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Information Management Division

OMS Frequently Asked Questions

OMS Questions & Answers

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Table of Contents

I. About OMS

1. **What is OMS?**

   The Organisation Management Service (OMS) manages one of the four domains of substance, product, organisation and referential (SPOR) master data in pharmaceutical regulatory processes.

   OMS is the source of organisation master data: The OMS Dictionary. It consists of a list of organisations with associated physical location details that can be used as a reference and in support of EU regulatory activities, including electronic applications forms.

2. **Which systems are consuming OMS data?**

   Since OMS is a public dictionary of organisation and location data, we may not have knowledge that is related to other consuming systems.

   Mandatory use of OMS has been already implemented for the following:

   - eAF for CAPS
   - IRIS SA
   - IRIS PD
   - IRIS OD
   - IRIS Inspections
   - Access to EudraVigilance
   - EMA Account Management

3. **In which Regulatory procedures is OMS integrated?**

   In the context of a regulatory procedure (which uses the OMS data) industry stakeholders will 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 for the following regulatory procedures:

Regulatory Procedure	System	Domain	What (ORG data)	Who	Information
Initial MAA/Line ext, Variations, Renewals, Transfers, presubmission activities, etc	eAF, other CP forms	H&V, CAPs only	Applicant, MAH, Manufacturers, …	Applicants	eAF platform news Q&A OMS Mandatory for CAPs
Clinical Trial application	CTIS	H only	Sponsors, CT sites,…	CT Sponsors	Clinical Trials Information System: training and support
All MAA procedures	UPD	V	MAH, Batch release	NCAs & MAH	Union Product Database
MIA, GMP inspections, WSD	EudraGMDP	H & V	EEA and non EEA manufacturers, importers and distributors medicinal products	Organisations currently regulated through EudraGMDP	EudraGMDP

Regulatory Procedure	System	Domain	What (ORG data)	Who	Information
Variations	DADI	H only, CAPs & Non-CAPs	Applicant, MAH, Manufacturers, …	Applicants	Digital Application Dataset Integration (DADI)

4. **Who do I contact with my OMS question?**

   For OMS related questions please contact the EMA Service Desk - subject: OMS.

5. **Where I can find OMS guidance and documents?**

   OMS available documentation can be found on the document repository of the OMS portal:

   • **A2 - Quick initiation process flow** contains an introduction with a quick reference for first time users regarding access and add/update records

   • **Z - SPOR User Registration Manual** will give you guidance on steps to take in order to have one account.

   • **F - OMS Web User Manual** will show you how to use the portal.

   • **E - OMS Change Requests** contains all the steps and documentation required to submit any request.

   • **X - SPOR SLAs** document contains the established SPOR SLA.

6. **What are the Service Level Agreement (SLAs) for OMS data services?**

   The current EMA's SLA is to process 75% of OMS requests, to add or update Organisation data, within five working days and 90% of requests within ten working days.

   Note that the SLA reflects EMA's best efforts and does not constitute a guarantee for every individual request. We strongly advise Applicants and MAHs to proactively verify their OMS entries in advance of any application to avoid undue delays during the process.

   However, for specific cases were turnaround times are or have been missed, please do not hesitate to bring these to the attention of EMA via the EMA Service Desk.

7. **What if the data displayed in the OMS Dictionary does not match my own documentation or the free-text field?**

   If discrepancies are found between OMS data and documentation provided in the application, and, according to the "C3 - OMS Guidance on Assessing Organisation Names and Location Data" (published in the document repository of the OMS portal) it is understood they both refer to the same legal entity, and there will be no validation questions or invalidation. In case of doubts the EMA validation team will contact OMS.

   Only when the data from OMS and the documents does not refer to the same legal entity a validation request for supplementary information will be raised.

II. Access & Roles

8. **How SPOR Industry Super User role can be requested?**

   In order to login into SPOR portal, you need to create an account via EMA Account Management Portal and submit a request for SPOR Super User role, attaching the SPOR Super User Affiliation Template Letter, to get the final approval of the role (https://www.ema.europa.eu/en/documents/other/how-request-first-spor-industry-super-user-role_en.pdf). More information on how to manage user roles can be found on the User Administrator Guide.

9. **How the unaffiliated SPOR role can be requested?**

   Please note that Access to SPOR as an unaffiliated user (not linked to an organisation) will be granted automatically on self-registration to EMA Account Management. This role allows to request the creation of an organisation in OMS.

   Guidance on how to Create an EMA Account is available on the EMA Account Management portal.

