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Veterinary Medicinal Products Regulation

HIGHLIGHTS

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

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INSIDE THIS ISSUE

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

The Union Pharmacovigilance Database (EVV), Union Product Database (UPD) and Collection of Antimicrobials Sales and Use Data (ASU) projects will soon cease their activities and be transitioned into a new agile governance, supported by the Veterinary systems improvement advisory group (VSIAG). VSIAG is composed of representatives from national competent authorities (NCAs), industry, veterinary healthcare professionals who will provide recommendations on the prioritisation of new or improved functionalities in the **UPD** and **EVV systems**.

The Manufacturers and Wholesale Distributors database (MWD) project is approaching its formal closure. Activities of the ASU project are advancing as planned.

The Agency continues supporting all stakeholders by providing refresher webinars for NCAs and marketing authorisation holders for the UPD and EVV systems, and holding dedicated ASU **change management sessions** for NCAs.

We also continue to look towards the future. With an increased amount of data gathered by the new digital systems put in place by the VMP-Reg and to discuss actions to be taken in the implementation of the **European Veterinary Big Data strategy**, EMA will host the 2nd Veterinary Big Data Stakeholder Forum on 23 November 2022. The discussion will focus on veterinary regulatory use cases that could benefit from the application of new digital technologies in the areas of **Veterinary medicinal product information**, **Pharmacovigilance** and **Antimicrobial resistance**.

I am looking forward to continuing the collaboration with all our stakeholders also on these topics.

Collection of Antimicrobials Sales and Use data

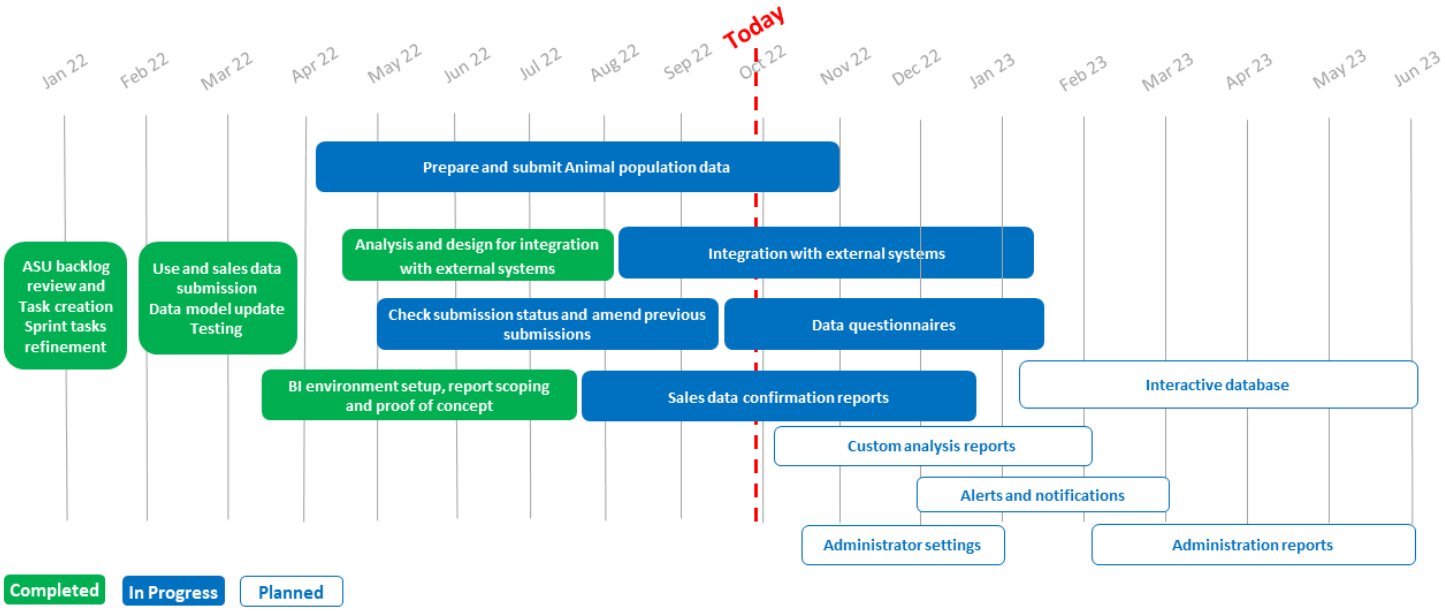
The **Collection of Antimicrobials Sales and Use Data (ASU)** IT project is progressing to plan.

