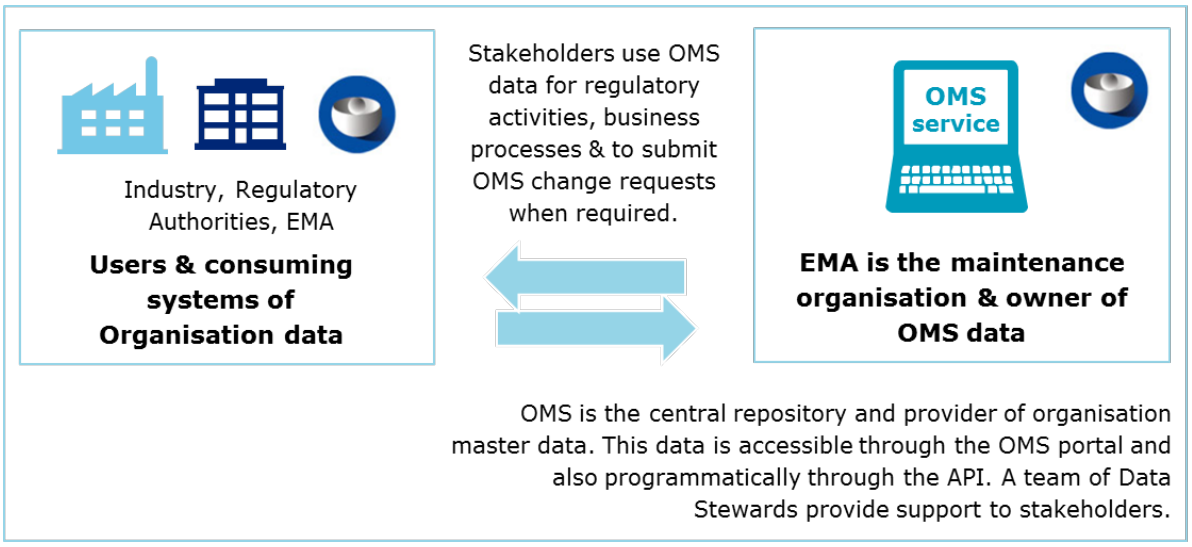
In future OMS data is expected to support regulatory submissions in Telematics systems such as; the Common European Submission Portal (CESP), CT portal and Art.57/xEVMPD.

The use of OMS data is also envisaged by the CTS system (Communication and Tracking System) which is used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures.

3. The OMS operating model in summary

In the OMS operating model, the stakeholders, new process and functional capabilities are the key components to ensure delivery of the service. This document describes the range of services available for stakeholders to use, the process to register organisation data or request data updates. It also outlines stakeholder interactions and identifies roles. The high-level concept of the OMS Operating Model is shown in Figure 1 below.

Figure 1. The OMS operating model.



OMS provides a **single source** of **validated** organisation **data** that can be used as a reference and in support of EU regulatory activities. In simple terms, OMS is a **list of organisations** with associated physical locations also referred to as the **OMS dictionary** (Figure 2). OMS data is master data and not regulatory data, and as such it represents the real world as much as possible. When the OMS data is used in the context of a regulatory activity or procedure, e.g. within a marketing authorisation application procedure, it becomes regulatory data.

If the organisation's name or any of its location-address related data changes, then it can be updated in OMS separately from any regulatory procedure. EMA does not wait for the medicinal product information to be updated before the organisation/location data is updated in OMS.

Figure 2. An example of a list of organisations from the OMS dictionary.

Organisation ID	Organisation Name ▲	Country	Location ID	City	Address	Postcode	Location status
ORG-100003451	Accord Healthcare S.L.U.	Spain	LOC-100002098	Barcelona	Edificio Este Planta 6	08039	ACTIVE
ORG-100007093	ASAC Pharmaceutical Immunology S.A.	Spain	LOC-100010940	Alicante	Calle Capricornio 15	03006	ACTIVE
ORG-100001785	Laboratorios Lestral S.A.	Spain	LOC-100007240	Madrid	Avenida Madronos 33	28043	ACTIVE
ORG-100004809	Laboratorios LETI S.L.U.	Spain	LOC-100006131	Barcelona	De Les Corts Catalanes 184 Planta 7	08038	ACTIVE
ORG-100004809	Laboratorios LETI S.L.U.	Spain	LOC-100000327	Tres Cantos	Calle Sol 5	28760	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100004944	Barcelona	Torrent Vidalet 29	08012	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100002016	Barcelona	Calle Provenca 386, 5º	08025	ACTIVE
ORG-100002683	Laboratorios Viñas S.A.	Spain	LOC-100005554	Rubi	Poligono Industrial Can Roses Nave 15	08191	ACTIVE
ORG-100003502	Mabo-Farma S.A.	Spain	LOC-100001926	Alcala De Henares	Carretera M-300 Km. 30,500	28802	ACTIVE
ORG-100004616	Octapharma S.A.	Spain	LOC-100000130	San Fernando De Henares	Avenida de Castilla 2	28830	ACTIVE

