Veterinary Medicinal Products Regulation
HIGHLIGHTS

News, views and interviews for the Veterinary Medicinal Products Regulation.
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Editorial

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Welcome to the tenth edition of the newsletter for the Implementation of the Veterinary Medicinal Products Regulation (VMP-Reg) programme.

The Union Product Database (UPD), Union Pharmacovigilance Database (EVV), and Manufacturing and the Wholesale Distribution Database (MWD) are in advanced support phase and we allocated three dedicated teams to respond to queries submitted by the users.

System upgrades are released every month to improve performance, guarantee robustness and deliver new and updated functionalities in alignment with agreed priorities.

The Veterinary Medicines Information website, a centralised public platform with broad information on all EU veterinary medicines, is now available in **all EU/EAA languages**. UPD data enrichment by national competent authorities and monthly website upgrades will continue to improve user experience.

Our dialogue with relevant stakeholders continues. In addition to regular meetings with specific stakeholder groups, the Agency held the Veterinary Medicines Info Day on 12-13 May 2022. More than 800 participants joined online to receive updates on topics related to the implementation of EU 2019/6, regulatory policy, pharmacovigilance and GMP revision.

Activities on the Collection of Antimicrobials Sales and Use Data project are progressing. The group is currently drafting the protocol on the format and exchange mechanisms for NCAs, which is to be published for consultation early Q3 2022.

What are the next steps?

Currently, the prioritisation of development activities for all systems is continuing under the existing VMP-Reg governance. From **September 2022 onwards**, the prioritisation process will be supported by a new **Veterinary System Improvement Advisory Group** (VSIAG).

VSIAG includes representatives from national competent authorities, industry, the European Commission and veterinary healthcare professionals, as well as from EMA.

Four times a year, the group will meet to discuss and prioritise new functionalities and improvements for the UPD and EVV systems, analyse the progress of the related initiatives, give strategic advice and recommendations to the EMA IT governance structure, to ensure the delivery of functional IT systems.

Collection of Antimicrobials Sales and Use data

The IT development on the **Collection of Antimicrobials Sales and Use Data (ASU)** started during Q1 2022.

The high-level architecture of the database system has been defined and the first functionalities have been developed. The ASU Project Group agreed to also act as the **ASU Product Owners group** and is working with the IT team to further define detailed business requirements and test and approve designed functionality. The plan is to deliver all required functionalities enabling NCAs to submit their data by end of 2022, so that NCAs know clearly what has to be submitted and how, thus enabling them to prepare their systems in time for the submission of the 2023 data in 2024.

EMA is drafting a **protocol** containing information on the format and exchange mechanisms, which is expected to be published for consultation in Q3 2022. The Agency will also provide **user guidance and training** in Q4 2022 to facilitate NCA readiness for the submission of antimicrobial sales and use data into the system developed by the ASU project.

