EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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OMS Mandatory for CAPs from November 1st onwards

The use of Organisation Management Service (OMS) data will become mandatory in Centrally Authorised Product applications as of November 1st, 2021.

OMS provides a single source of validated organisation data that will be used as reference to support EU regulatory activities and business processes.

November 2021 will mark the end of the transition period started in 2015 with the launch of OMS, followed by the first use of OMS in electronic application forms (eAFs) in 2017. As of November 2021, Centralised Procedure application submissions not using OMS data, will be filtered out during EMA validation and sent back to the applicant for remedial action. For applicants and Marketing Authorisation Holders, remedial action will include populating that data in the application form before resubmitting the updated application form. In addition, it may mean registering or enriching OMS data to make it available for use in the form.

The free text fields in eAFs will be removed for Centralised Procedure applications in line with the review and update cycles of the individual application forms. Until these updates are live, the free text field for "organisations" information will be visible in the eAFs, also for Centralised Procedure applications, however they should not be used.

While the application forms will not immediately change, the EMA business process and systems in the background will change. From November 2021 onwards organisational data other than OMS data can no longer be captured in EMA databases. Therefore, the Agency recommends applicants consider the turnaround time for OMS change request processing when planning to submit applications. Generally, the Agency strongly advises applicants to register OMS data, i.e. organisational information, in advance of any forthcoming applications submissions to avoid the risk of delaying the processing of their applications.

Questions and answers about OMS and this change can be found below.

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Questions & Answers

Contents

Version 1.1

General

1. **Why is using OMS becoming mandatory for Centralised Procedure applications now?**

   EMA is implementing ISO IDMP standards as mandated by Commission Implementing Regulation (EU) No. 520/2012 articles 25 and 26. SPOR is the mechanism through which ISO IDMP standards will be applied. ISO IDMP covers the *substance*, *product* and *referential* parts of Substance, Product, Organisation and Referential (SPOR) master data. In addition, EMA, National Competent Authorities and Industry in Europe agreed that *organisation* master data, although not covered by ISO IDMP, is essential to making the master data operating model work.

   The SPOR operating model which will support EU regulatory activities by bringing interoperability and efficiency gains, relies on standardised data to create value for a its stakeholders.

   Since its development, Organisational Management Service (OMS) data has gradually been integrated into the regulatory procedures via ongoing projects. The first use of OMS data was in electronic Application Forms (eAFs) in 2017. Many other systems/procedures have started using OMS data since then such as EMA Account management and EV registration (user administration), EudraCT (Clinical Trials), IRIS (Scientific Advice, Orphan designation, ITF, Marketing status, Parallel distribution, Inspections), SIAMED (Centralised procedure management) and xEVMPD/EV vet (safety reporting). With systems such as the Clinical Trial Information System (CTIS) and tools such as web-based electronic application forms expected to go live early 2022, OMS use becomes not just a reality but also a necessity to simplify process and technical integrations.

   Regarding eAFs, OMS was implemented in eAFs in 2017 with the expectation of it becoming mandatory at a certain point in time. Industry stakeholders have been and are involved in discussions on the intentions driven by the eAF Maintenance Group to mandate the use of OMS in eAFs.

2. **What are the implications of OMS becoming mandatory?**

   In the context of a regulatory procedure (which uses the OMS data) for centrally authorised medicinal products, industry stakeholders will need to register organisation data or request the update of data already registered in OMS. This is done by submitting a "Change Request" before submitting a regulatory application to EMA.

3. **What uses is OMS becoming mandatory for on November 1st, 2021?**

   The use of OMS data will become mandatory for the following Human and Veterinary Centralised Procedure applications:

   - **Procedures with eAF** - initial Marketing Authorisation Applications (MAAs), variations applications, and renewals.
   - **Other procedures**- Marketing Authorisation Holder (MAH) transfer applications, Procedures relating to Ancillary Medicinal Substances in medical devices, applications for EU-Medicines for all (Art. 58), pre-submission activities such as eligibility request, Rapporteurship or letter of intent request, notification of change request, ATMP certification, accelerated assessment request and pre-submission meeting request.

