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Information Management Division

Manufacturer organisations in the OMS dictionary

Who in the context of marketing application submissions (applicant, MAH or manufacturer), will be responsible for registration/updating organisation data about manufacturers in the OMS?

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1. Purpose of 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 management services. The information applies to both human and veterinary stakeholders. This document will be reviewed periodically to ensure accuracy.

2. Summary

Organisation Management System (OMS) stores **master data**[1] about organisations, comprising organisation name and location address(s). The data is mastered with **unique IDs** (Organisation_ID and Location_ID). OMS data is intended to **support** the business processes in different EU **regulatory activities**. Currently OMS supplies data to applications such as eAF (CESP dataset module in the future), EMA Account Management[2] or IRIS portal[3].

In eAF, applicants and MAHs can select OMS Organisation/Location data in the relevant section of the form, finalise and submit the form to the regulatory authority. The use of structured OMS data is implemented alongside an existing free text box option in eAF. Once the use of OMS is mandated through the CESP dataset module, the free text box will be removed. If Organisation and/or Location data needs changes or additions, users will need to submit change requests (CRs) through the OMS portal. The OMS CRs need to be submitted before the submission of the regulatory application. All change requests are processed by EMA Data Stewards and result in updates to the OMS dictionary and data available for consuming applications such as eAF.

By the end of Q2 2019 OMS dictionary will contain manufacturers organisations. In **Q3 2019 EMA will invite stakeholders to start submitting change requests (CRs) for manufacturers**. This, however, prompts the question **'who' in the context of marketing application submissions (applicant, MAH or manufacturer), will be responsible for registration / updating organisation data about manufacturers in OMS?**

To address this, we need to look at the manufacturer organisation data lifecycle in the context of regulatory activities, such as inspections activities, marketing authorisation applications activities and where the data is reported, processed, stored and used. We outline two scenarios:

Scenario one describes the 'as-is' process where OMS supplies organisation data to eAF (CESP dataset module in future). OMS contains mastered manufacturers sourced from Telematics and EMA corporate systems. There is no integration between OMS and EudraGMDP, and there are no changes to scope and the process of how manufacturing organisations liaise with regulatory authorities or how data is entered in EudraGMDP. Organisation data required for marketing applications is pre-registered in OMS before submitting the application to the relevant regulatory authority.

Scenario two describes a possible future state where OMS continues supplying data to eAF (CESP dataset module in the future). OMS is integrated with EudraGMDP, and NCAs read/consume manufacturing data from OMS through EudraGMDP. Organisation data required for marketing applications is pre-registered in OMS before the application is submitted to the relevant regulatory authority.

[1] Data mastering is a process of cleansing, consolidating and standardising the data.
[2] EMA Account Management portal is a central point to manage access to the EMA systems.
[3] IRIS is the web portal to apply to the EMA for orphan designation for a medicine.

2.1. Manufacturers data in OMS (as-is process)

Today, manufacturing site details are entered in the **EudraGMDP** database by the National Competent Authorities (NCAs) either manually by filling in a set of free text fields or automatically, by XML uploading, without being subject to data quality checks. This data is linked to manufacturing site data and supports inspection activities.

To populate the initial content of the OMS dictionary, EMA used EudraGMDP, xEVMPD – Art.57 and six EMA corporate systems as source of data. Data from these systems was loaded into OMS in Q4 2016. Since the data load, EMA Data Stewards have been cleansing, consolidating and standardising the data (mastering the data) and gradually publishing it in the dictionary. In parallel, they will continue updating the published organisations to reflect any data changes that have occurred in the source systems since the initial load (Q4 2016). The data alignment between OMS and xEVMPD and EudraGMDP will continue until OMS is mandated by the business processes supported by those systems. See figure 1 below.

Figure 1: Legacy data sources used to populate the initial OMS dictionary.

Inclusion of manufacturer organisations (human and veterinary CAPs[4] and NAPs[5]) in OMS is planned by the second half of 2019. In **Q3 2019** EMA will invite stakeholders to **start submitting OMS change requests** (CRs) **for manufacturer data**.

