1 16 July 2020
2 EMA/198149/2020
3 Veterinary Medicines

4 Union Product Database (UPD) Access Policy

5 Veterinary Medicinal Products

6	POLICY/no	0082
7	Status:	Consultation
8	Effective date:	tbc
9	Review date:	tbc
10	Supersedes:	n/a

11

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Executive Summary

The European Medicines Agency (hereafter referred to as “the Agency”) and the Member States’ competent authorities collectively comprise the European Union (EU) regulatory network. The network's responsibilities are the protection and promotion of public and animal health and the environment through the evaluation and supervision of medicines.

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (‘the VMP Regulation’), was adopted on 11 December 2018, entered into force on 28 January 2019 and will become applicable from 28 January 2022, following a 3-year implementation period. The VMP Regulation contains new measures for increasing the availability and safety of veterinary medicines, enhances EU action against antimicrobial resistance and will modernise the existing rules on the authorisation and use of veterinary medicines in the EU.

The VMP Regulation mandates that the Agency establish and, in collaboration with the Member States, maintain, a Union database on veterinary medicinal products (UPD), containing information on veterinary medicinal products authorised within the Union, homeopathic veterinary medicinal products registered within the Union, veterinary medicinal products exempted in a Member State from the marketing authorisation requirements, and parallel traded products. This database shall also register the annual volume of sales, information on the availability for each veterinary medicinal product and variations not requiring assessment for authorised veterinary medicinal products.

Furthermore, by means of implementing acts, the European Commission (‘the Commission’) will adopt the necessary measures and practical arrangements laying down detailed specifications to be implemented in order to fulfil the requirements of the VMP Regulation. In this context, it is mandated that a detailed access policy be drawn up and applied by the Agency, in collaboration with the competent authorities and the Commission, and in consultation with marketing authorisation holders, before the UPD becomes operational. It should enable actors to perform their obligations as provided for in the VMP Regulation, while protecting commercially confidential information and personal data. It should therefore provide different levels of access to the UPD processes.

1. Scope

This Access Policy defines the overall principles for providing access to veterinary medicinal product information held in the UPD in line with the EU legislative framework, considering that the interest in and the use of the data may vary between stakeholders.

The policy has been drafted with the aim of providing transparency and visibility of information on veterinary medicinal products while protecting commercially confidential information, as required in the VMP Regulation. Requirements to protect personal data based on Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 are reflected in the policy accordingly.

‘Veterinary medicinal products’ in this policy include

- authorised veterinary medicinal products;
- registered homeopathic veterinary medicinal products;
- veterinary medicinal products exempted in a Member State from the marketing authorisation requirements under Article 5(6); and
- parallel traded products

The VMP Regulation defines the level of UPD access as follows (Article 56):

1. *The competent authorities, the Agency and the Commission shall have full access to the information in the product database.*

2. *Marketing authorisation holders[1] shall have full access to the information in the product database as regards their marketing authorisations.*

3. *The general public shall have access to information in the product database, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, the assessment reports.*

The description of individual scenarios and veterinary medicinal products are further outlined in Annex A.

2. Policy statement

The following aspects are addressed in this policy:

- Objectives of the policy.
- Characteristics of the policy.
- Date of coming into effect of the policy.

3. Objectives

This access policy has been developed with the goal of facilitating the maintenance of and accessibility to information on veterinary medicinal products in the EU, within the overall aim of promoting and protecting animal and public health and the environment.

Furthermore, the access policy aims to meet the EU principles of transparency and openness and to ensure compliance with EU personal data protection legislation. The following objectives should be met, by providing proactive access to product information on veterinary medicinal products:

1. Increasing availability of and access to information on veterinary medicinal products authorised to treat and prevent animal diseases in the EU for veterinarians, farmers and pet owners and any other interested parties;
2. Supporting the functioning of the internal EU market for veterinary medicinal products;
3. Improving transparency of veterinary medicinal products used in the EU;
4. Strengthening the decision making for the Commission, competent authorities and marketing authorisation holders by providing access to data analytics and reports;
5. Simplifying the regulatory environment and reducing the administrative burden by giving marketing authorisation holders and competent authorities access to the functionalities of the variations without assessment module of the UPD.

