



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance on supporting documentation/information to be provided with OMS change requests

For OMS users



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1. Purpose of this document

This document provides guidance on the documentation which should be attached or referred to in the OMS change requests. The numbering indicates the order of documentation preference for each request type. Providing more than one document can also facilitate and speed up the validation process.

Organisation roles such as MAH, Applicant, Sponsor, Manufacturer, etc. are not defined as part of organisation master data in OMS. Indeed, a given organisation may perform multiple roles at the same time. An MAH can also be a manufacturer but also a Sponsor within the context of different medicinal products. Even for the same medicinal product, an organisation can act as the MAH and a manufacturer at the same location. Validation of change requests to update OMS dictionary will not be based on the role(s) the organisation may perform as part of different regulatory processes. The requirement for documentation supporting change requests considers the location as a more relevant factor. The availability of pertinent documentation about organisations located within the EEA may differ from those located outside the EEA, for example in regions such as USA, China or India.

Pre-requisite: This document is to be read in conjunction with the reference document: EMA/740982/2016: Organisation data quality standards in OMS (OMS Data Quality Standards) where you can find the quality standards applied when mastering Organisations names and addresses in OMS, which explains why as a result OMS data are not necessarily an exact copy of the data from National Business Registry (or other documents/sources), but reflect a reality and should likewise be considered as valid and correct by the business processes (e.g. regulatory procedures).

2. Request of a new Organisation

Definition and key concepts

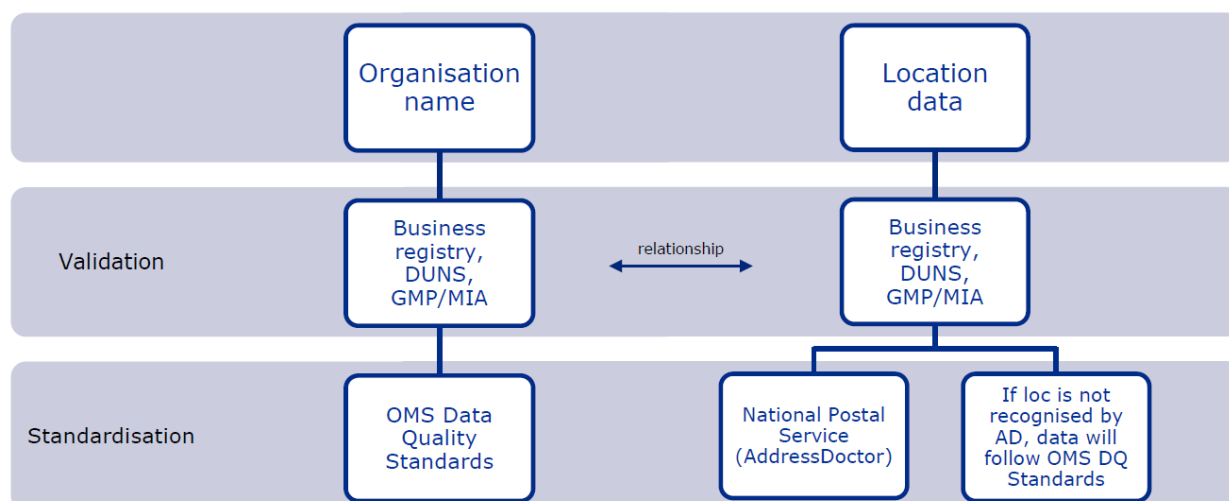
An organisation (name and location) represents a company registered as a **legal entity** in a certain country. A location represents a distinct physical address for a given organisation and such a physical address is unique for that organisation.

OMS does not capture organisation roles (e.g. MAH or manufacturer), but reflects “equivalent information” as in the National Business Registry of a certain jurisdiction:

- For Organisations located in EEA countries, the organisation name will be validated against National Business Registry (when available) and data (e.g. Organisation name and legal entity abbreviation) will be standardised as per OMS Data Quality Standards;
- For Organisations located in non-EEA countries, the organisation name will be validated against Business Registry (whenever available), official website and data (e.g. Organisation name and legal entity abbreviation) will be standardised as per OMS Data Quality Standards;

- Location data will be validated and standardised by the OMS address verification tool (AddressDoctor). AddressDoctor is populated with address reference data as provided by each National Postal Service.

Figure 1 Validation and Standardisation of organisation and location data




For any clinical trial sponsors, not registered in a National Business registry, OMS created a specific Change Request process designed to support onboarding to CTIS. Any organisation to be successfully added to the OMS Dictionary must be created using the OMS change request functionality with attached CT registration Headed letter¹ populated with all mandatory information.

