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SCIENCE MEDICINES HEALTH

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3 Veterinary Medicines Division

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 Chapter 3: Process for the initial submission and maintenance of veterinary 9 medicinal products information

10 Version 1

[1] Footer on page 1 has been corrected to the current address

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1. Introduction to Chapter 3

This chapter provides guidance on the process governing the electronic submission of information on medicinal products for veterinary use authorised in the European Economic Area into the UPD as part of the initial submission and the maintenance of the data previously submitted.

2. Submission operations

NCAs should electronically submit into the UPD information on newly authorised veterinary medicinal products, information on changes to existing veterinary medicinal products following completion of a variation procedure or another regulatory procedure, as applicable. The electronic submission of veterinary medicinal product information by NCAs is possible via:

- an application programming interface (API), in line with the specifications described in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database; or
- the user interface (UI), which provides functionality to create, view, edit and delete medicinal product information in the UPD.

Marketing authorisation holders should electronically submit into the UPD a defined set of information amending existing veterinary medicinal product following a variation to the terms of marketing authorisations which does not require scientific assessment, or relating to other post-authorisation data, e.g. updates to the availability status of a product. The electronic submission of veterinary medicinal product information by marketing authorisation holders can be performed via the user interface (UI) which provides functionality to view, edit and delete medicinal product information stored in UPD.

2.1. Endpoints and operation type

Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database describes the technical specifications of the data management operations such as create, update and nullify (hereafter referred as to 'endpoints') as well as the supported FHIR message format. Specifically, the following operations are possible:

- **Create of new veterinary medicinal product** in UPD (*EP309 Create Product*). Specifically, this operation type must be used in the submission of required information on a new veterinary medicinal product for which a marketing authorisation has been granted by the relevant competent authority (i.e. initial submission of medicinal product).
- **Update of an existing veterinary medicinal product** (*EP311 Update Product*). Specifically, this operation type must be used in the following circumstances:
  - To supply additional information on a previously created veterinary medicinal product in the UPD (e.g. Concerned Member States to supply national information supplementing the MRP/DCP/RUP common product information previously created by the Reference Member State);
  - To amend information on an existing veterinary medicinal product, due to changes to the terms of the marketing authorisation as part of a regulatory procedure (e.g. variation requiring assessment);

- notify changes to information of an existing veterinary medicinal product, which is not triggered by a regulatory procedure;
- amend incorrectly submitted information (e.g. typographical errors, misspellings and information submitted by mistake) and
- enrich and complete data on authorised veterinary medicinal products previously submitted as part of the legacy data provision as described in Chapter 4 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database.

- **Nullification** of a medicinal product must be used to remove any erroneous veterinary medicinal product previously submitted in UPD (e.g. duplicate products or products provided erroneously).

In summary, the endpoints within the FHIR message allow the UPD transactional system to adequately process the information contained in the message:

- For endpoint EP309 Create Product, the UPD transactional system checks compliance with all applicable business rules and format specification for the creation of a new product in UPD as described in Chapter 2 and 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database; should all the specifications be met, the relevant product, permanent and package identifiers are assigned by the UPD;
- For endpoint EP311 Update Product, the UPD transactional system checks compliance with all applicable business rules and format specification for the updated informational submitted for the specified product ID (or permanent ID or PCID) in UPD as described in Chapter 2 and 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database; should all the specifications and business rules be met, the relevant information for the product, permanent and package identifiers is updated in the UPD.

3. Submission by National Competent Authorities

This section provides details on the processes for the Competent Authorities to submit, electronically, information on all veterinary medicinal products authorised within their territories, in the format referred to in Article 55(3)(a) by the date of application of Regulation (EU) 2019/6. This includes centrally authorised medicinal products where the European Medicines Agency will upload the data on behalf of the European Commission as the Competent Authority.

3.1. Initial submission of an authorised veterinary medicinal product

- **Process**: Once the marketing authorisation has been granted by the competent authority, the Member State shall submit electronically the veterinary medicinal product information into the UPD. Once the initial submission has been made, and as applicable, the relevant EU Member States and the concerned marketing authorisation holder will receive a notification[2] indicating that the new veterinary medicinal product is available in UPD.

[2] Details of the notification process are still under discussion and will be laid out in the next version of this document. The notification to Competent Authorities of the creation of a new product in the UPD depends on the type of procedure by which the product is authorised:
- for CAP all EU Member States are notified;
- for NAP only the National Competent Authority who has created the product is notified;
- for MRP/DCP/RUP detailed rules are under development

The Agency will establish the necessary mechanisms to make available all relevant UPD product, permanent and package IDs to enable and facilitate the electronic submission of information on authorised veterinary medicinal products into the UPD by all relevant stakeholders.

