

# 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 fifth edition of the newsletter for the Implementation of the Veterinary Medicinal Products Regulation (VMP-Reg) programme.

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 by 28 January 2022.

The final version of the Implementation Guide for the Union Product Database (UPD) was published on 17 May, six weeks before the planned date. This allows national competent authorities a longer timeframe to prepare their legacy data before July, when they will start uploading product data into the UPD.

Additionally, the UPD will allow competent authorities to submit data in a phased approach, facilitating their preparatory and upload activities.

Activities of the Union Pharmacovigilance Database, the Collection of Antimicrobial Sales and Use data, and the Manufacturers and Wholesale Distributors database projects keep advancing.

The remarkable participation in all the events, webinars and trainings organised in the past months shows the engagement and commitment of all partners and stakeholders towards a successful implementation of Regulation (EU) 2019/6.

We are keeping an eye on the future, as shown by the recent publication '[From collection to connection – the EMA veterinary data strategy](#)' in the TOPRA Regulatory Rapporteur, which sets the scene for the topics to be discussed at the Veterinary Big Data Stakeholder Forum on 1-2 June.



*The entire Network is truly committed to the implementation of the VMP Regulation. Eight months remain before its date of application, considerable challenges lie ahead, so we need to stay even more focused in order to make the implementation a success.*

**Eva Maria Zamora-Escribano, Head of Unit, Animal nutrition, veterinary medicines, SANTE.DDG2.E.5, European Commission**

## Programme update

The next release of the Union Database is scheduled for **July 2021**, and it will allow NCAs to start submitting legacy data on veterinary medicinal products.

National competent authorities are progressing with the **preparation of the product data** held in their national systems.

The **dependency** of other projects and regulatory processes on the timely availability of legacy product data in the UPD is another key factor driving the network efforts to submit data in line with the deadline fixed in legislation. In particular, the Union Pharmacovigilance Database (EVV) will rely on the availability of all legacy data in the UPD to enable effective functioning of automatic recoding needed to support efficient signal detection and management.

EMA is supporting the **mapping efforts** via dedicated webinars, troubleshooting session, and extraordinary mapping activities performed by the Agency with regard to substance and organisation data.

Delivery of the **Union Pharmacovigilance Database (EVV)** is advancing to plan.

Delivery of the **Union Product Database (UPD)** is also progressing. The system will allow a phased input of information to facilitate data submission for NCAs.

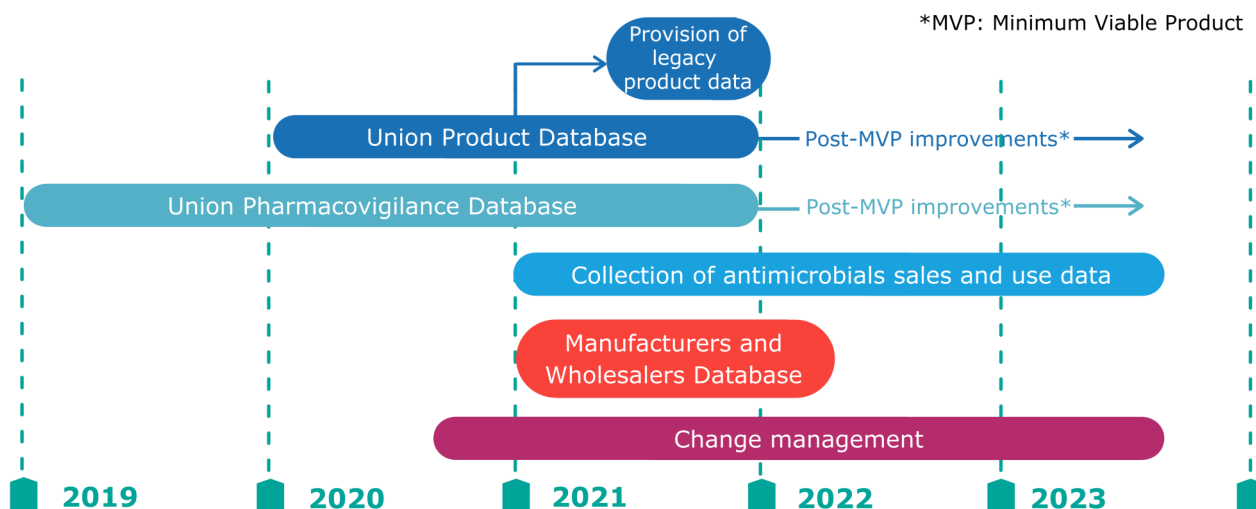
The **Collection of Antimicrobial Sales and Use data (ASU)** Project Group is working on an options analysis.