The development team continues to deliver the data submission functionalities, including integration with external systems such as Eurostat, SPOR RMS and the UPD. This work is expected to be complete in early Q4 2022. Until the end of 2022 and in line with the project plan (see picture insert below), functionalities related to the submission of antimicrobials sales and use data and an initial set of reports supporting subsequent data analysis will be delivered.

In 2023, the responsible national competent authorities will start collecting **data** on antimicrobial sales and use for the species required in the first stage of the stepwise approach defined in legislation, ie. cattle, pigs, chickens and turkeys. This data is first expected to be submitted into the ASU system in 2024.

In order to ensure and facilitate Member State readiness for the submission of antimicrobial sales and use data into the system developed by the ASU project, the Agency has initiated activities within the Change Management workstream.

In collaboration representatives from the national competent authorities, the EMA is holding **dedicated change management meetings** to raise awareness. Training sessions will be provided from Q4 2022 onwards, with the first session scheduled for mid-October 2022.



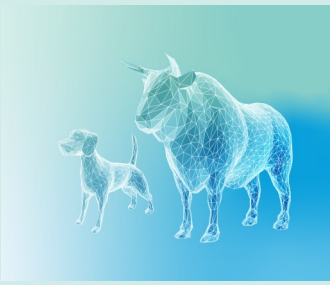
2nd Veterinary Big Data Stakeholder Forum

Registration is open!

Register now for the 2nd Veterinary Big Data Stakeholder Forum, a virtual meeting scheduled for **23 November 2022**.

We would like to continue the discussion and together identify veterinary regulatory use cases that would benefit from new digital technologies in the areas of **veterinary medicinal product information**, **pharmacovigilance** and **antimicrobial resistance**.

Stakeholders are welcome to share their views on the proposed use cases in our survey, by 30 September 2022. More information is available in the event page.



Union Product Database

Since the go-live of the UPD on 28 January 2022, nine system upgrades delivered additional functionalities, as well as defect fixes.

National competent authorities can now:

- **nullify** products;
- enter data for **parallel traded products**;
- amend entries in case of a **transfer** of marketing authorisation.

For more information on new functionalities and bug fixes delivered with the latest release, please check the release notes.

NCAs are approaching completion of the upload of legacy product data in the UPD. From Q3 2022 onwards, the Agency will also provide support to NCAs to improve data quality. Marketing authorisation holders (MAHs) are advised to liaise directly with the relevant EU/EEA national competent authorities contact points if they identify missing products or to address data quality issues.

The Agency's support to stakeholders includes ongoing training, such as the two webinars on VNRAs held in early September. Recordings of these webinars will be made available in the corporate website for MAHs, and on EU NTC for NCAs. Additional webinars will be organised later in the year.

The Veterinary Medicines information website has moved to its final address: https://medicines.health.europa.eu/veterinary/. Monthly improvements continue, now allowing users to navigate the website in **all EU/EEA languages**, access information on more than 45.000 products and run searches by product name, authorisation country, active substance, pharmaceutical form and route of administration.

The website **functionalities and benefits** for animal health practitioners were presented at a webinar held on 8 June 2022, co-organised by the EMA and the Federation of Veterinarians of Europe (FVE). The recording is available on the event page.

EMA communications perception survey: your feedback needed!

The EMA is carrying out a survey to assess how our communications to the general public are perceived and valued by our partners and our stakeholders.

The survey focuses on EMA communication activities to the general public (i.e. EMA information made public mainly through the EMA website such as press releases and news announcements). An electronic link to the survey can be found here. The survey is anonymous and should take around 15 minutes to complete. Once available, EMA will share the results of the analysis with you.

We value your feedback and your responses will help EMA to identify and address potential shortcomings and to better meet the communication needs of our partners and our stakeholders.

Please respond by 30 September 2022!

Manufacturers and Wholesale Distributors database

The remaining post go-live functionalities were delivered during the summer, including extension of the scope to veterinary medicines in the Good Distribution Practices (GDP) module (voluntary use), a facility to include alternative organisation names and further details linked to a specific unit inspected. The **Manufacturers and Wholesale Distributors database (MWD)** project is now approaching its formal closure.

From Q4 2022 onwards the dedicated user support will be discontinued and the activity transferred back to standard EMA IT service desk. Users will submit queries and report issues via the new EMA Service Desk platform, ServiceNow.

Relevant information, including **Q&As, training materials** and **recordings** from webinars held in 2021 and 2022 remain available for both national competent authorities in EU NTC and for industry users in the Agency's corporate website.

