EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Veterinary Medicines Division

Q&As Webinar for MAHs on Integration of EudraGMDP and OMS

1. Do changes to EudraGMDP impact both Human and Veterinary medicines domain?

A: Yes. The changes and the timeline presented apply to both domains.

2. Where is the legal or legislative basis for a veterinary GDP certificate?

A: For the Veterinary domain, there is no legal basis for GDP certificates in the Regulation or associated secondary legislative acts at this point in time. To provide consistency in the approach and use of EudraGMDP, EMA will update the GDP module after January 2022 in order to allow voluntary use by NCAs wishing to record GDP certificates for companies distributing veterinary medicines.

3. Even distributors have to ensure to be correctly registered in OMS - not just MAHs?

A: All Organisations whose activities are managed in EudraGMDP are impacted: Manufacturers, Holders, Importers, Wholesale distributors. The change request can be raised by anyone, which will be processed if the correct documentation is provided.

4. Does the Change Request need to be raised only before renewal or change?

A: Change requests are required if/when the information on Organisation/Location in OMS needs to be updated.

5. Starting from when, a change request can be sent? Already now or not before next year?

A: Change requests should be submitted after 28 January 2022, if the information on OMS is not up-to-date.

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6. Will data be entered by NCAs and (only) controlled/ corrected by industry or are MAHs etc. required to enter all details to the database?

A: Any registered SPOR user can raise a change request to OMS, which will be processed if the correct documentation is provided. We recommend industry users check that the information regarding their organisation and sites is correctly recorded on OMS as of 28 January 2022.

7. Should third party manufacturers/CMOS not ensure that OMS data are correct and raise change requests when they are requesting inspections or need updated GMP certificates?

A: If you are an EEA manufacturer or importer using manufacturing sites located in third countries: please liaise with the sites you use, which will need to be correctly registered in OMS. Any registered SPOR user can submit change requests providing the relevant supporting information and documentation – it is up to you to coordinate submission of the needed change requests.

8. In 2018, EMA published a guidance document called Manufacturer organisations in the OMS dictionary (ref. EMA/465039/2018). The to-be process proposed for OMS data entry has not been finalised and is indeed confusing since it divides OMS data responsibility for manufacturers and MAHs/Applicants, which is not optimal in the way industry manages their relationship with manufacturers via QAs. Will you release an updated guidance document with the final revised process and responsibilities for MAHs/Applicants and Manufacturers?

A: The document will be reviewed, and information in this topic is included in the event presentation.

9. As CEP certificates are issued by EDQM, will EDQM also consume OMS data?

A: CEP certificates are not in scope of EudraGMDP.

10. Will GMP certificates for Clinical trials sites be impacted too?

A: Current certificates or authorisations will not be impacted by the new sites added in OMS. Any new certificate/authorisation issued after 28th January 2022 will be impacted.

11. We already have a valid wholesaler certificate for veterinary medicines. Is there any renewal process? Has the GDP certificate an expiry date?

A: Validity of GDP certificate is not going to be impacted by the OMS integration. As per the agreed procedures, a re-inspection should occur after 5 years at the latest. Therefore, in that context, you would need to ensure that name and address of the company is correctly present in OMS.

12. Will you consider updating the organisations if their data has been amended (we noted times where our data has changed but that was not requested by us and we have had to submit CR to rechange)?

A: Any SPOR registered user can log a change request by providing the needed supporting documentation. The OMS Data Stewards will validate the information against Trade registry/Postal services and always align to it regardless of what is requested. In the end there should be only one

version of data aligned to reference sources. We recommend you familiarise with the OMS business rules to avoid raising any unnecessary change requests.

13. When will an updated OMS Operating Model will be released?

A: The OMS operating model remains unchanged - whoever needs the data for a given regulatory purpose needs to submit a change request to OMS and pre-register the data ahead of regulatory submission. This applies to eAF and well as other regulatory entitlements such as MIAs in this case. We will only update the document regarding Manufacturers due to planned integration with EudraGMDP. This is planned ahead of the go-live in January 2022.