- Sponsor** organisations will be created in the OMS Dictionary without any name validation process. OMS will be able to maintain sponsors records ACTIVE as long as we are able to verify that its being used as a sponsor in a current CTIS application. Such verification will be performed during our periodic re-validation to ensure that organisations that have remained unchanged for over 2 years are still valid. Any sponsor registered based on the CT registration Headed letter will be Deactivate if not used in CTIS as a sponsor or contact cannot be established after 3 consecutive attempts via the email provided upon registration.
- 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.
- CTIS sponsors should avoid submitting the request for the creation of the organisation in OMS via CTIS. If CTIS sponsors notice any error message with this functionality they should report it to EMA Service Desk and proceed to submit the change request directly via OMS portal.

¹ Template is available in SPOR portal under the [documents](#) section, as *J - CT registration Headed letter template*

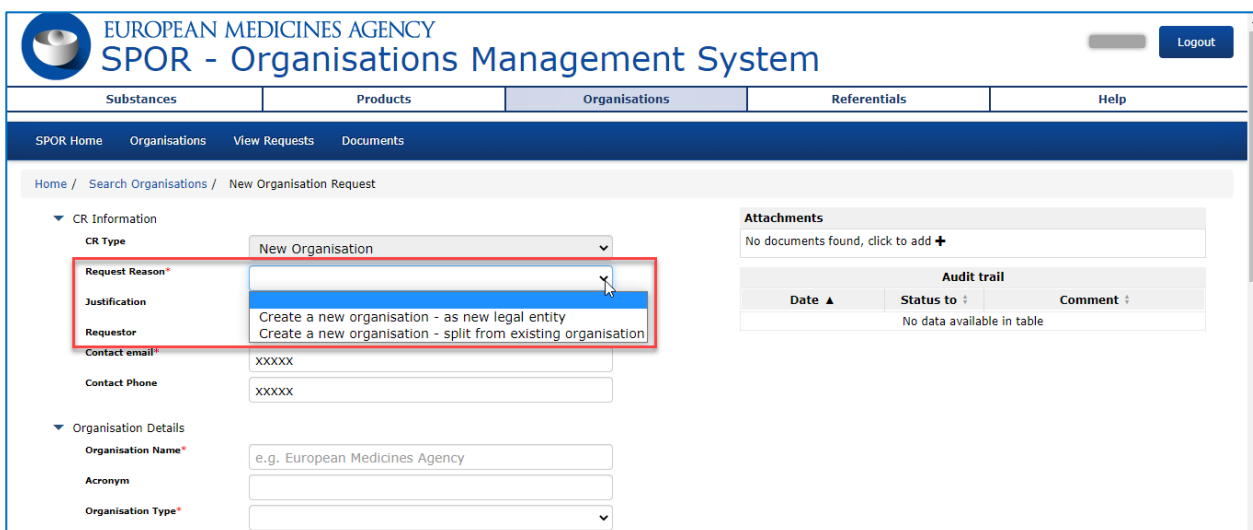
When to request a new Organisation

- If the organisation does not exist in OMS - Search OMS using Organisation Name and Country to determine if the organisation is present in OMS.


 Do not create a new organisation if the organisation name and/or location details are incorrect or incomplete. Instead, request an update (see section 3. Update Organisation Name)

- There are two cases (Request Reason) to request a new Organisation:
 - New organisation as legal entity or
 - As a consequence of a split from an existing organisation

Figure 2 Requests reasons available while creating a new organisation



The screenshot displays the 'SPOR - Organisations Management System' interface. The top navigation bar includes 'Substances', 'Products', 'Organisations', 'Referentials', and 'Help'. Below this, a secondary bar shows 'SPOR Home', 'Organisations', 'View Requests', and 'Documents'. The main content area is titled 'Home / Search Organisations / New Organisation Request'. On the left, under 'CR Information', the 'CR Type' is set to 'New Organisation'. The 'Request Reason' dropdown is highlighted with a red box, showing two options: 'Create a new organisation - as new legal entity' and 'Create a new organisation - split from existing organisation'. Below this, there are fields for 'Justification', 'Requestor', 'Contact email', and 'Contact Phone'. Under 'Organisation Details', there are fields for 'Organisation Name', 'Acronym', and 'Organisation Type'. On the right, there is an 'Attachments' section with a message 'No documents found, click to add +'. Below that is an 'Audit trail' table with columns 'Date', 'Status to', and 'Comment', and a message 'No data available in table'.

