

Veterinary Medicinal Products Regulation HIGHLIGHTS

News, views and interviews for the Veterinary Medicinal Products Regulation.
Published every two months by the European Medicines Agency

An agency of the European Union



Editorial



Ivo Claassen

**Head of Veterinary
Medicines Division, EMA**

INSIDE THIS ISSUE

Editorial **1**

Programme update **2**

Collection of
Antimicrobials Sales
and Use data **3**

Union Database on
Manufacturers and
Wholesale
Distributors **4**

Union Product
Database **5**

Union
Pharmacovigilance
Database **6**

Change
management **7**

Stakeholder views **8**

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

I am proud to announce the achievement of a major milestone for the programme — the release of the version of the Union Product Database (UPD) allowing competent authorities to start their submission of veterinary medicines legacy product data. This success reflects the hard work and collaboration of all stakeholders involved.

In this crucial phase, EMA will increase its support to national competent authorities in the timely upload of data via dedicated initiatives and assistance throughout the summer.

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

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.

However, this will not be the end of the journey: we will continue to further improve the systems to best support the Regulation. Considerations on the future governance and functionalities to be delivered beyond January 2022 will start after summer.

“ *The task of setting up the Union Product Database (UPD) is ambitious and we are very happy that the teams working on this big project delivered on time on this milestone. We should not forget that the UPD will only realise its true potential if it contains all the required information from the Member States. Now another big step of the process will need to begin following the preparations that we trust were ongoing in each Member State, and that is the timely provision of their information.*

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

Programme update

The latest release of the **Union Product Database (UPD)** went live on 27 July 2021. The system now allows national competent authorities (NCAs) to start submitting legacy data on veterinary medicinal products.

Over the past months, EMA supported the **mapping activities** of NCAs via dedicated webinars, troubleshooting session, and targeted mapping of substance and organisation data.

With the timely achievement of this latest milestone, EMA's efforts will refocus to provide **support to NCAs for their upload of legacy data** into the UPD. Weekly support sessions will be available to all NCAs, a coaching programme will accompany NCAs using the web user interface, and ongoing assistance will continue to be offered through the functional mailbox.

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

The **Collection of Antimicrobial Sales and Use data (ASU)** Project Group approved the preliminary business case and project vision, and is currently gathering the detailed requirements of the system.

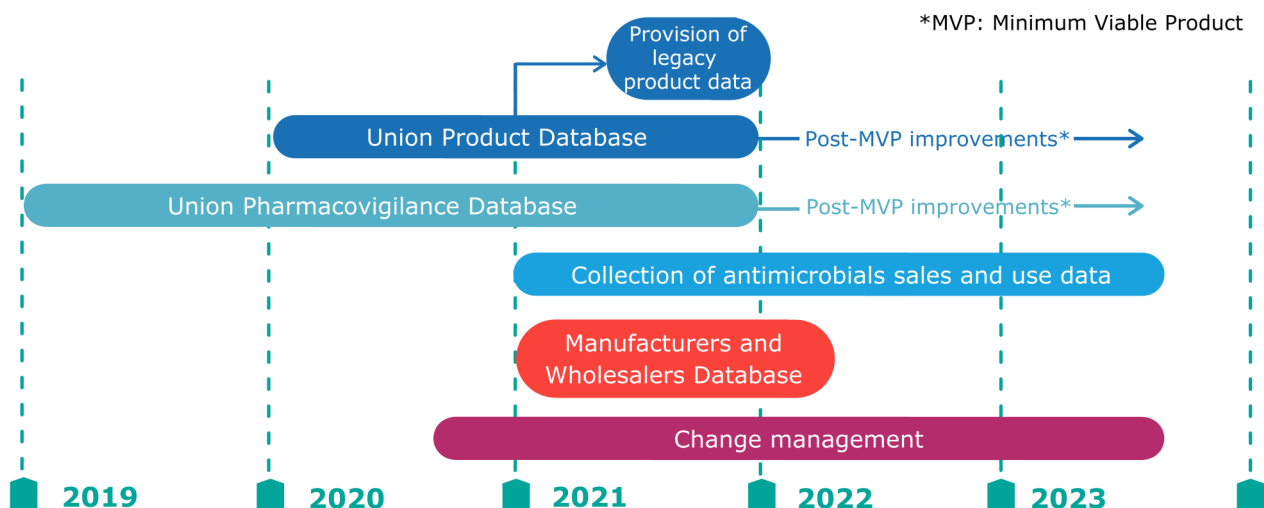
The project vision of the **Manufacturers and Wholesale Distributors database (MWD)** project was approved, and the Project Group finalised the detailed requirements needed to commence development.

