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Information Management Division

Using Referential and Organisation data in eAF

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1. Introduction

The use of pharmaceutical and regulatory data can vary between organisations. These data may be stored in different formats using different database systems, applications, or data models. As a result the same concept may be represented in a variety of ways. For example, in the context of Referential data "Capsule, hard" can be presented as "Capsule", "Hard capsule", or "Caps". This absence of standardisation also applies to organisation data where the same organisation name can be entered differently into various databases or applications, *e.g.* "Middle Trade Group Limited" could be entered as "MTG Limited" or "MTG Ltd". The consequence is that data is not consistent and it cannot easily be reused.

The goal of the SPOR programme is to deliver services that will centralise the management of pharmaceutical and regulatory data for **Substances**, **Products**, **Organisations,** and **Referentials;** this will **enable** a consistent basis for **reuse**.

SPOR data will be compliant with the ISO IDMP group of standards that define medicinal products uniquely. Use of ISO IDMP is mandated by the [Commission Implementing Regulation (EU) 520/2012](#) (articles 25 and 26), which obliges EU Member States, marketing authorisation holders and EMA to make use of the standards. This will impact on many areas of the pharmaceutical regulatory environment. Whilst the ISO IDMP standards relate to human medicinal products, SPOR applies to both **human and veterinary** domains.

Delivery of SPOR is phased. **Referential Management Services** (RMS) and **Organisation Management Services** (OMS) were the first two services deployed to production in June 2017. They provide a foundation for the subsequent delivery of **Products Management Services** (PMS) and **Substances Management Services** (SMS).

RMS and OMS data services are compliant with ISO IDMP standards ISO11239 and ISO11240. Their scope includes data content, functional capabilities, and a range of services:

- **single source of Referentials data**, including updated lists from EUTCT[1]. Flat lists have been re-structured to comply fully with ISO data elements, lists have been migrated from EUTCT, and new lists defined to support OMS;

- **single list of organisations and their physical locations** to be used as a reference and to support regulatory activities (also known as the "organisation dictionary");

- Referential and organisation data is accessible via the **[SPOR web portal](#)[2] and programmatically** via an application programming interface (API);

- **new process** for Industry and National Competent Authorities (NCAs) to register and update both organisation and referential data;

- specialised team of **EMA Data Stewards** to oversee management of data and to provide support to stakeholders. The overall objective of Data Stewards will be to apply consistent data quality rules and standards.

The launch of RMS and OMS services (June 2017) did not immediately change any regulatory submission procedures. EMA has been consulting stakeholders on the benefits of using SPOR data. Consultation with the [eAF](#) group resulted in the plan to integrate eAF with OMS. The integration implementation date was set for **15 December 2017**. eAF will be the first application to consume OMS data. RMS is already integrated with eAF and supplying Referentials data.

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[1] EUTCT - the European Union Telematics Controlled Terms (EUTCT) System.
[2] SPOR portal is compatible with web browsers Internet Explorer (version 10 and above) and Chrome (version 58 and above).

In future SPOR data is expected to support regulatory submissions in Telematics systems such as the Common European Single Submission Portal (CESSP). A minimum period of six months will be allowed before the use of RMS and OMS data services will be mandated in any given regulatory procedure.

Benefits are expected to be realised incrementally as all phases of SPOR are delivered and SPOR data is reused by different business processes (data enter once and reuse often).

2. How will SPOR be used in eAF and impacts on eAF applicants

2.1. Overview of Referential Management Services RMS

RMS replaces EUTCT (EU Telematics Controlled Terms) as the central repository and provider of Referentials data for the EU medicines regulatory network (EMRN). EMA will act as data broker (one-stop shop) and liaise with maintenance organisations and data owners to consolidate Referentials Lists into a single place and in a common format. RMS includes the following lists of controlled terms:

- lists migrated from EUTCT;

- EDQM lists and Units of Measurement (UoM) lists (these are ISO IDMP standard lists);

- EudraVigilance lists;

- new lists required for OMS.

Note: substance-related lists remain in EUTCT until the Substance Management Services (SMS) is delivered. EUTCT should be used only for browsing and downloading the Substances-related lists.