10. **How to view the 'Request new organisation' option?**

    Once you have the required SPOR role, and you are logged in OMS portal, you need to perform a search, using the organisation name. If the organisation is not available in the Dictionary, you will be able to submit a change request to create a new organisation by selecting the "Request New Organisation" at the bottom of the screen.

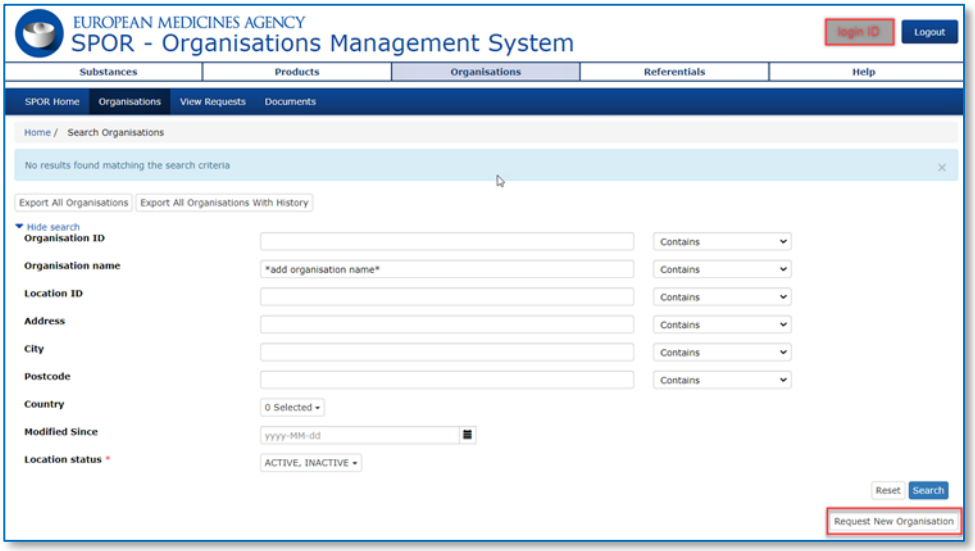

Figure 1. Request new organisation view.

11. **Why there are visible multiple/duplicated ORG-IDs that belong to different locations in OMS?**

    All the lines you see with the name (ORG name) belong to the same organisation, please notice that the ORG ID is the same, only the location data and location ID are different as follows:

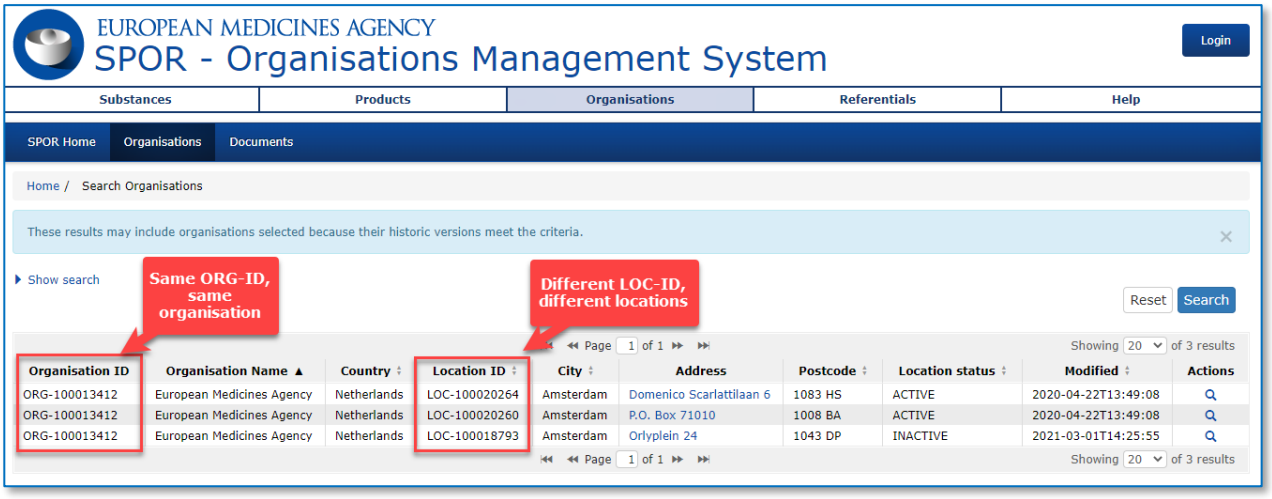

Figure 2. Organisation information view in OMS.

III. Change Requests

12. **How do I create or update OMS data?**

    To create or update entries in the OMS Dictionary you need to submit a Change Request through the OMS portal. EMA OMS Data stewards will assess the requested change and change the OMS data if it meets requirements.

