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Information Management Division

OMS Frequently Asked Questions

OMS Questions & Answers

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1. 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?**

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

- eAF for Centrally Authorised Products (CAPs)
- IRIS scientific advice (SA)
- IRIS parallel distributions (PD)
- IRIS orphan designation (OD)
- IRIS Inspections
- Access to EudraVigilance
- EMA Account Management and EV registration
- Clinical Trials Information System (CTIS)
- Digital Application Dataset Integration (DADI)
- SIAMED
- Union Product Database (UPD)
- Eudra Common Directory (ECD)
- EudraGMDP
- XEVMPD and EV Vet

3. **How and why data can change in OMS?**

Requestors can propose change to our OMS dictionary via change requests (New Org/Loc, New Loc, Update Org, Update Loc, Delete Org/Loc) and customer service tickets.

Additionally, OMS provide data services such as Service lead data curation which also lead to changes in our OMS dictionary. This includes:

−Mappings

−Simple cleansing

−Deltas (SAP/EV/...)

−Enrichments (geocodes, postcodes, district, ...)

4. **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

Regulatory Procedure	System	Domain	What (ORG data)	Who	Information
MIA, GMP inspections, WSD	EudraGMDP	H & V	EEA and non EEA manufacturers, importers and distributors medicinal products	Organisations currently regulated through EudraGMDP	EudraGMDP
Variations	DADI	H only, CAPs & Non-CAPs	Applicant, MAH, Manufacturers, …	Applicants	Digital Application Dataset Integration (DADI)

5. **Does every company have to register on OMS?**

   The necessity of registration in OMS results from the regulatory process, not from OMS. Users should register legal entities and addresses required for the purposes of regulatory processes that use OMS data, e.g. eAF CTIS, EV, EudraGMPD. A list of procedures and systems will be presented later in this session.

6. **Do all types of manufacturers have to register at OMS, including intermediate manufacturers? Does this also apply to decentralised and national applications?**

   All organisations/locations needed for the purpose of CAP eAF/PDF submissions need to be registered in OMS.

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

   For OMS related questions please contact the EMA via: https://support.ema.europa.eu/esc and log-in using your EMA Credentials.

   You can raise a question on the section IT > Ask a question > select Request for information form and choose the following fields:

   - Service: SPOR
   - Service Offering: OMS

   You can report an incident on the section IT > SPOR filling the following forms:

   - Request OMS services: to request support with a change request on organisation/location data that cannot be submitted via the OMS Portal.
   - Report an issue with OMS: to report a technical issue with the use of the OMS Portal

8. **Where can I 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.

9. **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 where turnaround times are or have been missed, please raise a Service request or Incident: https://support.ema.europa.eu/esc and log-in using your EMA Credentials.

10. **Can the attributes be exported in OMS to an Excel file for a specific group of organisations?**

Currently the option available is to export all the organisations and refine the search via excel filters. In case the attributes needed are not visible in the export file, we would kindly ask you to raise a request in ServiceNow.

2. Access & Roles

11. **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)

Please note that OMS do not capture any national and regulatory roles. OMS dictionary will use 'NCA' category for the established NCA by EMA (https://www.ema.europa.eu/en/partners-networks/eu-partners/eu-member-states/national-competent-authorities-human)

More information on how to manage user roles can be found on the User Administrator Guide.

12. **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.

13. **What is the role of the superuser if anyone can change information?**

The role of the superuser was to facilitate the management of users for a single organisation. Now it seems this is no longer needed, and we have implemented an enhancement to make this easier. Now anyone can raise any change request even with unaffiliated SPOR role and no further access is required from OMS perspective. However, if users want, they still can be users and superusers, but it is not mandatory.