Users can access the Referentials data via the RMS web portal, or programmatically via the application programming interface (API). A common process is in place for industry (and other stakeholders) to submit requests via the RMS web portal to register new terms or update existing terms, prior to submitting regulatory applications. This includes:

- creation of a new lists and terms, or

- request updates of existing lists and terms, or

- request deletion of terms.

In addition to standard functionality such as browsing and searching data, RMS allows users to set preferences to personalise their RMS experience: subscribe to receive notifications of changes to terms and lists, tag subsets of referential terms, and save frequently used searches.

2.2. Referentials data in eAF and impacts on applicants

RMS is integrated with eAF already (RMS data is pulled into eAF automatically). Referential terms must be registered in RMS before they can be used in eAF as part of a regulatory submission. The current process to request registration of new referential terms requires applicants to complete the eAF "Term Request Form" and then submit the form via e-mail to mdms@ema.europa.eu.

From December 2017 applicants will be encouraged to start using the RMS portal to submit change requests whenever they need to register new terms or update existing terms. 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.

Between December 2017 and June 2018 there will be a transition period during which the use of the mdms@ema.europa.eu e-mail address will operate in in parallel with the new RMS change request process for requesting new terms or updates to existing terms.

Figure 1 below summarises the high-level activities undertaken by Industry, EMA Data Stewards, and NCAs when using RMS data in eAF submissions. It focuses specifically on applicants pre-registering referential terms, before submission of regulatory applications via eAF. In this context, pre-registration of referential terms is done directly via the RMS portal.

The process starts with the preparation of the eAF application by the industry applicant and allows for different scenarios:

1. Referential term exists and does not require changes

In this scenario the electronic application form contains the referentials terms that you require for your application. Complete the application form by selecting the relevant terms from drop-down lists (which are populated with data from RMS), complete the rest of the form, and then submit it. The Regulatory Authority will receive and process the electronic application form.
Note: SPOR user role is not required in this case.

2. Referential term exists and requires an update – "Update Term"

In this scenario the referential **term exists** already, but a data change is required. The user should login to the RMS web portal and submit a change request for a term update.
Note: SPOR user role is required in order to submit an RMS change request.

After submitting an **"Update Term"** change request, **validation** by EMA Data Stewards will usually take 3-5 working days. No changes in the term will be reflected immediately after validation. EMA Data Stewards can reject the request at the validation stage if the proposed changes are not acceptable. In such a case you would need to submit a revised "Update Term" request (if still needed).

Following the validation stage there is a separate **approval process** that can take up to two months:

- if the "Update Term" request is approved the requested changes become visible in RMS (and therefore in eAF);

- if the "Update Term" request is rejected then there is no change in the term details presented by RMS (or eAF).

3. Referential term does not exist – "Add Term"

In this scenario the application form does **not** contain the required referential term for your application. Login to the RMS portal and submit a change request to add a new term.
Note: SPOR user role is required in order to submit an RMS change request.

After submitting an "**Add Term"** change request, **validation** by EMA Data Stewards usually takes 2-3 working days. Once validated, the new term will become **provisional** and will be available for selection in eAF.
EMA Data Stewards can reject the RMS change request at the validation stage if the request is clearly not valid – a new "Add Term" request would then have to be submitted.
EMA Data Stewards can also return the request at the validation stage in case it is not complete or if additional details are required – the requestor would need to re-submit it with additional information.

Following validation there is a separate **approval process** that determines the final term naming conventions. Depending on individual List Owners, this can take anything from 1 month to 1 year.

- When terms are approved their status becomes CURRENT (approved).

- When terms are rejected their status becomes NULLIFIED or NON-CURRENT (used but no longer recommended) => in this case a CURRENT term should be used instead.

