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Veterinary Medicines Division

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

Explanatory note on the application of Article 3(3) of Commission Implementing Regulation (EU) 2021/16

1. Introduction

This explanatory note has been prepared by the European Medicines Agency (hereafter "the Agency") to clarify the application of Article 3(3) of Commission Implementing Regulation (EU) 2021/16 laying down the necessary measures and practical arrangements for the Union database on veterinary medicinal products ("the Implementing Regulation"), in relation to the submission of information on veterinary medicinal products by the Competent Authorities for the initial ('legacy') input to the Union Product Database (UPD) and in response to the challenges raised by National Competent Authorities related to the upload of high-quality legacy data into the UPD by 28 January 2022.

Article 3(3) of the Implementing Regulation requires the following: Where a dataset for a specific veterinary medicinal product is incomplete for historical reasons (as a result of data or documents not being required from competent authorities or from marketing authorisation holders prior to the application of Regulation (EU) 2019/6), the competent authorities shall clearly indicate in the datasets they provide any fields for which no value is available at time of initial input.

The recommended mitigation solution outlined in this explanatory note is based on the following principles:

1. The UPD shall contain harmonised and consistent data of quality (Recital (5) of the Implementing Regulation).
2. Lack of specific data in the UPD shall not:
    2.1. prevent the UPD from generating and assigning the necessary UPD Identifiers (i.e. the Product ID, the Permanent ID and the Package ID) for the submitted veterinary medicinal product information;
    2.2. affect or hinder post-authorisation processes supported by the UPD, such as submission of variations not requiring assessment, changes to marketing authorisation status, reporting availability status, upload of sales data, integration with the Union Pharmacovigilance

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Database and with the Collection of Antimicrobials Sales and Use data, or the link to the Union Database on Manufacturers and Wholesale Distribution.

3. The initial public version of the UPD only contains the legally required mandatory data fields as outlined in the Implementing Regulation and, for legacy data, only the fields as specified in Chapter 4 of the EU Veterinary Implementation Guide have to be completed.
4. While striving for a more flexible system with regard to the set of data to be provided by January 2022, all veterinary medicinal products (VMP) with a valid marketing authorisation in the EEA shall be provided into the UPD by Competent Authorities, at the latest, by 28 January 2022 in order to deliver on the system functionality and comply with Regulation (EU) 2019/6 (Article 155).
5. New products upload after January 2022 will require complete datasets, to be submitted in accordance with the format and standards outlined in Chapter 2 of the EU Veterinary Implementation Guide.

2. Recommended mitigation actions

In order to alleviate the challenges faced by the Competent Authorities for the initial input of data on authorised VMPs, a phased input of information into the UPD can be pursued as follows:

1. The UPD business rules and terminology will allow flexibility for all VMPs and will not enforce an 'all or reject' system; hence NCAs will be able to submit authorised VMPs into the UPD (not always with all data fields completed) as a 'preliminary data submission'.
2. As part of the initial 'preliminary data submission', the following mitigations are proposed for unavailable data or documents:
    2.1. Information on the Qualified Person for Pharmacovigilance:

    QPPV name (free text): specify 'Data not Provided'

    QPPV Location: The OMS Location ID of the MAH of the VMP should be indicated temporarily;

    2.2. Any product cross-reference where applicable (i.e. Generic applications) can be specified as 'VMP authorised outside EEA' (e.g. for UK based products) or 'Withdrawn VMP' or 'VMP data not provided';

    2.3. Attachments for the national data set (i.e. national SPC, PIL, PL) can be added to be product data entry later;

    2.4. Either the package description or the structured package information (at least one of the two items of information shall be provided as part of the 'preliminary data submission' to enable the generation of the UPD Package Identifiers).
3. The 'preliminary data submission' shall be performed by one of the following transmission tools:
    3.1. The Application programming Interface (API)

    3.2. The UPD User interface (UI) or

    3.3. The manual upload of XML FHIR message(s) via HTTP client.
4. Enrichment of incomplete datasets from the 'preliminary data submission' shall be carried out via the same or a different route of transmission by 28 January 2022 the latest.

The recommended solution, if Member States are not in a position to adapt their national databases on time, is to execute the 'preliminary data submission' via the API or the manual upload of XML FHIR message(s) via HTTP client and enrich the data thereafter manually via the UPD user interface.