### List of acronyms

- AER:** adverse event report
- API:** Application Programming Interface
- ASU:** Collection of Antimicrobial Sales and Use data
- CVMP:** Committee for Medicinal Products for Veterinary Use
- DCP:** Decentralised procedure
- DEG:** Data Elements Guideline standard (current AER message format)
- ESVAC:** European Surveillance of Veterinary Antimicrobial Consumption
- EVV:** Union Pharmacovigilance Database
- 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
- HMA TF CIVR:** Heads of Medicines Agencies Task Force on the Coordination of the Implementation of the Veterinary regulation
- UPD:** Union Product Database
- VICH format message:** future AER message format, as of 28 January 2022
- VMP-Reg:** Veterinary Medicinal Products Regulation

The business case of the **Manufacturers and Wholesale Distributors database (MWD)** project was approved.

Specific updates on the four projects are provided on the next pages.



# Manufacturers and Wholesale Distributors database

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The **business case** of the Manufacturers and Wholesale Distributors database (MWD) was approved. The Project Group is finalising the project vision.

Most of the legislative requirements outlined by Regulation (EU) 2019/6 (the Regulation) are covered by the existing [EudraGMDP](#) system. However, some extensions of the current system functionality are required for full compliance. In particular, the modules on Wholesale Distribution Authorisations, application programming interface (API) Registration, and Good Distribution Practices need to be extended to the veterinary domain. The changes required impact **both manual updates and automatic (eXtended Mark-up Language - XML) upload** of updates, and will have an impact on both the veterinary and human domain.

The project team will ensure that gaps identified by comparing the current functionalities of EudraGMDP with the requirements of the Regulation are filled. In light of the project limited scope and tight timeline, an approach for development will be put in place whereby detailed requirements are gathered before development begins. If a business requirement needs crucial modification, the delivery team shall interrupt development, analyse once more and, if prioritised by the governance, apply the change.

Another guiding principle for development is that the MWD must be extended in a way that **avoids duplication of data input** across systems which are in scope of the VMP-Reg programme as much as possible, to ensure that there is a single source for each type of information.

# Collection of Antimicrobials Sales and Use data

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Regulation (EU) 2019/6 calls for the collection of relevant and comparable data on the volume of sales and on the use of antimicrobial medicinal products used in animals, which Member States shall collate and send to the Agency. The Agency will analyse those data and publish an annual report.

The Project Group of the Collection of Antimicrobial Sales and Use data (ASU) project approved the **high-level business requirements** covering the full cycle of data (submission, validation, transformation and reporting, and publication). Requirements are based on the legislative requirements currently known. The final technical specifications of ASU will be based on the delegated act adopted on 29 January 2021 and the implementing act to be adopted by 27 January 2022.

The group is now finalising the **project vision**.

A **phased approach** to the types of data collected is foreseen. Collection of antimicrobial sales data, currently coordinated by ESVAC project, will continue. Antimicrobial use data collection for the first applicable species groups will start in 2024. Hence, a phased approach for development shall be applied to prioritise functionalities enabling Member States to submit applicable data in 2024. As a result, a minimum viable product (MVP) should be delivered by Q4 2022, while additional non-MVP functionalities will be discussed and prioritised in collaboration with the Member States.

## Union Product Database

Development of the Union Product Database (UPD) is advancing. The next release of the system, planned for July 2021, will allow NCAs to enter product information on nationally authorised products and products authorised via the mutual recognition (MRP) and decentralised (DCP) procedures in the database, in line with the **indicative timeline for submission of legacy data** shown below. The initial load of product information on centrally authorised products will also be executed for the July 2021 release.

In order to alleviate the challenges faced by the NCAs for the initial input of data on authorised veterinary medicinal products, the UPD will allow a **phased submission of data** for all products and will not enforce an 'all-or-reject' approach, as detailed in the [explanatory note](#) of the Veterinary EU Implementation Guide. NCAs will be able to perform a preliminary data submission into the UPD via the API, user interface, or manual upload of compatible messages.

In case of a preliminary submission, NCAs will then need to **enrich incomplete datasets** submitted

via the same or a different route of transmission by 28 January 2022.