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

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
- 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
- MVP:** Minimum Viable Product
- MWD:** Manufacturers and Wholesale Distributors database
- NCA:** National competent authority
- OMS:** Organisation Management Service
- UPD:** Union Product Database
- VICH format message:** future AER message format, as of 28 January 2022
- VMP-Reg:** Veterinary Medicinal Products Regulation

The **programme timeline** shown below provides an overview of the development of the four IT systems to be delivered.





This issue of the newsletter marks a significant milestone in the VMP-Reg programme, with just 6 months to go before the legal go-live date on 28 January 2022. It will be an exciting 6 months and will begin with the launch of the 3rd version of the UPD, followed by user acceptance testing.

The EMA and the NCAs have achieved a fantastic amount with the time and resources available, but of course there is still a tremendous amount to be done, including the upload of legacy data by the NCAs. The EMA has provided massive support to the NCAs, particularly on mapping and training, to make this European project a success story, and during the next 6 months training of MAHs will take place. It is encouraging to know that the UPD project plan until 28 January 2022 has been finalised and good progress has been made with the Union Pharmacovigilance Database.

Industry is still hoping for a light-touch approach to the process for variations not requiring assessment. There are still a lot of technical questions to be solved and complex processes to implement, and the work will continue after 28 January 2022 in order to implement improvements, such as to add signal management functionalities.

AnimalhealthEurope is very grateful to our colleagues participating in the array of joint working groups and stakeholder groups.

Rick Clayton, Technical Director, AnimalhealthEurope

Collection of Antimicrobials Sales and Use data

The Project Group of the Collection of Antimicrobial Sales and Use data (ASU) approved the preliminary **business case** and **project vision**.

The Project Group has started working on gathering **detailed requirements** via weekly analysis sessions. No separate Product Owners Group for the project will be created at this point in time.

The **final business case** will be submitted for approval in late October 2021. This will allow the system **development** to start in November.

The ASU **minimum viable product** (MVP) will be delivered by November 2022. Subsequent releases including additional reports will be made available by April 2023. The timeline will be further defined and elaborated in the final business case.

This **phased approach for development** will ensure functionalities enabling NCAs to fulfil their legislative obligations to submit relevant sales and use data in 2024 are prioritised. Additional non-MVP functionalities will be discussed and prioritised in collaboration with the Member States.

In order to be ready for their first data submission in 2024, NCAs will have to collect relevant data on antimicrobial sales and use for the **first applicable species groups in 2023**. To further support NCA preparedness, information on the formats and exchange mechanism will be provided as early as possible in 2022.

Additionally, EMA will make available user guidance and training materials as early as possible, to best facilitate data collection at national level.

Manufacturers and Wholesale Distributors database

Development of the Manufacturers and Wholesale Distributors database (MWD) project started on 1 July 2021.

The Project Group finalised the **detailed requirements** for the four modules of [EudraGMDP](#) which will be impacted by new legislative requirements arising from the VMP-Reg, i.e. Manufacturing/Importers Authorisations (MIA), Good Manufacturing Practice (GMP), Active Pharmaceutical Ingredients Registration (API-Reg), and Wholesale Distribution Authorisations (WDA). Requirements related to the Good Distribution Practice (GDP) module have also been defined.

The VMP-Reg Coordination Group adopted the Manufacturers and Wholesale Distributors database **project vision**.

For the four modules in the MVP scope described above, the project team shared the **updated documentation** needed by those NCAs which will use automatic (eXtended Mark-up Language - XML) upload of documents to adapt their national systems.

EMA organised a **technical meeting with NCAs** representatives on 14 July to discuss the changes