Figure 1. RMS data in the eAF context
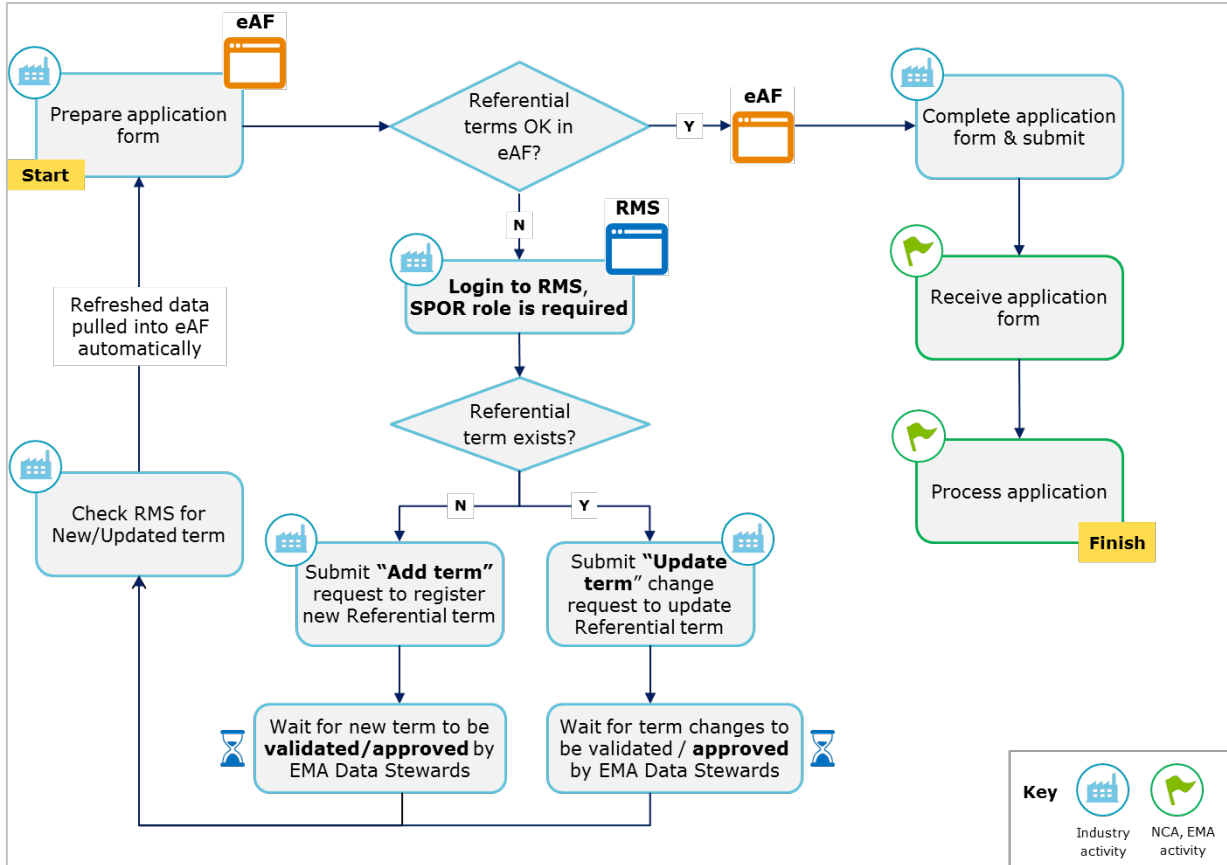
2.3. Overview of Organisation Management Services (OMS)

OMS is a new service that EMA is implementing for the EU medicines regulatory network. OMS will provide a central source of organisation data (OMS dictionary) that consists of lists of organisations with associated physical locations to be used in support of EU regulatory activities.

The initial content of the OMS dictionary derives from existing systems, i.e. xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems. In future new sources may be identified and organisation data incorporated in the OMS dictionary, e.g. CESSP, EV Vet, NCA systems. This source data has been standardised, cleansed and consolidated by EMA Data Stewards. Data has been segregated to align with business priority which is based on organisation roles. EMA will inform stakeholders once each data set has been included in the OMS dictionary (see Figure 2).

Figure 2. Data sets to be included in the OMS dictionary

Data sets for the OMS Content
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).
Data set 2: • Sponsors (H) CAPs and NAPs.
Data set 3: • Manufacturers (H+V) CAPs.
Data set 4: Manufacturers (H+V) NAPs.
Additional Organisation data will be published in the future and the prioritisation of its inclusion in the dictionary will be defined at a later stage: • Veterinary MAHs for NAPs; • Contract Research Organisations (CROs); • Clinical trials sites; • Academia; • Hospitals; • Wholesale distributers; • MAA/MAH and manufacturers in the context of herbal and homeopathic medicinal products or compassionate use medicinal products; • QPPV (Qualified Person for Pharmacovigilance).

