Dear Sir or Madam,

Today we would like to inform you in more detail about the following topics:

If you need further information, please do not hesitate to contact us.

With kind regards

Your DiaMed Team

1 OMS DATA IN ELECTRONIC APPLICATION FORMS

The European Medicines Agency (EMA) reminds all applicants and marketing authorisation holders that as part of the development of the Substance, Product, Organisation and Referential (SPOR) Data Management Service and in view of the upcoming Digital Application Dataset Integration (DADI) project, a registration of the facilities and organisations belonging to a medicinal product in the Organisation Management Service (OMS) needs to be made or a review and, if necessary, correction of the data is required.

The OMS provides a single source of validated organisation data that can and should be used as a reference to support EU regulatory activities. Master data consisting of the organisation's name and location address for organisations such as **marketing authorisation holders, sponsors, regulatory authorities and manufacturers** are stored and retrievable in OMS. The data is mastered with unique IDs, identified in OMS as "Organisation_ID" and "Location_ID".

The use of OMS data in electronic application forms (eAFs) for the centralised procedure (CAP) is mandatory since 01 November 2021. This applies to both human and veterinary medicinal products. The EMA has provided a "Questions & Answers" document on this topic.

The new version of the eAFs, currently version 1.26.0.0, and the corresponding release notes are available on the EMA's eSubmission website. The address details can no longer be entered manually (after selecting "Centralised procedure") via free text fields, but must be selected via OMS. The use of the new forms will become mandatory after a one-month transition period on 01 January 2022.

Regarding the obligation for DCP/MRP, according to CMDh, a longer transition period is currently under discussion. The EMA will evaluate the experience with CAP products and incorporate this for the OMS implementation for MRP/DCP products.

The EMA explicitly emphasises that registration in OMS prior to regulatory submission is important. This avoids any delay in starting the application processing. Applicants will otherwise be required to register their organisations/institutions during the validation phase before the procedure can be started.

2 USE OF OMS DATA IN THE EUDRAGMDP DATABASE

EMA announces that from 28 January 2022 on, the EudraGMDP database will also use data from the OMS . The EudraGMDP database will use the data for the following documents:

- Manufacturing and importation authorisation
- GMP compliance certificate
- Wholesale distribution authorisation
- Registration of an active substance manufacturer, importer or distributor

From this date, **manufacturers, importers and distributors** must ensure that organisation-related details such as name and address are correctly recorded in the EMA's OMS before applying to national competent authorities for the documents. This applies to all EU and non-EU manufacturers, importers and distributors of human and veterinary medicinal products or active substances, which are mentioned in documentation uploaded in the EudraGMDP database.

National Competent Authorities will no longer manually enter organisation-related information into EudraGMDP, but will rely on the master data stored in OMS from 28 January 2022.

3 PRODUCT DATABASE (UPD) FOR VETERINARY MEDICINAL PRODUCTS

In parallel to the EMA's SPOR project, a separate product database (UPD - "Union Product Database") is being set up for veterinary medicinal products in Europe. This is required by the Veterinary Medicines Regulation (Regulation (EU) 2019/6), which becomes applicable on 28 January 2022.

Although the UPD database is set up in parallel with the SPOR system for human medicinal products in accordance with the IDMP standards, it is closely interlinked with it. National Authorities and Marketing Authorisation Holders will be required to submit their product data in UPD before the regulation comes into force. A SPOR-OMS registration in combination with a check for correctness of the address data is a prerequisite for the use of the database. The EMA has published a "Questions & Answers" document on UDP.