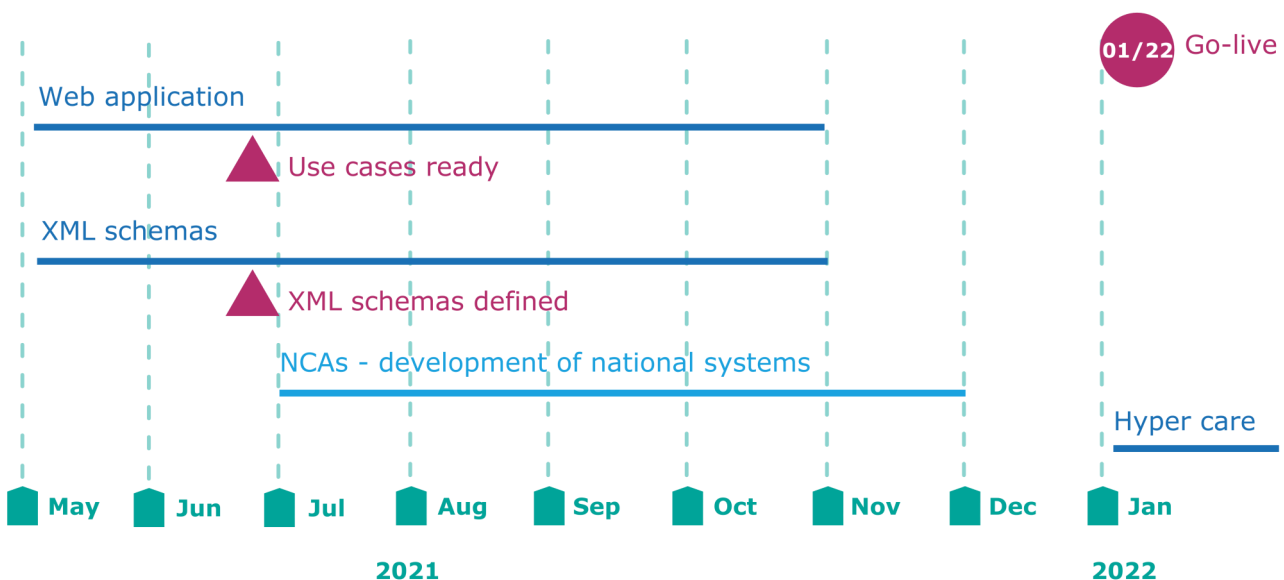
NCAs need to implement, the timeframe, and answer participants' questions and concerns.

End-to-end **testing** will start in September to ensure the system is ready for go-live in January 2022.

Additional improvements to the system identified during the project implementation fall outside the scope of the VMP-Reg programme, and would need to be submitted as change requests and prioritised by the maintenance governance under guidance of EMA's Human Medicines Division after January 2022.

Changes to **EudraGMDP** will impact NCAs in the veterinary and human medicines domains, both in the EU and for third-country authorities that have signed mutual recognition agreements with the EU. For this, the [GMP/GDP Inspectors Working Group](#) will play the role of Regulators' Change Liaison Network for the project, ensuring a two-way communication between NCAs and the project team to support the implementation activities at national level.

The project and its implications were discussed during several meetings of the GMP/GDP Inspectors Working Group.



Union Product Database

On 27 July, a new version of the Union Product Database (UPD) was released. This version allows 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 [release notes](#) contain all necessary information to register in the system and to use the available functionality for data submission via the Application Programming Interface (API) or the User Interface (UI).

EMA is supporting NCAs through weekly support sessions addressing practical questions and issues encountered while submitting data into the UPD. Additionally, the Agency is offering tailored coaching sessions for NCAs uploading data via the UI.

The [Vet EU Implementation Guide](#) Chapter 6 on **examples** and **overview of comments** received during the consultation were published. Chapter 6 provides NCAs with practical examples to support the preparations of their product data submission.

Revisions of Chapter 2 and Chapter 4 were also published, to provide further clarifications on questions received, and take account of minor technical changes arising from the current version of the FHIR standard.

As detailed in the [explanatory note](#) of the Veterinary EU Implementation Guide, the UPD will allow a **phased submission of data** for all products and will not enforce an 'all-or-reject' approach. This measure alleviates the challenges faced by the NCAs for the initial input of data on authorised veterinary medicinal products.

