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Veterinary Medicines Division

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

1. OMS knows no location names (site names) whereas EudraGMDP contains those (and site names are included in our manufacturing authorisations). Will location names be added in OMS?

A: In OMS, the company name and address will be displayed. Any additional information (e.g. additional door numbers, units/plot names) will not appear. However, when drafting a certificate or a licence in EudraGMDP, NCAs will be able to add additional information related to the specific site by using the "Restrictions" field.

2. What happens when a company (for whatever reason) fails to register in OMS? NCAs have to issue certificates.

A: The change request to the OMS team can be sent by any registered SPOR user. It will take from 5-10 days to process the request and 1 additional day for OMS data to be reflected in EudraGMDP. A certificate cannot be used in case the company details are not present in OMS therefore it is recommended to ensure that OMS registration is done as of 28th January 2022.

3. What happens if in inspection we detect that the address is not the correct one as registered in OMS?

A: The ongoing data cleansing exercise led by EMA's OMS team should avoid this scenario. However, NCAs can raise change requests to the OMS team.

4. Who shall inform companies? Many companies, especially smaller companies and university institutions, are not represented and informed by industry associations.

A: Communication to industry users is a shared responsibility of EMA and NCAs. EMA sent a letter on the changes arising from the integration of EudraGMDP with OMS to industry associations and to the GMP/GDP IWG, the project Regulatory Change Liaison Network, so that NCAs can communicate at national level. EMA also organised a webinar for industry scheduled for 12 October, which received over 1,000 requests for registration.

5. Will EudraGMDP do lockups in OMS or will EudraGMDP have its own OMS register with data copied from OMS?



A: OMS will be synchronised with EudraGMDP, therefore there will be no duplication.

6. How can companies to be recorded in OMS?

A: The process is explained here: [Organisation Management Service \(OMS\) | European Medicines Agency \(europa.eu\)](#). It is also detailed in the module presentation on this page.

7. Where can the site address be registered and part of the GMP and GDP certificates, as well as MIA and WDA?

A: Site name and address will be registered in OMS. In EudraGMDP modules, NCA users will be able to select the site from a drop-down menu, which will be common for all EudraGMDP modules.

8. In Spain there are some limited cases of different MIA located in the same site address (usually companies of the same group with different activities). In these cases, the companies will have different ORG ID but the same LOC ID. Is it possible? Sometimes the two MIA have their main activity in a specific plot, but general services (such as QC testing, warehouse) may be shared.

A: The OMS Dictionary captures organisations from the legal perspective, we will not create a different record to each business unit – they will all use the same ORG ID, remark section can be used to capture any additional information. We can create as many locations as needed, as long as we don't create duplicate physical places i.e. if Street 1-4 is already available in the Dictionary we cannot create Street 1 as a separate record.

In addition, please remember that an OMS record is created following 3 main principles: correct organisation/legal entity; correct relationship with its address and correct address. If data from one of those principles changes, a new ID will be generated i.e. if we have 2 different legal entities using the same physical place, we will display the same address data with 2 different LOC IDs.

The name of the organisation and also the name of the manufacturing facility will appear in OMS.

9. Do you plan to consider a site with multiple plots/units (for instance, some plots for intermediate manufacturer and some for-API manufacturer) as one location?

A: In OMS, the company name and address will be displayed. Any additional information (e.g. additional door numbers, units/plot names) will not appear. However, when drafting a certificate or a licence in EudraGMDP, NCAs will be able to add additional information related to the specific site by using the "Restrictions" field

10. If a company has several buildings with different authorizations at one location, it is grouped under the same LOC-ID. How can the respective unit then be selected in the eAF?

A: The below table illustrates examples of how the information on the Organisation details is captured in the MIA(s), in OMS and what consequently should be selected in eAF

MIA(s)	OMS	eAF
MIA 1 – Antibiotics: Building 30-36 Street 1 City 1 Country 1 MIA 2 - injectables: Building 30-36 Street 1 City 1 Country 1	If recognised by NPS (combined address): LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 If not recognised by NPS (only 1st building): LOC ID 10000000012 Building 30	LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1 OR (LOC ID 10000000012 Building 30 Street 1 City 1 Country 1

	<p>Street 1 City 1 Country 1</p> <p>If Industry also wants building 36 they need new CR and it will create a new LOC: LOC ID 10000000013 Building 36 Street 1 City 1 Country 1</p>	<p>AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1)</p>
<p>MIA 1 – Antibiotics: Building 30-36 Street 1 City 1 Country 1</p> <p>MIA 2 - injectables: Building 36 Street 1 City 1 Country 1</p>	<p>If Combined LOC existed it will be split!: LOC ID 10000000011 Building 30-36 Street 1 City 1 Country 1</p> <p>Into: LOC ID 10000000011 (updated) Building 30 Street 1 City 1 Country 1</p> <p>AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1</p> <p>If Industry also wants building between 30 and 36 they need new CR and it will create a new LOC.</p>	<p>eAF For antibiotics: LOC ID 10000000011 (updated) Building 30 Street 1 City 1 Country 1</p> <p>AND LOC ID 10000000013 Building 36 Street 1 City 1 Country 1</p> <p>Or even more</p> <p>eAF for injectables: LOC ID 10000000013 Building 36 Street 1 City 1 Country 1</p>