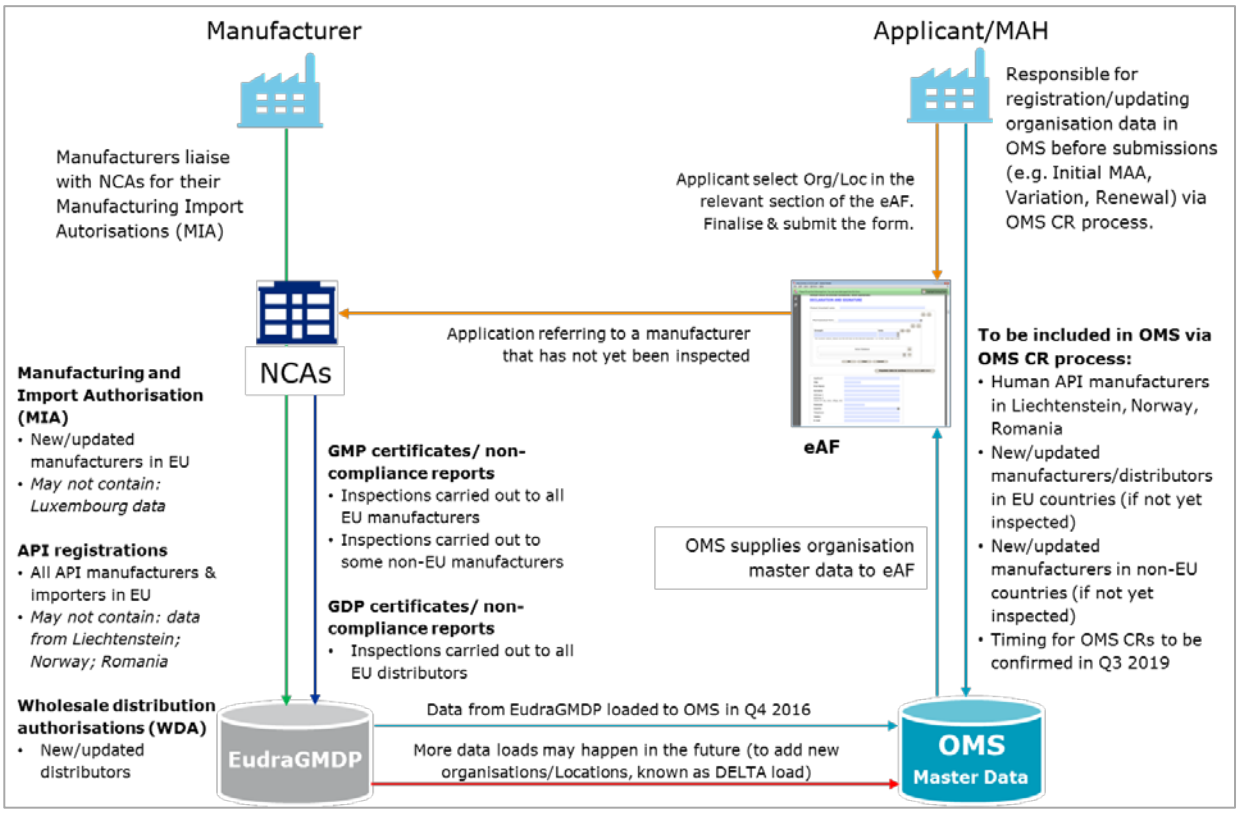
Change requests are predominantly driven by the business process which uses the OMS data. In the context of eAF this means that if Organisation and/or Location data needs changes or additions, users can request it through the OMS portal. Here **applicants and MAHs will be responsible for ensuring that all the manufacturer organisations are included in the OMS dictionary as needed, for the submission of the regulatory applications.** Although the use of OMS is not mandated yet in the eAF (it is implemented alongside the free text option), the plan forecasts that the CESP dataset module will mandate the use of OMS 6 months after CESP dataset module go-live date.

Note: the SPOR permissions allow any registered SPOR user to submit an OMS CR providing the relevant supporting information and documentation has been attached to the request. All stakeholders who use OMS services should be familiar with the Service Level Agreement (SLAs), which specifies the timelines to process the change requests. The SLA document is published on the OMS portal > Documents > View.

The figure 2 below summarised the scenario described in this section.

[4] Centrally Authorised Medicinal Products
[5] Nationally Authorised Medicinal Products

Figure 2: Manufacturers is OMS, the as-is process.



2.2. Manufacturers data in OMS (proposed to-be scenario)

The SPOR programme has been consulting with stakeholders on the benefits of using organisation master data in business processes and applications. Together with the GMP/GDP Inspectors Working Group (GMP/GDP IWG), the SPOR team has been exploring the integration of EudraGMDP with OMS, the opportunities and benefits it might bring, and any potential impacts.

Discussions so far have been exploratory and for these to materialise a business case will need to be formed and a project approved. Drafting the business case would fall under the remit of the EudraGMDP business owner, who would need to have the project established. The consultations with the network would also need to continue to agree on the approach to mandating the use of OMS in inspection activities. How such integration could potentially 'look' and what the benefits and impacts would be for stakeholders are outlined below, see figure 3.

