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Information Management Division

Using Referential and Organisation master data in eAF

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1. Purpose of the document

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

2. Introduction

The use of pharmaceutical and regulatory data can vary between organisations. This data may be stored in different formats using different database systems, applications, or data models. As a result, the same concept may be represented or entered in a variety of ways. The consequence is that data is not consistent and it cannot easily be re-used. Moving towards standardised data can create business value by providing trusted, accurate, validated master data that can be used for different purposes.

The goal of **SPOR** programme is to centralise the management of data for **Substances**, **Products**, **Organisations,** and **Referentials** and **enable** a consistent basis for **reuse**.

EMA has been consulting stakeholders on the benefits of using SPOR data in applications and business processes. Consultation with the eAF group resulted in the plan to integrate eAF with OMS. The integration implementation date was set for 15 December 2017. At that point, OMS started supplying organisation master data to MAA Human, MAA Vet, Renewal and Variation application forms. The applicants were encouraged to begin using the master data supplied from OMS, to become familiar with the process before its use is mandated. Use of OMS data in eAF is implemented alongside free text box. Mandating of OMS will not be through eAF.

In 2019 OMS data is expected to support regulatory submissions in the Common European Submission Portal (CESP) dataset module, which will mandate the use of OMS. A transition period of six months will be allowed after CESP dataset module goes live. At that point selection from OMS only for MAH, MA Applicant and manufacturer for initial MA Applications will be available. eAF initial MAAs will be removed (TBC). More information will be provided in due course by the relevant business process owner.

RMS was already integrated with eAF and supplying referentials data to the application forms. From 1 July 2018 use of RMS portal for submitting change requests to add new / update existing referentials will be replace the use of mdmd@ema.europa.eu to request new referentials and updates.

The scope of **Referential Management Services** (RMS) and **Organisation Management Services** (OMS) available for eAF users covers:

- **single source of referentials data** and "organisation dictionary" (**list of organisations and their physical locations**) to be used as a reference and to support regulatory activities;
- referential and organisation data is accessible through the **SPOR web portal**[2] and **programmatically** through an application programming interface (API);
- a **new process** for stakeholders to register and update organisation and referential data;
- **EMA Data Stewards** to oversee management of data and provide support to stakeholders.

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

3. Referential data in eAF and impact on eAF users

In June 2017 RMS replaced EUTCT (EU Telematics Controlled Terms) as the central repository and provider of referentials data for the EU medicines regulatory network (EMRN). All lists previously published in EUTCT were migrated into RMS, except for all substance-related lists which will remain in EUTCT until the Substances Management Services (SMS) is delivered (*EUTCT should be used only for browsing and downloading the Substances-related lists)*. EMA acts as data broker (the one-stop shop) and liaises with Maintenance Organisations and Data Owners to consolidate referentials lists into a single place and structured format and, where relevant, in line with ISO IDMP standards.

Referential data is available through the RMS portal and programmatically through the API. RMS is integrated with Electronic Application Form (eAF) and supplies referential master data to MAA Human, MAA Veterinary, Renewal and Variation application forms. The applicant can **select** the relevant **referential term from the drop down list**, complete and submit the form. The relevant authority (NCA or EMA) will receive the application and can process it without the need to validate referentials data against RMS. If an NCA disagrees with a term used by the applicant, they should ask the applicant to update the referentials list with the correct term before re-submitting the regulatory application. NCAs can request new terms and updates to terms on behalf of an applicant; however, they are encouraged to advise applicants to submit these requests themselves.

