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4 EU Implementation Guide (IG) on veterinary medicines 5 product data in the Union Product Database

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

8 Introduction

9 Version 1

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Introduction

1. Legal Provisions

In December 2018, Regulation (EU) 2019/6 on veterinary medicinal products and repealing Directive 2001/82/EC, which also amends the provisions of Regulation (EC) No 726/2004, was adopted by the European Parliament and the Council. The provisions laid down in Regulation (EU) 2019/6 came into effect on 28 January 2019 and are applicable from 28 January 2022.

Article 55(1) of Regulation (EU) 2019/6 requires the Agency to establish and, in collaboration with the Member States, maintain a Union database on veterinary medicinal products, also referred to as the "product database", "Union Product Database", or "UPD".

The minimum content of that product database is laid down in Article 55(2). Article 56 specifies the various levels of access to the database.

Articles 55(2), 58(6) and 58(12) require the marketing authorisation holder to record in the product database the dates when its authorised veterinary medicinal products and registered homeopathic veterinary medicines are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State and, as applicable, the dates of any suspension or revocation of marketing authorisations as well as the annual volume of sales for each of its authorised veterinary medicinal products.

Article 61 of Regulation (EU) 2019/6 places a responsibility on marketing authorisation holders to record variations to the terms of the marketing authorisation that do not require assessment in the product database, which are subsequently to be approved or rejected in the product database by the competent authority.

According to Article 74(2), the product database should be interconnected with the pharmacovigilance database provided for in Article 74(1).

Article 102(4) and (7) require the Member States to make available to the public information on veterinary medicinal products that are parallel traded in that Member State.

Article 155 requires the Member States to submit, electronically, information on all veterinary medicinal products authorised within their territories in the format referred to in point (a) of Article 55(3) by the date of application of Regulation (EU) 2019/6.

Further functional and non-functional requirements, as well as technical specifications arise from Commission Implementing Regulation (EU) 2021/16 of 8 January 2021 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products (Union product database).

2. Union Product Database: expected benefits and implementation strategy

The Union Product Database (UPD) is the cornerstone of achieving the objectives of Regulation (EU) 2019/6, also considering its interconnections with other relevant Union databases. It will collect, collate and allow sharing of pertinent data on authorised veterinary medicinal products and registered homeopathic veterinary medicines and, as a result, contribute to achieving the objectives of Regulation (EU) 2019/6 by:

- improving transparency on veterinary medicinal products approved for distribution in the EU,

- supporting the activities around the harmonisation of product information,
- implementing a reliable tool that veterinary practitioners can use to elaborate treatment options, also in case of unavailability of a specific product in a particular Member State,
- offering self-service access for marketing authorisation holders for certain regulatory activities and enabling the management of variations that do not require assessment,
- providing functionality to perform data analytics, as well as making data available that support regulatory processes outside the remit of the UPD.

Commission Implementing Regulation (EU) 2021/16 defines in its Article 9 the electronic data and document exchange mechanism for exchanging veterinary medicinal product data with other systems. Specifically, to the extent that optimal operability of the UPD does not adversely impact other Union systems, it places the responsibility on the Agency to ensure that the electronic exchange mechanism follows current recognised international standards for the identification of medicinal products and exchange of medicinal product information.

Prior to development of the UPD, the Agency already established four services, each dedicated to the management of one of the four domains of master data in pharmaceutical regulatory processes: substance, product, organisation and referentials (SPOR):

- Substance Management Service (SMS) – contains harmonised data and definitions to uniquely identify the ingredients and materials that constitute a medicinal product;
- Product Management Service (PMS) – will contain harmonised data and definitions to uniquely identify a medicinal product for human use based on regulated information (e.g. marketing authorisation, packaging and medicinal information);
- Organisations Management Service (OMS) – contains data comprising organisation name and location address, for organisations such as marketing authorisation holders, sponsors, regulatory authorities and manufacturers;
- Referentials Management Service (RMS) – contains lists of terms (controlled vocabularies) to describe attributes of products, e.g. lists of dosage forms, units of measurement and routes of administration.

The SPOR services are databases and services to manage the lists of controlled terminologies which will be supplied in the electronic submission of veterinary medicinal product information into the UPD. The SPOR is a set of separate systems that require registration as outlined in Chapter 1 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database (EMA/562455/2020).

The UPD is building on the existing PMS database structure with connection to the three other services of SPOR. The information and documents related to a veterinary medicinal product shall be submitted to the UPD via a Health Level 7 (HL7) Fast Healthcare Interoperable Resource (FHIR) message based on the terminology and reference standards available in the SPOR system. The overall submission implementation strategy is detailed below:

Step 1: Product data pre-submission

National competent authorities (NCAs) should align their electronic information systems on veterinary medicinal products with the released terminologies for referential, substance and organisation data and register any new referentials or substances required for the submission of veterinary substance and product data to the controlled vocabularies. Marketing authorisation holders should ensure that all

organisation data (addresses) for products under their responsibility are recorded in OMS and that records are up to date and complete.