The UPD Project Group signed off the **end-to-end user acceptance testing plan** prepared by NCA and MAHs volunteers together with the development team.

The Group also approved the prioritisation of the requirements for the **public UPD portal**, and development started in mid-May.

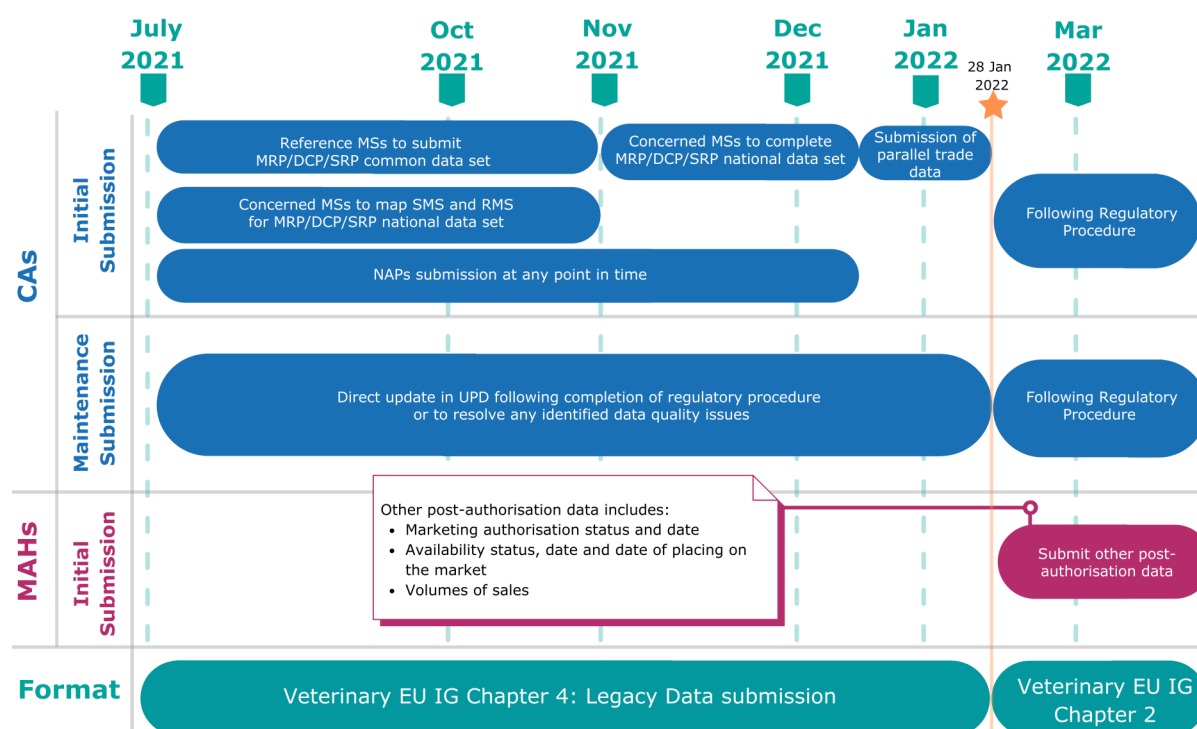
Usability testing of the **NCA user interface** is ongoing.

### Vet EU Implementation Guide

The public consultation on the Vet EU Implementation Guide for the UPD closed on 21 March 2021.

The VMP-Reg programme addressed the comments received and published the [final guide](#) on 17 May 2021, around six weeks ahead of the agreed timeline. The document contains guidance for national competent authorities and marketing authorisation holders on the submission of data on veterinary medicinal products into the UPD using standardised data formats and terminology. The overview and discussion of the comments received will be published shortly.

### Indicative timeline for submission of legacy data



# Union Pharmacovigilance Database

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

Work packages currently under development include:

- work on the implementation of the access policy and of the authentication and authorisation functionalities of **EV Web**, which will provide a web user interface. The migration of legacy data to the new database is also ongoing
- further development of the functionality linking active ingredients and authorised veterinary medicinal products in adverse event reports received in EVV, key to **data quality**
- development of the MAH dashboard and of public reports in the Data Warehouse.

The Committee for Medicinal Products for Veterinary Use (CVMP) adopted the **access policy**,

which will be presented during the June 2021 meeting of the EMA Management Board and published.