Organisation data will be structured with unique IDs (Organisation_ID and Location_ID) and mapped to records loaded from source systems, e.g. xEVMPD or EudraGMDP organisation IDs. In OMS there is no differentiation between an organisation created in the context of a human medicinal product versus a veterinary medicinal product. OMS will not define which role(s) the organisation performs since this depends on the context in which the data will be used e.g. in theory an organisation can act as an MAH (Marketing Authorisation Holder) in the context of one medicinal product but as Sponsor or Manufacturer for another medicinal product. Organisations are categorised by type: 'Industry', 'Regulatory Authority', 'Educational Institution', 'Healthcare', etc. or by size: SME as 'Micro', 'Small', or 'Medium'.

OMS data can be accessed directly via the OMS web portal or programmatically via the application programming interface (API). Anybody can access the SPOR portal and view / search OMS data. Users will be able to search for organisations and locations and view details of organisations and locations. Search is a starting point for the user to request changes to the organisation data. The following options are available:

• if the user is not able to find the requested organisation – defined by name in a given country – they can request 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.

2.4. Organisation data in eAF and impacts on applicants

EMA is the maintenance organisation of Organisation data. Organisation IDs and Location IDs will be generated and maintained by OMS, the organisational data management service from the EMA. OMS will be integrated in all four electronic application forms from eAF release v1.22.0.0, planned to go-live on 15 December 2017. Organisation names together with Location physical addresses will be selectable after performing a search. The use of OMS in eAF will initially be optional. Mandating of OMS in eAF is planned for Q3/Q4 2018 and will be aligned with CESSP (MAA) go-live.

Starting with the latest release of eAF, applicants are advised to perform a search from within the form to familiarise themselves with the use of OMS and to ensure they are familiar with the process **before** the use of organisation data from OMS becomes mandatory.

Two outcomes are possible after searching for an organisation:

1. **Location address is correct** – in this case users may proceed using the OMS supplied data. Note: SPOR user role is not required.

2. **Location address** is **not found or** is **incorrect** – in this case the users can:

   a) **Enter manually** the address details 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. This is a new process that users are advised to follow if the organisation data is in the context of a Marketing Authorisation Holder for all human application forms, and also for the submission of veterinary Centrally Authorised Products (CAPs) data (see Figure 3). Note: SPOR user role is required.

Figure 3. SPOR change request status in the context of eAF.

Domain	Data set	Procedure type	SPOR change request status
Human	MAA	CAP	✔ Stakeholders can start submitting the relevant OMS change requests.
Human	MAH	CAP	✔ Stakeholders can start submitting the relevant OMS change requests.
Human	MAH	NAP (MRP, DCP)	✔ Stakeholders can start submitting the relevant OMS change requests.
Veterinary	MAA	CAP	✔ Stakeholders can start submitting the relevant OMS change requests.
Veterinary	MAH	CAP	✔ Stakeholders can start submitting the relevant OMS change requests.

Domain	Data set	Procedure type	SPOR change request status
Veterinary	MAH	NAP (MRP, DCP)	● Do not submit OMS change requests until EMA has communicated.
Human and Veterinary	Manufacturers	CAPs and NAPs (MRP, DCP)	● Do not submit OMS change requests until EMA has communicated (planned Q3/Q4 2018).

Key:

MAH - Marketing Authorisation Holder

MAA – Marketing Authorisation Applicant

CAP – Centrally Authorised Product

NAP – Nationally Authorised Product

MRP – Mutual Recognition Procedure

DCP - Decentralised Procedure

Figure 4 below provides a high-level summary of activities undertaken by industry, EMA Data Stewards, and NCAs in the context of using OMS data in eAF. It focuses specifically on applicants submitting requests for adding or amending organisation and location data via the OMS web portal. This is also applicable for future requests made via the SPOR Application Programming Interface (API).

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 missing or requires changes, registered SPOR users can submit OMS change requests to register new organisations, request updates to organisations and locations, and add locations. *Note: SPOR user role is required in order to submit an OMS change request.*

Once an OMS change request is submitted, EMA Data Stewards 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) OMS data will be available for selection in the eAF.