The initial content of OMS contained the data set below (see section 4.3 for information on how the content will expand):

- 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 (V);
- Regulatory Authorities.

Users, such as industry stakeholders, NCAs, EMA and other parties, can access the organisation master data through the OMS web portal, or through the Application Programming Interface (API). They can use the dictionary of organisations for regulatory application submissions and other regulatory activities.

In the context of a regulatory procedure (which uses the OMS data) industry stakeholders may need to **register organisation** data **or** request the **update** of existing **data in OMS** (submit a "Change Request") before submitting a regulatory application to the relevant NCA or EMA. The Regulatory Authority will receive the application and process it without the need to validate the correctness of the organisation data against OMS as long as the organisation data is from OMS.

NCAs can also use the OMS data as a reference for the validation of their organisation data in support of their regulatory procedures such as inspections. There may be cases when an NCA may request registration or the update of organisation data in OMS (e.g. to prepare for an inspection). **Any registered SPOR user can submit an OMS change request**. A change request can be submitted for the organisation with which they are associated as well as any other organisation, although each request will require **supporting documentation/information**. EMA Data Stewards will validate and process all requests. Except for minor changes or administrative changes[2], the change request should be supported by the relevant documentation[3] to be approved.

OMS, supported by "Informatica Address Doctor service", provides an **address verification service**. This service uses reference address data from national postal services. The verification of the address by "Address Doctor" is also used to confirm the acceptability of the address data provided in each change request.

[2] Minor correction examples: typos in organisation name or location address, addition/correction of telephone and/or email address, to report a duplicate organisation, location (EN and/or non-EN address).
[3] See change request validation in OMS document for the detailed guidance.

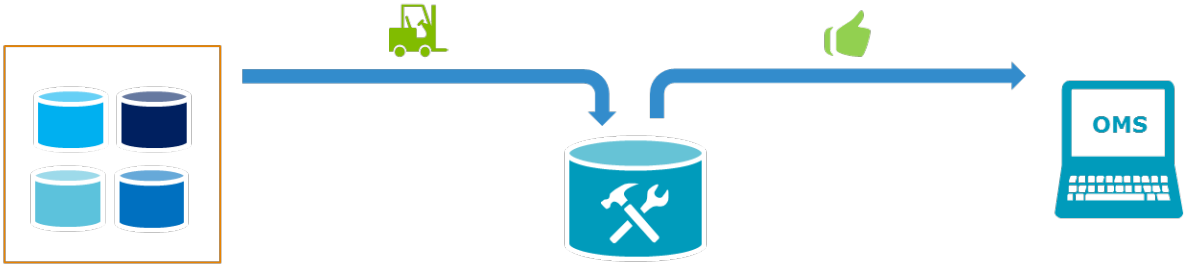
4. Organisation dictionary

4.1. Initial content of the OMS

The initial content of the OMS dictionary originates from the Telematics systems, i.e. xEVMPD – Article 57, EudraGMDP and other 3 EMA corporate systems. The IDs stored in the source systems have also been loaded into OMS and thus mapped as cross-reference IDs against each organisation/location record mastered in the OMS.

The data mastering process is managed by EMA Data Stewards who follow a set of business rules and a data quality standard[4] to cleanse, standardise and consolidate the data before its publication in the OMS dictionary.

Figure 3. Data sources for the initial content of the OMS dictionary.



Q4 2016 **source data** taken from the Telematics systems, i.e. xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems and **loaded in OMS**.

Data mastering process in OMS: cleansing, standardisation and consolidation.

Mastered organisation **data** has been published **in** the **OMS dictionary**.