Change Liaison (CL) network meetings for ASU are held on a bi-monthly basis, serving as a platform for change liaisons to **report on and discuss change management activities** in NCAs and member states.
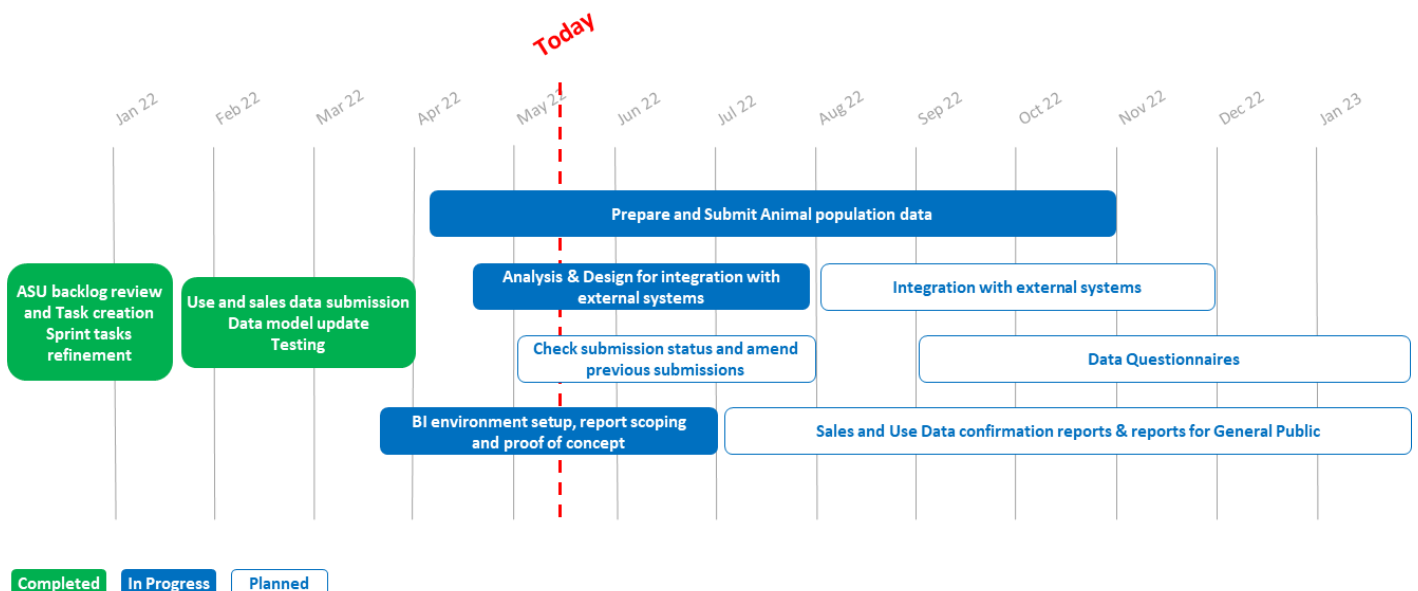
During the last CL meeting held in early April, results from the survey on the implementation status of systems for the collection of data on the use of antimicrobials in animals were presented, updating the network on the progress at national level. As a result of questions raised, EMA is developing a **ASU Q&A document** which will be updated and made available to the network regularly.

The **implementing act establishing the format of the data to be collected and reported in order to determine the volume of sales and the use of antimicrobial medicinal products in animals** was published in February 2022. This specifies:

- the format of data on sales of veterinary antimicrobial medicinal products and on use of veterinary and human antimicrobial medicinal products by animal species;
- the format of additional information of importance for data validation; and
- the format of animal population data

A stakeholders' info session on the antimicrobial **use data** collection will be held on 8 June 2022. The event is targeted at **national authorities and governance bodies** that will collect and submit the use data on antimicrobials in the future, and aims to showcase approaches in different member states to provide inspiration for those that have not fully analysed and designed their national collection systems yet. Examples how national systems are planned and implemented will be presented, including an approach that could utilise product data from the Union Product Database within national systems.

Jan 22	Feb 22	Mar 22	Apr 22	May 22	Jun 22	Jul 22	Aug 22	Sep 22	Oct 22	Nov 22	Dec 22	Jan 23	

Today

Prepare and Submit Animal population data

ASU backlog review and Task creation Sprint tasks refinement

Use and sales data submission Data model update Testing

Analysis & Design for integration with external systems

Integration with external systems

Check submission status and amend previous submissions

Data Questionnaires

BI environment setup, report scoping and proof of concept

Sales and Use Data confirmation reports & reports for General Public

Completed · In Progress · Planned

Manufacturers and Wholesale Distributors database

Since 28 January 2022, users of the **Manufacturers and Wholesale Distributors database (MWD)** from national competent authorities select the location of the manufacturers, importers or distributors from the Agency's Organisation Management Service (OMS) dictionary. The cleansing of existing EudraGMDP organisation data into OMS format was completed in February.