After the regulatory application is submitted, the Regulatory Authority will validate organisation data against OMS. Regulatory Authorities can verify the OMS data more confidently.

If the data does not exist in OMS, or is not accurate, Regulatory Authorities can ask industry to submit the relevant OMS change request. This is a general principle that will apply to different organisation data sets once these are included in the OMS dictionary. *Checking Organisation data in advance will help ensure completeness of the OMS dictionary and help MAHs prepare for when the use of OMS will become mandatory; this is paramount to support future business cases in the context of EU regulatory activities.*

This process will not be applicable for Veterinary-only NCAs until Manufacturers-related data is available in a later release of the OMS dictionary. However, for centrally-authorised products, veterinary applicants can already follow this process.

Figure 4. OMS data in the eAF context
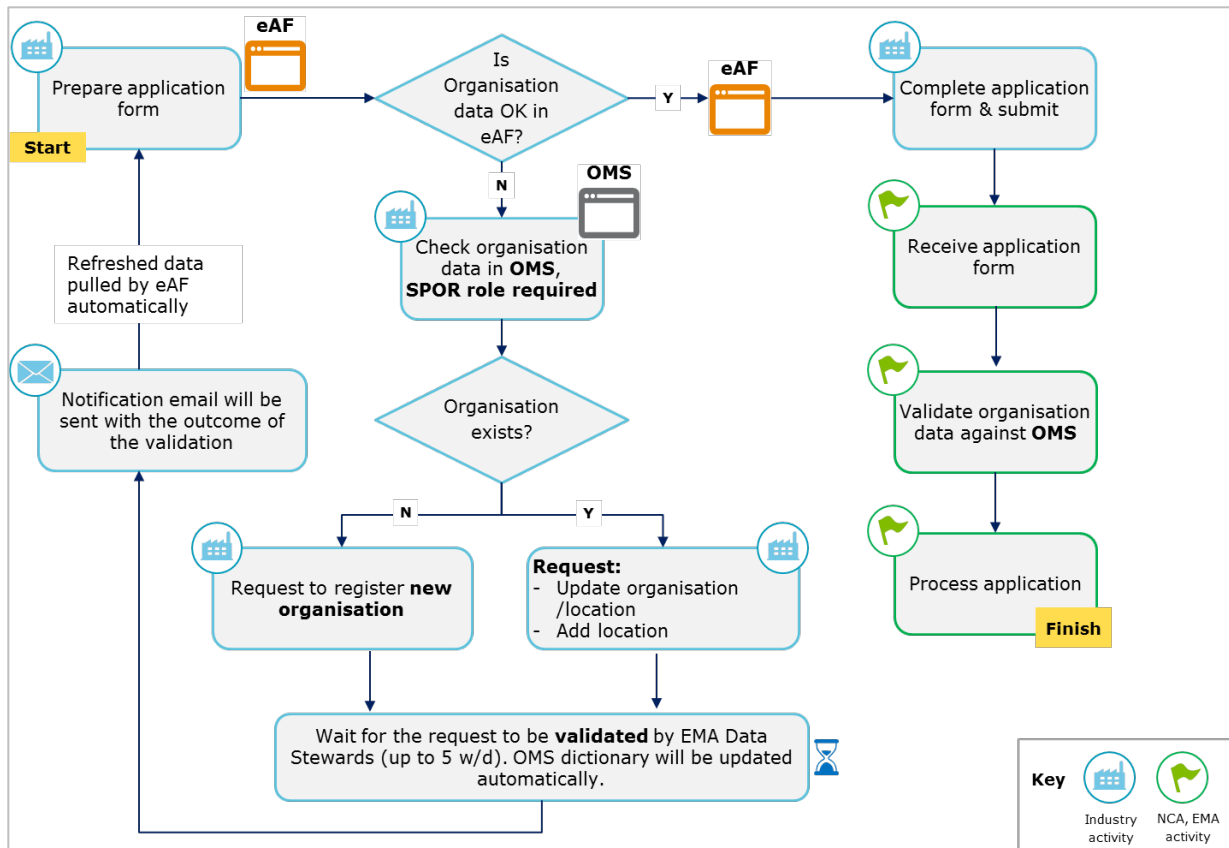
2.5. Requesting substance data for eAF

Substance-related lists remain in EUTCT until the Substance Management Services (SMS) is delivered. EUTCT should be used only for browsing and downloading the Substances-related lists.