 Please note that in case the organisation has changed the name (e.g. change from "Company A Pharma Kft." to "Company A Hungaria Kft."), the old name should already be present in the database. Please search for the old organisation name and create a change request to update it. Do not create a new organisation change request. In this case, the rules for updates apply – see section 3. Update Organisation Name.

In case the old organisation name is not present in the database, do not create obsolete data (legacy data), please proceed creating a new Organisation using the new name. Similar rules apply to location details, in cases e.g. a city administration would have renamed a street or changed the postcode of a given street (i.e. the organisations have not moved).

Required Documentation

Table 1 Required documentation to create new organisation

Jurisdiction	Organisation is...	Required Documentation
A. EEA	A1. Registered in the National Business Registry - please refer to table 5 - except for Organisations located in Germany, Sweden and Bulgaria	No document is required. Note: OMS data stewards will validate the information submitted against the National Business Registry website at the time when processing the CR and data will be added accordingly. Before submitting a change request, verification on National Business Registry references is required. In case the Organisation and location that are the subject of the change request is not present in the National Business Registry website, the change request will be rejected (apply point A3.)
	A2. Located in Germany, Sweden and Bulgaria registered in the National Business Registry	National Business Registry document which includes the full company name and address Note: German and Swedish National Business Registry do not display address data. Companies registered in Bulgaria with Cyrillic characters.
	A3. Not registered in the National Business Registry e.g. Hospital, University, Research Institution, etc.	The EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address
		If the above not available, a document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.)
		If none of the above exists, a headed letter document signed and dated by the organisation the user represents, stating the full company name and address
	A4. Not registered in the National Business Registry & performing as Clinical trial Sponsor in CTIS	CT registration Headed letter completed with all mandatory information – template is available as <i>J - CT registration Headed letter template</i> in SPOR portal under the documents section
	A5. Not registered in the National Business Registry e.g. Entrepreneurs	Individual registration Headed letter with all mandatory information – template is available as <i>K - Individual registration Headed letter template</i> in SPOR portal under the documents section.
B. outside the EEA	B1. Organisation registered in the National Business Registry - please refer to table 5	A National Business Registry document which includes the full company name and address Or state business registry document for United States and India which includes the full company name and address. For Indian Registration of Firms in Telangana, please provide Firm Registration No, Registration Year, and Registration District.
	B2. Not registered in the National Business Registry	If the above not available, the EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address

Jurisdiction	Organisation is...	Required Documentation
	e.g. Hospital, University, Research Institution, etc.	If none of the above exists, a headed letter document signed and dated, by the organisation the user represents, stating the full company name and address
	B3. Not registered in the National Business Registry & performing as Clinical trial Sponsor	CT registration Headed letter completed with all mandatory information – template is available as <i>J - CT registration Headed letter template</i> in SPOR portal under the documents section.

All documentation supplied should be dated.

3. Update Organisation Name

When to request an update to an Organisation Name

- If the organisation name details are incorrect or incomplete (e.g. incorrect spelling, capitalisation as per National Business Registry, information missing).
- Organisation name will follow title case standardisation unless National business registry website displays the organisation name in case sensitive format. Applicable only for EEA countries. For further information please refer to **Table 5**. This is only applicable to organisation name and the legal entity type will continue to follow the OMS data quality standards. ([C-OMS Data Quality Standards](#): Annex I – Standard legal entity types and location details per country)
- If the organisation has changed the name and the previous name is present in OMS (e.g. *Pharma Company A* to *Pharmaceutical Company B*).
- If the Organisation has changed the legal entity (e.g. from *Company A 'S.A.'* to *Company A 'S.A.S'*).
- If the organisation was acquired by another organisation (e.g. *Pharma Company A* bought *Laboratory Pharmaceutical B* and *Laboratory Pharmaceutical B* does not exist anymore – update the name of the organisation purchased).
- If the organisation is required to update legal entity for Spanish organisation to include Unipersonal status

Note: EMA will proceed merging both records, not only to be able to have all the existing locations reflected under the same organisation but also to keep access to all historical information of the organisation purchased.

- Do not update organisation details if the organisation has changed the address (location) while remaining in the same country – the rules for add a new location apply – see section 4.
- Do not update organisation details if the organisation moves to a different country. The rules for request a new organisation apply – see section 2.