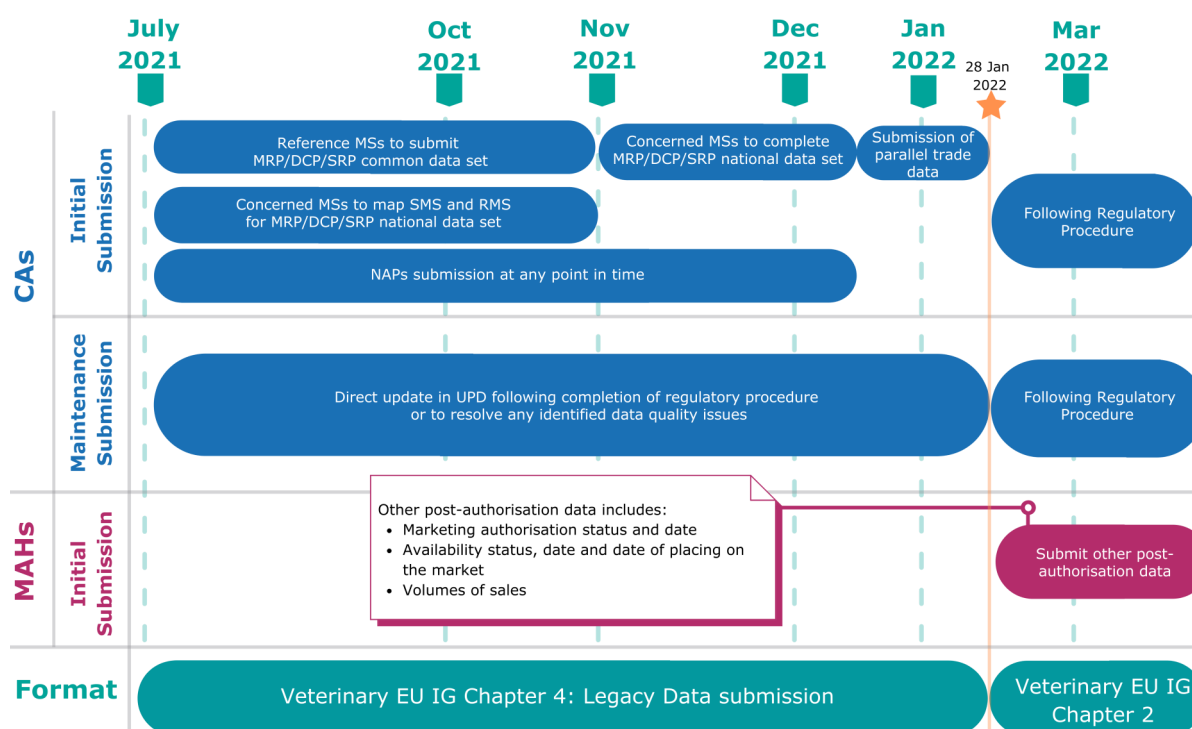
In case of a preliminary submission, NCAs will subsequently need to **enrich incomplete datasets** submitted by 28 January 2022.

The second round of usability testing of the **NCA user interface** was finalised.

The **end-to-end user acceptance testing** on the current release will start in September 2021. The activity will see the participation of volunteers from industry associations, NCAs using the UPD API or UI, and the project team.

Development of the UPD **public portal** and **user interface for marketing authorisation holders** is progressing.

Indicative timeline for submission of legacy data



Union Pharmacovigilance Database

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

EVWeb, the system user interface, was deployed in the **external compliance testing environment (XCOMP)**.

Work packages currently under development include:

