

Veterinary Medicinal Products Regulation HIGHLIGHTS

News, views and interviews for the Veterinary Medicinal Products Regulation.
Published quarterly by the European Medicines Agency

An agency of the European Union



Editorial



Ivo Claassen

Head of Veterinary
Medicines Division, EMA

I am proud to announce: we are live!

On 28 January 2022, the Veterinary Medicinal Products Regulation became **applicable**. On the same date, we celebrated the go live of three systems which will support the simplification of many regulatory procedures: the Union Product Database, the Union Pharmacovigilance Database, and the Manufacturing and Wholesale Distribution Database.

The **successful go live** of the systems above was underpinned by the release of nine IT systems at EMA in total. It has been a challenge, and I hope all the programme stakeholders share our pride in achieving this milestone. This success was only possible because of the consistent collaboration with and support by the regulatory network, the European Commission and our stakeholders in industry and the veterinary healthcare professionals.

The **[Veterinary Medicines information website](#)** is live and enables anyone to search for information on all veterinary medicines authorised in the EU/EEA.

Thanks to the immense effort and collaboration between national competent authorities and EMA, most of the product data has been uploaded into the Union Product Database.

During the next weeks, national competent authorities and EMA are **completing and enriching their submissions**, which will allow marketing authorisation holders to timely perform regulatory procedures such as the submission of variations not requiring assessment.

Marketing authorisation holders have now **full access** to the Union Product Database and Union Pharmacovigilance Database. In order to support all users of the new systems, EMA established a dedicated **[VMP-Reg user support service](#)**.

After a press and social media launch on 28 January to mark the occasion, we continue to further develop and improve the IT systems to increase robustness and enhance user experience.



INSIDE THIS ISSUE	
Editorial	1
Collection of Antimicrobials Sales and Use data	2
Union Database on Manufacturers and Wholesale Distributors	3
Union Product Database	4
Union Pharmacovigilance Database	5
Change management	6
VICH format messages / List of acronyms	7

Collection of Antimicrobials Sales and Use data

IT development on the Collection of Antimicrobials Sales and Use Data (ASU) project started in January 2022.

On 13 December, EMA and the ASU Project Group introduced the project to the members of the European Surveillance of Veterinary Antimicrobial Consumption (**ESVAC**) network, which includes representatives from the national competent authorities (NCAs). This was the first of the awareness raising meetings aimed at preparing NCAs for the implementation. The ESVAC Network will be the **Change Liaison Network** for the project, ensuring two-ways communication with the competent authorities involved.

In 2023, the relevant national competent authorities will have to start collecting the **relevant data** on antimicrobial sales and use for the first applicable species groups. In 2024, this data will subsequently be submitted into the system developed by the ASU project.

The **delegated act on the requirements for antimicrobial sales and use data collection** was published in 2021. The **implementing act on the format of data submission** is expected to be adopted shortly.

The **ASU Minimum Viable Product (MVP)** will be delivered in Q4 2022 and will include the submission functionalities for sales and use data, and selected analysis functionalities for use data. A subsequent release including additional reports will be made available in Q2 2023.

EMA will publish an **implementation guide** including information on the format and exchange mechanisms in Q2 2022. The Agency will also provide user guidance and training materials in Q4 2022.



Have your say

The Agency also works on other aspects ensuring **prudent and responsible use of antimicrobials** in animals and implementing the requirements of Regulation (EU) 2019/6, for example by providing guidance on prophylactic use of antimicrobials.

Promoting the responsible use of antimicrobials in animals is one of the main aims of Regulation (EU) 2019/6. Amongst the measures introduced are restrictions on the use of antimicrobial medicinal products for prophylaxis, so that they may only be used in exceptional cases, in an individual or a restricted number of animals, when the risk of infection is very high and the consequences are likely to be severe (Article 107(3)). For antibiotics specifically, prophylaxis is limited to administration to an individual animal only.