    Guidance on how to search, view, export, input or update data is published on the OMS portal. Consult "F – OMS Web User Manual" in the document repository of the OMS Portal for more information.

    To submit a Change Request, you will need a SPOR user role. Guidance on how to register for EMA systems and request SPOR user roles is also published on the OMS portal. Consult "Z - SPOR User Registration Manual" in the document repository of the OMS Portal for more information.

13. **Who can change OMS data?**

    Anyone can submit a Change Request for any Organisation or Location published in the OMS Dictionary, provided they submit the required supporting documentation. EMA OMS Data stewards will assess the requested change and updated OMS data if it meets requirements.

    Guidance on rules and supporting documentation required for each Change Request type is published on the OMS portal. Consult "E - OMS Change Requests" in the document repository of the OMS Portal for more information.

    Change Requests are generally driven by the business process which uses the OMS data. The user who needs to use the data should take the lead in updating it. In the context of eAFs this means,that Applicants and MAHs will be responsible for ensuring, that all the manufacturer organisations are included in the OMS dictionary as needed for the submission of their regulatory applications. Consult – "H – Manufacturer organisations in OMS dictionary" in the document repository of the OMS Portal for more information.

14. **Is there a risk that Requestors could submit contradictory requests to OMS?**

Regardless of how many companies provide different details the OMS team will always validate the accuracy of the data against the same reference sources (i.e. National Business Registry, DUNS and/or GMP/MIA certificates –(see question 8), and standardise it according to the OMS rules agreed with the Network. There can be only one entry for each Organisation/Location.

Guidance on the OMS data quality rules used are described in detail in the document "C - OMS Data Quality standards" published in the document repository of the OMS portal.

15. **How is a Change Request processed?**

EMA OMS Data Stewards validate the organisation name and its relationship to the location details against reference sources including National Business Registries, Data Universal Numbering System (DUNS) numbers as well as available Good Manufacturing Practice (GMP) and Manufacturing Importation Authorisation (MIA) certificates. Once the information is validated and an EMA OMS Data Steward verifies that the record is not already available in the OMS Dictionary, the data will be added or modified following standardisation as follows:

- Organisation name: standardised as per "OMS Data Quality standards" - published in the document repository of the OMS portal for more information.
- Location data: standardised as per information provided by each National Postal Service by the address verification tool (AddressDoctor).

16. **Whach documentation is required to submit a Change Request?**

Guidance on which documentation is required for each type of request is described in detail in the document "E - OMS Change Requests" published in the document repository of the OMS portal.

17. **How to request deactivation of an organisation published in OMS?**

The OMS Dictionary manages organisations as legal entities from a business perspective. Therefore, it is not possible to deactivate an organisation, if it is still operating as a company and it is Active in the national business registry.

The deactivation of an organisation can only be requested if the organisation has ceased to exist as a legal entity in a certain country.

In order to request the deactivation of an organisation, an "Update organisation" change request needs to be submitted, attaching documentation from the National Business Registry, where it clearly states, that the organisation has ceased to exist as a legal entity. In its absence, a headed letter document signed by the organisation the user represents, clearly stating that the organisation in question has ceased to operate/exist in that Country.

Steps to follow in SPOR portal on how to create a Change request to deactivate an organisation are described in detail in the document "E - OMS Change Requests" published in the document repository of the OMS portal.

18. **How to request deactivation of a location published in OMS?**

In order to deactivate an old location (LOC-ID), you need to submit an "Update location" Change Request to the old location: (LOC-ID). Searching LOC-ID in SPOR portal > select the 'Request change' button > Request reason andchoose the option "deactivate location". Fill in the 'Justification' field with 'old location'. For this type of Change Request, it is not mandatory to attach documentation, only to fill in the justification section.

19. **How to request an update on EudraGMPD/xEVMPD codes in OMS?**

Currently EudraGMPD/xEVMPD codes cannot be modified manually, as the information was imported directly from EudraGMPD/XEVMPD into OMS in 2016. We are planning to update the synchronisation between OMS and EudraGMPD/XEVMPD in the future and the data will be updated accordingly.

This doesn't have any impact on future regulatory submissions. As a general principle, you can submit change requests via SPOR portal in order to update the Organisation name, translation, physical locations and communication details. EudraGMPD site numbers and xEVMPD codes are not maintained by EMA Data Stewards. Updates will be part of the next synchronisation.

20. **Who should register organisation/locations information in OMS?**

    In the context of eAFs, Applicants and MAHs are responsible for ensuring that all the required organisations and locations are included in the OMS dictionary, regardless of the organisation role (Applicant, MAH, Manufacturer) if needed in the forms for the submission of regulatory applications.