Throughout Q1 2022, the team focused on ensuring robustness of the changed system and addressing identified post go live issues. Further **improvements and additional functionalities were delivered**, e.g. a search field allowing to filter for additional information added in "restrictions" (GMP module) and improved synchronisation of EudraGMDP with OMS.

A **dedicated user support team is available** to help resolve queries, *e. g.* related to legal bases, assistance with the use of new functionalities, data discrepancies resulting from the integration of the system in OMS and data changes requests.

In Q2 and Q3 2022, the team continues to focus on bug fixing and the delivering the remaining agreed updated functionalities, including **extension of the scope to veterinary medicines in the Good Distribution Practices** (GDP) module (voluntary use), allow indication of organisations' alternatives names and addition of further details linked to the unit inspected.

EMA organised **webinars to support the preparedness** for both NCAs (available in EU NTC) and industry and made available recordings, presentations, and Q&As (for industry users).

More recently, two relevant webinars took place in March: recordings of the webinar for industry users on **introduction to Organisation Management Service (OMS) and Referentials Management Service (RMS) services and activities** and the webinar on **requesting access to and using EMA's substance, product, organisation and referential (SPOR) application programming interface (API)** will be available in the respective event pages.

European Veterinary Big Data strategy 2021 - 2027

Regulation (EU) 2019/6 on Veterinary Medicinal Products presented an opportunity to shape a strategic vision towards the **implementation of new digital technologies and to pioneer the digital transformation** at the Agency and across the Regulatory Network.

On 4-6 May 2022, the European Veterinary Big Data strategy for 2021-2027 was adopted at the 108th meeting of Heads of Agency (HMA).

The strategy focuses on increasing interoperability across regulatory systems that shall be using an optimized set of scientific resources, to reduce administrative and economic burden and enhance consistency, transparency and responsiveness within the regulatory network.

The HMA/EMA Veterinary Big Data work plan will reflect the short-phase tasks initiatives which will build upon a solution in principle on the context of VMP-Regulation implementation.

Union Product Database

The **Union Product Database** (UPD), the first centralised database of all veterinary medicines authorised in the EU/EEA, went live on 28 January 2022, together with its multilingual **public interface** (www.medicinesinfo.eu) containing information on all authorised veterinary medicinal products in the EU and EEA.

The months since the launch were dedicated to ensuring stability and robustness of the system and fixing known defects, as well as adding further functionalities. A dedicated **user support service** is available, where currently 90% of the issues reported by users resolved within a week.

Functionalities for the submission of VNRAs, **volume of sales** and **homeopathic medicines** are now available.

EU/EEA national competent authorities continue to complete and enrich product data submission and the majority of products have now been uploaded and can be used by Marketing Authorisation Holders (MAHs) for system-relevant post-authorisation activities. MAHs should contact the relevant NCA via the **list of procedural contact points** in case of products still missing in UPD, or when they identify data quality issues.

The fixing of known defects and new functionalities such as the addition of parallel traded products, and automation of data changes arising from VNRAs will continue in Q2 and Q3 2022.

Scheduled downtimes to deploy new and improved versions of UPD system will be **communicated to users via email** who are advised to refrain from using the system during these periods. After each deployment, release notes available here provide detailed guidance on the changes in comparison to the previous version, and any known issues that remain.

Also in Q2 2022, the project will start focusing on **improving data quality**. This aims to identify inconsistencies across the UPD dataset as well as within individual veterinary medicinal product records, and to compare the data provided with the guidance and specifications outlined in the Vet EU Implementation Guide. Support will be provided to NCAs, where needed, to improve data quality, focusing on key areas such as product names, strength, withdrawal periods and package information.

EMA's support to NCAs is continuing and user interface coaching sessions are still available. The Q&A for industry users will be updated by the end of May and **new bite-sized videos tutorials** of different system functionalities are available for both NCAs and marketing authorisation holders.

Work to improve the Veterinary Medicines Information website is ongoing, with a new release every month. This included making the public portal available in **all EU/EAA languages**, enable **searching by ATCvet code**, and the **display of withdrawal periods is now linked to the relevant species**.