4. **What other plans are there to make OMS mandatory?**

In 2022, EMA expects to integrate OMS with the Clinical Trial application procedure (via CTIS), Union Product Database (UPD), Variation applications (via DADI project) and also Manufacturing / Importers Authorisations (MIAs), Good Manufacturing Practice (GMP) inspections and Wholesale distribution authorisations (via EudraGMDP). Further details will be made available via the respective ongoing projects.

5. **Who do I contact with my question?**

   For OMS related questions please contact the EMA Service Desk - subject: OMS.

   For eAF related questions please contact the EMA Service Desk - subject: eAF

   For CAP procedure questions e.g. Validation, please contact the EMA in line with standard practice.

   For pre-submission queries, please raise a ticket via EMA Service Desk, using the Question option "Pre-Submission Phase Request", followed by the relevant sub-option ""Withdrawal of request", "Notification of Change request", "Letter of Intent request", "Letter of Intent request" or "Eligibility Request" as appropriate to your query.

About OMS

6. **What is OMS?**

   The Organisation Management Service (OMS) manages one of the four domains of substance, product, organisation and referential (SPOR) master data in pharmaceutical regulatory processes.

   OMS is the source of organisation master data: The OMS Dictionary. It consists of a list of organisations with associated physical location details that can be used as a reference and in support of EU regulatory activities, including electronic applications forms.

7. **How do I create or update OMS data?**

   To create or update entries in the OMS Dictionary you need to submit a change request through the OMS portal. EMA OMS Data stewards will assess the requested change and change the OMS data if it meets requirements.

   Guidance on how to search, view, export, input or update data is published on the OMS portal. Consult "F – OMS Web User Manual" in the document repository of the OMS Portal for more information.

   To submit a change request, you will need a SPOR user role. Guidance on how to register for EMA systems and request SPOR user roles is also published on the OMS portal. Consult "Z - SPOR User Registration Manual" in the document repository of the OMS Portal for more information.

8. **Who can change OMS data?**

   Anyone can submit a change request to any organisation or location published in the OMS Dictionary, provided they submit the required supporting documentation. EMA OMS Data stewards will assess the requested change and change the OMS data if it meets requirements.

   Guidance on rules and supporting documentation required by change request type is published on the OMS portal. Consult "E - OMS Change Requests" in the document repository of the OMS Portal for more information.

   Change requests are generally driven by the business process which uses the OMS data. The user who needs to use the data should take the lead in updating it. In the context of eAFs this means that 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 their regulatory applications. Consult – "H – Manufacturer organisations in OMS dictionary" in the document repository of the OMS Portal for more information.

9. **How does EMA assess an OMS change request?**

EMA OMS Data stewards validate the organisation name and its relationship to the location details against reference sources including national business registries, Data Universal Numbering System (DUNS) numbers as well as available Good Manufacturing Practice (GMP) and Manufacturing Importation Authorisation (MIA) certificates. Once the information is validated and an EMA OMS Data stewards verifies that the record is not already available in the OMS Dictionary, the data will be added or modified following standardisation as follows:

Organisation name: standardised as per "C - OMS Data Quality standards" - published in the document repository of the OMS portal for more information;

Location data: standardised as per information provided by each National Postal Service (AddressDoctor).

10. **Is there a risk that requestors could submit contradictory requests to OMS?**

    Regardless of how many companies provide different details the OMS team will always validate the accuracy of the data against the same reference sources (i.e. national business registry, DUNS and/or GMP/MIA certificates – see question 8) and standardise it according to the OMS rules agreed with the Network. There can be only one entry for each Organisation/Location.

    Guidance on the OMS data quality rules used are described in detail in the document "C - OMS Data Quality standards" published in the document repository of the OMS portal.

11. **Will EMA maintain the OMS five working day Service Level Agreement (SLA)?**

    The EMA's SLA is that the Agency will process 75% of OMS requests to add or update Organisation data within five working days and 90% of requests within ten working days.

    Note that the SLA reflects EMA's best efforts and does not constitute a guarantee for every individual request. We strongly advise applicants and MAHs to proactively verify their OMS entries in advance of any application to avoid undue delays during the process.

    However, for specific cases were turnaround times are or have been missed, please do not hesitate to bring these to the attention of EMA via the EMA Service Desk.