EMA published the draft **Reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6** for **public consultation**.

The purpose of this reflection paper is to establish an **understanding of the term 'prophylaxis'** as defined in Article 4(16) of the Regulation and to develop high level principles to guide the implementation of the restrictions on prophylactic use as required by the provisions of Article 107(3). Comments should be provided **by 29 April 2022** using [this template](#).

The completed comments form should be sent to vet-guidelines@ema.europa.eu.

Manufacturers and Wholesale Distributors database

The **Manufacturers and Wholesale Distributors database (MWD)** was released on 28 January 2022. The system is an enhanced and upgraded version of EudraGMDP, the EU database of manufacturing authorisations and certificates of good manufacturing practice, with changes affecting both the veterinary and the human domains.

The MWD Project Group has also adopted **requirements for aligning the GDP** module with the change made to the system so far. Changes to the module will be delivered in a subsequent release scheduled for Q1 2022. In addition, enhanced search facilities on the GMP module will be delivered in the same release.

EMA has progressed in the cleansing of EudraGMDP organisation data, as part of the integration of the system with the Agency's **Organisation Management Service (OMS)**, with the work scheduled to be completed by the end of February. The **integration with OMS** is the most notable change for NCAs and industry users.

From 28 January 2022 onwards, users of EudraGMDP from national competent authorities will no longer introduce organisational data directly in the

EudraGMDP system. Instead, they will choose the location of the manufacturers, importers or distributors (including sites or legal addresses) from the Agency's organisation dictionary. This change will ensure more reliable data in the EudraGMDP system through the consistent use of organisation master data, reduce the need for data entry and cleansing, and enhance interoperability across other EU IT systems and projects, e.g. the Union Product Database and the **Clinical Trials Information System**.

It is therefore necessary that all organisations currently mentioned in EudraGMDP – including EU and non-EU manufacturers, importers and distributors of human and veterinary medicinal products and active substances – are **registered in OMS**.

A **refresher webinar for NCAs** to support their preparedness with regard to the changes in the system was organised on 20 January, following the one held on 11 October 2021. Industry users can refer to the materials shared during the webinar held on 12 October 2021. The recordings, presentations, and Q&As for industry users are available on the [event webpage](#).

User-friendly platforms for vet companies

Animal health companies, do you know there are new online platforms that will help you manage some procedures in an easier way?

Union Product Database

After three years of hard work, the go live version of the Union Product Database (UPD) was released on 25 January 2022. While previous versions of the UPD were only accessible to NCAs and EMA for the upload of legacy product data, this version is also accessible to marketing authorisation holders (MAHs). MAHs can now submit additional data on their veterinary medicinal products, including the **annual volume of sales and the availability status**. The UPD also provides self-service access for specific regulatory activities, including the management of variations not requiring assessment, and amending the marketing authorisation status in case of a suspension or revocation.

As of 28 January 2022, industry **Super Users** who had requested access can access the database and approve roles of other users for their organisation(s), once they have requested access. The release notes available [here](#) provide detailed guidance.

A huge increase in the upload of **product data** into the Union Product Database has been observed in the past months. As of today, CAPs, almost all NAPs, and common datasets of almost all MRP/DCP have been submitted. Furthermore, 34% of national datasets for MRP/DCP products have been uploaded.

EU/EEA national competent authorities are currently **completing and enriching product data** submission. Marketing authorisation holders are kindly asked to allow time until **14 February** for NCAs to

complete data submission before liaising with the [contact point of the respective NCA](#) to add any missing products which are urgently needed, for example for the submission of a variation not requiring assessment.

EMA's support to NCAs will continue, and help is also accessible to industry users. All users of the system who need technical support can contact EMA's [VMP-Regulation User Support Service](#) and select the 'Union Product Database' tab on the left of the page.

Work to improve the system functionalities during 2022 has begun.

