

Veterinary Medicinal Products Regulation HIGHLIGHTS

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



Ivo Claassen

Head of Veterinary
Medicines Division, EMA

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

With only ten months to go until 28 January 2022, when Regulation (EU) 2019/6 (the Regulation) will become applicable, 2021 will be an incredibly busy year for all of us.

Thanks to the strong commitment of Member States representatives, stakeholders, and project teams the programme is on track towards the delivery of the legislative requirements.

The second version of the Union Product Database (UPD) went live on 16 March. This milestone is the result of the hard work and collaboration of all stakeholders involved, and will support the national competent authorities in initial testing activities surrounding the connection of national systems to the UPD.

The Union Pharmacovigilance Database (EUV) project has also considerably progressed its delivery activities and is on schedule to deliver a robust system compliant with the legislative requirements.

Activities of the two more recent projects, the Collection of Antimicrobial Sales and Use data and the Manufacturers and Wholesale Distributors database are also advancing according to plan.

I am pleased to see an unprecedented participation in all the events and webinars organised, which shows immense interest in our joint efforts to implement the Veterinary Medicinal Products Regulation.



Once the VMP Regulation is fully applicable, the Commission hopes that our open and constructive dialogue with EMA, NCAs and stakeholders on the practical implications of the new obligations and procedures will continue in order to achieve a harmonised and efficient new regulatory system for veterinary medicinal products.

Eva Maria Zamora-Escribano, Head of Unit Animal nutrition, veterinary medicines, European Commission

Programme update

Since January, national competent authorities have progressed with the **preparation of the product data** held in their national systems. Timely completion of these mapping activities is key to start submitting legacy data on veterinary medicinal products into the UPD in summer 2021, in line with the timeline shown on page 4.

The multi-stakeholder governance of the VMP-Reg programme recognises the challenges for NCAs associated with upload of comprehensive and high-quality product data into the UPD, but considers this pivotal for the success of the programme.

EMA is supporting the **mapping efforts** via dedicated webinars, troubleshooting session, and supportive mapping activities performed by the Agency.

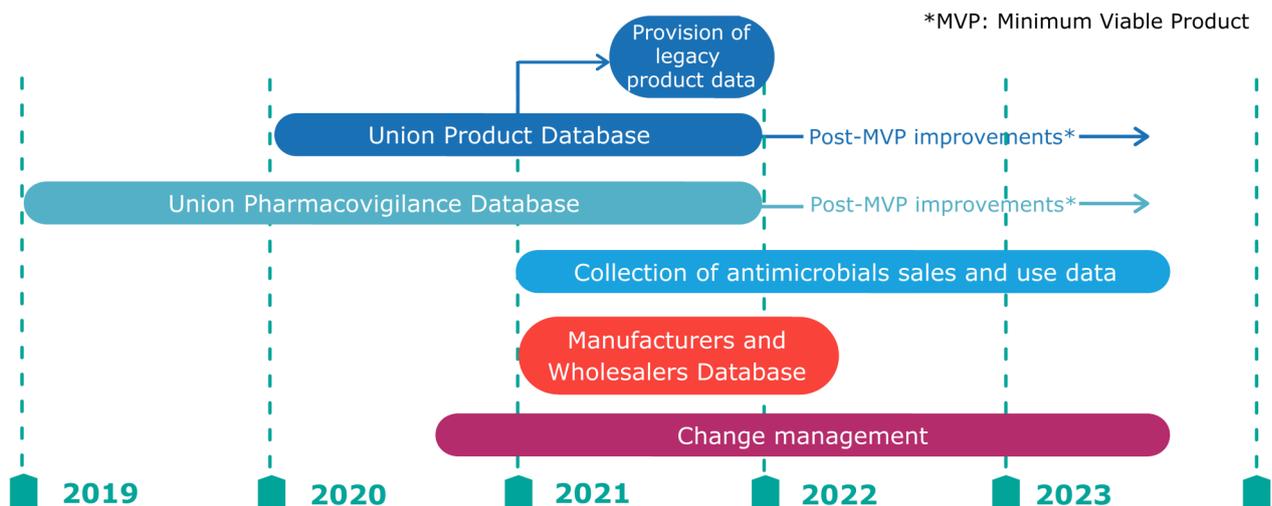
Delivery of the Union Product Database (UPD) and the Union Pharmacovigilance Database (EVV) is advancing, with the second iterative version of the UPD released on 16 March — see additional information on page 4.