The OMS data is mastered with unique IDs (Organisation_ID and Location_ID see section 4.2) and mapped[5] to records taken from source systems. The structured data supports the implementation of ISO IDMP standard 11615 for medicinal product identification and ISO 11238 for substance identification[6].

In OMS there is no difference between an organisation created in the context of a human medicinal product and a veterinary medicinal product. OMS does not define which role(s) the organisation perform(s) since it depends on the context in which the data is used. 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 in OMS by type: 'Industry', 'Regulatory Authority', 'Educational Institution', 'Healthcare', etc. or by size: SME as 'Micro', 'Small', or 'Medium'.

4.2. Organisation ID vs Location ID in OMS

The Organisation IDs stored in the source systems have been loaded to OMS and thus mapped as a cross-reference ID against each organisation/location record mastered in OMS. Organisation and location can be defined as follows:

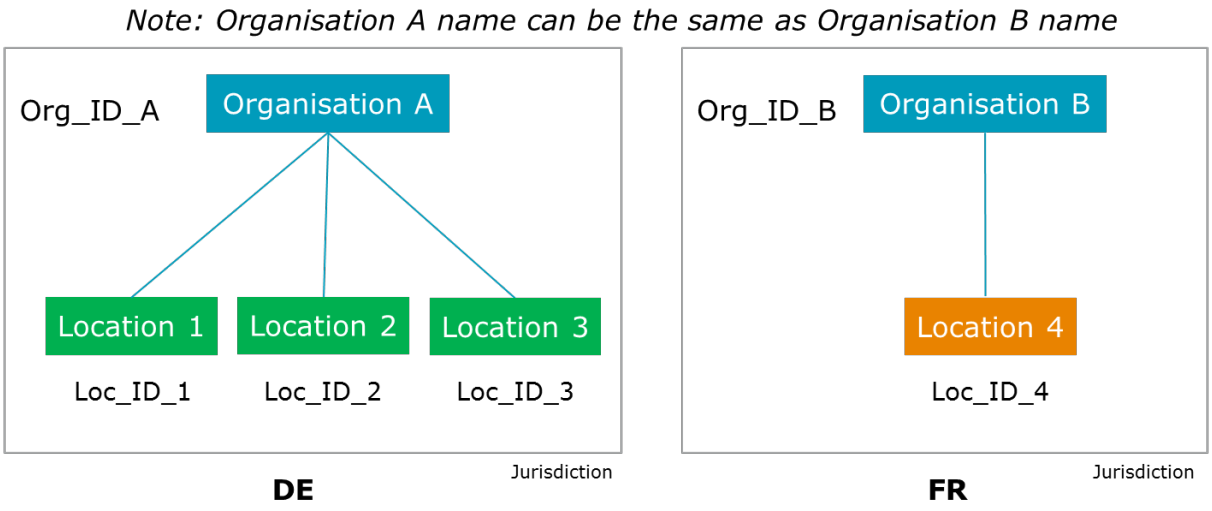
Organisation - An organisation is a legal entity (e.g. organisation name). Organisations are country-specific. All locations under one organisation must be located in the same country (or must belong to

[4] Data quality Standard in OMS document is available on the OMS Web portal
[5] Mapped – matched data elements between two (or more) distinct sets of data
[6] Although these standards apply to human medicinal product only SPOR services will also support veterinary regulatory activities.

the same jurisdiction). For OMS, organisations registered in different jurisdictions are treated as different legal entities, and as such, each will have a unique ID. OMS does not currently manage the hierarchical relationships between organisations.

Location – This is the physical location (address) of an organisation. A location can only be associated with a single organisation at any one time. Each active organisation must have at least one active location associated with it. An address can be present in multiple locations as long as they are associated with different organisations. Each location will have a unique location ID. This location ID remains the same if a location is moved from one organisation to another organisation.

Figure 4. Organisation ID vs. Location ID in OMS.



4.3. Expansion of the OMS dictionary

The content of the OMS will be expanded incrementally, and EMA will inform stakeholders about the timing of the release of new organisation data in the dictionary and specify when users can start submitting change requests for the organisation data that has been added (Figure 5).

Figure 5. Data sets to be included in the OMS dictionary.