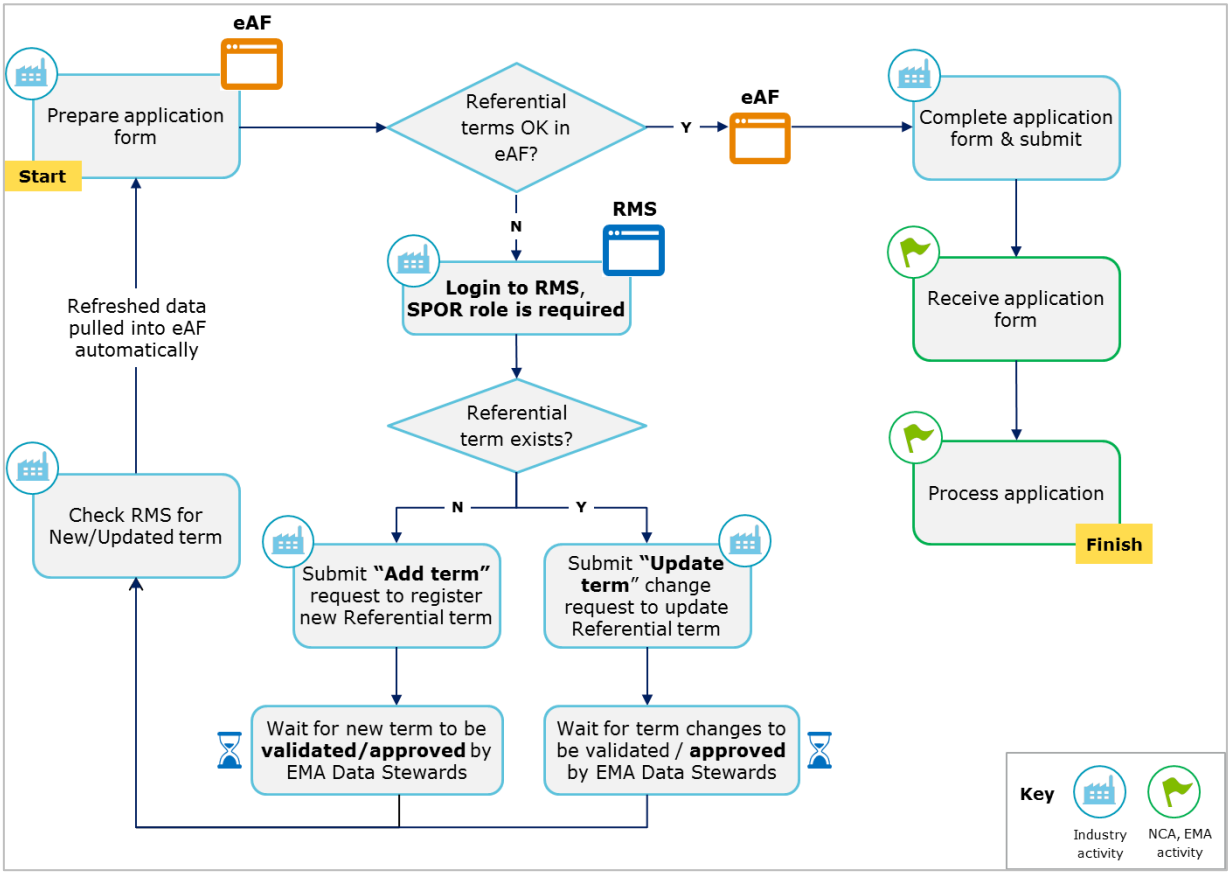
If the **term** is **not in the eAF drop-down list or** the term exists, but it **requires** an **update**, an applicant should request pre-registration of a new term or request a term update (by submitting a change request) through the RMS portal. This step should take place **before** the **application is submitted** to the relevant regulatory authority.

EMA Data Stewards will manage all change requests and undertake a data quality check before pre-registration of new or updated terms, independently of whether or not EMA owns the lists. For terms owned by external organisations, Data Stewards will check with the relevant organisation to validate any requested changes. Once a term is registered, it will be made available in the RMS portal and supplied to the eAF. Figure 1 below summarises the high-level RMS process in the context of eAF submissions. It identifies activities undertaken by the applicant, EMA Data Stewards, and regulatory authority.

Note: There are some exceptions around how to register new or updated terms in cases where EMA is not the Maintenance Organisation. These are explained the RMS operating model document.

From July 2018 the use of the RMS web portal will become mandatory for submitting data change requests – at this point submission of change requests via *mdms@ema.europa.eu* will no longer be accepted.

Figure 1. RMS data in the eAF context



4. Overview of Organisation Management Services (OMS)

OMS is a new service that EMA has implemented. It provides a central source of validated organisation data (OMS dictionary) that consists of lists of organisations with related physical locations. OMS data can be used to support EU regulatory activities. OMS does not define which role(s) the organisation perform(s) since this depends on the context in which the data is used. An organisation from the OMS dictionary can act as an MAH (Marketing Authorisation Holder) in the context of one medicinal product but also as a Sponsor or Manufacturer for another medicinal product.