The Collection of Antimicrobial Sales and Use data (ASU) Project Group is drafting high-level business requirements and working on the implementation timeline.

List of acronyms

- API:** Application Programming Interface
- ASU:** Collection of Antimicrobial Sales and Use data
- DCP:** Decentralised procedure
- DEG:** Data Elements Guideline standard
- ESVAC:** European Surveillance of Veterinary Antimicrobial Consumption
- EVV:** Union Pharmacovigilance Database
- MAH:** Marketing authorisation holder
- MRP:** Mutual recognition procedure
- MS:** Member State
- MWD:** Manufacturers and Wholesale Distributors database
- NCA:** National competent authority
- HMA TF CIVR:** Heads of Medicines Agencies Task Force on the Coordination of the Implementation of the Veterinary regulation
- UPD:** Union Product Database
- VICH:** Veterinary International Conference on Harmonization
- VMP-Reg:** Veterinary Medicinal Products Regulation

Work related to the Manufacturers and Wholesale Distributors database project is also ongoing. The VMP-Reg programme is identifying the additional functionalities required to align EudraGMDP with the legislative acts.



Manufacturers and Wholesale Distributors database

The VMP-Reg programme is working to bring the existing [EudraGMDP](#) system in line with the legislative requirements arising from the VMP-Regulation.

By identifying the **additional functionality** needed, the programme is preparing the project **business case** which is scheduled for discussion in late April 2021. The Project Group including MS representatives has been established, the draft business requirements are being reviewed and the project plan is under development.

The link to the GMP/GDP Inspectors Working Group is established through the involvement of relevant EMA staff.



AnimalhealthEurope appreciates the intense work done within all the EMA expert groups working on multiple facets of implementing Regulation 2019/6, and the EMA's high level of stakeholder engagement. We are ready to play our part and support the process as responsible stakeholders. Our focus is on practical implementation of the legislation, in line with its original objectives, avoiding unnecessary administrative burden, while making the most of what telematics has to offer in efficient administrative processes.

Rick Clayton, Technical Director, AnimalhealthEurope

Collection of Antimicrobials Sales and Use data

The Collection of Antimicrobial Sales and Use data (ASU) project was initiated in 2020 with the definition of its **mandate and governance**.

The **Project Group** including representatives of competent authorities meets monthly and is progressing on the development of the project vision and business case.

In this context, the group has started drafting **high-level business requirements**, based on the legislative requirements currently known. The final technical specifications of ASU will be laid down in the implementing act and delegated act expected for adoption in Q2 2021 and January 2022, respectively.

A **phased approach** to the types of data collected is foreseen in the VMP-Reg. Collection of antimicrobial sales data, currently coordinated by ESAC project, will continue. Antimicrobial use data collection for the first applicable species groups will start in 2024.

The project delivery timeline is under discussion and will be made available soon.

Union Product Database

The second release of the Union Product Database went live on 16 March. This version provides:

- Additional functionality of the UPD **Application Programming Interface (API)**, including document management. This allows IT systems of competent authorities automated access to the Union Product Database to test uploading national product information in the UPD. The [release notes](#) contain all required information to register and connect to the API and use the available functionality.
- The first version of the **competent authorities User Interface**, providing search, view and create functionality on nationally authorised products (NAPs) and centrally authorised products (CAPs) information.

EMA recommends to use this version for testing purposes only.