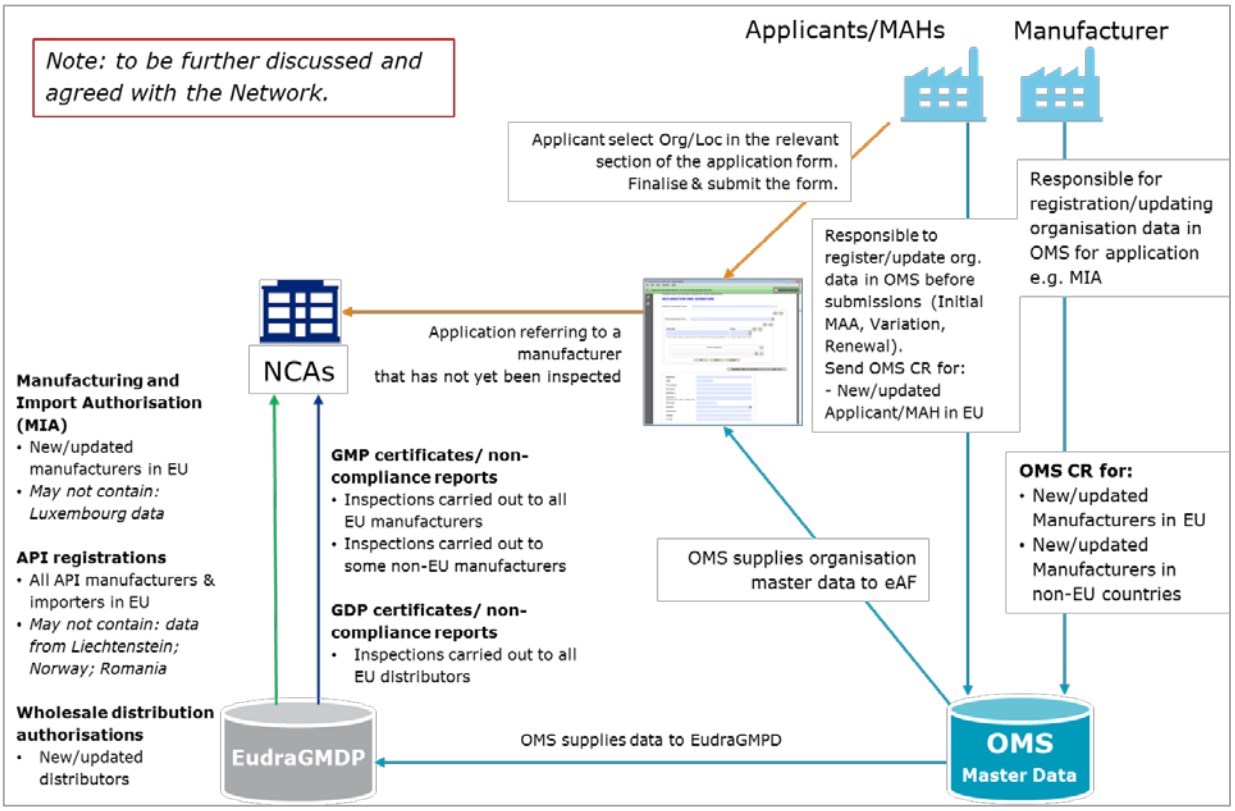
In this scenario OMS continues to be a single source of organisation master data. The OMS dictionary includes 'mastered' manufacturer organisation data from EudraGMDP. Organisations, which are not in EudraGMDP, are added to OMS through a change request process. OMS supplies organisation data to eAF (CESP dataset module in future).

In the context of marketing application submissions the Applicant / MAH is responsible to ensure the data is in the OMS dictionary, before submitting the regulatory applications (e.g. initial MA, Variation, Renewal).

In the context of **Inspections** and **Manufacturing Import Authorisations** which are managed by the relevant NCAs, **manufacturers** themselves would need to **register in OMS** before the Inspection request is submitted. Since OMS would supply data to EudraGMDP, NCAs can use this data to support their inspection activities. Therefore, for these types of organisations and during the pre-MAA phase or during the Marketing Application Evaluation phase, some of these manufacturers could register

themselves in OMS. To support this scenario, the NCA performing the inspection would need to mandate that the manufacturer registers their organisation in OMS.

Figure 3: Manufacturers is OMS, proposed to be process.



3. OMS related information and documents

A selection of related information produced as part of the SPOR programme development that may be a useful starting point for those who are new to the SPOR or are part of the implementation teams: OMS operating model (link), Overview of OMS change request process (link), On-boarding of users to SPOR data services (link).

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