In OMS, organisation data is structured and with unique IDs (Organisation_ID[1] and Location_ID[2]). An organisation name is unique in a given jurisdiction but not across different jurisdictions. Two organisations with the same name in different jurisdictions will have different Organisation_ID. For an organisation to be published in the OMS dictionary, it must be associated to at least one Active or Inactive Location. The Location_ID will be kept when the Location is moved to another Organisation. An address can be used in multiple locations under different organisations. In addition to this, a location can only be linked to one organisation at one point in time.

Organisation data is available through the OMS portal and programmatically through the API. OMS users will be able to search for organisations and locations and also view details of them. Search is a starting point for the user to request changes (submit change requests) to the organisation data. The following options are available:

[1] Organisation_ID is used to uniquely identify organisations in OMS
[2] Location_ID is used to uniquely identify physical locations in OMS

- if the 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;
- if the organisation is found, but the required location is not found, the requestor needs to submit a request to add a new location to the existing organisation;
- alternatively, a user locates an existing organisation and location but determines that the organisation and/or location need to be changed.

Not all organisations are included in the OMS dictionary yet. Its content is gradually expanded with additional data sets (see Figure 4 under Annex).

For more information about OMS please see the OMS operating model document.

5. Organisation data in eAF and impacts on applicants

In December 2017 OMS was integrated with all four eAF forms (release v1.22) - Marketing Authorisation Application, Variation, Renewal (veterinary and human) and started supplying organisation master data. Organisation names together with location physical addresses are available to select in the forms after performing a search. This option is implemented alongside the "Free Text" box which still exists and can be used. In July 2018 version 1.23 of eAF will bring a further OMS integration enhancement - OMS Location (address) versions will become available in eAF for Variation form (veterinary and human). The use of OMS data in eAF is initially optional, and eAF will not mandate the use of OMS.

The go-live of the CESP dataset module & OMS integration for Human & Veterinary MAAs is planned for Q1 2019 (TBC). Following the go-live there will be a transition period after which the CESP dataset module will mandate the use of OMS data, but only for MAH, MA Applicant and Manufacturer for Initial MA Applications (planned for Q3 2019). At that point eAF initial MAAs will be removed (TBC). More information will be provided by the relevant business process owner in due course.

5.1. Using OMS in eAF

Applicants should use the drop-down list in the form to perform a search for organisation data and familiarise themselves with the use of OMS **before** the use of organisation data from OMS becomes mandatory.

Applicants can search for the following organisation attributes in eAF:

- IDs: **Organisation_ID** and **Location_ID**
- Name: **Organisation name** (Main name and alternative names)
- **Country**
  - eAF v1.22 forms allow search only on the current version (no historical/previous versions)
  - A change will be implemented in the eAF variations form (v1.23), in the **Present/Proposed** section, to also allow searching for historical/previous versions in the **Present** section (but not on Proposed)

Two outcomes are possible after searching for an organisation:

1. **Organisation name & address/location are correct** – in this case, users may proceed with using the OMS-supplied data.

2. **Organisation name and/or address/location is not found or is incorrect** – in this case, the users can:

   a) Enter the address details **manually** in the free text fields, as previously in the eAF;

   or

   b) **Follow the OMS process** to submit requests for adding or amending organisation data before the eAF submission for the following data:

   - MAHs for Human medicinal products CAPs & NAPs, and MAHs for Veterinary CAPs;
   - MA Applicants for Human and Veterinary CAPs.

Note: From September 2018 stakeholders will be able to submit OMS change requests to include MA Applicants and MAHs for Veterinary NAPs.

Figure 2 summarises when given data content will be available in the OMS dictionary and as of when stakeholders can start submitting relevant OMS change requests.

Figure 2. SPOR change request status in the context of eAF and mandating of OMS

"Role"		Content available in OMS	Stakeholders can start submitting OMS CRs from:	Mandatory in CESP dataset module (only for initial MA application)
Applicants	H CAP	Yes	**As of January 2018**	6 Month after CESP dataset module goes live. (eAF forms will be removed)
	H Non-CAP (MRP, DCP, National)	No plans, we expect many will fall within data set 4 (Sponsors target end Q3 2018)	**As of Q3 2019**	
	V CAP	yes	**As of January 2018**	
	V Non-CAP (MRP, DCP, National)	Content populated via submission of OMS CRs	**As of September 2018**	
MAH	H CAP	End of Q4 2017	**As of January 2018**	
	H Non-CAP (MRP, DCP, National)	End of Q4 2017	**As of September 2018**	
	V CAP	End of Q4 2017	**As of January 2018**	
	V Non-CAP (MRP, DCP, National)	Content populated via CRs	**As of September 2018**	
Manufacturers	H CAP	By end of Q2 2019	**As of Q3 2019**	
	V CAP	By end of Q2 2019	**As of Q3 2019**	
	H Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As of Q3 2019**	
	V Non-CAP (MRP, DCP, National)	By end of Q2 2019	**As of Q3 2019**	
Other	Eg. CROs, Billing Orgs., Contact people Organisations, etc.	Not planned yet.		

