

Veterinary Medicines HIGHLIGHTS

News, activities and interviews from the Veterinary Medicines Division.
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Editorial



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Welcome to the 12th edition of the VMP-Reg newsletter. Following a pause in the publication of this newsletter to review the focus, we now plan to return to the quarterly frequency, with a new table of contents that broadens the information provided here.

The Veterinary Medicinal Products Regulation has been applicable for over a year now. It has certainly been an interesting year for all of us. Although we had to make changes to our processes and learn new ways of working, I am pleased that together we continue to move towards the realisation of the benefits the regulation set out to achieve.

Our work continues at many levels, including stakeholder engagement. We have seen that interest in our events remains high, with more than 800 people connected for the Veterinary Info Day 2023, which provided updates on regulatory policy, procedural developments and discussions innovation in Europe.

In the regulatory area, among many other activities, marketing authorisation holders have aligned their product information

the QRD template version 9 for more than 35% of the centrally authorised veterinary products already.

What's next? This newsletter was set up to provide progress updates on the implementation of the Veterinary Medicines Regulation (VMP-Reg) Programme. Regular communication on this work brought the Veterinary Medicines Division closer to the different stakeholder groups.

We want to maintain the level of engagement of the last three years and with the formal closure of the programme, the format and scope of this communication are shifting. Starting from this edition, we will highlight activities of the Veterinary Medicines Division, ranging from stakeholder events, regulatory news and activities in the margins of the Veterinary Big Data strategy, to notable CVMP outputs.

But we would like to hear from you! Respond to our [survey](#) (on page 3) to let us know what you would interested to read about in this newsletter in the future. I hope you find the new format informative and useful!

Latest updates

QRD template v.9 update – deadline 27 January 2027

Marketing authorisation holders are required to update their product information in line with QRD template v.9, by **27 January 2027**. They should do so by submitting a variation requiring assessment, classification G.I.18, in line with the CMDv/EMA [guidance](#) and are kindly advised to carefully plan full coverage of their product portfolio, progressively.

Further guidance was circulated via email to Veterinary Industry associations on 7 February 2023 and is available on the [Agency's corporate website](#).

Update of QPPV and PSMF information in the Union Product Database

Marketing authorisation holders (MAHs) are requested to update in UPD the information related to the **qualified person for pharmacovigilance (QPPV)** and **Pharmacovigilance System Master File (PSMF)** information.

MAHs should submit VNRAs with classification C.6 and C.4. For CAPs, no fee will be charged. More guidance on how to submit VNRAs in UPD for QPPV and PSMF information can be found in the [video tutorials](#).

Progress with EU-US mutual recognition agreement for inspections for veterinary medicines

The European Union (EU) and the United States (US) have made important progress towards enabling **mutual recognition of inspections of manufacturing facilities** of certain veterinary products. The Food and Drug Administration (FDA) has recognised the capability of 16 EU Member States to carry out good manufacturing practice (GMP) inspections for certain veterinary products at a level equivalent to the US. At the same time, the EU also recognised the FDA as an equivalent authority for GMP inspections of sites manufacturing veterinary medicines.

This follows the extension of the scope of the [mutual recognition agreement](#) (MRA) between the EU and the US to veterinary products on **11 May 2023**.

The Member States whose GMP inspections for veterinary medicines are recognised by the FDA are Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Greece, Hungary, Ireland, Luxembourg, Netherlands, Poland, Portugal, Slovenia and Spain.

Detailed information can be found [here](#).

CVMP statistics Q1-Q2 2023*

	Q2 2023 (end of May)	Q1 2023	Total 2023
Marketing authorisations (MA) applications submitted	6	7	13
MA positive opinions	1	5	6
Withdrawn MA applications	-	-	-
G.I.18 VRAs submitted to align product information with v. 9.0 of the QRD template	8	28	36
Opinions on G.I.18 VRAs	12	24	36

* Detailed information can be found in the [CVMP meeting highlights](#).

Veterinary IT system updates

In 2019, EMA established the VMP-Reg programme with the purpose to deliver on the IT systems required by Regulation (EU) 2019/6. On 28 January 2022, the VMP-Reg programme delivered:

- **Union Product Database (UPD)**, the first central database on veterinary medicinal products and the first network IT system compatible with ISO IDMP.
- **Union Pharmacovigilance Database (UPhV)**, connected to UPD and compliant with **VICH** standards.
- Alignment of the **manufacturing and wholesale distribution database** with veterinary requirements.

The implementation of the system for the **Collection of Antimicrobials Sales and Use Data (ASU)** is progressing and will be delivered in Q1 2024.

The VMP-Reg programme paved the way for continued improvements in functionality and data quality in the past three years and in early 2023 the programme was formally closed.

The constituent projects of the programme were transitioned into a new delivery model at the Agency. Future improvements to the IT systems will be developed, prioritised and resourced in accordance with [EMA's Agile way of working](#).

The new governance is supported by the Veterinary IT systems improvement advisory group (VSIAG), with representatives from national competent authorities (NCAs), industry, and veterinary healthcare professionals, who will recommend priorities for new or improved functionalities in the UPD and UPhV systems.

Under the new governance model, [Quarterly system demos](#) are held to inform stakeholders what is being delivered.

