

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 seventh edition of the newsletter for the implementation of the Veterinary Medicinal Products Regulation (VMP-Reg) programme.

In July, a new version of the Union Product Database allowing competent authorities to submit legacy product data for authorised veterinary medicines went live. Data submission began – I am pleased to see the tremendous efforts of national competent authorities in the activities related to data preparation and upload.

Supporting national competent authorities in their timely product data submission through a set of tailored activities is one of EMA's current priorities in the VMP-Reg programme.

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.

In the next two months, we will focus on:

- Delivering the minimum viable product on all systems that have to be launched by 28 January 2022

- Ensuring their technical robustness
- Training and providing guidance to future users.

We have seen a steady increase in the interest of stakeholders and citizens in our work. It is our joint responsibility to ensure they will benefit from what we will deliver.



The Federation of Veterinarians (FVE) is following every step of the process to get ready for the new Regulation 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**

Collection of Antimicrobials Sales and Use data

The Project Group for the **Collection of Antimicrobials Sales and Use data (ASU)** has been working on the **detailed requirements** of the systems via weekly sessions over the summer. We really appreciate the dedication and commitment of all Project Group members in this important phase.

The detailed requirements currently include considerations on:

- Submission of sales data
- Submission of animal population data
- Sales data reporting
- Use of reference data
- Submission of use data
- Use data reporting
- Amending previous submissions
- Recording supplementary information
- Reporting for general public

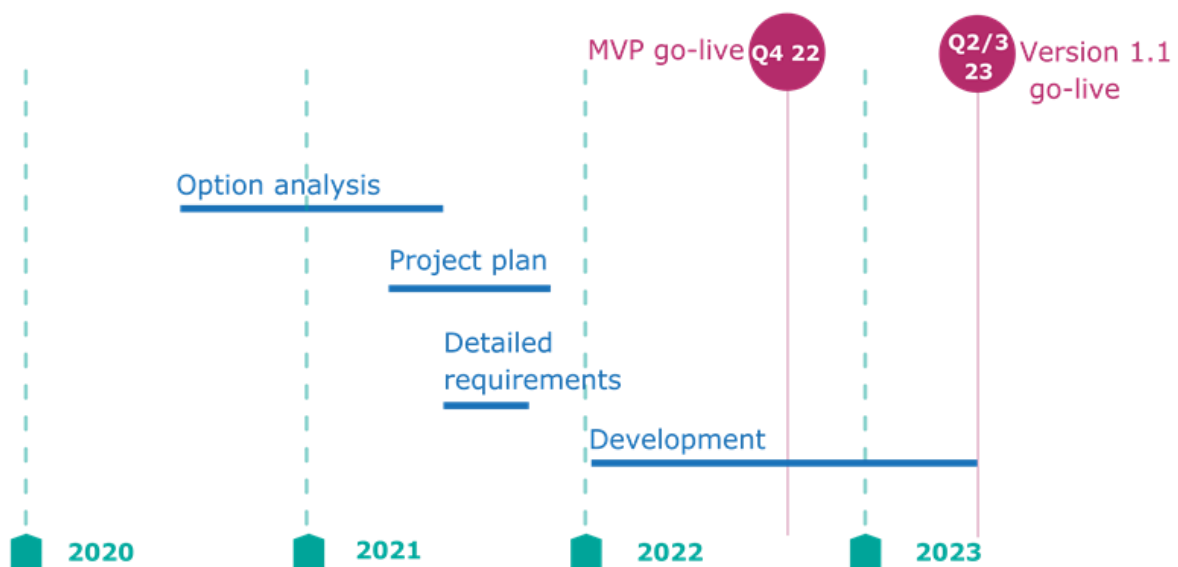
This detailed analysis and design phase will be the foundation to allow development of the solution to start in January 2022.

The **ASU Minimum Viable Product (MVP)** will be delivered by November 2022. **Subsequent releases** including additional reports will be made available by Q2 2023, according to the current draft timeline.

In 2023, national competent authorities (NCAs) will have to start **collecting the relevant data** on antimicrobial sales and use for the first applicable species groups for submission into the ASU in 2024. Ensuring the delivery of the ASU MVP by 2022 supports **timely preparedness** of NCAs.

Essential information for NCAs is available in the European Commission Delegated Act on requirements and will also be made available in the implementing act on formats, expected for adoption in early 2022.

EMA will also provide an **implementation guide** including information on the format and exchange mechanisms, as well as **user guidance and training materials** as soon as possible after the publication of the implementing act, in 2022.



Manufacturers and Wholesale Distributors database

Development of the Manufacturers and Wholesale Distributors database (MWD) project started on 1 July 2021 and is progressing according to plan. The first demonstration of the system under development to NCAs in September 2021 was received well.

EMA data stewards are working on the cleansing of EudraGMDP organisation data as part of the integration of the system with the Agency's [Organisation Management Service](#) (OMS).