As of January 2018 new substance requests and updates should be submitted via requests made to the EMA Service Desk portal. When submitting a substance request to the EMA Service Desk please provide supporting documentation for the substance (e.g. product SmPC or substance specifications) (please see Figure 6). mdms@ema.europa.eu email address is planned to be discontinued in Q1 2018.

Figure 5. Requesting substance data for eAF
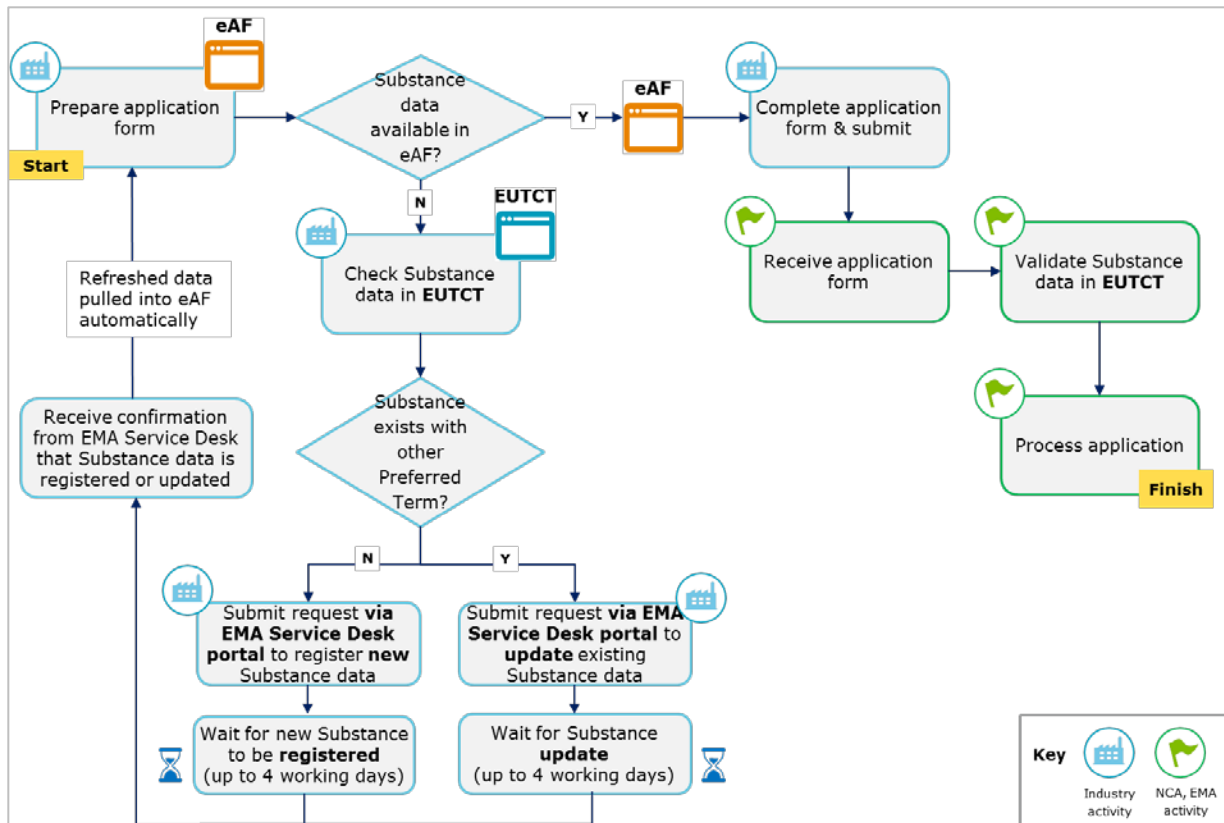
3. Summary of key milestones and impacts

The table below (Figure 6.) summarises key RMS and OMS-related milestones, associated impacts, and actions for SPOR stakeholders in 2018. This information is also presented graphically Figure 7 below.