The first version of the [Veterinary Medicines information website](#) was also released. The multilingual website is the public interface of the Union Product Database and it enables everyone with an interest in veterinary medicines to:

- search and view information on all authorised veterinary medicines in the EU / EEA, irrespective of the authorisation route;
- find out in which Member State a specific veterinary medicine is available;
- find information which could help identify potential treatment alternatives.

The **website functionalities will be further improved** in the upcoming months, also considering users' feedback.

Status update of product data submission into the Union Product Database on 2 February 2022

	Products in UPD (Permanent IDs)	National dataset in UPD
Decentralised Procedure	35881	5780
Mutual Recognition Procedure	1440	1425
National Procedure	7529	7521
Centralised Procedure	593	593
Subsequent Recognition Procedure	2	2
Total	45445	15321

Please note: In 2020, NCAs estimated approximately 44.000 products to be uploaded.

Union Pharmacovigilance Database

On 28 January, the Union Pharmacovigilance Database (EVV) was successfully released. **User guidance** and the release notes are available [here](#).

Registered users from national competent authorities and marketing authorisation holders can log into the following environments:

- **EVWeb**: allows the sending and receiving of safety and acknowledgement messages via the web user interface.
- **Data Warehouse** (EVVet DWH): query tool to access EVVet data in the Data Warehouse (signal detection and data analysis).
- **EVWeb test environment**: allows the sending and receiving of safety and acknowledgement messages in the test environment.
- **IRIS**: for signal management and inspections outcomes.

In the first week, **over 500 suspected adverse events reports have already been received** and the number of users is steadily increasing.

Training activities for NCA and industry users intensified in December and January (please see change management on page 6 for additional information).

All users of the system who need **technical support** can contact EMA [VMP-Regulation User Support Service](#) and select the 'Union Pharmacovigilance Database' tab on the left of the page.

The availability of accurate product data in UPD is key to enable effective signal detection and management via EVV. Marketing authorisation holders will be able to see the full cases, including the narrative information as per the level 2 of the access policy for the products that have been uploaded into the UPD. For other products, industry users will have level 1 access (without case narratives).

While information is not complete in UPD level 2 access may not be available for some reports, this situation can take up to 2-3 months from the date that all product information is available in UPD to be completely resolved.

VICH format messages in EVV: action needed for NCAs and MAHs

The submission of adverse event reports in the current standard (DEG) will be possible during a transition period. However, messages submitted by other stakeholders in VICH format will not be available for download in the current DEG format.

From 28 January 2022 onwards, the following **new business rules** are being applied to **DEG format messages** to ensure their compatibility with the conversion to VICH format:

- Species (DEG R.17.02 (species name)): Must exist in the DEG species list
- Breeds (DEG R.17.03.02 (breed name)): Must exist in the DEG breeds list
- AER ID (DEG R.05 (case number)): Must comply with VICH format (e.g. PRT-PRTDGVFV-...).

Change management

During the two months before the go-live of the three systems, the programme change management workstream focused on supporting NCAs in timely submission of legacy data into the Union Product Database, and on preparing future users of the systems going live in January 2022 through training and assistance.

The **weekly support sessions** to NCA users submitting product data via UPD API or user interface continue, together with the one-to-one coaching sessions for submission via user interface, and one-to-one sessions to facilitate bulk upload via the API. EMA's SPOR team completed the mapping of substances needed by NCAs for their data submission.

Six training sessions for NCAs and stakeholders were organised in December and January. The training sessions dedicated to industry users registered several hundred participants each. The questions raised during the events and the respective answers are made available in the events webpage.

Q&As for industry on the UPD were updated.

In 2022, the **programme newsletter** will be issued quarterly.

The Agency set up dedicated channels to ensure timely support for all users after 28 January 2022 (see page 7).