14. Are all MAHs impacted?

A: Yes, any company should be registered in OMS in order to have a MIA, WDA, GDP or API reg. This registration should be done by the company, MAH using that company or the national competent authority.

15. How does it work when two legal entities have the same address? Will they be two different OMS entries? Whereas a legal entity with two locations would be one OMS entry?

A: Each organisation is an entry with a distinct ORG ID, although the legal address is the same of another. A legal entity with two locations will have one ORG ID, and two LOC IDs.

16. We are a manufacturer of APIs and already present with our GMP certificate in the GMDP database - do we have to register or are we already registered in the OMS?

A: If you are already registered in EudraGMDP, your data are being cleansed by EMA and therefore the Org/Location details will be reflected in OMS as of January.

17. How do we get the role of 'User Administrator' of an organisation responsible for approving and revoking access for users of the same organisation?

A: We did not cover user registration in the webinar but there is a user registration process and manual on SPOR Portal - documentation area. If you still need support, you can also raise a ticket with EMA's Service Desk.

18. Is it foreseen that CEP certificates will be in the scope of mandatory OMS-consuming? Any potential date?

A: We are now integrating OMS with EudraGMDP and CEPs are not covered by EudraGMDP, they are managed by EDQM. We are not aware of any plans for EDQM/CEP to consume/integrate with OMS.

19. In some countries, sites are outsourced to a third party. Who is/will be responsible for entering/updating records in OMS?

A: If you are an EEA manufacturer or importer using manufacturing sites located in third countries: please liaise with the sites you use, which will need to be correctly registered in OMS. Any registered SPOR user can submit change requests providing the relevant supporting information and documentation – it is up to you to coordinate submission of the needed change requests.

20. How are differences between the specificity of EudraGMDP and OMS being handled? For example, when EudraGMDP contains additional data such as plots in large manufacturing sites.

A: Any additional details (unit inspected, plots, ...) will be added by the company authority in the "Restrictions" part of the certificate. These details will not appear in the address stored in OMS.

21. How is it ensured that the requester is authorised to change the data of the legal entity for which the change is requested?

A: It does not matter to EMA who requests the change because we always verify the request against the reference sources (e.g. Trade registry). Only OMS Data stewards change the data after verifying that it is as per reference source (e.g. Trade registry).

22. While OMS data will not be mandatory in eAF for non-CAPs, how would a discrepancy between the eAF and EudraGMDP now using OMS be handled for non-CAPs?

A: Use of OMS data in EudraGMDP is mandatory from 28th January 2022. Therefore, NCAs need to ensure that the relevant organisations are available in OMS before submitting information into the system. This applies to CAPs and non-CAPs equally. It is suggested to ensure that the OMS data is present and correct for those organisations/sites, even if the use in eAF is not mandatory for the time being.

23. Will there be someday standardisation with information on sites currently in the EDQM Certification Database (or already in place)?

A: We are not aware of any plans for EDQM/CEP to consume/integrate with OMS.

24. Does every company need to register in OMS? Also, wholesalers with WDA?

A: Yes.

25. Is it possible to have a super user industry account, and have two different companies' organisation in the same user?

A: A user can have only one account, but it can be affiliated to as many organisations as needed and indeed have the role of Super user for many companies.

26. What about changes, practicalities around acquisitions/MAH transfers - can both parties change the data?

A: Any registered SPOR user can submit change requests providing the relevant supporting information and documentation.

27. Is it necessary to register to OMS, after Jan 28th, 2022` as manufacturer of API, for human and veterinary drug substance? Is a single registration for both sufficient?

A: If the Org/Loc are already certified by EudraGMDP, they should be in OMS as of January 2022. Afterwards, you can verify the details and apply for change request if needed. Change requests can be raised after 28th of January 2022 at any time and depending on your needs. In OMS, one legal entity is one organisation, irrespective of the human/veterinary domain and of the role. Therefore, for 1 API manuf., one OMS ID will be given irrespective of whether you manufacture API for human or veterinary use.

28. How does it work when 2 legal entities have the same address? Is it necessary to have two different super user industry accounts? Can be same account make the registration for both companies?