4. Characteristics of the policy

4.1. Union Product Database

The UPD comprises a range of functions required for the administration and quality management of information related to veterinary medicinal products and its secure electronic transmission. Additionally, the UPD offers a specific mechanism for handling a change to the data that occurs when

[1] 'Marketing authorisation holder' is defined in this policy to include: holder of the marketing authorisation for a veterinary medicinal product, of the registration for a homeopathic veterinary medicinal product, of the exemption for products allowed for use in accordance with Article 5(6) of Regulation (EU) 2019/6 or of the approval for parallel trade

such changes are based on a variation that does not require assessment. A set of components has been designed, enhanced or reutilised to support such functionalities:

- **Access management component** which manages the control of access to data or functionalities and ensures that all stakeholders have the appropriate access to the resources provided by the UPD and the proper permissions to perform actions in the UPD.
- **Data and document submission component** which manages the requests for submission to the UPD of data and documents relating to new veterinary medicinal products in order to create a new dataset, variations and other post-authorisation changes to the datasets already existing in the UPD for veterinary medicinal products.
- **Application programming interface** for the exchange of data and documents with the systems used by marketing authorisation holders, competent authorities, the Agency and the Commission.
- **UPD portal** which, with the use of data publishing, data searching, viewing and exporting, as well as data analytics, presents information to users and makes certain features available to them in accordance with their access rights (objective 4).
- **Data and document repository component** which manages all data and documents that enter into the UPD.
- **Component to manage variations that do not require assessment component** which allows the marketing authorisation holder to submit a variation that does not require assessment and allows the relevant competent authority or the Commission, as applicable, to be notified and to approve or reject such variations prior to the update in the UPD, to update the dataset accordingly and to store and update related documentation (objective 5).
- **General public module** which is part of the UPD portal and allows the general public to search and view all publicly available data and documents on veterinary medicinal products referred to in Article 56 of the VMP Regulation (objectives 1, 2 and 3).

Different levels of access to these components must be defined and implemented to ensure that the different stakeholders interacting with the UPD can access the information necessary to fulfil their responsibilities as outlined in the VMP Regulation and related Implementing Acts or enjoy their right to access information.

4.2. Access to Union Product Database

4.2.1. Stakeholder groups

The stakeholders being granted access to UPD data can be grouped as follows:

- **The Commission, competent authorities and the Agency**;
- **Marketing authorisation holders**, including relevant external service providers;
- **General Public**: persons or organisations, other than the two groups referred to above.

4.2.2. General principles

Veterinary medicinal products are recorded in the UPD as derived from legal obligations placed on competent authorities and marketing authorisation holders.

The VMP Regulation gives the widest possible access to veterinary medicinal product data and to the related documents while protecting certain public and private interests, such as personal data and commercially confidential information in accordance with Regulation (EC) No 1049/2001.

The data elements for veterinary medicinal product data stored in the UPD are defined in the *Commission Implementing Regulation (EU) laying down the necessary measures and practical arrangements for the Union product database on veterinary medicinal products*[2] ('the Implementing Regulation') and further detailed in *Product Management Services – Implementation of Regulation 2019/6 standards for the identification of medicinal products in Europe* ('the EU Vet Implementation Guide').

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) 679/2016 or General Data Protection Regulation (GDPR)). The protection of personal data is a fundamental right of Europeans. The access is further defined at different levels considering that due to the nature of the information not all data elements can be disclosed to avoid identification of data subjects or dissemination of commercially confidential information.

Annex A lists all UPD veterinary medicinal product data elements and outlines which can be accessed by the different stakeholder groups, based on the access levels described in Table 1.