Data sets to be mastered and included in the OMS dictionary	Status of data mastering	Submission of CRs
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); • EU National Competent Authorities; • Regulatory Authorities.	Completed	Users can submit change requests.
.Data set 2:	Completed	Users can submit change

Data sets to be mastered and included in the OMS dictionary	Status of data mastering	Submission of CRs
• EV (EudraVigilance) organisations to support EV user management.		requests.
Data set 3: • Orphan Designation organisations (supporting IRIS platform).	Completed	Users can submit change requests.
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.	Mastering of manufacturers is ongoing. Target to complete - by the end of Q4 2019 (aligned with CESP dataset module).	Timing of the submission of CRs to be communicated in Q4 2019.
Data set 6: • Veterinary MAHs & MAAs for NAPs.	Completed	Users can submit change requests.
Data set 7: • Parallel distributors (supporting IRIS platform).	Completed	Users can submit change requests.
Data set 8: • Organisations supporting the Clinical Trial application procedures Note: The exact content of the organisations to be added will be communicated. The organisations will be added through the OMS change request process.	Not started	Timing to be communicated.

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. This will include:

- Contract Research Organisations (CROs);
- Clinical trials sites;
- Academia;
- Hospitals;
- Wholesale distributors;
- MAA/MAH and manufacturers in the context of herbal and homeopathic medicinal products or compassionate use medicinal products.

New sources for organisation data, to be incorporated in the OMS dictionary, may be identified in the future.

5. Implementation of the OMS operating model

The use of OMS data can be mandated by a given regulatory process when it is integrated with OMS. The application owners supporting the process using OMS data will have to establish the approach of mandating the use of OMS data. The SPOR programme has been consulting stakeholders on the benefits of using the master data, and these consultations have resulted in a number of integration initiatives.

In December 2017, OMS was integrated with eAF and started supplying organisation master data to the electronic application forms. Use of OMS in eAF is not mandatory yet. However, applicants are encouraged to use OMS data (as opposed to the free text) when completing the application forms to become more familiar with it. If the organisation is not in the eAF drop-down list, it should be requested through the OMS portal before the application is submitted to the relevant regulatory authority (refer to Figure 5 to see for which data set stakeholders can start submitting OMS CRs).

A business process that mandated the use of OMS data is IRIS platform to support the end-to-end orphan designation procedures. Also, the new EV user management solution mandated the use of organisation data from OMS.

In future OMS data is expected to support regulatory submissions in Telematics systems such as the Common European Submission Portal (CESP), CT portal and product data submissions in Art.57/xEVMPD. The use of OMS data is also envisaged by the CTS system (Communication and Tracking System) which is used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures.

There may be a transition period before the use of OMS data services becomes mandatory in any given regulatory process. More information will be provided by the relevant business process owner in due course to explain the relevant process changes and timings.

5.1. OMS process in the regulatory context

As described above, EMA manages the process for industry stakeholders and other parties to register organisation data or request update of existing data through the OMS portal. In the context of regulatory procedures, this step is required **before** submitting a regulatory application to the relevant NCA or EMA and also referred to as **"pre-registration" of an organisation/organisation update**.

OMS users will be able to search for organisations and locations and view details of organisations/locations. A search is a starting point to request changes or additions to the organisation data (submit a change request). The following options are available:

- the user is not able to find the organisation, defined by name in a given country, so that they can request the creation of a new organisation;
- if the organisation is found, but the required location is not found, the requestor will need 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 either the organisation or both the organisation and location need to be changed.

Any registered SPOR user can submit an OMS change request. The OMS portal will not prevent a user from submitting a request for an organisation to which they are associated as well as any other organisation. Each request will require supporting documentation/information which will be **validated** by EMA **Data Stewards**, who process all change requests. EMA Data Stewards will undertake data **quality checks** upon pre-registration of a new organisation or receipt of a change request of existing organisation data.