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?

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Union Pharmacovigilance Database

Union Pharmacovigilance Database (EVV) registered users from national competent authorities and marketing authorisation holders can, since 28 January 2022, log into four different work environments:

- EVWeb: Users can record suspected adverse event reports (AERs). The web user interface allows the sending and receiving of safety and acknowledgement messages.

- Data Warehouse (EVVet DWH): query tool to access EVVet data in the Data Warehouse for signal detection and data analysis.

- IRIS: for signal management and inspections outcomes.

- EVWeb test environment: allows the sending and receiving of safety and acknowledgement messages in the test environment.

Since the go live, reports show that on average approximately 500 AERs are received daily. The dedicated support service is available to assist EVV users; by the end of April, 95% of the circa 350 tickets received were resolved.

In Q1 2022, the team **improved system performance** and performed analysis for functionality to save and resume draft AERs, improvements of the search function, bulk export and duplicate management. The prioritisation of the backlog and **new functionalities are agreed quarterly.**

The availability of accurate product data in UPD remains key to enable effective signal detection and management via EVV. The **recoding of AER reports** is continuing.

The **recommended due dates for centrally authorised products (CAPs)** for the submission of annual statements for the period of July-December 2022 are now available, together with the veterinary signal assessment report template. The recommended due dates non-CAPs will be published after July 2022.

The transition period where the submission of adverse event reports in the current standard (DEG) and VICH format was scheduled to end in July 2022. By then, national competent authorities (NCAs) and marketing authorisation holders (MAHs) need to **ensure their systems are ready to send, receive and process VICH format messages**. The Agency has assessed the current situation in terms of compliance with the VICH standard and will extend the transition period to Q4 2022. More guidance can be found here.

Recordings of webinars for NCAs and MAHs on adverse event collection and recording, signal management and pharmacovigilance inspections are available in the EVV webpage.

User guidance for EVWeb and EVVet DWH is available for MAHs and NCAs in EudraVigilance Veterinary 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?

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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.

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Change management

The months after the go live of the three systems, the programme change management workstream focused on **supporting NCAs** on the completion and enrichment of product data submission into the UPD.

EMA continues to provide **weekly support sessions** to NCA users. These sessions focus on the discussion of recurring issues and practical examples in submitting product data via UPD API or user interface. In addition, one-to-one coaching sessions are available for submission via user interface or to facilitate bulk upload via the API .

The training sessions dedicated to industry, NCAs' users and veterinarians held during the months before the go live, registered a total of around eight thousand participants (*see pie chart below*). This is testament to the high interest of impacted stakeholders in learning more about the IT systems that went live with the Regulation in January 2022.

After each webinar, post-webinar surveys were circulated to participants asking for feedback. This served as a communication channel with users of the IT systems, collecting participant views and identifying specific and individual needs, in order to improve participants' experience in future events.