Figure 3 Requests reasons available to update organisation

Required Documentation

Table 2 Required documentation to update organisation name

Jurisdiction	Update is...	Required Documentation
A. EEA	A1. Available in the National Business Registry - please refer to table 5	<p>No document is required.</p> <p>Note: OMS data stewards will validate the information submitted against the National Business Registry website at the time when processing the CR and data will be updated accordingly. Before submitting a change request, verification on National Business Registry references is required. In case the Organisation name update that is the subject of the change request is not present in the National Business Registry website, the change request will be rejected (apply point A3.)</p> <p>if partial capitalization is available in organisation name at National Business Registry website, no document is required.</p> <p>if National Business Registry have organisation name all in capital letters, then as title case rule is applicable, unless company requests to update the organisation name providing a headed letter document signed by the organisation.</p>
	A2. Not available in the National Business Registry - please refer to table 5	National Business Registry document which includes both, old and new, organisation names

Jurisdiction	Update is...	Required Documentation
	A3. Organisation not registered in the National Business Registry e.g. Hospital, University, Research Institution, etc.	A document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.) If the above not available, a headed letter document signed by the organisation the user represents, stating the previous full company name and address of at least one of its locations registered in OMS and the new full company name and same address
	A4. To add unipersonal status to a Spanish Organisation	National Business Registry document where it is clearly stated that the organisation has a unipersonal status.
B. outside the EEA	B1. Organisation registered in the National Business Registry - please refer to table 5	A National Business Registry document which includes the previous company name with the National Business Registry number and the updated National Business Registry document which includes the new company name with the National Business Registry number. Or state business registry document for United States and India which includes the previous company name with the National Business Registry number and the updated state Business Registry which includes the new company name with the National Business Registry number.
	B2. Organisation not registered in the National Business Registry e.g. Hospital, University, Research Institution, etc.	If the above not available, a headed letter document signed by the organisation the user represents, stating the previous full company name and address of at least one of its locations registered in OMS and the new full company name and same address

All documentation supplied should be dated.

4. Update Organisation Alternative Name

Definition and key concepts

Alternative names have 'language' defined. Language can be repeated to show different variations of names business deem necessary to be stored. Alternative names will be added to OMS upon user's request or if they are present in any of the source systems.

For Belgium and France Organisation name in the register has no legal entity type as preferred name. Alternative name field can contain the legal entity type.

When to request an update to an Organisation Name

- If a local language translation of the organisation name does not exist in OMS. Note that Organisation names can be stored in multiple languages. When available, English name will be the preferred name.

- If a trade name apart from the preferred name does not exist in OMS. Preferred name in OMS is verified by public information in the National Trade registries.
- Trading-as companies name
- For Belgium and France: If legal entity is not present in OMS
- Do not update/add Alternative names for internal corporate structures (e.g. Departments, Divisions, Factories, Units...) and Personal Names. The mentioned structures cannot be considered as organisations in OMS.
- Do not update/add Alternative names for trade names or translations not possible to verify.
- Request Reason: 'Update of organisation name – Alternative name change'

Required Documentation

No specific documentation is required. However, it is recommended to provide an explanation for the easier verification of the alternative name.

5. Update Organisation National Business Registry number

reqDefinition and key concepts

A company registration number is a unique combination of numbers and, in some cases, letters. The company registration number is used to identify your company and verify the fact that it is an entity registered with the national business registry of a particular country.

Note: Currently, this information is only available through the API and export from the OMS portal.

Any changes to wrong National Business Registry number needed can be submitted using justification field with brief comment e.g., Update NBR number to XXXX

The screenshot displays the SPOR - Organisations Management System interface. The top navigation bar includes links for Substances, Products, Organisations, Referentials, and Help. The main content area shows a form for updating organisation details. The 'Justification' field is highlighted with a red rectangle. The form includes sections for CR Information, Request Reason, Justification, Requestor, Contact email, Contact Phone, Organisation Details, and Attachments.

When to request update organisation National Business Registry number

- If the organisation registration number details are incorrect or incomplete

Required Documentation

- National Business Registry document which includes both organisation name and its registration number.

6. Add a new Location

Definition and key concepts

A location represents a distinct physical address for a given organisation and such a physical address is unique for that organisation. If two/more organisations operate at the same physical address, each location will have a unique LOC ID.

A location represents the physical address. Although, additional addresses can be generated and linked to the same location, business will only manage a single physical address per location.

Location data is validated and standardised by the OMS address verification tool. This tool is populated with address reference data provided by each National Postal Service.

