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Information Management Division

Overview of OMS change request process

Table of contents

1. About this document

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

This document will be reviewed periodically for accuracy.

2. Executive summary

OMS data services opened to stakeholders in December 2017. They were invited to start registering their SPOR users and to begin requesting changes and additions to the organisation data content. Since the launch, the uptake of OMS has been very good, with over a thousand change requests submitted in the first six months. OMS change requests are one of the key aspects of the service. They enable the creation of a new organisation, the addition of a location or updating of an existing organisation and/or location data. The process itself is simple and consists of three steps: submission, validation and approval.

Starting with a brief introduction to the type of changes users can request, this document provides an overview of the OMS change request process, focusing on the validation step and highlighting some of the data quality principles applied by EMA data stewards.

Key challenges and observations

- Often change requests do not include relevant documentation/information;

- Low awareness of the OMS data quality standards and the approach to data mastering applied by the EMA data stewards.

Recommendations

- Change request should include **relevant documentation/ information,** except for very minor (administrative e.g. spelling mistakes) changes where documents are not required;

- OMS Data Stewards have observed the change requests including the DUNS document, as the supporting document, have proven to be the easiest to validate so far. The **DUNS document is one of the best reference documents** as the EMA Data Stewards are able to validate the organisation and, specifically, the address data with it;

- All change requests are validated using the OMS data quality standards as guidance. It describes the business rules and approaches for registering new organisations and/or locations in OMS. OMS users will also find the document useful when requesting additions and/or updates to organisations/locations in the OMS dictionary;

- OMS users are advised to become familiar with **Change requests validation in OMS** guidance**, Organisation data quality standards in OMS** guidance and **OMS Controlled Vocabularies (CVs)** guideline. The documents are available on the SPOR portal > Organisations > Documents > View.

3. What type of changes can users request in OMS?

OMS users can search for organisations and locations and view details of them. **Search** is a **starting point** to request changes to the organisation data (submit **change requests** (CRs)). The following options are available:

1. if a user is not able to find the requested organisation – defined by name in a given country – they can request the **creation of a new organisation**;

2. if the organisation is found, but the required location is not found, a user can request to **add a new location** to the existing organisation;

3. alternatively, a user locates an existing organisation and location but determines that the **organisation and/or location data** needs to be **updated**;

4. when the Location status is Inactive, but the organisation is Active a user can request to **update organisation data** or **add new locations**;

Note: when the **organisation** status is **Inactive**, a user **cannot request any changes**.

4. Summary of the OMS change request (CR) process

The change request process in OMS is simple; there are three steps: **submission**, **validation** and **approval**.

The process starts with the requester completing the request form with the required information. At this point, it is important to highlight that the request **must include relevant documentation,** except for very minor changes (administrative changes such as spelling mistakes) when documents are not required.

After the request is submitted, it is **validated** by EMA Data Stewards (an indicative 5 working-day SLA applies). At the validation stage, Data Stewards review the request data against the information in the document(s) provided with the request. The purpose of the validation is to ensure that the information provided can be accepted. There are **two** possible scenarios:

- **Request has met validation** criteria and relevant information and/or document(s) are provided. This results in the request approval and automatic update of the OMS dictionary. OMS service will also send a change request validation confirmation message once the process is completed and data is published.

- **Validation criteria** are **not met.** Here the possible outcomes are:

  a) Change Request (CR) is put **on hold** if Data Stewards need to query or ask for specific information from the change request submitter. Once the response is received, the CR validation process resumes.

  b) Change Request is **rejected.** There could be different reasons for rejecting a CR, for example an Organisation/Location already exists, there isn't enough information to validate a request or document provided is not admissible.

See OMS Controlled Vocabularies (CVs) guideline available on the OMS portal.

4.1. Validation of OMS change request

All change requests are validated using the **OMS data quality standards** as **guidance**. The data quality standard describes the business rules and approach for registering new organisations and/or locations in OMS. OMS users can also find the document useful when requesting additions and/or updates to organisations/locations in the OMS dictionary. The section below highlights some of the data quality principles that are described in this guidance.

OMS supports the management of organisation and location-related data represented mainly in **Latin characters**, specifically the extended ISO Latin character set. OMS Data Stewards will be able to ensure the quality of the data if it is provided in the Latin character set. Organisation and/location data is also accepted in Bulgarian and Greek characters; however, an accurate validation of the data will not be guaranteed. Data that is submitted in Bulgarian and Greek will be accepted without manual validation and published as it is provided, except for location address data which can be transformed by the address validator service in OMS.