Training activities will continue during 2022 as the IT systems are being enhanced and new fundamental functionalities are being deployed in the production environments.
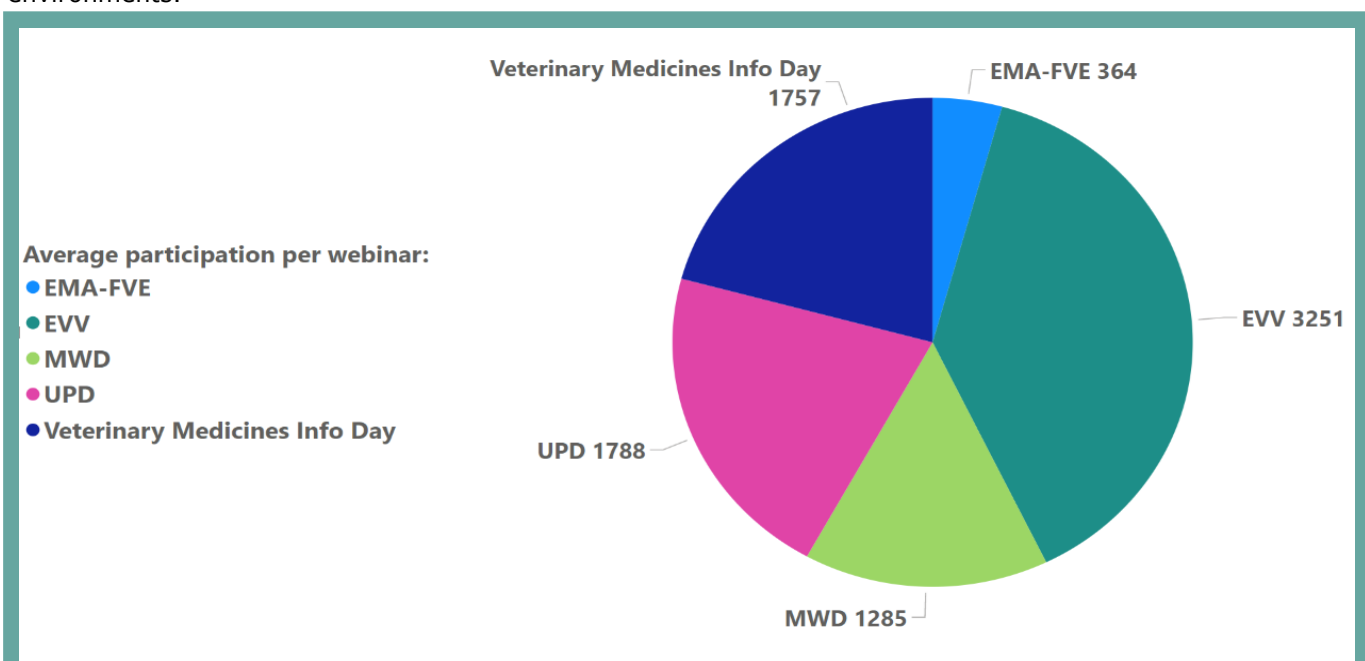
Upcoming activities:

- **7 June:** 4th ESVAC-Change Liaison Network meeting for ASU

- **8 June:** Antimicrobial use data collection stakeholders' info session for NCAs

- **5 July:** VMP-Reg Stakeholders Group meeting

Recent activities:

- **10 March:** webinar for industry on introduction to OMS and RMS services and activities**

- **18 March:** webinar on requesting access to and using EMA SPOR application programming interface**

- **5 April:** VSIAG kick-off meeting

- **5 April:** 3rd ESVAC-Change Liaison Network meeting for ASU

- **6 April:** EMA-HMA Vet Big Data Strategy workshop*

- **12-13 May:** EMA Veterinary Info Day 2022**

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

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

Veterinary Medicines Info Day 1757 | EMA-FVE 364 | EVV 3251 | UPD 1788 | MWD 1285

Average participation per webinar:
- EMA-FVE
- EVV
- MWD
- UPD
- Veterinary Medicines Info Day

Dedicated helpdesk

For questions on:	Please contact:
Technical matters related to UPD	UPD VMP-Regulation user support service
Technical matters related to EudraVigilance Veterinary	EVV VMP-Regulation user support service
Technical matters related to EudraGMDP (VMP-Reg functionalities only)	EudraGMDP user support service
Technical matters related to other EMA IT systems	EMA service desk
Regulatory matters relating to the Regulation (EU) 2019/6	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
EudraGMDP: Database on manufacturing, import and wholesale-distribution authorisations, and good manufacturing-practice and good-distribution-practice certificates
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
RMS: Referentials Management Service
SPOR: Substance, product, organisation and referential data
UAT: user acceptance testing
UPD: Union Product Database
VICH format message: future AER message format, as of 28 January 2022
VSIAG: Veterinary IT systems improvements advisory group

Read the previous issues of the VMP-Reg newsletter

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