When to request a new Location

- If the location does not exist in OMS. Search OMS using Organisation Name and Country to determine if the location is present in OMS.
- If the organisation owns multiple locations/addresses within the same country and not all of them are captured.
- If the organisation has acquired a new location/address within the same country.
- Do not create a new location if the organisation moves to a different country. The rules for request a new organisation apply – see section 2.
- Do not create a new location if the location details are incorrect or incomplete. The rules for updates apply – see section 5.

Figure 4 Requests reasons available to add location

The screenshot shows the SPOR - Organisations Management System interface. The top navigation bar includes links for Substances, Products, Organisations, Referentials, and Help. The main navigation bar includes links for SPOR Home, Organisations, View Requests, and Documents. The breadcrumb trail indicates the current path: Home / Search Organisations / View Organisation Location / New Location Request. The form is titled 'New Location Request' and contains several sections. The 'CR Information' section includes a 'CR Type' dropdown set to 'Add Location', a 'Request Reason' dropdown with a red box around it, a 'Justification' field with a blue highlight, and a 'Requestor' field. The 'Request Reason' dropdown menu is open, showing three options: 'Add a physical location - as new legal entity', 'Add a physical location - move from one physical location to another', and 'Add a physical location - following a merger/take over'. The 'Justification' field is highlighted in blue. The 'Requestor' field is highlighted with a red box. The 'Contact email' field is highlighted with a red box. The 'Contact Phone' field is highlighted with a red box. The 'Organisation Details' section includes fields for 'Organisation ID', 'Organisation Name', 'Acronym', and 'Organisation Type'. The 'Attachments' section shows 'No documents found, click to add +'. The 'Audit trail' section shows 'No data available in table'.

Required Documentation

Table 3 Required documentation to add new location

Jurisdiction	Location is...	Required Documentation
A. EEA	A1. Available in the National Business Registry - please refer to table 5 - except for Organisations located in Germany, Sweden and Bulgaria	No document is required. Note: OMS data stewards will validate the information submitted against the National Business Registry website at the time when processing the CR and data will be added accordingly. Before submitting a change request, verification on National Business Registry references is required. In case the location that is the subject of the change request is not present in the National Business Registry website, the change request will be rejected (apply point A3.)
	A2. Located in Germany, Sweden and Bulgaria registered in the National Business Registry	National Business Registry document which includes the full company name and address Note: German and Swedish National Business Registry do not display address data. Companies registered in Bulgaria with Cyrillic characters.
	A3. Not available in the National Business Registry	The EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address If the above not available, a document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.)

Jurisdiction	Location is...	Required Documentation
	e.g. Hospital, University, Research Institution, etc.	If none of the above exists, a headed letter document signed and dated by the organisation the user represents, stating the full company name and address
B. outside the EEA	B1. Registered in the GS1 database	A document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.)
	B2. Not registered in the GS1 database	A National Business Registry document which includes the full company name and address
		If the above not available, the EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address
		If none of the above exists, a headed letter document signed and dated, by the organisation the user represents, stating the full company name and address

All documentation supplied should be dated.

7. Update Location

When to request an update Location

- If information is missing or incorrect (e.g. incorrect spelling, incorrect postcode only if the address remains the same).
- If the floor has changed or is missing.
- Do not update the location details 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.
- 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.

Note: If the organisation has moved to a different address within the same country, EMA will proceed creating a new location.

Figure 5 Requests reasons available to update location

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type: Update Location

Request Reason*:
Update to physical location data - Administrative data change
Deactivate location

Justification:

Requestor:

Contact email*: XX

Contact Phone:

Organisation Details

Organisation ID:

Organisation Name*:

Acronym:

Organisation Type*: Industry

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ▾	Comment ▾
No data available in table		

- If the organisation has moved to a new country i.e. meaning it has no longer any working locations (addresses) in the country of origin, proceed as follows:
 - deactivate the organisation, status to set as INACTIVE - the rules for deactivation apply - see section 6
 - create a new organisation in the new country - the rules for creation apply - see section 2
- To update address in the local language (address localised) select the language from the dropdown list and update location data.