A: 2 legal entities means 2 different ORG Ids/records, each of which will have its own different address LOC ID even if that is the same. If the user works for both legal entities, s/he needs to be affiliated to both.

29. After the registration, the local regulatory authority will upload the GMP and API-Reg always in the EudraGMDP website, is it correct?

A: Yes.

30. We are a small wholesaler located in Bulgaria but the MAH is located in France. Who has to do the registration in OMS?

A: The WSG in Bulgaria and the MAH in France are different legal entities, across different countries. For this, in OMS they are represented as separate ORGs -- you both need to verify your details are up-to-date in OMS after 28 January 2022.

31. In case of changes to an organisation in OMS, will the updates be automatically shown in EudraGMDP after a refresh? If yes, what is the timeframe for it?

A: In case of changes to OMS, the dictionary part of EudraGMDP gets refreshed (for subsequent selections) but no change is reflected in the documents already issued unless there is a specific action on them. The synchronisation between OMS and EudraGMDP will reflect changes in OMS in the EudraGMDP dictionary on the following business day.

32. For WDA and API Reg for vet Org, you are advising to wait until 28.01.2022 before submitting change requests. But there is an expectation in the field that WDA should be granted on 28.01.2022. How to reconcile this difference in timing? Is there a transition period for Inspectorates to issue WDA?

A: Competent authorities are informed as well about the changes impacting EudraGMDP as of 28th of January 2022 in order for them to plan in advance in case a certificate is intended to be issued in the near time.

33. Must every location of a legal entity be entered?

A: Yes -- before applying for a new/updated manufacturing or wholesale distribution authorisation with national competent authorities, relevant locations have to be recorded.

34. If there are two warehouses registered for the same company one veterinary and the other human at the same address. Will two separate lines with two different ID numbers appear in the database?

A: If the warehouse is the same (1 company, 1 address) OMS will only have 1 contact. At the time of drafting the certificate or licence, the national competent authority will be able to select if the certificate applies to human or vet; additionally, the NCA will be able to add any remarks/clarifications as free text.

35. Does this have an impact on the variation submission for medicinal products?

A: The Org ID will also have to be submitted.

36. Is it possible to get the current list of persons who are registered in the OMS for one organisation?

A: The Organisation Super user can see all of the users affiliated to the Organisation they manage in EMA's Account management portal. Only a current Super user can see this (hence we check the registration of the first super user on behalf of the company).

37. Is the registration of distribution only necessary for wholesalers or also for API distribution?

A: API distributors will be registered under the module API reg.

38. Will it be possible to change user roles afterwards?

A: You can change (grant/remove) the user roles and users affiliated at any point in time, this management needs to be done by the Organisation Super user.

39. Is a change request required in each case or is it possible that the data are transferred correctly in the first place and a change request is not needed?

A: We expect that the data resulting from the cleansing will be correct, but it will be standardised according to OMS rules, please familiarise yourselves with them so that change requests are not requested/rejected unnecessarily.

40. The various subsidiaries with API distribution will be clustered by one superuser - correct? Headquarter?

A: This is of for each company to decide whether you want one person to manage all or only parts of the access.

41. Is there a legal mandate for a manufacturer to enter data in OMS, e.g. from India or China? Or will the MAHs be responsible eventually?

A: We expect that Manufactures in EU will have to be registered in OMS ahead of receiving a MIA. For those not in EU, they are likely to be required in the context of an application before even an inspection is triggered/needed. The OMS operating model foresees that whoever needs the data needs to submit it to OMS.

42. We are a MAH and are registered in OMS, we have warehouses on different location (we are not the owner of this location), do we have to add additional location in OMS as second location for organisation (as GDP licence refers usually to warehouse location)?

A: The data needed in EudraGMDP to correctly populate a certificate will need to be made available in OMS. The data cleansing of EudraGMDP is still happening in OMS, if warehouse is already available in EudraGMDP we will import it to OMS, if not available today in EudraGMDP please submit a change request.

43. We as a legal entity ensure that our information in OMS is correct, but the national Health Authorities will submit the applicable certifications to EudraGMDP?

A: Yes.