For the veterinary medicinal product authorised following a MRP, DCP or RUP, the Reference Member states shall submit electronically the veterinary medicinal product into the UPD providing the European ('common') data set and the national data set pertaining its own territory as defined in the Annex I of Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database. The product ID and the applicable package IDs (PCIDs) will be assigned by the UPD and will be notified to all relevant member states. Once the marketing authorisation has been granted by the relevant Concerned Member State(s), the additional national data set as outlined in Annex I of the Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database shall be submitted into the UPD by the NCA of the Concerned Member State.

- **Data standard requirements**: The veterinary medicinal product information shall meet the requirements described in Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database and follow the technical specification outlined in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database.

- **Operation**: Submission via the API shall be carried out as described in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database and section 2. of this document (Submission operations , whereby the endpoint for initial submission is *EP309 Create Product* which defines the payload as FHIR transaction bundle. The submission of a national data set for a veterinary medicinal product shall be carried out by means of the endpoint *EP311 Update Product* (e.g. for a veterinary medicinal product authorised via MRP/DCP/RUP, the Concerned Member State shall update the veterinary medicinal product initially created by the Reference Member State by submitting additional national product information to the applicable Product ID and by selecting the relevant PCIDs of the packages authorised in their territory).

3.2. Maintenance submission for an authorised veterinary medicinal product

This section describes the process required for the maintenance of veterinary medicinal product information contained in the UPD by NCAs. The scope of the maintenance submission is to:

- reflect any changes to the terms of the marketing authorisation following regulatory procedures such as variation and transfer (as well as renewal for products authorised before 28 January 2022), or surrender of the marketing authorisation which affect structured or non-structured product information contained in the UPD; this also applies to suspension or revocation of a marketing authorisation if the marketing authorisation holders fail to record the information within 30 days;

- correct any erroneously submitted information.

The maintenance submission shall be carried out as follows:

- **Process**: Any changes to the terms of the marketing authorisation affecting structured or non-structured information contained in the UPD shall be submitted via a FHIR compatible message within 30 calendar days from the date of which the amendments have been authorised by the Competent Authority or, for changes not requiring assessment, by when changes are implemented (e.g. following variation, transfer, renewal, suspension, revocation or surrender of the marketing authorisation, changes of QPPV). For MRP/DCP/RUP, the European data set that is in common for

the entire procedure (and referenced by the Concerned Member States in their national entitlement) shall be updated by the Reference Member State only.

- **Data standard requirements**: the information shall meet the requirements described in Chapter 2 and the technical specification outlined in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database.
- **Operation**: where applicable, the submission via the API shall be carried out as described in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database and section 2. of this guidance (Submission operations), whereby the endpoint for maintenance submission is *EP311 Update Product.*

3.2.1. Nullification of a veterinary medicinal product

National Competent Authorities should flag veterinary medicinal products created by mistake in the UPD as "**nullified**", e.g. duplicate products (the same medicinal product information was submitted multiple times) or products submitted erroneously (e.g. they were not supposed to be submitted).

Only the owner of the product data in the UPD (i.e. the Competent Authority that submitted in the veterinary medicinal product information into the UPD) can nullify such data.

4. Submission by Marketing Authorisation Holders

Article 58(6) and Article 58(12) of Regulation (EU) 2019/6 require the marketing authorisation holder to record in UPD the dates when its authorised veterinary medicinal products 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 the marketing authorisations concerned as well as the annual volume of sales for each of its veterinary medicinal products.

Article 61 of Regulation (EU) 2019/6 places a responsibility on marketing authorisation holders to record in the UPD any variation to the terms of the marketing authorisation of a veterinary medicinal product that do not require assessment within 30 days of making the change. Such variations should subsequently be approved or rejected in the UPD by the relevant competent authority.

- **Process**: Once the applicable regulatory procedure is completed, the marketing authorisation holder can submit the required data 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.
- **Data standard requirements**: the information shall meet the requirements described in Chapter 2 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database and the technical specification outlined in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database.
- **Operation**: where applicable, the submission shall be carried out as described in Chapter 5 of the EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database and section 2. of this guide (Submission operations , whereby the endpoint for this submission is *EP311 Update Product.*

NOTE: details on the formats for the submission of certain data by MAHs are still under discussion and will be included in the next version of the Veterinary EU IG as necessary.