    Take into consideration that relevant documentation needs to be provided when registering the organisation.

    Please find attached a link to the guidance:

    http://esubmission.ema.europa.eu/eaf/eAF_1.25.0.0/OMS%20Mandatory%20CAPs%20QandA.pdf

21. **How Organisations are captured in Northern Ireland?**

    Following the published guidance on the implementation of the Protocol on Ireland/Northern Ireland, locations in Northern Ireland will be captured as a different country "United Kingdom (Northern Ireland)"

    - Page:https://www.ema.europa.eu/en/about-us/brexit-uk-withdrawal-eu/brexit-related-guidance-companies
    - Document:https://www.ema.europa.eu/en/documents/other/questions-answers-stakeholders-implementation-protocol-ireland/northern-ireland_en.pdf

IV. Data Quality Standards

Organisation data Quality Standards

22. **Why organisation names are different in Business Registry than OMS?**

    OMS Dictionary intends to provide a standardize list of organisation/location data following OMS data quality standards (rules used by OMS). Standardised list that may not be an exact copy from the official documentation as long as the meaning is the same.

    Examples of OMS standard for organisation names are:

    - **Commas** used to separate name from the legal entity type are not captured as part of the organisation name - rule applicable to all the OMS Dictionary.
    - Organisation names are stored in **Title Case** (First letter of the first word is in capital) generally.

23. **How are Legal entities in Belgium and France reflected in OMS?**

Legal entity types may or may not need to be part of the organisation name. It can be different in each country. For Belgium and France, the Organisation name in the national Business register has no legal entity type as the preferred name. Translation names can contain the legal entity type.

24. **How to register: Departments, Divisions, Factories, Units… as an organisation in OMS?**

    Internal corporate structures (e.g. Departments, Divisions, Factories, Units...) and Personal Names cannot be considered as organisations in OMS as they are not legal entities.

    OMS will maintain the records as registered in the National Business Registry. Such information as Departments, Divisions, Factories, Units etc. will be captured at consuming system level.

25. **How is the identifier (ORG-ID) of an organisation which has been merged reflected in OMS?**

    As per OMS data quality standards, when two active organisations are merged, their original Organisation IDs are grouped in order not to lose any historical data. The ID associated to the oldest record (organisation) will be kept as the main or golden ID for the merged organisation. To search for the organisation in SPOR, either of the Organisation's ID can be used.

26. **In which language should I register the Organisation name?**

    Preferably, in order to facilitate standardisation across OMS Dictionary, it is recommended to request the Organisation name in English. In addition, the local translation of the Organisation name can be stored as a translation under "Alternative names" section.

27. **Why the "U" on legal entities for Spanish organisation names is not added?**

    Preferably, in order to facilitate standardisation across OMS Dictionary, it is recommended to request the Organisation name in English. In addition, the local translation of the Organisation name can be stored as a translation under "Alternative names" section.

    According to ROYAL LEGISLATIVE DECREE 1784/1996 the use of S.L.U. is not regulated as a legal entity, for now, the S.L.U. legal entity type, will be considered only if the single membership can be validated against Spanish Business Registry.

    - Document: III. https://www.boe.es/buscar/act.php?id=BOE-A-1996-17533 art. 403.

Location data Quality standards

28. **If a company has several buildings with different authorisations at one location, it is grouped under the same LOC-ID. How can the respective unit then be selected in the eAF?**

    The below table illustrates examples of how the information on the Organisation details is captured in the MIA(s), in OMS and what consequently should be selected in eAF:

MIA(s)	OMS	eAF
MIA 1 – Antibiotics: Building 30-36 Street 1 City 1 Country 1 **MIA 2 - injectables:** Building 30-36 Street 1 City 1	**If recognised by NPS (combined address):** LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 **If not recognised by NPS (only 1st building):** LOC ID 10000000012	LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 **OR** (LOC ID 10000000012 Building 30 Street 1 City 1

MIA(s)	OMS	eAF
Country 1	Building 30 Street 1 City 1 Country 1 **If Industry also wants building 36 they need new CR and it will create a new LOC:** LOC ID 10000000013 Building 36 Street 1 City 1 Country 1	Country 1 AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1)
MIA 1 – Antibiotics: Building 30-36 Street 1 City 1 Country 1 **MIA 2 - injectables:** Building 36 Street 1 City 1 Country 1	**If Combined LOC existed it will be split:** LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 **Into:** LOC ID 10000000011 **(updated)** Building 30 Street 1 City 1 Country 1 AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1 If Industry also wants building between 30 and 36 they need new CR and it will create a new LOC.	**eAF For antibiotics:** LOC ID 10000000011 (updated) Building 30 Street 1 City 1 Country 1 AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1 **Or even more** **eAF for injectables:** LOC ID 10000000013 Building 36 Street 1 City 1 Country 1

29. **How to request an update of the location when the documentation does not follow National Postal Services sources?**

    Addresses stated in the reference sources (i.e. National Business Registry, DUNS and/or GMP/MIA certificates) are standardised/enriched by an automatic address management tool, called AddressDoctor and validated by EMA data Stewards.