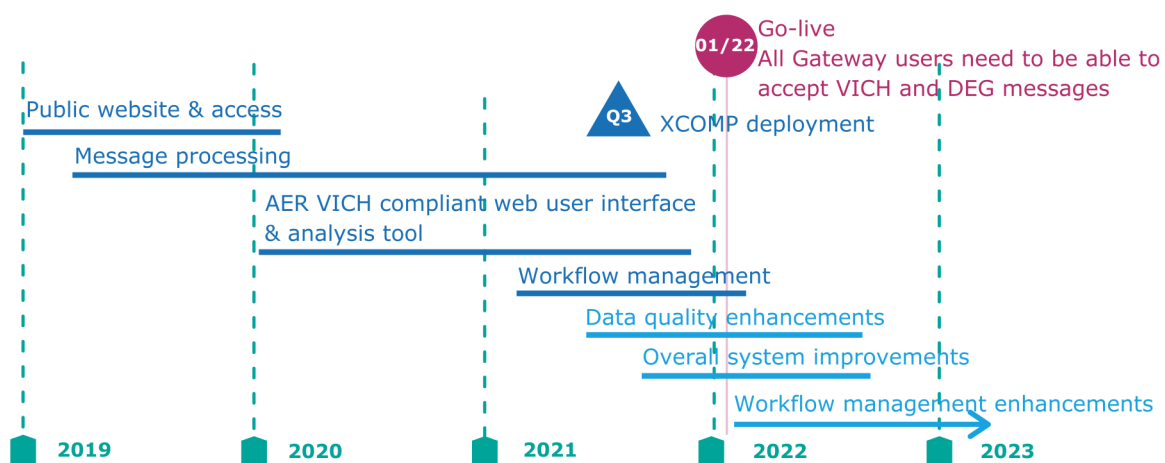
EMA published the **new VICH schema** that NCAs and MAHs can use for the implementation of their systems to exchange Adverse Event Reports (AER) information via gateway. The schema is composed of multiple files and the VICH root element is defined by the schema located [here](#).

The draft **EU AER VICH Implementation Guide** will be published in June 2021 for a 2-month public consultation.

In Q3 2021, the **external compliance testing environment** (XCOMP) will be deployed. This release will include:

- VICH compliant messaging functionality
- preview of new AER VICH compliant Web user interface.

It will allow **NCAs and MAHs** to start **testing** their implementations, and to update their **access** to the EVV system.



## VICH format 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 VICH format will not be available for download in the current DEG format.

Therefore, **national competent authorities and marketing authorisation holders** need to ensure that they are **able to process 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 format messages.

# Change management

The programme learning and awareness-raising activities progressed 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.

Ongoing support to NCAs mapping activities is offered through monthly **troubleshooting sessions** organised in cooperation with the EMA's SPOR programme to address issues encountered. Where appropriate, the questions and answers provided at the webinars are published in Q&A documents.

Additionally, the SPOR team offered NCAs extraordinary support in mapping substance and organisation data for interested NCAs.

## Recent webinars for NCAs:

- **Technical webinar on UPD API and NCA UI** – 23 March (recording available to NCA staff on EU NTC)
- **Business process to submit legacy data into the UPD** – 14 April (recording soon available to NCA staff on EU NTC)
- **Best practices for legacy data upload into the UPD via the API** – 29 April. Content kindly developed by **AGES** for the Network, in cooperation with the UPD team (recording soon available to NCA staff on EU NTC). A follow-up session will be organised after the next UPD release.

In cooperation with the VMP-Reg programme, EMA's SMEs office is organising the 2021 edition of the **Veterinary SMEs Info Day**. The event will take place on 28 October and it will address the needs of micro, small and medium-sized enterprises (SMEs) in relation with the implementation of the Veterinary Medicinal Products Regulation. The registration link will be shared in due time, meanwhile please mark your calendars.

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](mailto:vetchange.programme@ema.europa.eu)

## Upcoming activities:

**1–2 June:** Veterinary Big Data stakeholder forum, a first opportunity to bring together all interested stakeholders to discuss the use of innovative digital technologies in the veterinary regulatory environment.

### [Agenda and registration links](#)

**23 June, 15:00–16:30:** joint EMA/FVE webinar for animal health professionals on the AMEG categorisation of antibiotics for use in animals and its implications for veterinarians.

[Online registration form](#) (click on 'Register', no password is needed).

## Veterinary electronic Application Forms

The Network launched a telematics project called Digital Application Dataset Integration project (DADI) to modernise and improve use of the EU electronic Application Forms (eAFs).