44. Where is possible to find the precise definition of "Organisation" in case of a pharmaceutical company and/or Manufacturers? Should all the organisations report in the chamber of commerce to be reported?

A: An organisation is a legal entity in a certain jurisdiction – i.e. a registered company in a country, regardless of the role they have in a regulatory procedure.

45. What is a location?

A: Locations are all the address information where an organisation actually exists and has activities, regardless of its role as a MAH or a major manufacturing facility, for example. OMS can record as many locations as needed. PO boxes addresses are not recognised by national postal service, however EMA has standards to record those too. Addresses of legal representatives of MAHs can also be recorded, provided the needed supporting documentation is made available.

46. Is only one super user per entity possible? What happens if this person is accidentally unavailable?

A: You can have as many Super users as desired, in fact we recommend having at least two to ensure one is always available/active.

47. How does it work when I need to move my organisation to a new Location (= new address)? The OMS needs to change via CR before the WDA/MIA can be authorized at the new address. But then there will be a gap where the new location is registered in OMS before the new authorisation is actually given.

A: Yes, but while the current certificate is valid you should not be having an issue. In general, it is expected that the discrepancies between current companies available in EudraGMDP and the formal OMS it would not be major as the OMS team is cleansing the current records.

48. In case of manufacturing sites, if details such as buildings or plots are not in OMS, but in the GMP certificate, it means the information from the eAF will not be aligned with the info on the GMP certificate/dossier documents. Questions at application validation can be expected.

A: This extra info will be included in the certificate remarks ('Restrictions' section). We expect that in eAF you will select the same ORG/Loc as the one in the certificate. In terms of questions on this for CAPs, please refer to the OMS mandatory use Q&A.

49. As the certificates remain valid, how can we handle validation issues where EudraGMDP has been updated, but the certificate hasn't? Will EU NCAs have to accept EudraGMDP data and ignore the discrepancies in the certificates?

A: OMS is only becoming mandatory for CP and indeed we are working closely with EMA regulatory colleagues to minimise questions on discrepancies - more info on OMS mandatory use Q&A. This has not yet been agreed/implemented for MRP, DCP, NP nor agreed with other NCAs.

50. As said, location ID doesn't change even after moving the location under another organisation. In this case the location ID will be associated with both organisation IDs, so the first one will be replaced?

A: OMS has the technical functionality to move the location from an organisation to another, however this is not a rule we use on a day-2-day bases - there are a number of factors/validations that we need to assess before taking such action i.e. required supporting documentation to help us validate such transfer and the impact such transfer would have on OMS consuming systems.

One of the practical challenges/negative impact would actually be with the integration of EudraGMDP, a record in EudraGMDP and OMS is actually composed by 2 parts: organisation & location information, if we were to move 1 of these part we would be breaking the business rules of both the systems. And because today we have a better understanding of these business rules we recently corrected the statement below in our presentations.

51. Can a "subsidiary"(= a correspondence address of the MAH) also be registered (ex; MAH in France with several subsidiaries in different countries): will we then have as many organisations as number of countries?"

A: One Organisation relates to one country only, so if it is present in multiple countries, we will have multiple ORG IDs.

52. In case of an Indian site, would you have 1 Loc ID per plot?

A: In India some plots (e.g. 100-110) are recognised as one address by National postal services, in that case we have 1 LOC ID. In other cases, if the plot is not recognised by postal services as a single address, we will split it into different LOC IDs in line with how they are recognised.

53. If a wholesaler company is registered in OMS with two addresses as per the Trade register document (establishment address & administrative/office address) but there are 3 more warehouse different locations mentioned also in the wholesaler certificate issued by the CA, do we need to request a change in OMS in order to include these 3 warehouse locations in terms of certificate updates activities?

A: If not yet reflected on OMS, yes.

54. For GMP Certs that have expired but still listed in EudraGMDP, will these facilities still transition to OMS?

A: Only current data are being cleansed and recorded in OMS. Current GMP certificates will not be amended following OMS integration into EudraGMDP.

55. Will Agencies accept differences in organisation name or address selected in eAF/GMP and what MAH put (or already have it) on labelling, PIL, SmPC? Was this agreed with National Agencies?