Veterinary Medicines highlights: please RESUBSCRIBE

The Veterinary Medicines highlights is moving to a new platform, Newsroom, a user-friendly and GDPR compliant tool that will allow more efficient subscription management. **Resubscribe [here](#) to receive future editions of Veterinary Medicines Highlights.**



Tell us what you would like to see in future newsletters, by responding to our **anonymous survey** ([link](#)). We value your feedback and your responses will help us to improve and respond to your needs.

Please respond by **15 June 2023!**

Targeted Signal Management

The Committee for Veterinary Medicinal Products (CVMP) and the Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products (CMDv) recommended performance of a targeted signal management (Regulation (EU) 2019/6, Article 81.3/4) for **injectable veterinary medicinal products in combination with anaphylactic reactions in cattle**.

NCAs in the EU/EEA have noticed a significant increase of adverse event reporting of anaphylactic reactions in cattle in 2020, 2021 and 2022.

The adverse event reports were related to the use of injectable veterinary medicinal products (pharmaceuticals and vaccines), and relevant updates to the product information have been already introduced for certain products. Most of the reported cases occurred in France, Spain, Italy and Belgium.

This issue is currently followed-up by competent authorities at national and EU/EEA level. No conclusive causal association has been established yet and investigations are ongoing.

Veterinary Big Data

EU Veterinary Big Data: we have a plan!

Following the progress made in 2022, the discussions around big data in the veterinary domain are moving from vision to action as the **EU Veterinary Big Data work plan to 2025** was endorsed at the Heads of Medicines (HMA) meeting in May 2023. The work plan transposes the strategy's pillars into the following actionable workstreams with the overall ambition of prioritising digital veterinary use cases for the coming years at EU level:



Analytics discoverability: the **UPD Data Quality Framework** was launched and presented to NCAs in April, to help improve the robustness and reliability of VMP information available in the UPD. In addition, EMA is funding the “**Big Data in Veterinary Medicines Regulation: a data landscape analysis**” research project. Over the next 12 months, Wageningen Research will undertake the research project aimed at identifying and characterising suitable animal health data sources and developing a veterinary data catalogue to support the delivery of the Vet Big data strategy.

Governance and Literacy: the **Veterinary Data Hub** will be formally established in June 2023 and will oversee the activities scheduled in the Vet Big Data work plan. This multidisciplinary expert group will also contribute to the advancements of veterinary regulatory science, by defining sustainable and ethical digital solutions and promoting data-driven practices based on real-world evidence.

Stakeholder engagement: the [Veterinary Big Data webpage](#) was launched in May 2023, a one-stop shop for the latest news on Veterinary Big Data activities. In November 2022, the Agency held the [2nd Veterinary Big Data Stakeholders Forum](#), which gathered more than 300 representatives from the pharmaceutical industry, animal healthcare professionals, academia, regulatory authorities and other national and international government bodies. Following this successful event, EMA and the Vet Data Hub are preparing the forum's third edition, penciled in for Q4 2023. The event will continue the earlier discussions on how new digital technologies can foster veterinary regulatory activities in key business areas, namely veterinary medicines availability, pharmacovigilance, disease monitoring and antimicrobial resistance.



Veterinary Big Data events and activities

Would you like to receive early information on veterinary big data events? Please send an email to vet.bigdata@ema.europa.eu to express your interest.

Stakeholder engagement

Refresher webinars on VNRA for NCAs and marketing authorisation holders on UPD will be scheduled later in the year, following the delivery of new functionalities in UPD.

The **first system demo of 2023**, held by EMA as part of its Agile transformation took place on 22 March 2023. The public demos are organised to present the developments achieved with EMA products and collect stakeholder feedback. In the March edition, EMA showed, among others, developments with Union Product Database (UPD) and Veterinary Union Pharmacovigilance (UPhV) Database. Recordings of those sessions are available in the relevant event webpages.

2022 activities:

- **27 October 2022:** [Union Pharmacovigilance Database: refresher webinar on signal management](#)**
- **10 November 2022:** Webinar on the ASU protocol on antimicrobial sales data*
- **23 November 2022:** [2nd Veterinary Big Data Stakeholder Forum](#)**
- **6 December 2022:** Webinar on the ASU protocol on antimicrobial use data*

Recent activities:

- **16-17 February 2023:** [EMA veterinary medicines info day 2023](#)**
- **22 March 2023:** [EMA Quarterly system demo for Q1 2023](#)**
- **24 April 2023:** [Volume of Sales UPD webinar for MAHs](#)**
- **25 April 2023:** UPD Data Quality Framework Info session for NCAs*
- **24 May 2023:** [CVMP Interested Parties' meeting](#)

Upcoming activities:

- **27 June 2023:** Webinar on the ASU data quality**
- **September 2023:** EMA Veterinary Awareness Day**
- **4 October 2023 :** Webinar on ASU protocol on animal population data*
- **27 November 2023:** Refresher webinar on ASU platform*
- **Q4 2023:** 3rd Veterinary Big Data Stakeholder Forum**

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

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

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, OMS and other EMA IT systems	EMA ServiceNow
Regulatory questions relating to Regulation (EU) 2019/6 and other general queries	AskEMA *

*The vetchange@ema.europa.eu mailbox is to be discontinued on 1 July 2023. All general questions relating to the implementation of the Veterinary Medicines Regulation, which do not fall under the topics listed in the table above, should be submitted via [AskEMA](#).

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