Regular updates on the development and progress of the changes will be communicated via the SPOR programme pages on the EMA corporate site. In addition, relevant SPOR documents (business and technical) will also be published on the SPOR portal and can be accessed via the following the path: *SPOR > OMS / RMS > Documents > View*. Information on key milestones will also be disseminated to the relevant stakeholders through the establish channels, *e.g.* SPOR Change Liaison network. This information can be shared freely with stakeholders involved in data maintenance and regulatory submissions.

Figure 6. Summary of key milestones, impact and actions

SPOR related milestones	Description of impact & actions
15 December 2017: SPOR services open to Industry stakeholders	**SPOR user registration:** • Commencing 15 December 2017, Industry stakeholders are invited to start requesting SPOR Industry Super Users roles; • Commencing January 2018, Industry stakeholders can start requesting SPOR Industry User roles. Note: Industry Super Users must exist first. **Related documents:** SPOR user registration manual is published on the SPOR portal and can be accessed following the path: *SPOR > OMS / RMS > Documents > View* Referentials Management Service (RMS) and Organisations Management Services (OMS) user on-boarding plan. **Access to Application Programming Interface (API):** Commencing 15 December 2017, Industry stakeholders can start requesting access to the SPOR API (to access data programmatically). **Related documents:** The API access process is published on the SPOR portal and can be accessed following the path: *SPOR > OMS / RMS > Documents > View*
15 December 2017: eAF integration with OMS (MA application, Renewals, and Variations for Human and Veterinary). RMS already supplies data to eAF.	**Referential Management Services (RMS)** • Current process for Industry to request new/amended referential terms is via mdms@ema.europa.eu; • Commencing 15 December 2017, Industry can start submitting change requests via the RMS portal for adding or updating referential terms. Note: SPOR user role is required; • This new change request process for requesting new and updated referential terms will be mandatory from 01 July 2018; from that date any requests submitted via mdms@ema.europa.eu will no longer be accepted. **Related documents and training videos:** RMS web user manual is published on the SPOR portal and can be accessed via the following the path: *SPOR > RMS > Documents > View* Service Levels for the validation of change requests to update RMS content are defined in the "SPOR SLAs" document available from the Documents tab of either the RMS web portal or the OMS web portal. RMS training videos are published on the @emainfo YouTube channel. The videos are available freely and cover core functionality for users of RMS.

SPOR related milestones	Description of impact & actions

	Organisation Management Services (OMS)
	
	• Currently, applicants enter organisation data manually into eAF.
	
	• Commencing 15 December 2017, Industry can start requesting new organisations and updates to organisation data via the OMS portal for:
	
	   – MAHs (Human + Veterinary) CAPs + (Human) NAPs.
	   – MAH (Human + Veterinary) CAPs.
	
	Note: SPOR user role is required to submit OMS change requests.
	
	• Use of OMS will be mandated in Q3/Q4 2018 once CESSP (MA) is planned to go live.
	
	Related documents and training videos:
	OMS web user manual is published on the SPOR portal and can be accessed following the path: SPOR > OMS > Documents > View.
	
	Service Levels for the validation of change requests to update OMS content are defined in the "SPOR SLAs" document available from the Documents tab of either the OMS web portal or the OMS web portal.
	
	OMS data standards - guidance on the data quality standards applicable to OMS available from the Documents tab of the OMS web portal.
	
	Guidance on the supporting documentation required to support OMS change requests validation is provided in the "Change requests validation in OMS" document available from the Documents tab of the OMS web portal.
	
	OMS training videos are published on the @emainfo YouTube channel. The videos are available freely and cover core functionality for users of OMS.

January 2018: introduction of EMA Service Desk portal for Substance-related requests	**Requesting Substance in eAF** • Currently, requests from Industry stakeholders for new Substance terms are submitted via mdms@ema.europa.eu. • Commencing January 2018, the EMA Service Desk portal will be introduced for handling these same requests. When submitting a substance request to the EMA Service Desk please provide supporting documentation for the substance. *Note: SPOR user role is NOT required.* • From April 2018 mdms@ema.europa.eu will be discontinued for Substance-related requests.

Figure 7. Summary of key milestones, impact and actions – plan-on-a-page.