Table 1. Description of access levels

Access Level	Description
Level 1	Public subset of veterinary medicinal product data elements with focus on the General Public user group.
Level 2	Extended subset of veterinary medicinal product data elements with focus on the marketing authorisation holder user group to fulfil their legal responsibilities for their own products, which have been recorded in the database by the authorities.
Level 3	All veterinary medicinal product data elements without restrictions with focus on the competent authorities, the Commission and the Agency, taking into account their roles and responsibilities to protect public and animal health and the environment.

4.2.3. Personal Data Protection

The Agency, competent authorities and marketing authorisation holders are all responsible for ensuring confidentiality of veterinary medicinal product data and protecting personal data by implementing appropriate technical and organisational measures to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss in accordance with the applicable law on personal data protection.

Personal data shall mean any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; (Article 3(1) of Regulation (EU) 2018/1725).

[2] Number and date to be added following adoption of the Implementing Regulations

For the Agency, the provisions set out in Regulation (EU) 2018/1725 apply; for competent authorities and marketing authorisation holders, the rules set out in Regulation (EU) No 679/2016 (GDPR) apply.

4.2.4. Methods of providing access to veterinary medicinal product information held in UPD

Access to UPD data is provided through query and data retrieval functions based on the UPD system components described in section 4.1. Table 2 provides an overview of the UPD system components applied to provide access to UPD data for each stakeholder group and outlines the overall format of the data outputs.

Table 2. UPD system components with UPD product data outputs by stakeholder group

UPD System Component	Data Outputs
Stakeholder: the Commission, competent authorities and the Agency	
Data and document submission portal	Structured electronic content (XML and JSON formats) and unstructured content (e.g. PDF)
Application programming interface	Structured electronic content (XML and JSON formats) and unstructured content (e.g. PDF)
UPD portal	Web page(s) in HTML format; showing all product data and providing search functions
Stakeholder: marketing authorisation holders	
Data and document submission portal	Structured electronic content (XML and JSON formats) and unstructured content (e.g. PDF)
Application programming interface	Structured electronic content (XML and JSON formats) and unstructured content (e.g. PDF)
UPD portal	Web page(s) in HTML format; showing only data in accordance with their access rights and providing search functions
Stakeholder: General Public	
General Public Module	Web page(s) in HTML format; showing only the subset of data that is available to the public and providing search functions

4.2.5. Detailed description of access to veterinary medicinal product data held in UPD, by Stakeholder

4.2.5.1. The Commission, competent authorities and the Agency

4.2.5.1.1. Veterinary medicinal products in UPD

In accordance with the VMP Regulation, the competent authorities, the Agency and the Commission shall have full access to the information in the UPD.

Table 3. Access to UPD data by the competent authorities, the Agency and the Commission

Stakeholder	Access Level	Access Type
• Competent authorities • Agency • The Commission	• UPD Level 3: - All data elements for veterinary medicinal products reported to UPD (for details refer to Annex A)	Authorised personnel only

4.2.5.1.2. Methods of access

A description of how access is provided to these stakeholders including the main data outputs is given in Section 4.2.4

4.2.5.1.3. Access authorisation

Access is granted to authorised personnel of the Commission, the Agency and competent authorities. The identification of 'authorised personnel' is detailed in the **UPD registration process** described in the registration guide[3]. External service providers are also considered "authorised personnel" and their access rights are administrated by the relevant organisation on whose behalf access is granted.

4.2.5.1.4. Personal data protection requirements

Data access and provision is based on a defined veterinary medicinal product data set (Level 3) in compliance with the VMP Regulation. A Privacy Statement[4] is included on the UPD Portal, explaining in detail how personal data are processed. The Agency is also operating a procedure for access and rectification in line with the aforementioned Regulation.

4.2.5.2. Marketing authorisation holders

4.2.5.2.1. Veterinary medicinal products in the UPD

In accordance with the VMP Regulation, the marketing authorisation holders[5] shall have full access to the information in the UPD as regards their products.