Union Pharmacovigilance Database

In Q3 2022, the EVV project focussed on the implementation of **duplicate management** and **signal management improvements**. Work on functionality to save and resume draft adverse event reports (AERs) and bulk export is due to begin in Q4 2022.

The recommended due dates for submitting annual statements for centrally and non-centrally authorised veterinary medicinal products for 2022 are available in the pharmacovigilance page, as well as the veterinary signal assessment report template.

The Agency is organising a **refresher webinar** on signal management for national competent authorities (NCAs) and marketing authorisation holders on 27 October 2022 (registration link). Recordings of previous webinars on adverse event submission, signal management and pharmacovigilance inspections remain available in the EudraVigilance Veterinary page.

Changes to the EMA Account Management Platform

The EMA Account Management is the European Medicines Agency's (EMA) online platform where you can request and manage access to EMA applications, such as **Eudravigilance Veterinary, IRIS** and the **UPD**. Since August 2022, a new access request form workflow with enhanced Organisation Search function is available, making easier for users to find their affiliated organisation based on different criteria and select multiple organisations within the same request. For more details on the new access request workflow visit our interactive guide or EMA Account Management documentation. In the course of the coming weeks, other changes will be introduced. Additional information will be provided in the **EMA Account Management training webinar**, scheduled for **3 October 2022**. For further details on the project or to share any feedback, please contact the EMA Service Desk.

Change management

While the **Regulator's Change Liaison Network** (HMA TF CIVR) dedicated change management meetings have ended, EMA support continues for all stakeholders.

EMA provides assistance to national competent authorities (NCAs) with the completion and enrichment of product data in the UPD, including **weekly support sessions** and one-to-one coaching, where necessary. The dedicated VMP-Reg helpdesk (see next page) remains in place for UPD and EVV.

Refresher webinars on VNRAs for NCAs and marketing authorisation holders were held in early September and supplementary sessions will be scheduled later in the year, following the delivery of new functionalities in UPD. A webinar on EVV and signal management is scheduled for 27 October and registration is open here.

To foster NCAs preparedness for the legislative requirements for ASU, the EMA has scheduled regular **ASU change liaison meetings** with representatives of the authorities until July 2023. These dedicated sessions will focus on monitoring progress at national level, provide support to raising awareness of the need for change at national level, as well as identify learning needs and preparing training.

The Veterinary Medicines information website has a **new address** (https://medicines.health.europa.eu/veterinary/) and the Agency launched a promotional video animation of this public platform, targeting veterinarians and pet owners. EMA produced subtitles in all EU/EEA languages and NCAs are welcome to use the animation at national level.

Recent activities:

- **8 June:** Antimicrobial use data collection stakeholders' info session for NCAs
- **27 June:** EMA/FVE webinar on UPD public portal**
- **6 September:** UPD webinar on VNRAs for national competent authorities*
- **8 September:** UPD webinar on VNRAs for marketing authorisation holders**
- **15 September:** ASU Change Liaison Network

Upcoming activities:

- **27 October:** Union Pharmacovigilance Database: refresher webinar on signal management **
- **17 November:** ASU Change Liaison Network meeting
- **23 November:** 2nd Veterinary Big Data Stakeholder Forum**

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

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

Did you know that…

- … since 28 January 2022, there is a free platform available in all EU/EEA languages that allows you to search and view information on veterinary medicines authorised in the EU/EEA?
- … this platform enables veterinarians to find out in which country a specific veterinary medicine is available, compare medicines or find information on potential alternatives?
- … the platform includes information on registered homeopathic veterinary medicines and veterinary medicines that are parallel traded between two EU/EEA countries?

Visit now

https://medicines.health.europa.eu/veterinary

Questions and support

For questions on:	Please contact:
Technical matters related to UPD	UPD VMP-Reg user support service
Technical matters related to EudraVigilance Veterinary	EVV VMP-Reg user support service
Technical matters related to other EMA IT systems	EMA ServiceNow
Regulatory questions relating to Regulation (EU) 2019/6	AskEMA
Other queries	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 (previous AER message format)
EMA	European Medicines Agency
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EudraGMDP	Database on manufacturing, import and wholesale distribution authorisations, 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	Referential Management Service
SPOR	Substance, product, organisation and referential data
UAT	User acceptance testing
UPD	Union Product Database
VSIAG	Veterinary systems improvement advisory group
VMP-Reg	Veterinary Medicinal Products Regulation

Read the previous issues of the VMP-Reg newsletter

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