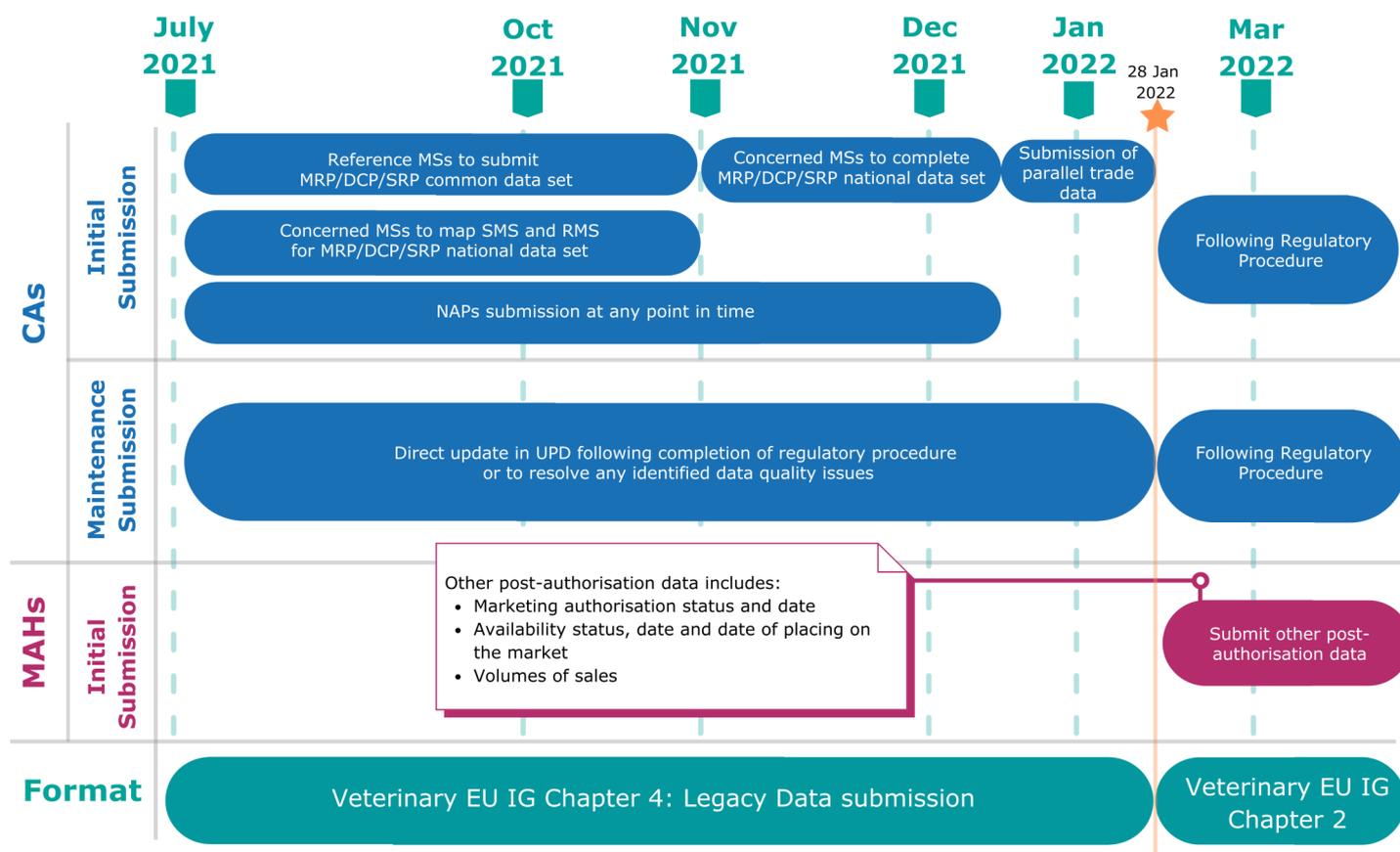
The UPD team held a **technical webinar** for competent authorities on 23 March to demo the system functionalities and explain how to access it. The recording will soon be available to NCA staff on the EU Network Training Centre.

The next release of the UPD, planned for July 2021, will also allow entry of mutual recognition procedure (MRP) and decentralised procedure (DCP) product information that will be retained in the database, in line with the **indicative timeline for submission of legacy data** shown below. This will be the release enabling NCAs to submit legacy product data into the UPD via the API or User Interface.

NCA volunteers and the development team have started preparing the end-to-end user acceptance testing scheduled for Q3/Q4.

User research for the **public UPD portal** is completed and development will start soon. In parallel, to future-proof the development of the NCA User Interface, usability testing of the interface was started in March.

Indicative timeline for submission of legacy data



Union Pharmacovigilance Database

Development of the Union Pharmacovigilance Database (EVV) is advancing.