Table 4. Access to UPD data by marketing authorisation holders

Stakeholder	Access Level	Access Type
• Marketing Authorisation Holders	• UPD Level 2: - Subset of data elements for veterinary medicinal products reported to UPD (for details refer to Annex A)	Authorised Personnel only

4.2.5.2.2. Methods of access

A description of how access is provided to these stakeholders including the main data outputs is given in Section 4.2.4

[3] The registration guide is being developed will be published before the launch of the UPD.
[4] The Privacy Statement will be published together with the Access Policy document
[5] Companies that are part of the same corporation or group of companies are considered as a single MAH.

4.2.5.2.3. Access authorisation

Access is granted to authorised personnel of the marketing authorisation holders. The identification of 'authorised personnel' is detailed in the UPD registration process described in the registration guide[3]. External service providers are also considered "authorised personnel" and their access rights are administrated by the relevant organisation on whose behalf access is granted.

4.2.5.2.4. Personal data protection requirements

Data access and provision is based on a defined veterinary medicinal product data set (Level 2) in compliance with the VMP Regulation. A Privacy Statement[6] is included on the UPD Portal, explaining in detail how personal data are processed. The Agency is also operating a procedure for access and rectification in line with the aforementioned Regulation.

4.2.5.3. General public

4.2.5.3.1. Report of veterinary medicinal product

In accordance with the VMP Regulation, the general public shall have access to information in the UPD, without the possibility to change the information therein, as regards the list of the veterinary medicinal products, the summary of product characteristics, package leaflets and, after the deletion of any commercially confidential information by the competent authority, assessment reports.

Table 5. Access to UPD data by general public

Stakeholder	Access Level	Access Type
• General public	• UPD Level 1: - Subset of data elements for veterinary medicinal products reported to UPD (for details refer to Annex A)	Not required/controlled

4.2.5.3.2. Methods of access

A description of how access is provided to these stakeholders including the main data outputs is given in Section 4.2.4

4.2.5.3.3. Access authorisation

No registration, authorisation or authentication shall be required for access to publicly available information.

4.2.5.3.4. Personal data protection requirements

Data access and provision is based on a defined veterinary medicinal product data set (Level 1) in compliance with the VMP Regulation. A Privacy Statement[7] is included on the UPD Portal, explaining in detail how personal data are processed. The Agency is also operating a procedure for access and rectification in line with the aforementioned Regulation.

[6] The Privacy Statement will be published together with the Access Policy document.
[7] The Privacy Statement will be published together with the Access Policy document.

5. Entry into force of the UPD access policy

This access policy will enter into force as soon as it is approved.

Amsterdam, <DD Month YYYY>

Guido Rasi

Executive Director

Annexes

Annex A – Product data elements accessible by stakeholder group

RCUD = Read, Create, Update, Delete

Y/N = yes, no

UPD fields[8]	Level 3												Level 2				Level 1			
	RCUD = Read, Create, Update, Delete																			
	Commission				Competent Authorities				Agency				Marketing authorisation holders				Public			
	R	C	U	D	R	C	U	D	R	C	U	D	R	C	U(1)	D	R	C	U	D
Product Domain	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Product Category	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Product Name	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Active Substance(s)	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Strength/Composition	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Manufacturing Sites	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y(2)	N	N	N
Operation type (for manufacturing site)	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y(2)	N	N	N
Dates of Placing on the Market	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	Y(6)	N	N	Y	N	N	N
Documents (SPC, PL, PuAR)[9]	Y	N	N	N	Y	Y(5)	Y(5)	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Product Owner	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Annual Volume of Sales	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y(6)	Y(6)	Y(6)	N	N	N	N	N
Date of Availability Status	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	Y(6)	Y(6)	N	Y	N	N	N

[8] The available information in the data fields depends on the authorisation procedure type of veterinary medicinal product (authorised, registered homeopathic, Art. 5(6) exemption or parallel traded product)