12. **When will OMS revisions become visible in eAF?**

    OMS revisions/changes usually become visible in eAF after an overnight refresh. That means i.e. you will be able to search for the updated entry the day after your revision was processed.

    In addition to waiting for the overnight refresh, you will also need to reopen the eAF form you were working on, click the update lists (if a new term has been added) and pick the new value. For addresses, you will need to perform a new search in the form. The update is not automatically reflected in the eAF. This was a conscious design decision that was taken at the time when OMS was integrated in the eAFs to prevent any changes in data that the applicant would not be aware of while filling in the form.

13. **Is it possible to the see the history of OMS changes?**

    Although historical versions are available via the OMS Application Programming Interface (API) and exports, OMS only shows the latest data on the SPOR Portal (User Interface).

    The eAF does not allow searching for old, historical entries from OMS, the search will always only show the latest version.

About Use of OMS data in Centralised Procedure applications

14. **How is mandatory use of OMS for centralised procedures progressively being enforced through eAFs?**

    Step 1 - OMS was included in eAFs as optional (2017 onwards)

OMS was included in eAFs and its use was optional. Applicants could choose to pre-register organisation data in OMS and select it through a search functionality in the eAFs. Alternatively, applications could enter the Organisation/location data in the free text fields available in eAFs.

Step 2 – Free text fields for organisations remain available but should not be used – Applicable for Centralise Procedures only (November 1st, 2021 onwards)

While the application forms will not immediately change, the EMA business process and systems in the background will change resulting in only OMS data being accepted as part of applications for centralised procedures.

Note that although the free text field for organisational information will still be visible in the eAFs, also for Centralised Procedure applications, they should not be used.

Step 3 – Free text fields for organisations will be removed in the eAFs for Centralised Procedures (rolling updates)

The free text fields in eAFs will be removed for Centralised Procedure applications in line with the review and update cycles of the individual forms.

Step 4 – Extension to National Procedures (under discussion)

Further steps are under discussion, including whether, when and how the transition to OMS for National Procedures may take place. However, with the progressive replacement of the current eAF forms with web-based application forms (through the DADI project) over the next two years OMS will de facto become a requirement for Nationally Authorised Products (NAPs) as well. This is because web-based application forms are the same for CAPs and NAPs by design.

The discussion on exactly how OMS will be implemented in DADI in different forms and different fields is still ongoing.

Please check eSubmission: Projects (europa.eu) for the Q&A document on the DADI project and the latest updates on eAFs.

15. **When will OMS become mandatory for NAPs?**

    Mandatory use of OMS for NAPs is still under discussion. However, with the progressive replacement of the current eAF forms with web-based application forms (through the DADI project) over the next two years OMS will de facto become a requirement for NAPs as well. This is because web-based application forms are the same for CAPs and NAPs by design.

    Please check eSubmission: Projects (europa.eu) for the Q&A document on the DADI project and the latest updates on eAFs.

16. **Do I need to register the contact person name and contact details such as email address and telephone number in OMS?**

    No, contact person name and contact details are not OMS data. This data should be provided in the relevant free text fields in the eAFs. The organisation to which the contact person is affiliated should however be registered in OMS.

17. **Do I need to register historical information, e.g. my entry for the "present" section in a variation form, in OMS?**

    No, you do not need to register historical data in OMS. The OMS team will always register the latest and current/valid Organisation/Location data, not historic data.

    Therefore, in the **Human and Veterinary Variation forms** EMA only expects the data used in the "proposed" section to be registered in OMS. For the "present" section Industry can still use free text.

18. **What will happen if I submit non-OMS organisational information i.e. entering only the free-text field or image?**

As of November 1st, Centralised Procedure submissions not using OMS data will be filtered out during validation and a validation request for supplementary information will be raised. The Applicant or MAH will be requested to provide responses to the issues.

For applicants or MAHs, remedial action will include populating that data in the application form before resubmitting the updated application form. In addition, it may mean registering or enriching OMS data to make it available for use in the form.

Insufficient responses will lead to complete or partial invalidation of the application.

Note that OMS data is not required for the "proof of payment" section nor the "present" section in a variations form.