With regard to **organisation names** in OMS, there are three key data elements i.e. main name, acronym and alternative names. The **main name** is **most often in English** (when available, English name will be the preferred name). The **acronym** is only populated if it is available and it is **not mandatory**. Organisations do not need to have an acronym for them to be published in the dictionary. The same follows for change requests; these will be validated without any acronym value. **Alternative names** are also published in the OMS dictionary to support business processes which may have specific needs.

e.g. Martindale Pharmaceutical Limited - preferred name
Martindale Pharmaceutical Limited Trading as Martindale Pharma - EN alternative name

Alternative names can be added by submitting an Update Organisation change request. The existing name should be replaced with an alternative name in the request, and in the "Justification" field an alternative given name should be added.

The mastered location data consists of the address data and communication details (telephone and email) if provided. The address data can be represented in multiple languages. If the English representation of the language exists, this will be used as the main address. The address verification service can also automatically generate the same address in other languages associated with a given country, jurisdiction or subdivision; this is known as 'address localised' in OMS. The OMS dictionary publishes all the existing address representations with a language code. The user can request changes to a main address and/or address localised via the update Location change request.

Once an address is verified the **address validator** ('address doctor' services – part of the master data management (MDM) tool) will validate the address data based on the national postal services reference address files which are available in the MDM toolkit. The address validator identifies the country/jurisdiction first, where the address is present, and then maps the address against the same jurisdiction as the postal service reference address file. If it finds a match for the address, it may transform and enrich the existing data based on the information in the reference address files.

Enrichment can also take place for the sub-locality, county, state/region values as well as the GPS coordinates. The data transformation, standardisation and enrichment can be applied to the main address as well as the 'address localised'. The OMS users **should not** submit change requests to remove this additional data unless it is fundamentally wrong. The OMS service team will review the address transformation approach and rules and adjust the service as needed in the future. Submitting a change request for the deletion of this data is likely to be rejected by EMA data stewards. This and

other aspects of OMS data management will be discussed in the RMS and OMS Key User Group once it is operational.

Communication details are collected regarding the location and not the organisation. Users are advised to provide a generic email contact (mailbox) as well as telephone number pertaining to the location, not to an individual.

One of the OMS validation rules that enables the successful validation of change requests is the requirement of **supporting documentation**. The supporting documentation can vary from Business registry documentation, which indicates the organisation's name and registered address, to the GXP certificate document, the DUNS or GS1 registration document or self-certified document stating the organisation's name and address. On the OMS portal, in the documents section, the **Change requests validation in OMS** document lists the supporting documentation for the different types of change requests.

One of the **formatting standards** in OMS is that the organisation name, as well as the address data, is in **title case**, this is manually updated for organisation names when there are acronyms in the name or when the Trademark of the name is entirely or partly in capitals, these needs are accommodated as necessary. For **legal entities**, different standards are applied and adhered to mainly for consistency across the different jurisdictions. Guidance has been provided detailing how the legal entity types are defined in the organisation name, country by country. This is a live document and it is continuously updated.

For the location address, the data is in title case. When the address is verified and validated for most countries (as GPS coordinates do not cover every single country) the relevant GPS code is included and published on the web portal. OMS users **should not** submit requests for changes to address data pertaining to title case formatting. EMA data stewards will most likely reject such requests.

OMS Location ID is mapped to xEVMPD or EudraGMPD data, and the relevant IDs of the source records are published together with the location ID when the legacy data consolidation takes place. One or more source records, e.g. from xEVMPD or EudraGMPD, can be mapped to the OMS Location ID. These mappings are visible on the web portal as well as through the API (Application Programming Interface).

GDPR requirements

In December 2017, a release of a new feature was introduced in the change request form. The form included a tick box which the data submitter must select to indicate that they are happy with the publication of the data, specifically in relation to the location telephone number and email address. This tick box was introduced to satisfy the new GDPR requirements and enable the data submitter to provide proactive consent for EMA to publish the submitted Organisation and location data, including the email address and telephone number.

5. Access to SPOR

Any member of the public (as a guest user) can view and search all OMS content, without having to log in. Users must be registered with the EMA Account Management portal (this is a central point to manage access to EMA systems, including SPOR) and have a relevant SPOR user role to request changes and additions to existing data. They will need to be affiliated with a specific industry or NCA organisation.

6. Where to find related information and documents

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

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

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