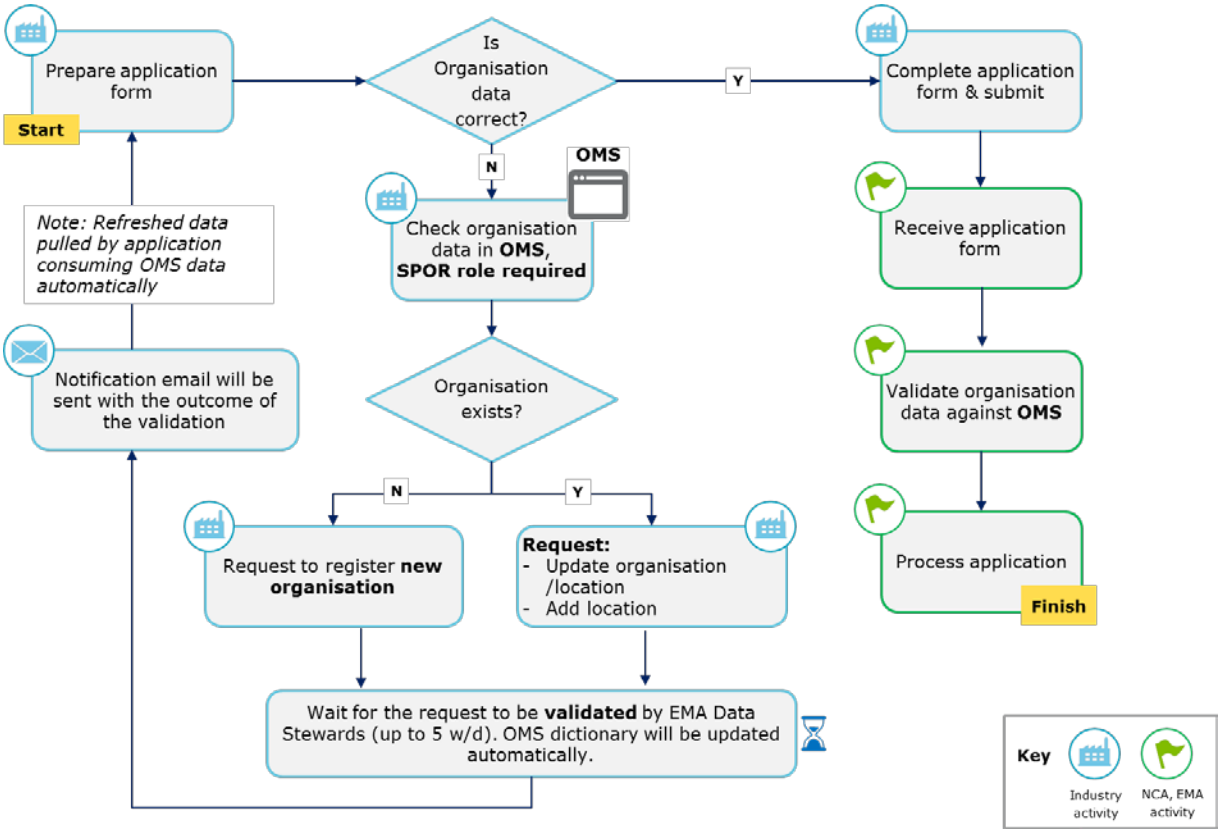
OMS has a built-in address verification service for all EEA countries called "Informatica Address Doctor". This service uses reference address data from the main postal service in each country and verifies the address to confirm the validity of the address data provided in the change request. In the case of any inconsistencies between the EMA Data Stewards and requestors, these will be reviewed and resolved individually.

Once an organisation is registered, it is available in the OMS portal and supplied to the consuming system (e.g. eAF). At that point, the applicant can continue with the completion and submission of the application form. The relevant authority, NCA or EMA will receive the application and can process it without needing to validate the organisation data against OMS, as long as the organisation data feeding through to the application form is from a list that is available in OMS as that time.

In case of eAF, the regulatory authority receiving the application will know the data comes from OMS as on the application form it will have the OMS ID.

This process is outlined below and can be applied to different regulatory processes that plan to use OMS data.

Figure 6. The OMS process in the context of the electronic submission.



6. Accessing the OMS services

Any member of the public (as a guest user) can view and search all OMS content, without having to log in.

Users must be registered with the EMA Account Management portal (this is a central point to manage access to EMA systems, including SPOR) and have a relevant SPOR user role to request changes and additions to organisation data. They will need to be affiliated with a specific industry or NCA organisation. For more information, please refer to the user registration guide available of the SPOR portal.

7. Where to find related information and documents

A selection of documents produced as part of the SPOR programme development, as well as slide decks, form numbers of webinars SPOR team held in 2017-2018, are available on the EMA corporate web site. These documents may be a useful starting point for those who are new to the SPOR programme or are part of the implementation teams.

More comprehensive documents such as user guides or technical documents are published on the SPOR portal under the OMS>Documents section.

OMS training videos are published on the @emainfo YouTube channel. These cover the core functionality for users of OMS.