19. **What if the data displayed in the OMS Dictionary does not match my own documentation or the free-text field?**

    If discrepancies are found between OMS data and documentation provided in the application, and, according to the "C3 - OMS Guidance on Assessing Organisation Names and Location Data" (published in the document repository of the OMS portal) it is understood they both refer to the same legal entity, there will be no validation questions or invalidation. In case of doubts the EMA validation team will contact the OMS Data Stewards.

    Only when the data from OMS and the documents do not refer to the same legal entity will a validation request for supplementary information will be raised.

    EMA will request the MAH provide responses to the issues. Insufficient responses will lead to complete or partial invalidation of the application.

20. **What if I select the wrong OMS data in an application by mistake e.g. error in ORG / LOC ID?**

    The applicant or MAH is responsible to ensure that correct data is included in their applications. EMA relies on the data provided by the applicant or MAH. In many cases this will be identified during validation, however in cases where it isn't the MAH will need to submit an updated application form to correct the data.

21. **What rule will apply in case of work-sharing procedures including CAPs and NAPs/MRP products?**

    In case of work-sharing, EMA validation rules for OMS will apply. Although mandatory use is only applicable to CAPs, the OMS data is common across the application even if it contains CAPs and non-CAPs products.

22. **How will OMS work for applications for which there is no validation, e.g. Type 1A (Do and Tell)?**

    Type IAs are checked by EMA and MAHs should ensure they use OMS data when submitting their application.

23. **How will OMS be used in procedures for which there is no application form e.g. transfers?**

    MAHs are expected to enter the OMS "ORG/LOC ID" as well as the data as displayed in OMS in the cover letter of the application.

    As of November 1st, 2021, Centralised Procedure submissions not using OMS data will be filtered out during validation and a validation request for supplementary information will be raised. The MAH will be requested to provide responses to the issues. For applicants, remedial action will include populating that data in the cover letter. In addition, it may mean registering or enriching OMS data to make it available for use in the form. Insufficient responses will delay the start of the application.

24. **How will OMS be used in procedures that use forms without integrated OMS functionality e.g. pre-submission applications such as eligibility request, letter of intent request,**

notification of change request, accelerated assessment, ATMP certifications, pre-submission meeting requests, applications for Ancillary Medicinal Substances in medical devices and EU-M4all procedures?

EMA Pre-submission applications and number of other procedures, have dedicated forms (not the same as the 4 interactive pdf format eAFs) and are also impacted by the mandatory use of OMS. This means that all Organisation data used in "applicant" and "contact person affiliated organisation" sections of pre-submission applications needs to be correctly registered in OMS ahead of the processing of the application.

Applicants are expected to enter in the free text (address) fields the relevant "Org/LOC IDs" as well as the data as displayed in OMS.

As of November 2021, 1st, Centralised Procedure submissions not using OMS data will be filtered out during validation and a validation request for supplementary information will be raised. The MAH will be requested to provide responses to the issues. For applicants, remedial action will include populating that data in the relevant form before resubmitting the updated form. In addition, it may mean registering or enriching OMS data to make it available for use in the form. Insufficient responses will delay the start of the application.

About Use of OMS data in eAFs

25. **For what sections exactly is OMS becoming mandatory in eAFs?**

The use of OMS data will become mandatory in the electronic Application Forms (eAFs) for all Human and Veterinary Centralised Procedure applications including initial MAAs, variations and renewals as well as for other administrative procedures without eAFs such as Marketing Authorisation Holder (MAH) transfers.

For the **Human MAA, Veterinary MAA** and **Human and Veterinary Renewal forms** this means that all Organisation data used in, among others, "applicants", "marketing authorisation holders", "manufacturers" and "CROs" sections needs to be correctly registered in OMS ahead of the processing of the application. This does not apply to addresses provided in the "proof of payment" section.

For the **Human and Veterinary Variation form** this applies to all Organisation data used in all address fields except the "present" section or those addresses provided in the "proof of payment" section. EMA recommends to only enter the manufacturers impacted by a change in the eAFs.

With the upcoming eAF release (eAF V.1.25.0.0) for Medical Devices this also applies to all Organisation data used in "Device Manufacturer", "Notified Body" and "Companion diagnostic" sections.

The OMS team will register all and any organisation for which there are change requests and relevant supporting documentation to support the change.