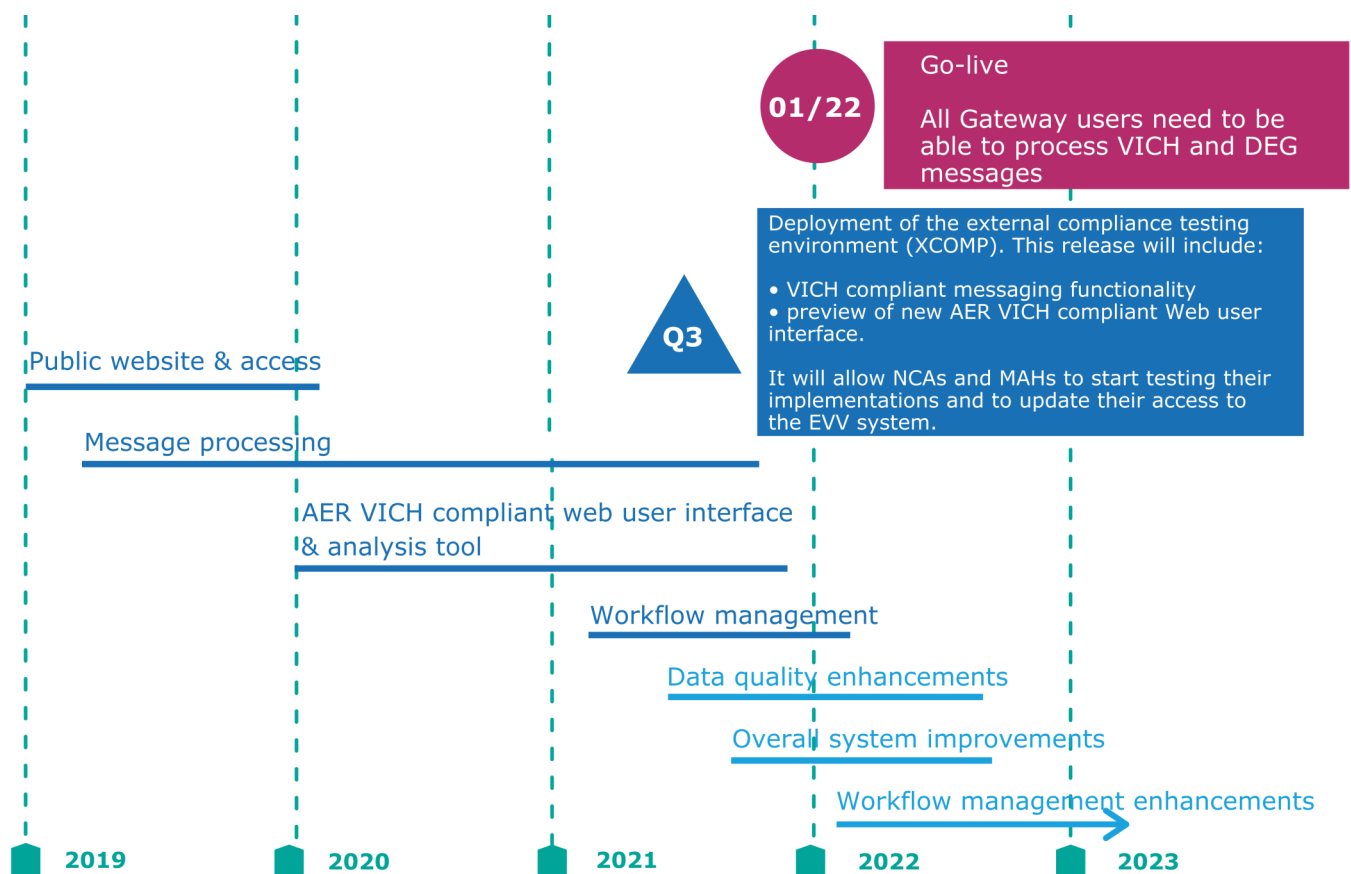
- further development of the functionality linking active ingredients and authorised veterinary medicinal products in adverse event reports received in EVV, key to **data quality**;
- continued work on the implementation of the restricted area;
- migration of legacy data to the new database and synchronisation with the data warehouse.

The analysis of the **signal management** requirements was finalised and an additional team started working on the development of this module. This is the last functionality required for the completion of the system minimum viable product before its go-live in January 2022.

The project team will soon begin to prepare the end-to-end **user acceptance testing**, which will start in early Q4 2021.

Following minor adjustments to facilitate optimal implementation of the system functionalities, the EVV **access policy** was presented during the June 2021 meeting of the EMA Management Board and subsequently published [on the EMA website](#).

The draft **EU AER VICH Implementation Guide** was [published](#) on 4 June 2021 for a 2-month public consultation. Comments should be provided by 4 August using this [template](#). The completed comments form should be sent to vetchange.programme@ema.europa.eu



Change management

The programme change management workstream progressed in close collaboration with the **Regulators' Change Liaison Network** (HMA TF CIVR).

EMA is **assisting NCAs in the preparations for uploading data** into the UPD via weekly support sessions addressing the practical issues encountered by NCAs during data submission. Additionally, the Agency supports NCAs using the UPD web user interface through tailored, 1-1 coaching sessions. A [Q&As document](#) on the upload of legacy data was published and will be regularly updated.

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.

The SPOR team continued to provide substantial support in mapping substance and organisation data for interested NCAs.

Changes to **EudraGMDP** arising from the implementation of the Manufacturers and Wholesale Distributors database project will impact NCAs in the veterinary and human medicines domains. Additionally, not only will they concern EU NCAs, but also third-country authorities that have signed mutual recognition agreements with the EU. For this, the [GMP/GDP Inspectors Working Group](#) took the role of Regulators' Change Liaison Network for the project, ensuring a two-way communication between NCAs and the project team to support the implementation activities at national level.