14. **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.
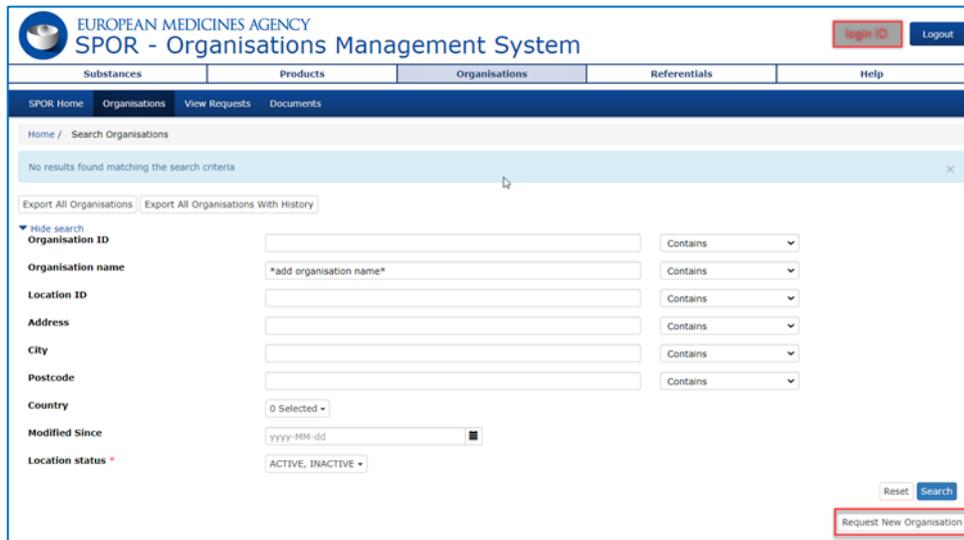
Figure 1. Request new organisation view.

15. **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:
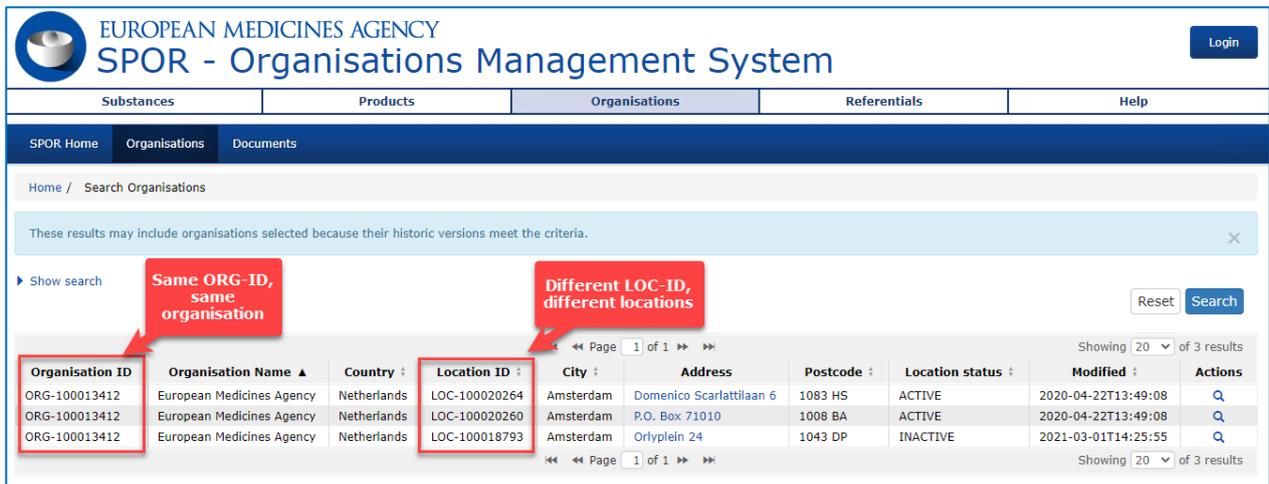
Figure 2. Organisation information view in OMS.

16. **If any change is applied in OMS, is the affiliated user notified by the system?**

Currently, it is possible to export all organisations and refine the search using Excel filters. If the required attributes are not visible in the export file, please make a request in ServiceNow

3. Change Requests

17. **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.

18. **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.

19. **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.

20. **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 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).

21. **Which 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.

22. **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 do not refer to the same legal entity a validation request for supplementary information will be raised.

23. **When to request Location Deactivation?**

only when the company is no longer operating/ doing business in a certain location

24. **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.

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.

25. **How to request an update of the National Business Registry Number in OMS?**

If the organisation registration number details are incorrect or incomplete, you can submit change requests via SPOR portal in order to update the National Business Registry Number for your organization using justification field with brief comment (e.g., Update NBR number to XXXX) providing National Business Registry document which includes both organisation name and its registration number.