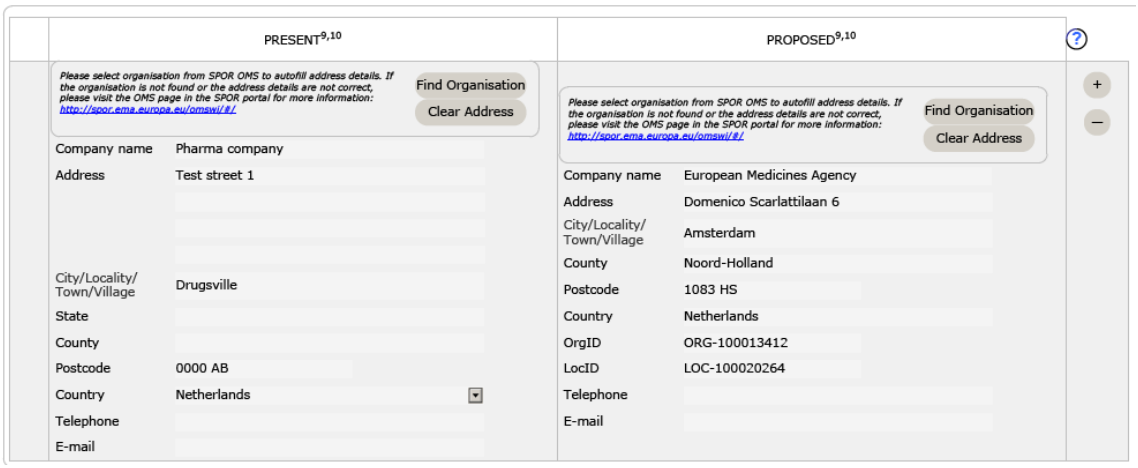
26. **Should I enter all manufacturers in a Variation form?**

EMA recommends MAHs to only enter the manufacturers impacted by a change in the eAFs for a variation. Those entries will need to make use of OMS data.

Example 1: How do I describe what is being changed? Please describe what is being changed as free text and refer to LOC IDs in OMS entries in the "proposed" section. There is no need to type the address itself as free text into "proposed", you can simply refer to the LOC ID. Proposed LOC IDs must be entered via OMS search. You can use the manufacturing activities as described in the RMS list (human) although this feature is not included in the current variation form.

Example 2: For the addition of a new manufacturer, should I list all current manufactures under the "present" section? No, if there is no change to the current manufacturers as a result of the variation, there is no need to list them. Only the manufacturers who are impacted by the variation need to be entered. In this case, only the new manufacturer ORG/LOC ID should be added in

"proposed", section. You can use the manufacturing activities as described in the Referential Management Service (RMS) as free text. The drop-down list to make using RMS easier is not yet included in the current version of the variation form.



27. **If the administrative site and manufacturing site are not identical, do both need to be registered in OMS and entered in the eAF?**

    Only manufacturing site addresses are needed for the application dossier however if both addresses are provided, both addresses will need to be entered in the eAF and both will need to be recorded in OMS.

28. **I still see free text fields for organisational data in the eAFs, when will the forms be updated to no longer allow free text entry?**

    The free text fields in eAFs will be removed for Centralised Procedure applications in line with the review and update cycles of the individual forms.

    Human: EMA expects to release a version (v1.26.0.0) removing the free text fields for Centralised procedures for human medicinal products in December 2021. This version can be used immediately after the release in December 2021.

    Veterinary: Version v1.26.0.0 which will align the forms with the VMP-Reg will also remove free text fields in Veterinary application forms. This version is expected to be released in December 2021. However, it can only be used for applications from January 28th, 2022 onwards in line with the veterinary regulation.

    Until these updates the free text field for organisational information will be visible in the eAFs, however it must not be used after November 1st, 2021.

    EMA recommends applications and MAHs regularly check the eAF portal for updates.

29. **Will the new web-forms also use OMS?**

    Yes, as part of the development of web-forms by the DADI project all the latest requirements will be considered, including the mandatory use of OMS. The web-based forms are in fact explicitly meant to further enable the SPOR operating model of which OMS is part. Further details on exact implementation on each field will be decided in the context of the DADI project.