Key:

MAH - Marketing Authorisation Holder

MAA – Marketing Authorisation Applicant

CAP – Centrally Authorised Product

NAP – Nationally Authorised Product

MRP – Mutual Recognition Procedure

DCP - Decentralised Procedure

5.2. Summary of the process

Figure 3 below provides a high-level summary of activities undertaken by an applicant, EMA Data Stewards, and NCAs in the context of using OMS data in eAF. It focuses specifically on applicants submitting requests through the OMS portal to add or amend organisation and location data.

The process starts with the preparation of the electronic application form (eAF) by the applicant. Users have access to the organisation dictionary via drop-down lists in the eAF. If the required organisation data is correct, users can continue with completion and submission of the application.

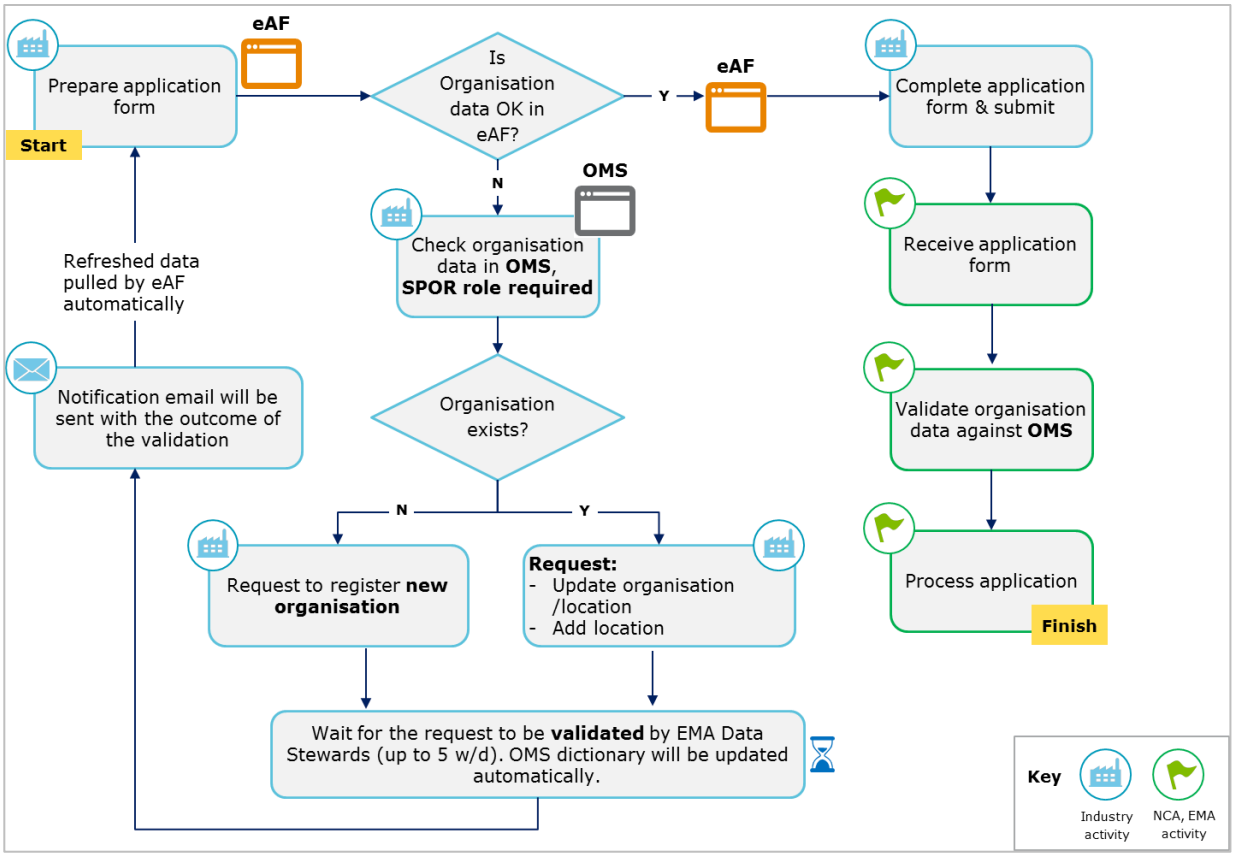
If the organisation data is not found or requires changes, applicants can submit OMS change requests to register new organisation(s), request updates to organisation(s) and location(s), and add location(s). *Note: SPOR user role is required to submit an OMS change request.*

