The new regulatory framework for veterinary medicines (Regulations 2019/6 and 2021/16, Article 9(h)) requires the following changes to the EudraGMDP database which will come into effect from 28 January 2022:

- Integration of EudraGMDP with EMA's Organisation Management Service (OMS);
- Extension of the two following modules of EudraGMDP to the veterinary domain:
  - Wholesale Distribution Authorisations (WDA)
  - Active Pharmaceutical Ingredients Registration (API-Reg).

The most notable change is the integration of EudraGMDP with OMS. From 28 January 2022, users of EudraGMDP from national competent authorities will no longer introduce organisational data (organisation name and location address details) directly into the relevant fields on the EudraGMDP database. Instead, they will select the relevant organisation name and location address details, including the legally registered address, of the manufacturers/importers/distributors from the Agency's organisation dictionary (so-called OMS). This change will be reflected in the associated human and veterinary associated documents (including MIAs, WDAs, GMP Certificates, GDP certificates, API Registration) and investigational medicinal products (including MIAs, GMP Certificates).

This change will ensure more reliable data in the system through the consistent use of organisation master data in EudraGMDP, reduce the need for data entry and cleansing, and enhance consistency of these master data across other EU IT systems and projects, e.g. Clinical Trials Information System and Union Product Database.

It will only be possible for a national authority to issue a document on EudraGMDP from 28th January 2022 if the relevant organisation master data is available in OMS. This applies whether the document is being issued on EudraGMDP for the first time following a new application (e.g. new MIA, WDA, Active Substance Registration) or where a document is being re-issued (e.g. a new version of the MIA following a variation to the existing information). The same applies for certificates issued on EudraGMDP following an inspection process.

It is therefore necessary that all organisations currently regulated through EudraGMDP (which appear on documents within EudraGMDP, including EU and non-EU manufacturers, importers and distributors of human and veterinary medicinal products and active substances) are registered in OMS.

In order to assist in populating data into OMS, EMA has undertaken a project to map existing organisation data associated with sites which are listed on various documents within EudraGMDP to OMS. As the data is introduced into OMS, it is checked for accuracy and cleansed through a standardised process. As a result of the standardisation used by OMS, it is possible that this could result in minor changes to the organisation data currently in EudraGMDP. This process will not affect existing documents on EudraGMDP (e.g. MIA, GMP Certificates, WDA etc.).

As of 28 January 2022, before applying for a new/updated manufacturing or wholesale distribution authorisation with national competent authorities, please check whether your organisation is correctly registered in OMS.

Read only access and searching of OMS is possible without having an 'EMA account'. However, you need to ensure that relevant personnel in your organisation have registered for an EMA Account and requested a SPOR role for your organisation to maintain existing master data.

- **If your organisation and its relevant locations are already correctly registered in OMS**, no further action is needed at this time.
- **If your organisation and its relevant locations are not registered in OMS, or if the information in OMS is not up-to-date**: please raise a change request with the OMS team to register new or updated organisation master data in OMS **after 28 January 2022**. The Service Level Agreement (SLA) for change requests on OMS is 5-10 working days, based on the type of change needed. Raising a change request prior to a formal application for new authorisation or variation to details on an existing document (e.g. MIA or WDA) will ensure that national competent authorities

SLA timeframes for new/updated authorisations are not shortened due to the time needed to validate the change request in OMS. This is particularly important if your site is to undergo inspection.

- **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. This is particularly relevant for any sites where an inspection is foreseen shortly and the related potential certificate may be issued after 28th January 2022. The same guidance applies:
  - **If the site is already correctly registered in OMS**, no further action is needed at this time.
  - **If the site is not registered in OMS, or in case the information in OMS is not up-to-date**: a change request needs to be raised with the OMS team to register new or updated master data in OMS. The SLA to process change requests on OMS is 5-10 working days, based on the type of change needed. 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.

For information regarding the revised national application procedures, we suggest industry stakeholders contact relevant national competent authorities.

Comprehensive information on OMS and its services for any organisation/users is available here:

- OMS website
- SPOR portal
- Video tutorial: Overview of OMS