In May 2021, the IT Directors Executive Committee approved prioritisation of development of Human variations form. Development of Veterinary variations form remains in scope of DADI but is postponed to early 2022.

As a result of this decision, the veterinary variation application form provided by the DADI project will not be available before the Veterinary Medicinal Products Regulation becomes applicable. EMA has started working on the update of the PDF format eAFs (both initial MAA and variations) for use from 28 January 2022 onwards and will provide updates on the activity in the next newsletter issues. Veterinary stakeholders have been invited to remain part of the DADI Requirements Group as observers.





# Stakeholder views

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We have asked our stakeholders what key benefits of the Veterinary Medicinal Products Regulation they are especially looking forward to. Their contributions are reflected below, and show the diverse viewpoints and focus areas of our different stakeholders.

“The increase of transparency on information for all veterinary medicinal products (VMPs) in the EU – including VMPs for pets – is a key benefit of the Veterinary Medicinal Products Regulation. This includes the availability and reliability of information on sales data and surveillance for the same time period, which further enhances the quality of the signal management process. Furthermore, information on the availability of VMPs is facilitated by the UPD. Additionally, the VMP regulation provides some valuable key measures to address the issue of antimicrobial resistance more effectively and efficiently.”

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

“The reduction of administrative workload was one of the objective of the Regulation, as well as the enhancement of the functioning of the internal market, increased availability and safeguard public health, animal health, animal welfare and the environment. The reduction of administrative burden, improvement and harmonisation of procedures will be a great benefit for the CMDv.”

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

“The VMP-Reg includes provisions to: support innovation and product development (e.g. greater flexibility to deal with the complex area of novel therapies, the ability to authorise products for limited markets in the absence of complete dossiers); increase efficiency of regulatory processes and in doing so reduce burden; and, implement risk-based approaches to activities/ decision-making. From a CVMP perspective, these are key benefits of the regulation; however, in order for these benefits to be realised, the network as a whole needs to be smart in its approach to implementation such that the provisions are exploited to the maximum, while ensuring a high-level of protection for animal and public health.

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

“The VMP Regulation will contribute to achieving the objective of the Farm to Fork strategy to reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030. It follows the One Health principle and provides for a number of measures aiming to ensure a more prudent and responsible use of antimicrobials, while seeking to preserve the efficacy of existing antimicrobials.

The VMP Regulation will also reduce administrative burden, enhance the single market and increase the availability of veterinary medicinal products. The Union veterinary databases will play a crucial role in enabling some regulatory processes and providing information to the public.”

**Eva Maria Zamora-Escribano, Head of Unit E5, Animal nutrition, veterinary medicines, Directorate E, Food and feed safety, innovation, DG Health and Food Safety (SANTE), European Commission**

“I think that NCAs are looking forward to a better harmonisation and a reduction of workload through the development of performant IT databases. Not all functionalities will be available and operational in January 2022, but I hope that, in the medium-term, an improvement in the functioning of the Network and in sharing harmonised information will be made. This means also that the review of fees regulation shall be finalised and shall take into account the consequences of the implementation of the Veterinary Medicinal Products Regulation.”

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

“Industry was greatly looking forward to the objectives of the revised legislation being delivered, however our expectations have been quite downgraded, and we are reassessing what residual benefits there might actually be. Two big objectives were a reduction in administrative burden and incentivising innovation. At this stage we are not sure whether a net benefit will be the outcome. Supporting innovation should be for both new products but also for significant investments to upgrade existing products. Perhaps the biggest potential benefits lie in the new Annex II, particularly if the regulatory pathway for novel therapies can be improved and some challenging regulatory hurdles for vaccines can be removed.”

**Rick Clayton, Technical Director, AnimalhealthEurope**

“The key benefits veterinary practitioners are hoping for is that the new Regulation will provide them more tools to treat animals safely and effectively. In other words, that the availability of veterinary medicines (including vaccines) will increase, that the pharmacovigilance system will give more value to veterinarians, and for new products to enter the market.”

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

1. Widening of the centralized procedure for generic VMPs.
2. A fully EU-harmonized regulatory environment, with new rules in guidelines and secondary legislation allowing more efficient operations and use of resources by all.
3. Preparation of robust risk-benefit guidance in the area of antimicrobial resistance.
4. More consistent, science-based and efficient approach to ecotoxicity requirements for all VMPs.”

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

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

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