Steps to follow in SPOR portal are described in detail in the document "E - OMS Change Requests" published in the document repository of the OMS portal.

26. **If an organisation changes name but not address and it is still the same legal entity, which change request is most appropriate? "Update organisation name" or "Create new organisation"? Are both names required in eAF, DADI?**

Request should replicate the business registry process:

- if only the name has been updated in the business registry, being the registry number the same, the request would be "update organisation name";
- if a new organisation has been created with the new name and the organisation with the old name has been deactivated in the business registry, the request would be "new organisation change request" for the new name, and "update organisation change request" to deactivate the old name;

- If a new organisation has been created with the new name and the organisation with the old name has been deactivated in the business registry and both exist in OMS as separate records, the request would be "Merge-Take over"

27. **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.

Steps to follow in SPOR portal on how to create a Change request to deactivate location are described in detail in the document "E - OMS Change Requests" published in the [document repository](#) of the [OMS portal](#).

28. **How do I request activation of a location that has been deactivated in OMS?**

An OMS location can only be deactivated once the organisation is no longer using it for any business purpose. To deactivate a location, it is mandatory to provide the reasoning for the same (e.g. old address no longer in use). Such deactivated locations which are no longer operational cannot be reactivated and user can create a ticket (https://support.ema.europa.eu/esc) to get more information on the process.

29. **How do I request activation of an Organisation that has been deactivated in OMS?**

An OMS organisation can only be deactivated in accordance with business registry. If the Organisation ceased to exist as a legal entity as per business registry, then such deactivated Organisations cannot be reactivated, and user can create a ticket (https://support.ema.europa.eu/esc) to get more information on the process.

But if the Organisation still exists as a legal entity in business registry, reactivation could be requested via ServiceNow ticket (https://support.ema.europa.eu/esc) providing relevant documents.

30. **When to request Create new organisation?**

Only when a new company is registered as new legal entity in the National Business Registry

31. **When to request Update organisation name?**

Only when the company changes the legal name in the National Business Registry

32. **How to request an update of a location published in OMS?**

Do not request an update location if they are not a copy from those on your reference document, but still correct, since this may be due to the OMS address verification tool and/or Quality standards applied.

The update at location level is applicable if the organisation has moved to a different address within the same country and the old location is no longer valid/being used by the company. Proceed as follows:

1) update the location details and

2) provide a comment under justification mentioning the old location should be deactivated (e.g. site no longer in operation).

In the absence of justification, we will create the new location and leave the old one ACTIVE. If the organisation has moved to a different address within the same country, EMA will proceed creating a new location.

Steps to follow in SPOR portal on how to create a Change request to update location are described in detail in the document "E - OMS Change Requests" published in the [document repository](#) of the [OMS portal](#).

33. **If there are different address details in different official documents, is there one document that is more reliable than others to define the correct address?**

Address data is standardized by the address verification tool (AddressDoctor) based on information provided by each national postal service. On the website of the National Postal Union, the postal addressing system and the universal postal code database for each country are available:https://www.upu.int/en/Postal-Solutions/Programmes-Services/Addressing-Solutions

34. **Why the changes requested and approved via change request are not visible in OMS?**

Please note that EMA's SLA is that the Agency will process 75% of OMS requests to add or update Organisation data within five working days and 90% of requests within ten working days. 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: https://support.ema.europa.eu/esc and log-in using your EMA Credentials.

35. **Why haven't I received the change request notification email?**

Review the Junk folder of the email address of the user who submitted the request. If the notification email is not present, please do not hesitate to bring these to the attention of EMA via: https://support.ema.europa.eu/esc and log-in using your EMA Credentials.

36. **How to request an update on xEVMPD codes in OMS?**

Since 4/Mar/2024 synchronisation between OMS and XEVMPD is now in production. OMS receives information from EV in real time and data stewards can take up to 5 working days to validate, standardised and implement EV changes in the OMS dictionary.

If there is any misalignment between EV and OMS, please report it through ServiceNow helpdesk (https://support.ema.europa.eu/esc)

Please find below scenarios from PMS Info Day -

37. **How to request an update on EudraGMDP codes in OMS?**

The Eudra ID's that are currently placed in OMS, these are internal EudraGMDP keys and were facilitated during initial integration between OMS and EudraGMDP. Since EudraGMDP is consuming from OMS now, these IDs are no longer maintained.