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

Recent activities:

- **1–2 June:** Veterinary Big Data stakeholder forum. Event summary, presentations, and video recording available on the [event page](#).
- **23 June:** joint EMA/FVE webinar for animal health professionals on the AMEG categorisation of antibiotics for use in animals and its implications for veterinarians. Event summary, presentations, and video recording available on the [event page](#).

Upcoming activities for NCAs:

- **Webinar on the usage of the API and NCA UI of UPD 01.03** – 4 August. The project team will demo the latest release of the system and its functionality to NCAs, to enable them to start data upload.
- **Follow-up session on best practices for legacy data upload into the UPD via the API** – 16 September. Content kindly developed by the **Austrian Agency for Health and Food Safety (AGES)** for the Network, in cooperation with the UPD team.

Upcoming activities for MAHs:

- **Introduction to the UPD** – 15 September. A session to show marketing authorisation holders available functionality of the system and answer participants' questions. Participants shall pre-register online via this [registration form](#).
- **Veterinary SMEs Info Day** – 28 October. The event will address the needs of micro, small and medium-sized enterprises (SMEs) in relation with the implementation of the VMP-Reg. The registration link will be made available soon.

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.

Stakeholder views

We have asked our stakeholders what key performance indicators would make them consider the VMP-Reg implementation fully accomplished.

Their contributions are reflected below, and show the diverse viewpoints and focus areas of our different stakeholders.

“The timely adoption of the remaining delegated and implementing acts, the establishment of the Union Product Database and the initial input of information into it, as well as the adaptation of processes will be crucial for all stakeholders to prepare effectively for the upcoming changes and ease the transition to the new legislative framework.

We should not forget though that the implementation of the VMP Regulation will continue beyond its date of application. The Commission will continue to work on a number of legal acts whose deadlines for adoption are up to 5 years after 2022.

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 E5, Animal nutrition, veterinary medicines, Directorate E, Food and feed safety, innovation, DG Health and Food Safety (SANTE), European Commission

“1. Increased product availability, in particular novel therapies, vaccines and products for limited markets.

2. Reduction in resource requirement in the network, as a whole, to address variation and pharmacovigilance activities, without a compensatory increase in regulatory inspections.

3. Continued reduction in AM use (in particular high priority CIAs [*critically important antimicrobials*]) in the Community, while ensuring the availability of effective antimicrobial medicines for the treatment of infectious diseases of animals.”

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

“1. Union Product Database populated and easy to search for veterinary practitioners.

2. New Pharmacovigilance system up and running with good reporting back functionality for veterinary practitioners.

3. A well working ‘new cascade’.

4. SPC revision/harmonisation.”

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

“It is not easy to identify performance indicators for the CMDv. The most important will be the percentage of the CMDv documents updated.

Then, but it is not possible to calculate it, the availability of the UPD functionality to handle procedures such as variations, and the update of the CTS database as an important tool for NCAs to handle marketing authorisation procedures.”

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

“1. Complete and quality data migration from national databases (national competent authorities) into the Union Product Database without any prior transposition of the administrative burden to the MAHs.

2. Fully operational Union databases allowing complete life-cycle management, including reporting VMPs data and post-marketing operations (VNRAs, pharmacovigilance operations) in its entirety and at one single point only.

3. Timely adaptations of current (EU or national) procedures and guidelines to the new requirements, to a smooth transition and that a pan-European and harmonized regulatory environment is put in place.”

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

“1. Secondary legislation: 12 items of secondary legislation need to be adopted and published by 27 January 2022.

2. Telematics: 3 new databases need to be functioning to allow all parties to comply with the legal requirements of the new legislation.

3. Stakeholder preparation: all stakeholders, both within the animal health sector (manufacturers, vets, wholesalers) and within the EU regulatory network, are prepared, and know what they have to do to comply with the new legislation and new procedures.”

Rick Clayton, Technical Director, AnimalhealthEurope

“The successful delivery of the required databases and IT systems is the primary performance indicator for a successfully accomplished VMP-Reg implementation. This includes the completion of data migration and mapping (second performance indicator) as well as the full implementation of all functions for all impacted stakeholders (third performance indicator). For the latter, trainings need to be made available to ensure that all functionalities are understood. Furthermore, a full implementation of the VMP regulation should also allow every NCA to reduce its administrative burden when working with the new IT systems and databases.”

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

“It is difficult to reduce the implementation to three indicators. I would stress the importance of:

- Databases delivery and the ability of NCAs to interact fluently and automatically with European databases (UPD, for example);
- Implementation of national regulation.”

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

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

An agency of the European Union