A: It is understood by National Agencies that the OMS data is standardised, so that minor differences between the display of name or address might occur between OMS, national systems, and/or labelling.

56. If I plan to submit a variation package mid/end Nov 2021 (no additional testing/manufacturing site), do I need to perform any actions with regard to checking OMS?

A: Industry is informed about the mandatory use of OMS for CAPs and the deadline was extended – in this case not in relation to EudraGMDP – to November. See the OMS mandatory use Q&A.

57. In some Asian countries, strict regulation exists about company name & address. Is the impact of this taken into account?

A: The OMS Dictionary provides a standardise list of organisation name and address data, including Asian countries.

58. What about an NCA that has never issued WDA for vGDP?

A: If the company is not present in EudraGMDP, a change request to OMS is needed.

59. Follow-up-question to the variation question: eAF for variations covered only MAH, my question is do I need to check only MAH in OMS or all sites register red for this product?

A: All sites that are impacted by the procedure should be included in OMS – but if there are other manufacturing sites that are not impacted by the procedure, they do not need to be included in the eAF. Please see the question 26 of the Q&A document.

60. In case that one legal entity has more locations, will we have more entries based on the location or just one of the based on the headquarter?

A: We can have as many addresses (locations) as needed, for headquarters, for sites, for correspondence, for billing, etc.

61. When my company has an address with multiple door numbers like 30 - 33 and is already registered in OMS with this address. Did I understand correctly that this will create several entries in the data base (one for each door number) with a LOC-ID for each? Do I have to select each of these entries when filling in an eAF?

A: It will depend on the country and the rules from each postal service. Combined addresses 30-33 may be acceptable/recognised and in that case, they will be 1 LOC ID only, in other countries this may not be the case. This is on a case by case and depending on the standards defined by the postal services of the concerned country.

62. 1 organisation per country means 1 super user per organisation?

A: The Super user manages the users of a given Organisation (is affiliated to the Organisation). A super user can be affiliated with as many organisations as wanted, and then administrate the other users of those organisations. EMA recommends at least 2 super users per organisation. Please note that regardless of their affiliation/role assigned, any user can change any data Org/LOC in OMS (not just their own Org/Loc!), as long as the required supporting documentation is submitted.

63. Please give the examples for "supporting documentation".

A: The list of supporting documents is available in the SPOR Portal – Documentation, in the document E - OMS Change Requests.

64. Can wholesale distribution authorisation holders also be super users?

A: Yes, for their organisation or any other organisation that appoints them as a super user.

65. Is it possible to delegate edition of the data in the OMS to another legal or physical person? How will this authorized legal or physical entity register into the system?

A: It is possible via the EMA Account management system. Please consult the SPOR Portal for instructions (ppt and manual) on how to register and what roles are available. If you still have questions, please raise a Service Desk request.

66. Do I have to register as a SPOR user?

A: Yes, if you are responsible or need to create/update data in the OMS Dictionary. Please consult the SPOR Portal for instructions (ppt and manual) on how to register and what roles are available. If you still have questions, please raise a Service Desk request.

67. How do I get Login data as a SPOR user?

A: Guidance is available in the SPOR Portal – Documentation, in the document Z - SPOR User Registration Manual. If you still have questions, please raise Service Desk request.

68. Where would we add alternate names for an organisation on the existing OMS change request form?

A: Please use the Justification field to add any alternative names.

69. Should the MAH not create a change request for a new location that will be effective before 28 January 2022?

A: MAH/applicants that need the data for eAF should of course raise a change requests in due time, but if no eAF is going to be submitted we kindly request that you do not start updating/creating change requests until the data cleansing is completed.

70. Considering the data cleansing period, when shall a company check its potential presence in the OMS dictionary? Right now, or always from 28 January 2022?

A: Please check as of 28 Jan 2022, so that you will see potential changes arising from the cleansing process.

71. I have only "Request New Organisation" option and don't see any "change request" option. How exactly I initiate the change request process?

A: If you only have "Request New Organisation" option since you have SPOR Unaffiliated role – role automatically assigned to every new user to EMA Account Management to allow users to create their organisation in OMS, in a case where such data is not available. To have access to other change request options you need to request a SPOR Industry (Super) User role to your organisation.