In addition, kindly note that OMS doesn't capture EudraGMDP Document Reference Number.

38. **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

39. **How are Organisations 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

40. **What if the data displayed in the dictionary OMS is not updated because they are historical organisations in OMS that are not currently valid legal entities? For organisations that use historical data in their applications (e.g., eAF), is there a check to see if the ORG is valid?**

OMS has begun reviewing organisations/locations that have not been updated for more than 18 months to ensure that the data is still valid/correct, i.e., exists as a legal entity. We anticipate that various checks will also take place during the regulatory process: The applicant intentionally selects the legal entity; the regulator verifies that it may be used in this context.

4. Data Quality Standards

<u>Organisation</u> data Quality Standards

41. **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 if 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.

- EEA organisation name can be maintained as captured in national business registry. NON-EEA Organisation names are stored in **Title Case** (First letter of the first word is in capital) generally.

42. **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.

43. **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.

As an alternative, the clinical trial sponsor can also submit the request to OMS via CTIS through the option "+New Organization". In this case the sponsor can add a new investigational site when it is not found in OMS, submit the registration form from CTIS to OMS and then proceed with the submission of the application without the need to wait the OMS validation period. Below are some screen shots that explain the process and the specific steps to be followed:

1. User is obliged to search the organization in OMS

2. If the user does not find the organization in OMS, then has the option to select "+New Organization"

3. The user complete the forms that pop up when clicking in "+New Organization", which will then be submitted to OMS and if does not meet the OMS Data quality standards it will be rejected

4. The user will have displayed the site in CTIS and can continue adding the additional information required. The sponsor does not need to wait for the validation of the Organization in OMS and can proceed with the submission of the CTA, once all required information has been entered.

44. **How to register Clinical Trial sponsors and/or sites as an organisation in OMS?**

Any organisation that is to be successfully included in the OMS dictionary must be created using the OMS change request submission. For clinical trial sponsors not listed on a National Business registry, OMS has developed a special process to support the registration by attaching a dedicated headed letter with all mandatory information populated: "J - CT registration Headed letter template" published in the document repository of the OMS portal.

Clinical trial sites which were TEMPORARILY created in the OMS Dictionary will be deactivated since we now have the new CTIS functionality, which allows Clinical trial sites to register directly in CTIS. Only register sites that can be validated by National business registries will remain ACTIVE in the OMS Dictionary. For more information, see "E - OMS Change Requests", Chapter 2 "Request of a new Organisation" in the document repository of the OMS Portal.

45. **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.

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

The use of Unipersonal legal entity for Spanish organisations in OMS is allowed, as long as users submit a change request to update the organisation name along with a proof of registry issued by Spanish business registry where the unipersonal status is available.

<u>Location</u> data Quality standards

47. **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 Country 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 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	LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 **OR** (LOC ID 10000000012 Building 30 Street 1 City 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
		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

MIA(s)	OMS	eAF
	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.	Building 36 Street 1 City 1 Country 1

48. **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 also includes 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.

49. **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.

50. **How does the system handle multiple locations/door numbers in one street?**

Door numbers in the same street are considered as different locations, as they are standardised according to the information provided by each national postal service. In case of large properties, OMS recognises the numbers specified in the house number as large properties for each national postal service. On the website of the National Postal Union, the postal addressing system and the universal postal code database for each country are available: https://www.upu.int/en/Postal-Solutions/Programmes-Services/Addressing-Solutions

51. **How to request Entrepreneur/Natural Person registration in OMS?**

Whilst a long-term solution is under assessment, certain registered Entrepreneurs need to be added to OMS to be able to proceed with veterinary procedures in UPD, EudraGMDP certificates and EV MAH obligations

OMS will register Individuals/Entrepreneurs not registered with official National Business Registry but registered in the publicly available official Entrepreneur database* of each country

The sources* used are published in the OMS Data Quality Standards, other possible sources should be requested/reported via ServiceNow

Individuals/Entrepreneurs will be registered in OMS with two categories:

• Industry/Pharmaceutical company – to ensure downstream systems can use them

• Individual/Entrepreneur (NEW)

5. 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
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

6. 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