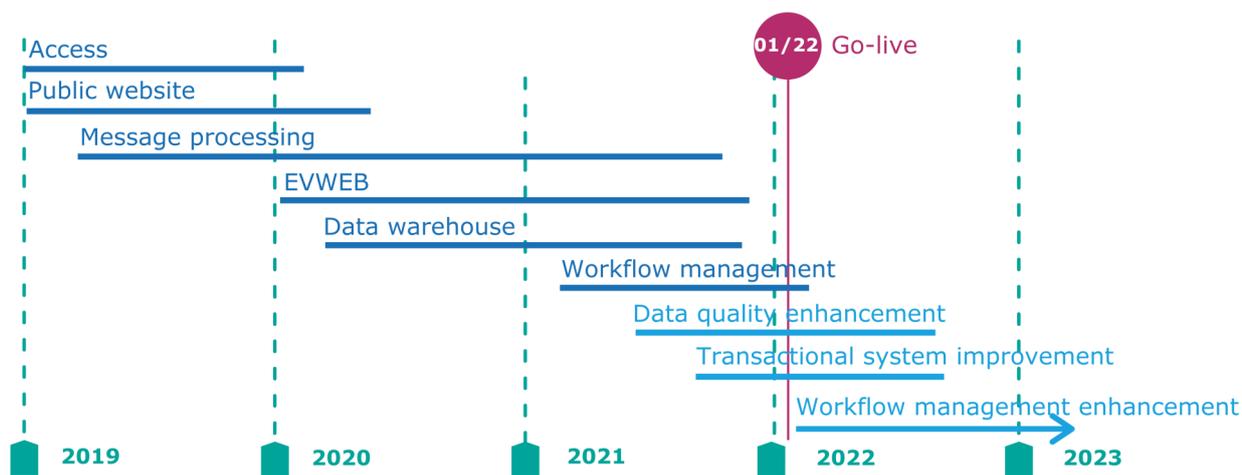
Work packages currently under development include:

- work on the **signal management** process;
- further development of the **messaging platform**, including completion of the functionality allowing automatic recoding of substances in adverse event reports received in EVV;
- further development of **EVWEB component**, providing a web user interface;
- development of further **reports** in the DataWarehouse (DWH).

Following a two-month public consultation concluded in March, the EVV team is finalising the **access policy** which will include minor improvements identified during the practical implementation of the policy.

The **timeline of the activities** planned for 2021 and beyond is shown below. It reflects the components or functionalities that will be available by January 2022, and those that will be added after this initial release.

The system will rely on product information submitted into the Union Product Database to allow for efficient signal detection and access management. For this reason, the timeline for submission of legacy data into the UPD shown on page 4 is not only relevant for the EVV system, but completion of legacy data submission in line with this timeline is absolutely essential.



VICH messages in EVV — action needed for NCAs and MAHs

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

For this, **national competent authorities and marketing authorisation holders** need to ensure that they are **able to read VICH standard messages from the go-live of EVV onwards**, which may necessitate development and temporary use of a conversion tool, until their systems are ready to receive VICH messages.

Change management

Activities within the Change Management workstream progressed especially in the areas of learning and awareness-raising. This is done in close collaboration with the **Regulators' Change Liaison Network** (HMA TF CIVR), driving the change management activities at national level and exchanging experiences on their progress and challenges.

A **webinar for National Competent Authorities** on mapping of **substance data** held in their national systems was organised in cooperation with the SPOR programme on 9 February, with a participation of over 160 attendees. The recording is available to NCA staff on the EU Network Training Centre learning management system.

To further support NCAs mapping activities, EMA's SPOR programme organises monthly **troubleshooting sessions** addressing issues and questions raised by NCA staff. Where appropriate, the questions and answers provided at the webinars will be published in Q&A documents.

Two **webinars for industry** were organised in February by the SPOR programme on **Referentials Management Service** (RMS) and **Organisation Management Service** (OMS). The recordings are available on YouTube at the links provided.

After a three-year break due to Brexit and its implications for the Agency, EMA organised its **Veterinary Medicines Info Day** on 25 March, with the support of AnimalhealthEurope. The focus of this

year's event was the progress made in implementing the Regulation. Almost 800 participants joined the event, which is a record for the Veterinary Medicines Info Day and shows the immense interest in the work linked with the implementation of the Veterinary Medicinal Products Regulation. Speakers' presentations will be made available on the [event webpage](#).

Activities to engage the **veterinary healthcare community** and raise their awareness of the changes arising from the VMP-Reg have also started with the first webinar jointly organised by **EMA and the Federation of Veterinarians of Europe** (FVE). The webinar was held on 30 March and focused on the importance of pharmacovigilance monitoring and reporting and sources of information for veterinarians on the safety of medicinal products in animals. Over 320 participants joined the event. The recording will be made available on [EMA's YouTube channel](#).