    These are the principles the AddressDoctor uses:

    - This tool pulls address information from the local postal services in every country.
    - This postal service includes also information on city municipality/district/province/state/county etc. which normally would not be on physical letters or official documents.
    - Address quality is defined by its 'mailability' once it is verified, i.e. likelihood of successful delivery to the validated address.

    The location data that we have in the system follows the National Postal Service standards to assure the standardisation process and its consistent with the local authorities.

30. **Where the National Postal Services source can be found?**

In the National Portal Union website is available the Postal addressing system and the universal Post Code database per country.

V. References & links

SPOR portal	https://spor.ema.europa.eu/sporwi/
OMS portal	https://spor.ema.europa.eu/omswi/#/
OMS Document repository	https://spor.ema.europa.eu/omswi/#/viewDocuments
SPOR Super User role Template Letter	https://www.ema.europa.eu/en/documents/other/how-request-first-spor-industry-super-user-role_en.pdf
User Administrator Guide	https://register.ema.europa.eu/identityiq/help/useradmin.html
How to Create an EMA Account guide	https://register.ema.europa.eu/identityiq/help/selfregister.html
Service Desk	Service Deskhttps://servicedesk.ema.europa.eu/jira/servicedesk/customer/portals
EMA Account Management Portal	https://register.ema.europa.eu/identityiq/home.html
EudraGMDP Information	https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/eudragmdp-database
eAF webpage	http://esubmission.ema.europa.eu/index.htm
Q&A OMS Mandatory for CAPs	http://esubmission.ema.europa.eu/eaf/eAF_1.25.0.0/OMS%20Mandatory%20CAPs%20QandA.pdf
Clinical Trials Information System	Clinical Trials Information System: training and support | European Medicines Agency (europa.eu)
Union Product Database Information	https://www.ema.europa.eu/en/veterinary-regulatory/overview/veterinary-medicines-regulation/union-product-database#veterinary-medicines-information-website-section
Union Product Database – Q&As for industry users	https://www.ema.europa.eu/en/documents/other/union-product-database-questions-answers-industry-users_en.pdf
Protocol on Ireland/Northern Ireland	https://www.ema.europa.eu/en/about-us/brexit-uk-withdrawal-eu/brexit-related-guidance-companies

VI. Glossary

OMS	Organisation Management System – provides a dictionary of organisation data and respective locations
SPOR	Substance, product, organisation and referential
EMA Account Management	Secure online platform where you can request and manage access to EMA applications
ORG	Organisation - Company registered with the National Business Registry of a certain jurisdiction/country
LOC	Location - Representation of a physical address
ORG-ID	Organisation unique identifier number in OMS (ORG-1XXXXXXXX)
LOC-ID	Location unique identifier number in OMS (LOC-1XXXXXXXX)
AddressDoctor	Automatic address management tool
National Business Registry (BR)	Registration database of legal entities of a certain jurisdiction/country
EEA	County that is part of the European Economic Area
Non EEA	Country that is not part of the European Economic Area
NCA	National competent authorities
SLAs	Service-level agreements
EudraGMDP	Database on manufacturing, import and wholesale-distribution authorisations, good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates
GMP	Good Manufacturing Practices
MIA	Manufacturing / Importers Authorisation
XEVMPD	Extended EudraVigilance medicinal product dictionary
EudraVigilance	System for managing and analysing information on suspected adverse reactions to medicines
eAF	Electronic application form
IRIS SA	Online platform for handling product-related scientific advice with EMA
IRIS PD	Online platform for handling product-related Parallel distribution with EMA
IRIS OD	Online platform for handling product-related Orphan Designation with EMA
IRIS Inspections	Online platform for handling product-related Inspections with EMA
DADI	Digital Application Dataset Integration
CTIS	Clinical Trials Information System
CT	Clinical Trials

UPD	Union Product Database
WSD	Wholesale distributors
MAA	Marketing authorisation applications
MAH	Marketing Authorization Holder
H	Human
V	Veterinary
CAPS	Centrally authorised products