Figure 6 How to requests update address in the local language (address localised)

Location Details

Location ID

PT EN PT

Choose local language

Update location data

Only the version of the address currently being displayed will be included in the request

Update location data

City

Postcode

County

Country* Portugal

Required documentation

Table 4 Required documentation to update location

Jurisdiction	Location is...	Required Documentation
A. EEA	A1. Available in the National Business Registry - please refer to table 5	No document is required. Note: OMS data stewards will validate the information submitted against the National Business Registry website at the time when processing the CR and data will be updated accordingly. Before submitting a change request, verification on National Business Registry references is required. In case the Organisation name update that is the subject of the change request is not present in the National Business Registry website, the change request will be rejected (apply point A3.)
	A2. Not available in the National Business Registry - please refer to table 5	National Business Registry document which includes the full company name and address
	A3. Not registered in the National Business Registry	The EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address
	e.g. Hospital, University, Research Institution, etc.	A document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.) If the above not available, a headed letter document signed by the organisation the user represents, stating the full company name and address
B. outside the EEA	B1. Registered in the GS1 database	A document stating the GS1 identifier number along with the full company name and address (in the form of letter/email/scanned printout, etc.)

Jurisdiction	Location is...	Required Documentation
	B2. Not registered in the GS1 database	A National Business Registry document which includes the full company name and address If the above not available, the EudraGMDP site reference number or document for the GxP certificate which includes the full company name and address If the above not available, a headed letter document signed by the organisation the user represents, stating the previous full company name and address

All documentation supplied should be dated.

8. Deactivate Organisation

When to request to deactivate an organisation

- If the organisation has ceased to exist as a legal entity in a certain country.
- Please note that the deactivation of the organisation will deactivate all the locations linked to that organisation by default.
- Therefore, in OMS the organisation and respective locations will remain visible with a status INACTIVE.
- Nothing is deleted from the OMS Dictionary, however, once a record is Deactivated, it will no longer be available to consumer systems (e.g. EV registration, eAF, IRIS).


 Please note that OMS does not capture any regulatory classification (e.g. MAH, Sponsor, affiliates or headquarters), it captures only Organisations from a legal entity perspective in a certain jurisdiction. If an organisation is no longer an MAH but it still exists as a legal entity, no changes should be submitted to OMS.

Figure 7 Request reason available to Deactivate organisation under CR type Update Organisation

Required Documentation

1. A document from the National Business Registry clearly stating that the organisation has ceased to exist as a legal entity or
2. 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

9. Deactivate Location

When to request to deactivate a location

- If the location is no longer being use by a legal entity in a certain country.
- If the selected location is the only ACTIVE location for the organisation, the user should request to deactivate the organisation instead, see section 6. Deactivate Organisation.


 Please note that nothing is deleted from the OMS Dictionary. In OMS the location will remain visible with a status INACTIVE. Once a record is Deactivated, it will no longer be available to consumer systems (e.g. EV registration, eAF, IRIS).

Figure 8 Request reason available to Deactivate location under CR Type Update Location

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type: Update Location

Request Reason: Update to physical location data - Administrative data change
Deactivate location

Justification:

Requestor:

Contact email: XX

Contact Phone:

Organisation Details

Organisation ID:

Organisation Name:

Acronym:

Organisation Type: Industry

Location Details

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to ▼	Comment ▼
No data available in table		

Required Documentation

No specific documentation is required. However, it is recommended to provide an explanation for the deactivation of the location (e.g. site no longer in operation).

10. Request change on Location communication details

No documentation is required to add/update communication details. OMS data steward will not validate this information.

Please provide a general email/phone - personal communication details will be more difficult to maintain and it's only possible to have 1 email address and 1 phone number per location.


 Please note that this information will be visible to the general public.

Figure 9 Where to find the Location communication details

▼ Location Details

Address*

e.g. 30 Churchill Place

e.g. Canary Wharf

City

e.g. London

Postcode

e.g. E14 5EU

County

e.g. London

Country*

Location Email ⁽¹⁾

e.g. john.doe@ema.europa.eu

Location Phone ⁽¹⁾

Intl Code: e.g. +44

e.g. 02036606000

Ext:

DUNS ID

e.g. 01-234-5678

GS1 ID

e.g. 0-00-12345-67890-5

☐

Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields.

If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

Telephone number should consist of Country code preceded by '+' and the number. Extension number is stored separately as shown in the screenshot above.

11. Request change on DUNS and/or GS1:

Required the provision of supporting documentation from DUNS and/or GS1 indicating the correct number, full company name and address.