Step 2: Product data submission

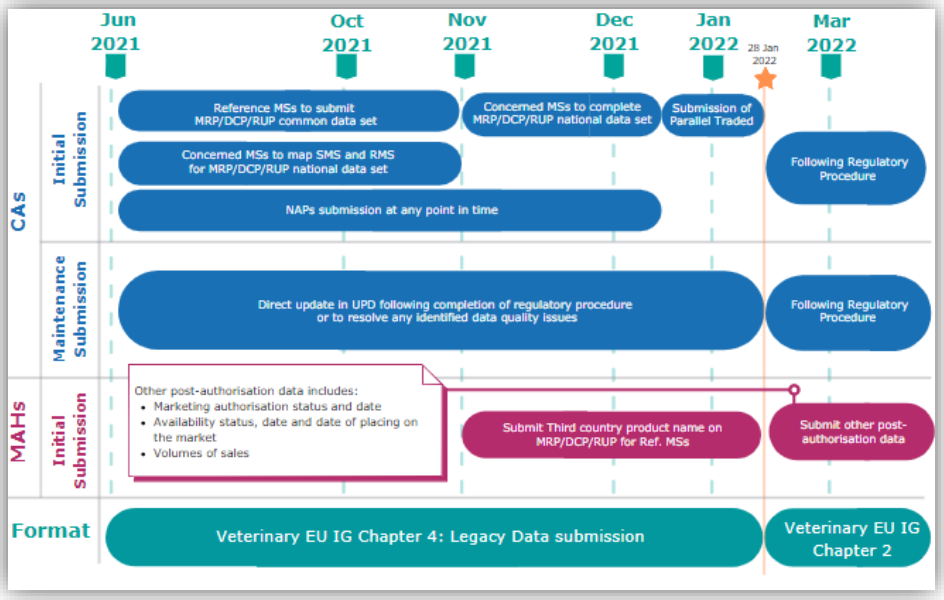
- By 28 January 2022, NCAs shall register a core set of information on veterinary medicinal product authorised in the territory of their Member State in the UPD using the FHIR format (i.e. legacy data upload as described in Chapter 4 of this document);
- From 28 January 2022 onward:
  - **NCAs** or the **European Commission**, as applicable, shall create entries on newly authorised or registered veterinary medicinal products, as relevant, in the UPD for products under their responsibility by providing the set of data and documents as described in Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database. It shall be possible to upload the information from a dataset in the format referred to in Article 10 of Commission Implementing Regulation (EU) 2021/16 in the user interface (Article 6) or via the API (Article 9i).
  - **marketing authorisation holders** shall record in the UPD the following information in line with the guidance provided in Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database:

    (a) the dates when their authorised veterinary medicinal products are placed on the market, information on the availability for each veterinary medicinal product in each relevant Member State, and the dates of any suspension or revocation of the marketing authorisations concerned.

    For existing veterinary medicinal products that were placed on the market before 28 January 2022 dates for placing on the market and availability should be recorded by 28 January 2023.

    (b) the annual volume of sales for each of their veterinary medicinal products.

The complete overview on the planning for the submission of veterinary medicinal product data into the UPD is as follows:



Step 3: Product data enrichment:

NCAs should submit any relevant additional data that were not previously provided into the UPD as part of the initial (legacy data) submission, when the relevant information becomes available at the end of a regulatory procedure or at approval of any subsequent variation of the relevant veterinary medicinal product.

In the context of future evolution of UPD (i.e. following the initial implementation of the so-called 'UPD minimum viable product' on 28 January 2022), additional data on veterinary medicinal product may be required to be submitted. Any future enrichment of UPD data (i.e. post UPD minimum viable product implementation) should be achieved by means of a stepwise approach with due regard to prioritisation of submission of additional data and information in UPD. Such prioritisation should be defined based on business and regulatory needs to be supported by the UPD and in close cooperation with the relevant stakeholders.

3. Structure of the Veterinary EU Implementation Guide (Vet EU IG) for the Union Product Database

This implementation guide is provided to support competent authorities and marketing authorisation holders in submitting veterinary medicinal product data into the Union Product Database in compliance with agreed formats and terminologies.

The business objective of this guide is to standardise the definition of the data elements used in electronic transmission of veterinary medicinal product information across Europe.

The technical objective of this guide is to assist competent authorities in implementing or adapting systems to exchange messages containing veterinary medicinal product information.

Following this short introduction, the Vet EU IG will provide guidance on:

- how to register for the submission of veterinary medicinal product information to UPD in **Chapter 1: Registration and data access requirements for the User Interface (UI) and Application Programming Interface (API)**;
- the format and the conventions (including the FHIR elements and business rules) for the submission of veterinary medicinal product information into the UPD in **Chapter 2: Format for the electronic submission of veterinary medicinal products** information;
- the processes for the initial submission and maintenance of veterinary medicinal product information in **Chapter 3: Process for the initial submission and maintenance of veterinary medicinal products information**;
- the processes for the preparation and submission of legacy medicinal product data (i.e. data on veterinary medicinal products authorised before 28 January 2022) in **Chapter 4: Processes for the submission of legacy data on veterinary medicinal products**;
- the technical specifications of the electronic submission message to provide veterinary medicinal products information in UPD in **Chapter 5: API Technical specifications**;
- examples of veterinary medicinal products in the UPD format (**Chapter 6: practical examples**).