72. How can I check the EudraGMDP Number listed under Location Details?

A: When the cleansing is complete, you will be able to search the ORG/LOC Ids in EudraGMDP modules.

73. So, every SPOR user is allowed to submit a Change request after registration, correct? (with supporting documents of course)

A: Yes.

74. Can a MAH submit a change to modify some data of an API manufacturer used in its procedure? In this case, will the change be reflected only in the MAH documentation and no changes occurs to the API manufacturer registration?

A: If you submit a change request to the name and/or address of a manufacturer and the request is validated and processed, then the way you have changed it will be the only way the company will be recorded in OMS and used in all databases sourcing data from OMS.

75. If the API manufacturer is listed at https://iris.ema.europa.eu/, is it necessary to register to OMS?

A: IRIS is already consuming from OMS so if it appears there you do not need to register. The info on IRIS is the same as the one in OMS. You can also check the list of companies present in OMS as this is public.

76. The company where I work is registered in OMS/SPOR and at the time it was registered in an Organisation type as INDUSTRY-Pharmaceutical Company. It is any way to place in the Organisation type Veterinary Wholesaler Distributor? Also, in EudraGMDP the Certificates from DGAV are still not available in this site. When can be available?

A: The OMS category is dividing the data into Industry/NCA/Educational/Healthcare, it does not classify the roles/activities of the Organisations. Additionally, please liaise with DGAV for the publication of the certificates.

77. My Organisation submitted copy of MIA which is not in line with the current version placed in EudraGMDP database. How shall I update the same?

A: If you do not need to update the information now (e.g. for eAF), we kindly request you wait for the data cleansing to be complete (i.e 28th January 2022). Once done, OMS will reflect the latest information available from Trade registry and Postal services, not necessarily what is in the MIA.

78. With regards to change request, is it possible to update to new address in location details or do we have to create a new record with new location?

A: If the change is to update details of the same physical location (e.g. postcode, typo) then we update the Loc ID. If you move from one physical location to another (e.g. from building 1 to 5), then we create a new LOC Id.

79. Are there fees for Change Requests?

A: No, they are free of charge.

80. We need to update the information at the earliest. Can you please advise how this can be done?

A: MAH/applicants that need the data for eAF should of course raise a change request, but if no eAF is going to be submitted we kindly request that you do not start updating/creating change requests until the data cleansing is complete.

81. In case we have one address for HQ and more addresses for manufacturing locations that cover different GMP activities, how will this be connected with the issued GMP certificates? Will there be a separate GMP certificate for each manufacturing location and the related address (this is the current situation) or will the GMP certificate be issued only for the HQ address?

A: The procedures for issuing GMP certificates are not going to be changed. The current process would still apply.

82. How to affiliate SPOR Super User to another company?

A: The request should be sent from a work email affiliated to the same organisation for which the user is requesting access. Comprehensive guidance on user roles and how to request those is available in the SPOR portal.

83. If anyone can submit change request for any organisation, wouldn't it create discrepancies?

A: Anyone can log a change request, but the OMS Data Stewards will validate the information against Trade registry/Postal services and always align to it regardless of what is requested. In the end there should be only one version of data aligned to reference sources.

84. If we see that one of the records should be deactivated since it is wrong - this should be done through CR?

A: Yes, we inactivate Orgs/Loc if they cease to exist legally (not if they are not being used), via a change request.

85. How an industry super user can affiliate to another company? Is it need to resend the SPOR Affiliation template?

A: Please consult the SPOR Portal for instructions (ppt and manual) on how to register and what roles are available. If you still have questions, please raise a Service Desk request.

86. How long would it take for a new user to self-train to OMS user guidance (user registration, OMS data quality, CR process, ...)?

A: Initially familiarising with the portal may take half an hour. The portal is very intuitive, and people will be able to navigate through it smoothly. You can always reach out to Service Desk should you need additional guidance than what provided in the comprehensive information available.

87. We already are registered in SPOR Portal, but everything is blocked. Why?

A: Please log a Service Desk ticket for technical assistance.