11. You mentioned UAT testing is to start shortly. However, we would be using the xml schema as we don't have admin rights to EudraGMDP anymore. We probably won't be ready to test the schemas during this period. Will there be another opportunity for us to test our new updated schemas before go live?

A: Yes, also for XML schemas EMA is running testing activities between October and November 2021. EMA has contacted all concerned authorities.

12. Why will take one day to see a new organisation in EudraGMDP if it is a direct lockup in OMS?

A: The synchronisation between OMS and EudraGMDP is scheduled to take place once a day, every business day.

13. Will the name and the legal form be mentioned together in the name field for the company?

A: Yes, the only exceptions to the rule are French and Belgium organisations where we follow the standards provided by the National business registry i.e. if a French company have the legal entity part of the name, we will add the record in OMS accordingly.

14. How exactly will EudraGMDP / OMS deal with an individual holding a manufacturing authorisation?

A: Individuals who are registered entities within a jurisdiction are considered a company and can be recorded in OMS.

15. How will you control the ORG and LOC ID of companies not located into EU, e.g. Switzerland?

A: Switzerland is part of our validation processes; we are able to validate the organisation name against the National business registry and the location data against the National Postal service information.

16. If an organisation is both a MA holder and a Wholesale Distributor, will it be registered twice? Or once with two roles?

A: The organisation will appear in both modules, but name and address will be sourced from the same location, which is OMS. The organisation will be registered only once and will have no roles in OMS.

17. I would like to refer to WDA. How to change the registered address of WDA owner?

A: You would need to raise a change request with OMS.

18. Is China one of the 240 countries included?

A: Yes. For further clarification on the 240 countries listed available on the [Informatica webpage](#).

19. Is it possible to have a location-ID without street name or postal code?

A: Only in two cases: large volume receiver sites or PO Box; and Swedish addresses (if the OMS team can validate data against national postal services).

20. Will it be impossible in the future to search for GMP Certificates by the actual location of the site?

A: Any future query will be possible via organisation and location IDs through OMS, and later also via the "Restrictions" field. This latter functionality will not be available in EudraGMDP until approx. one month after the go-live on 28 January 2022.

21. For multi door addresses, will it be needed to update the MIA according to the OMS register?

A: Current MIAs do not need to be updated.

22. Is DUNS anything official?

A: We use the DUNS to help us validating data outside the EEA. The Dun & Bradstreet D-U-N-S Number is a unique nine-digit identifier for businesses, identifies a company as being unique from any other available in D-U-N-S database.

23. Is the concerned NCA informed at any time?

A: No, the NCA will not be notified of a change in OMS. It is the responsibility of the company to provide such information to the concerned NCA.

24. How can NCAs see organisation IDs on EudraGMDP?

A: When drafting a certificate, NCA users will view a drop down list - which is the OMS list.

25. When a company changes its name, are the linked authorisations (MIA-WDA) or API registrations or certificates (GMP-GDP) automatically updated?

A: Current certificates will not be updated. Any changes to OMS master data will not automatically update certificates. NCAs have the option to update them on a one-to-one basis.

26. Will the official address and the site addresses be available in OMS?

A: Yes, the official address and the site addresses will be available in OMS (if they are different addresses).

27. How are mergers between companies handled? Will they receive a new ORG-ID or be registered under one of the original ORG-IDs?

A: Mergers will be registered under one of the original ORG-IDs, lowest ID in value.

28. If a company has, for example, 4 different official sites at different addresses, will that company be in OMS 4 times?

A: We represent the company/legal entity as 1 Organisation. If it has 4 addresses, OMS will contain 4 Locations.

29. We have several confidential addresses that we only want NCAs to see in EudraGMDP and not the general public. Will the address now be visible in OMS?

A: The confidentiality rules will still apply and CCI will not be shown in the database. OMS dictionary is public and anyone can see the data.

30. Are all addresses publicly available?

A: When NCAs mark specific sites as confidential, those addresses will not be available to the public in EudraGMDP. All addresses will be available on OMS, however certificates linked to those confidential addresses would not display details of the addresses in the public version of EudraGMDP.

31. Relevant changes should be previously made in MIA/WDA (to be authorised by NCA), before making the change request in OMS.

A: NCA users will not be able to modify the site address in EudraGMDP as of 28 of January 2022. As of then, a change request to OMS is needed.