NCAs, industry, veterinarians and all interested stakeholders are welcome to address **questions** and requests for clarification to the email address vetchange.programme@ema.europa.eu

Upcoming activities:

14 April, 9:30—12:30: webinar for NCAs on the business process related to the submission of legacy data into the UPD.



Stakeholder views

We have asked our stakeholders in what areas their entity has achieved considerable progress. Their contributions are reflected below, and show the diverse viewpoints and focus areas of our different stakeholders.

“The Commission’s focus remains on the delegated and implementing acts which need to be in place by the date of application of the VMP Regulation, January 2022, or of the Animal Health Law, April 2021, respectively. We are working on 14 acts in parallel and are on track to meet the deadlines set in the legislation. In any case, we are aiming to finalise those acts as soon as possible to ensure smooth implementation. Two implementing acts were already published in the Official Journal. Two more have been adopted and are now with the European Parliament and the Council for scrutiny. Others are in the pipeline, making good progress.”

Eva Maria Zamora-Escribano, Head of Unit Animal nutrition, veterinary medicines, European Commission

“I think that the main progress achieved by the TFCIVR is awareness of the ongoing work in the different working groups and more especially on IT projects. The set-up of the traffic light table and the implementation of the change management programme allowed NCAs to identify all the work to do and the difficulties encountered.”

Jean-Pierre Orand, Co-Chair of the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation

“2021 is a key transition year for veterinary medicines industry. At present, MAHs are busy preparing staff and adapting resources to be ready in time. EGGVP has also provided considerable online training for all its members, so as to support them to effectively adapt to and implement the corresponding business changes. The area where there has been more interest, preparations and investments is on the new IT structure, and how to operate with it. However, most projects in this area are still under development, and MAHs fear that they will only be able to do adaptations at last minute. The perception is that there is still a huge amount to be done in a very short period of time.”

Elsa Vecino, Technical Director, European Group for Generic Veterinary Products (EGGVP)

“BVL is actively engaged in the development and implementation of the legislative required IT-systems. So far, considerable progress has been made in the delivery activities for the Union Product Database (UPD) as well as the Pharmacovigilance Database (EVV). In the area of the UPD, BVL advanced in the preparations for the completion of the mapping concerning SMS, OMS and RMS terms. Furthermore, BVL considers active engagement of all stakeholders crucial for a timely implementation of the Veterinary Medicinal Products Regulation and successfully hosted the HMA Veterinary Stakeholder Meeting within Germany’s presidency of the Council of the European Union in November 2020.”

Prof. Dr. Thomas Heberer, Head of Dept. 3 “Veterinary Medicinal Products”, Federal Office of Consumer Protection and Food Safety, BVL, Germany

“The Federation of Veterinarians (FVE) is following every step of the process to get ready for the new Regulations and keeps our members up-to-date. We are glad to have been granted the opportunity to provide input in all consultations regarding practical aspects of the new rules that will matter very much to practitioners in their daily life, such as on the use of antimicrobials, oral medication and pharmacovigilance matters. We will continue the process of preparing all veterinarians for the new rules and to do so, welcome very much the joint webinars we are planning together with EMA soon.”

Rens van Dobbenburgh, President of the Federation of Veterinarians of Europe (FVE)

“For the past two years, much of CVMP activity that is not assessment-related has been focussed on implementation of the VMP-Reg. During this time, the Committee and experts supporting it have delivered a number of large pieces of work in the form of scientific recommendations/advices in response to requests from the EC. These include including the recommendations relating to: dossier

data requirements (Annex II), classification of variations, pharmacovigilance, data to be collected on antimicrobial use, criteria for antimicrobials to be reserved for human use and on safe and efficient use of orally administered VMPs. These were very significant pieces of work given the resource input (in terms of both numbers of people involved in the drafting and the time that those individuals had to devote to the work) and their importance to the future regulation of VMPs.”

David Murphy, Chair of the Committee for Medicinal Products for Veterinary Use (CVMP)

“The CMDv has made considerable progress on the SPC harmonisation, on Variations and on the impact of the Regulation on SPC templates. The CMDv has also made progress on the re-examination procedure and on the timetable for the marketing authorisation procedures.”

Laetitia Le Letty, Chair of the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv)

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

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

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