Once an OMS change request is submitted, EMA Data Steward will validate the request. In most cases, validation will be completed within five working days. Applicants should allow sufficient time for validation of OMS change requests before making their eAF submissions to Regulatory Authorities (NCA or EMA). Once the request is validated, a notification email will be sent to the requestor with the outcome of the validation. At the same time, the new (or updated) organisation data will be available for selection in the eAF.

The relevant authority, NCA or EMA will receive the application and can process it without needing to validate the organisation data against OMS, as long as the organisation data feeding through to the application form is from a list that is available in OMS at that time.

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

Figure 3. OMS data in the eAF context



6. Access to the SPOR portal

Any member of the public (as a guest user) can view and search all RMS lists and terms and 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.

7. Summary of key messages

- OMS delivers a list of organisations with associated physical locations (OMS dictionary) that can be used to support regulatory business processes such as eAF and CESP in future;
- OMS content is growing, and data quality is expected to improve over time;
- Business owner of the process using OMS data decides how to use it and when to mandate its use;
- **Use of OMS data in eAF, CESP:**
  - **eAF will not mandate** the use of **OMS** data; **free text will still be available.**
  - **CESP will mandate the use of OMS data in the application form**. Organisation data will have to be pre-registered in OMS (before submitting the form) and can be selected in CESP. For initial MA Applications, this is not planned before Q3-2019.
  - Applicants are advised to **familiarise** themselves **with the use of OMS data** and with the process **before the use of OMS data will be mandated.**
  - **Applicants and MAHs** are responsible for **registering/updating organisation data in OMS** before regulatory submissions (e.g. Initial MAA, Var and Renewal) see Figure 2.
- Submission of OMS Change Requests for Veterinary MAH & MAAs for NAPs starts from September 2018
- Forum to discuss OMS operational issues:
  - Key User Group is planned to be set up in Q4 2018.
  - Use of OMS data in eAF - a focus group is in operation for eAF/CESP. This group is composed of representatives from CMDx, regulatory EMA (H+V) and NCAs.
- Informing manufacturers in & outside EEA about OMS implementation.
  - Applicants/MAHs are responsible for ensuring manufacturers data needed for the regulatory applications is in OMS see Figure 2.

8. SPOR related information and documents

A selection of documents produced as part of the SPOR programme development, as well as slide decks from some of the webinars held by the SPOR team in 2017 and 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 Documents sections.

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

9. Annex

Figure 4. Data sets to be included in the OMS dictionary

Data sets to be included in the OMS dictionary	Status
Data set 1: • Marketing Authorisation Holders (MAHs): Human (H) + Veterinary (V) Centrally Authorised Products (CAPs) and Human (H) Nationally Authorised Products (NAPs); • Marketing Authorisation Applicants (MAAs): (H+V) CAPs; • Maximum Residue Limit (MRL) applicants (Veterinary); • EU National Competent Authorities; • Regulatory Authorities.	**Completed.** **Users can start submitting change requests (CR) for Data set 1.**
Data set 2: • EV (EudraVigilance) organisations to support EV user management.	**Completed.**
Data set 3: • Orphan Designation organisations (OMS data supporting IRIS portal for submitting an orphan designation (OD) application).	**Completed.**
Data set 4: • Sponsors (H) CAPs and NAPs.	Target to complete: Q3 2018
Data set 5: • Manufacturers (H+V) CAPs; • Manufacturers (H+V) NAPs.	Target to complete: by end of Q2 2019
Data set 6: • Veterinary MAHs & MAAs for NAPs. Note: **EMA proposes to include the MAHs for NAPs Veterinary via the OMS change request process. As of September 2018 stakeholders can start submitting the OMS change requests for this data set.**	Submission of change requests begins as of September 2018.
Data set 7: • Organisations supporting the Clinical Trial application procedures Note: The exact content of the organisations to be added will be communicated before the end of 2018. The organisations will be added via the OMS change request process.	Start of submissions of changes will be in 2019 – to be communicated before end of 2018.