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Veterinary Medicines Division

EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database

Implementation of the requirements of Regulation (EU) 2019/6 for the Union database on veterinary medicinal products in the European Economic Area

Chapter 1: Registration and data access requirements for the User Interface (UI) and Application Programming Interface (API)

Version 1

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Table of contents

1. Introduction to Chapter 1 3
2. SPOR on-boarding of users 3
2.1. SPOR access to data 3
2.2. OMS registration requirements 4
3. UPD registration and access 4

1. Introduction to Chapter 1

This chapter outlines the steps to follow to be registered to the relevant systems enabling the submission of veterinary medicinal product information into the UPD. It also explains the registration requirements for the users to fulfil in order to be granted appropriate access to data on medicinal products for veterinary use in the EEA. This chapter provides guidance on:

- SPOR on-boarding of users;
- UPD registration steps;
- Access management for different parts of the information held in UPD.

2. SPOR on-boarding of users

Prior to the submission of veterinary medicinal product information into the UPD, the underlying terminologies must be available in the SPOR services. It is therefore advisable to register to the Referential Management Services (RMS) and Organisation Management Services (OMS). SPOR user guidance for on-boarding must be considered as well as the reference guidance including the type of users available for SPOR, the permission matrix listing access to functionalities in accordance to available roles, information and requirements for registration. Therefore, users should read this guidance in conjunction with SPOR user guidance for on-boarding available on the EMA website.

2.1. SPOR access to data

Access to SPOR data will be provided through the SPOR application programming interface (API) or User Interface (UI) and will be based on the **user roles** available for each stakeholder group as described in the 'On-boarding of users to SPOR data services' document.

The stakeholders are grouped as follows:

- competent authorities: The European Commission (EC), national competent authorities (NCAs) and EMA, responsible for regulating medicinal products;
- industry: marketing authorisation holders (MAH), registration holders, product owners and applicants, including relevant external service providers (e.g. consultants), and medicines developers;
- general public: persons or organisations, other than the competent authorities and industry referred to above.

Access is defined based on the stakeholder's interests and needs as well as the requirement to comply with EU personal data protection legislation (Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, and Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)). The protection of personal data is a fundamental right of EU citizens. In addition, the principles applied to delete commercially confidential information on the disclosure of EMA and NCA regulatory documents are also applied to determine access to information. Therefore, due to the detailed nature of some of the

information contained in SPOR, not all data elements can be disclosed, which is also detailed in the annex of the SPOR Access policy document.

To manage product data in the UPD, a NCA and MAH user must be registered in the EMA Account Management portal (EAM) and affiliated to a specific organisation with the required **user roles**, as described in the 'On-boarding of users to SPOR data services' document. The first step involves the registration of a 'Super User' in EAM. Once approved by EMA, the 'Super User' will have permissions to approve or revoke any other users affiliated to the same organisation (i.e. related to the so-called 'Controlled users'). Having the role of a 'Controlled user' is necessary to create or edit medicinal product data. It is recommended that each organisation (i.e. NCA and MAH) should have at least two 'Super Users' registered in EAM.

The 'SPOR User Registration Manual' provides a comprehensive step-by-step guidance which describes all existing SPOR user roles and authorisation process flow. In addition, it provides detailed instructions on how to register and manage SPOR roles.

2.2. OMS registration requirements

In order for the NCAs and MAH to complete veterinary medicinal product record in UPD with organisation information, all organisations included in the set of UPD data related to the authorisation or application for a veterinary product must be registered in the Organisation Management Service (OMS). For the initial submission of veterinary authorised or registered medicinal products in UPD (i.e. so-called legacy data), this requirement is limited to the provision of information on the MAH and the Manufacturer batch release site as defined in Chapter 4 of the Vet EU IG on veterinary medicines product data in the Union Product Database.

Furthermore, the MAH or product owner of each product must be registered with the Organisation Management Service (OMS) to be able to record the non-regulatory post-authorisation data as required by Regulation (EU) 2019/6 and Commission Implementing Regulation (EU) 2021/16.

The 'OMS web user manual' describing how to register an organisation in OMS can be found on the OMS portal, in section 'Help'.

3. UPD registration and access

The detailed prerequisite steps and processes to be undertaken by NCAs and MAHs for being able to submit veterinary medicinal product information in UPD are described in the UPD registration guidance, to be published in 2021.

Implementing the requirements of Regulation (EU) 2019/6, the UPD Access Policy published in January 2021 defines the overall principles for providing access to veterinary medicinal product information held in the UPD in line with the EU legislative framework.