[9] The document types are: Summary of Product Characteristics, package leaflet and public assessment report

UPD fields[8]	Level 3												Level 2				Level 1			
	RCUD = Read, Create, Update, Delete																			
	Commission				Competent Authorities				Agency				Marketing authorisation holders				Public			
	R	C	U	D	R	C	U	D	R	C	U	D	R	C	U(1)	D	R	C	U	D
Availability Status	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	Y(6)	Y(6)	N	Y	N	N	N
Authorisation Status	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y(6)	N	Y(3)	N	N	N
Date of Authorisation Status Change	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	Y(6)	N	Y	N	N	N
Source Wholesale Distributor	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Destination Wholesale Distributor	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Permanent Identification Number	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y	N	N	N
Product Identification Number	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Route of Administration	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Pharmaceutical Form	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Target species	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
ATCvet Code	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Withdrawal Period	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
PSMF Number	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
PSMF Location	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
QPPV Name	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y(6)	N	N	N	N	N	N	N
QPPV Location	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y(6)	N	N	N	N	N	N	N
Package Description	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Legal Status for Supply	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Authorisation Procedure Type	Y	N	N	N	Y	Y	Y	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N

UPD fields[8]	Level 3												Level 2				Level 1			
	RCUD = Read, Create, Update, Delete																			
	Commission				Competent Authorities				Agency				Marketing authorisation holders				Public			
	R	C	U	D	R	C	U	D	R	C	U	D	R	C	U[(1)]	D	R	C	U	D
Procedure Number	Y	N	N	N	Y	Y	Y	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Marketing Authorisation Date	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Authorisation Country	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Reference Member State	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Member States Concerned	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Legal Basis	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y	N	N	N	Y	N	N	N
Authorisation Number	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Reference Product Identifier	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Source Product Identifier	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Responsible authority (Organisation)	Y	N	N	N	Y	Y	Y	N	Y	Y	Y	N	Y	N	N	N	Y	N	N	N
Procedural information for post-authorisation changes																				
Application Identifier	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	N	N	N	N	N	N	N
Procedure Number	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y[(6)]	Y[(6)]	N	N	N	N	N	N
Responsible Authority	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	Y[(6)]	N	N	N	N	N	N
Variation Classification Code	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	Y[(6)]	N	N	N	N	N	N
Submission Comment	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	Y[(6)]	N	N	N	N	N	N
Date of Submission	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	N	N	N	N	N	N	N
Decision	Y	N	N	N	Y	Y	N	N	Y	Y	N	N	Y[(6)]	N	N	N	N	N	N	N
Date of Decision	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	N	N	N	N	N	N	N

UPD fields[8]	Level 3												Level 2				Level 1			
	RCUD = Read, Create, Update, Delete																			
	Commission				Competent Authorities				Agency				Marketing authorisation holders				Public			
	R	C	U	D	R	C	U	D	R	C	U	D	R	C	U[(1)]	D	R	C	U	D
Author of Decision	Y	N	N	N	Y	N	N	N	Y	N	N	N	Y[(6)]	N	N	N	N	N	N	N
Nullification comment	N	N	N	N	N	Y	N	N	Y[(4)]	Y	N	N	N	N	N	N	N	N	N	N

260 [(1)] Marketing authorisation holders can request the update of some of these fields, by the relevant Competent Authorities, via a variation that does not require assessment; this
261 footnote reference will be added to all relevant fields once the Implementing Regulation on variations not requiring assessment has been adopted
262 [(2)] Only visible for batch release manufacturing sites
263 [(3)] Only veterinary medicinal products that have been authorised will be shown
264 [(4)] EMA Data Stewards can read this information
265 [(5)] For mutual recognition (MRP), decentralised (DCP) and repeat use procedures (RUP), the reference member state (RMS) is responsible for creating or updating the English
266 version of the documents
267 [(6)] Only visible to the marketing authorisation holder that owns that veterinary medicinal product