Figure 10 Where to find the DUNS and GS1 identifier

Location Details

Address*

e.g. 30 Churchill Place

e.g. Canary Wharf

City

e.g. London

Postcode

e.g. E14 5EU

County

e.g. London

Country*

Location Email ⁽¹⁾

e.g. john.doe@ema.europa.eu

Location Phone ⁽¹⁾

Intl Code: e.g. +44 e.g. 02036606000 Ext:

DUNS ID

e.g. 01-234-5678

GS1 ID

e.g. 0-00-12345-67890-5

☐

Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields.
If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

12. Reference of National Business Registry websites, within and outside the EEA:

Table 5 National Business Registry (NBR) website per country and if it has public information on previous organisation names

Country Code	Country	Reference	Information on previous organisation names?	NBR number publicly available	capitalization on NBR
AT	Austria	Kompany	Yes	Yes	Mix
BE	Belgium	Belgian Business register	Yes	Yes	Mix

Country Code	Country	Reference	Information on previous organisation names?	NBR number publicly available	capitalization on NBR
BG	Bulgaria	Ministry of Justice, Registry Agency	No	Yes (UIC/PIC)	Yes
CH	Switzerland	Swiss Business register	Yes	Yes (UID)	Mix
CY	Cyprus	Cypriot Registrar of Companies	No	Yes	Yes
CZ	Czechia	Czech Business register	Yes	Yes (IČO/ID)	Mix*
DE	Germany	German Company register	Yes	Yes	Mix
DK	Denmark	Danish Business register	Yes	Yes	Mix
EE	Estonia	Estonian Business Register	No	Yes	Mix
EL	Greece	Greek Business Registry	Yes	Yes (No. Γ.Ε.ΜΗ)	Yes
ES	Spain	Spanish Chamber of Commerce	No	Yes	Yes
FI	Finland	Finland Business Information	Yes	yes (Business ID)	No
FR	France	Trade and Companies Register	Yes	Yes (first 9 digits of SIRET no.)	Mix
HR	Croatia	Croatian Court Register	Yes	Yes (MBS)	Mix
HU	Hungary	Hungarian Business Register	No	Yes	Mix
IC	Iceland	Iceland Directorate of Internal Revenue / Icelandic Trade Directory	Yes	Yes (Social Security no.)	No
IE	Ireland	Companies Registration Office	No	yes	Mix
IT	Italy	Italian Chamber of Commerce	No	No	Mix
LI	Liechtenstein	Liechtenstein Enterprise Register	No	Yes (FL-Number)	Mix
LT	Lithuania	State Enterprise Centre of Registers	No	Yes	Mix
LU	Luxembourg	Luxembourg Business Register	Yes	Yes (RCS Number)	Mix
LV	Latvia	The Register of Enterprises of the Republic of Latvia	Yes	Yes	Mix
MT	Malta	Malta Business Registry	No	Yes	Mix
NL	Netherlands	Dutch business register	No	Yes	No
NO	Norway	Norwegian Business Register	Yes	Yes	Mix
PL	Poland	Polish Court Register	Yes	Yes	Yes
PT	Portugal	Portuguese Justice ministry	Yes	Yes	Yes
RO	Romania	Romanian Business Register	No	Yes	Yes

Country Code	Country	Reference	Information on previous organisation names?	NBR number publicly available	capitalization on NBR
SE	Sweden	Swedish Companies Registration Office	No	Yes	Mix
SI	Slovenia	Slovenian Business Register	Yes	Yes	Mix
SK	Slovakia	Slovakian Business Register	Yes	Yes	Mix
UK	United Kingdom	Companies House	Yes	Yes	Yes

Outside EEA

Title case rule is followed by default for organisations outside EEA and the links to each jurisdiction are captured in the "OMS Data Quality standards" document.

*Mix: mixture of organisation name patterns including partial capitalisation, full capitalisation and title cases in some cases.

GS1 (Global Location Number) <https://gepir.gs1.org/index.php/search-by-qtin>

13. Glossary

DUNS	Data Universal Numbering System - identifies a company as being unique from any other in the Dun & Bradstreet Data Cloud
EEA	Country that is part of the European Economic Area
Outside EEA	Country that is not part of the European Economic Area
EudraGMDP	Database on manufacturing, import and wholesale-distribution authorisations, good manufacturing-practice (GMP) and good-distribution-practice (GDP) certificates
GS1	Global Location Number - Identification Key used to identify physical locations or legal entities
Location	Representation of a physical address
Organisation	Company registered with the National Business Registry of a certain jurisdiction/country
OMS	Organisation Management System – provides a dictionary of organisation data and respective locations
National Business Registry	Registration database of legal entities of a certain jurisdiction/country