Upcoming activities:

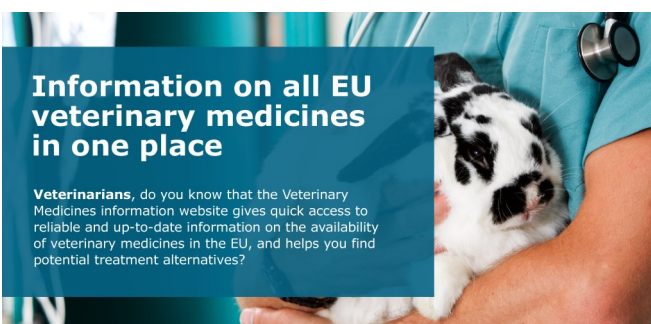
- **7 February:** 2nd ESVAC-Change Liaison Network meeting for ASU
- **Date to be announced:** EMA/FVE webinar for veterinarians on Union Product Database
- **Date to be announced:** EMA/FVE webinar for veterinarians on Union Pharmacovigilance Database

Recent activities:

- **8 December 2021:** Webinar for NCAs and MAHS on [pharmacovigilance \(PhV\) inspections](#) and systems, their quality management systems and PhV system master files: Introduction and principles**
- **13 December 2021:** First awareness-raising webinar with ESVAC network on the ASU programme
- **18 January 2022:** EVV – Follow up webinar for NCAs and MAHS on [collection and recording of suspected adverse events](#) for veterinary medicinal products**
- **19 January 2022:** EVV – Follow up webinar for NCAs and MAHS on [signal detection](#), evaluation and yearly reporting**
- **20 January 2022:** MWD – Refresher training for NCAs on EudraGMDP integration with OMS*
- **21 January 2022:** UPD – Webinar for NCAs on variations not requiring assessment (VNRAs)*
- **25 January 2022:** UPD: follow up [webinar](#) for marketing authorisation holders**

* Recording and materials available/shortly to NCA staff on the EU NTC.

**Event materials and recording available/shortly available on the event webpage.



Information on all EU veterinary medicines in one place

Veterinarians, do you know that the Veterinary Medicines information website gives quick access to reliable and up-to-date information on the availability of veterinary medicines in the EU, and helps you find potential treatment alternatives?

Dedicated helpdesk

For questions on:	Please contact:
Technical matters related to UPD, EudraVigilance Veterinary and EudraGMDP (VMP-Reg functionalities)	VMP Regulation support service
Other EMA IT system	EMA service desk
Regulatory matters relating to the Regulation	AskEMA
Other queries regarding implementation on the Regulation	vetchange.programme@ema.europa.eu

List of acronyms

- API:** Application Programming Interface
- ASU:** Collection of Antimicrobial Sales and Use data
- DCP:** Decentralised procedure
- DEG:** Data Elements Guideline standard (current AER message format)
- EMA:** European Medicines Agency
- ESVAC:** European Surveillance of Veterinary Antimicrobial Consumption
- EVV:** Union Pharmacovigilance Database
- HMA TF CIVR:** Heads of Medicines Agencies Task Force on the Coordination of the Implementation of the Veterinary Regulation
- MAH:** Marketing authorisation holder
- MRP:** Mutual recognition procedure
- MS:** Member State of the European Union
- MWD:** Manufacturers and Wholesale Distributors database
- NCA:** National competent authority
- OMS:** Organisation Management Service
- UAT:** user acceptance testing
- UPD:** Union Product Database
- VICH format message:** future AER message format, as of 28 January 2022
- VMP-Reg:** Veterinary Medicinal Products Regulation

Read the [previous issues](#) of the newsletter

Information on all EU veterinary medicines in one place

Pet owners, you care about your pet's health. Do you want to know more about the medicines your vet might prescribe? Check out the Veterinary Medicines information website where you have data on all authorised animal medicines in the EU.



#VeterinaryMedicines

European Medicines Agency

Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

Send a question via email: vetchange.programme@ema.europa.eu

An agency of the European Union