14. Annex I - Business scenarios vs. Business rules on OMS IDs

Business scenario ID	Business scenario	Business scenario - Examples	New Org_ID (Yes/No)	New Org_ID Version ³ (Yes/No)	New Loc_ID (Yes/No)	New Loc_ID Version ² (Yes/No)	Comments
BS001	Change of Organisation name	Pfizer Limited -> Pfizer UK Limited	No	Yes	No	No	If legal entity changes in business sense (according to GS1) the ID would change.
BS002	Change of Organisation address (physical)	Physical move from one physical location to another with a different legal address. 23 Peter Street --> 10 Harley road	No	No	Yes	No	
BS003	Change of Organisation address (Administrative)	Authorities change the street name. 23 Peter Street --> 23 Roman Street Authorities change the municipality name. London --> Londonium	No	No	No	Yes	
BS004	Change of Organisation contact/communication related details	Change of email address or phone number	No	No	No	Yes	One Email address and one telephone number will be stored for address Locations.

² Versions are recorded as time stamps i.e. Active Start date & Active End date.

Business scenario ID	Business scenario	Business scenario - Examples	New Org_ID (Yes/No)	New Org_ID Version ³ (Yes/No)	New Loc_ID (Yes/No)	New Loc_ID Version ² (Yes/No)	Comments
BS005	Take over of a company but both companies still exist legally with same name and physical address. If name(s) changes following this take over, we apply scenario 1.	Glaxo Plc. now owns Biogen Pharma	No	No	No	No	
BS006	When a physical address changes as a consequence of the merger or split	An organisational unit (location) becomes a new legal entity with different name. Organisation A-address 'x' merges with Organisation B-address 'y', resulting with Organisation A-address 'y'.	No for both A and B	No for A / Yes for B	No for both 'x' and 'y'	Yes for 'y' and Yes for 'x'	Location_ID 'y' is moved to the surviving organisation. Web services to include the time_stamps which can be used for system to system querying based on IDs and time stamps. Requirements document and API UC on search need to be updated. Web service design should also meet this requirement.
BS007	When a physical address changes as a consequence of the merger or split	An organisational unit (location) becomes a new legal entity with different name. Organisation A has 2 locations 'x' and 'y'. Location 'y' becomes a different legal entity with a new name. Organisation B created with location 'y'.	No for A / Yes for B	No for both A and B	No for both 'x' and 'y'	Yes for 'y' and No for 'x'	A new organisation is created and Location_ID 'y' is moved to be under this new organisation.
BS008	Different legal entities operating at the same location	Same building different floors	Yes	n/a	Yes	n/a	
BS009	A new/changed function(s) of an organisation		No	No	No	No	Functions of organisations are not stored in Organisation data

Business scenario ID	Business scenario	Business scenario - Examples	New Org_ID (Yes/No)	New Org_ID Version ³ (Yes/No)	New Loc_ID (Yes/No)	New Loc_ID Version ² (Yes/No)	Comments
BS010	A new/changed relationship between organisations		No	No	No	No	Hierarchical relationship management will not be implemented in this project. This service is dependent on other 3rd party organisation services which will provide information about relationships between HQs & Affiliates and horizontally between organisations.
BS011	A new/changed relationship between organisation and individual acting as contact		No	No	No	No	Contacts can be associated on the organisation level or location level. The approach taken is to link contacts on the location level. When new 'individuals' are linked to an existing location, this has no impact on the version of the location. The same happens when the 'individual' is de-linked to the existing location. The changes to relationship between parties (organisation/individual) are traceable through party association 'time stamps'.
BS012	Change of floor within the same building for the same legal entity	15 Greenwich Road. Floor 5 --> 15 Greenwich Road. Floor 7.	No	No	Yes	No	
BS013	Different legal entities functioning at the same location even the same floor		Yes	n/a	Yes	No	Since organisation name is also a component of issuing ID, this is not a problem.

Business scenario ID	Business scenario	Business scenario - Examples	New Org_ID (Yes/No)	New Org_ID Version³ (Yes/No)	New Loc_ID (Yes/No)	New Loc_ID Version² (Yes/No)	Comments
BS014	A legal entity moves from one building to the another under the same site/complex/campus/park owned by the same legal entity	HQ offices of the legal entity moves from one building to another.	No	No	Yes	No	
BS015	Correction of previous data entries such as typos - treated as administrative changes.	A typo on organisation name or street name for instance.	No	Yes	No	Yes	