The integration with OMS is the most notable change for NCAs and industry users. From 28 January 2022, users of EudraGMDP from national competent authorities will no longer introduce organisational data directly in the EudraGMDP system. Instead, they will choose the location of the manufacturers, importers or distributors (including sites or legal addresses) from the Agency's organisation dictionary. This change will ensure more reliable data in the EudraGMDP system through the consistent use of organisation master data, reduce the need for data entry and cleansing, and enhance interoperability across other EU IT systems and projects, e.g. the Union Product Database and the Clinical Trials Information System.

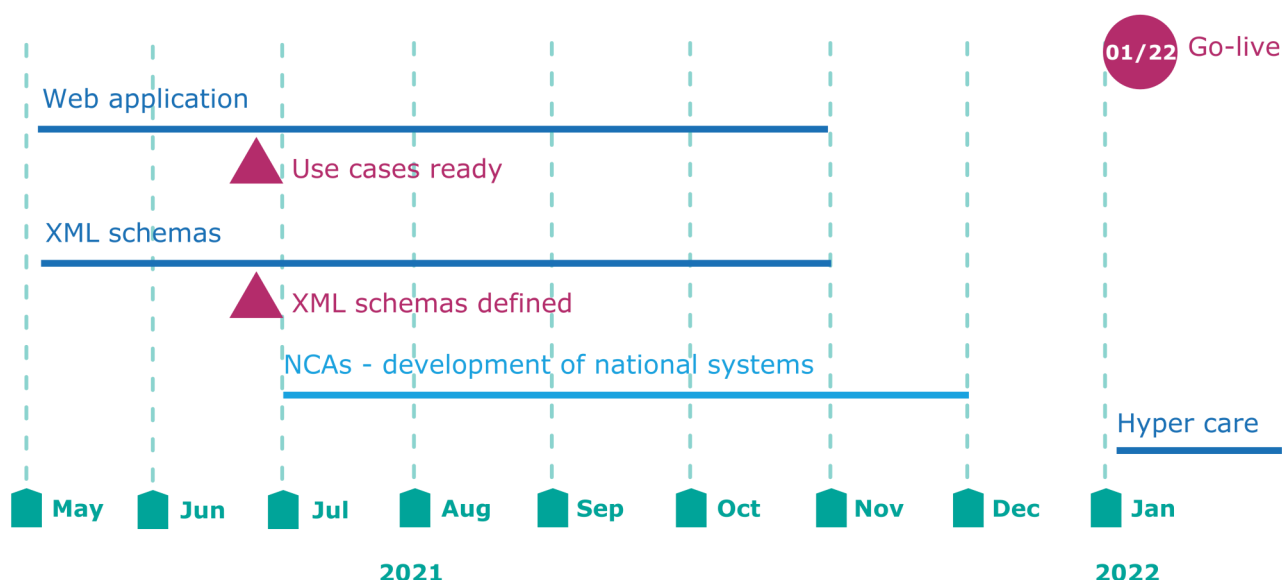
As of 28 January 2022, before applying for a new/updated manufacturing or wholesale distribution authorisation with national competent authorities, organisations need to verify that their relevant locations are correctly recorded in OMS.

Dedicated webinars on OMS services will be held respectively on 11 October 2021 ([NCA webinar - registration link](#)) and 12 October 2021 ([event page](#)), to support NCAs and industry preparedness.

The project progress is discussed during the meetings of the GMP/GDP Inspectors Working Group, which acts as 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 end-to-end user acceptance testing for NCAs that will use automatic (eXtended Mark-up Language - XML) upload of documents will start in October.

A training session on the integration of the GMP module with OMS for NCAs that will use the user interface will also be held in October.



Union Product Database

National competent authorities (NCAs) have started the **upload of legacy data** into the Union Product Database (UPD) after July's release.

EMA is providing NCAs training sessions, individual coaching sessions on the usage of the UPD NCA User Interface (UI), weekly support sessions to Application Programming Interface (API) and UI users, and troubleshooting sessions. Additionally, the Agency offered to complete the residual organisation mapping to assist the preparation of data for timely submission into the UPD.

EMA migrated all data related to **centrally authorised veterinary medicines** into the UPD.

The preparation for the release of the **next version** of the UPD is ongoing. Until the next milestone is reached, a new version will be deployed in the UAT and Production environments every three weeks, to progressively increase functionalities. After the next milestone is reached by deployment of all MVP functionalities in the production environment (expected in mid-November), the focus will shift to improving the system stability and resolving any remaining bugs.

The development of a **user interface** for marketing authorisation holders (MAHs) is also ongoing. Guidance for MAHs to **submit the data on the volume of sales** were published in September

2021. In the next month this guidance will be enriched and completed with information on other post-authorisation activities.

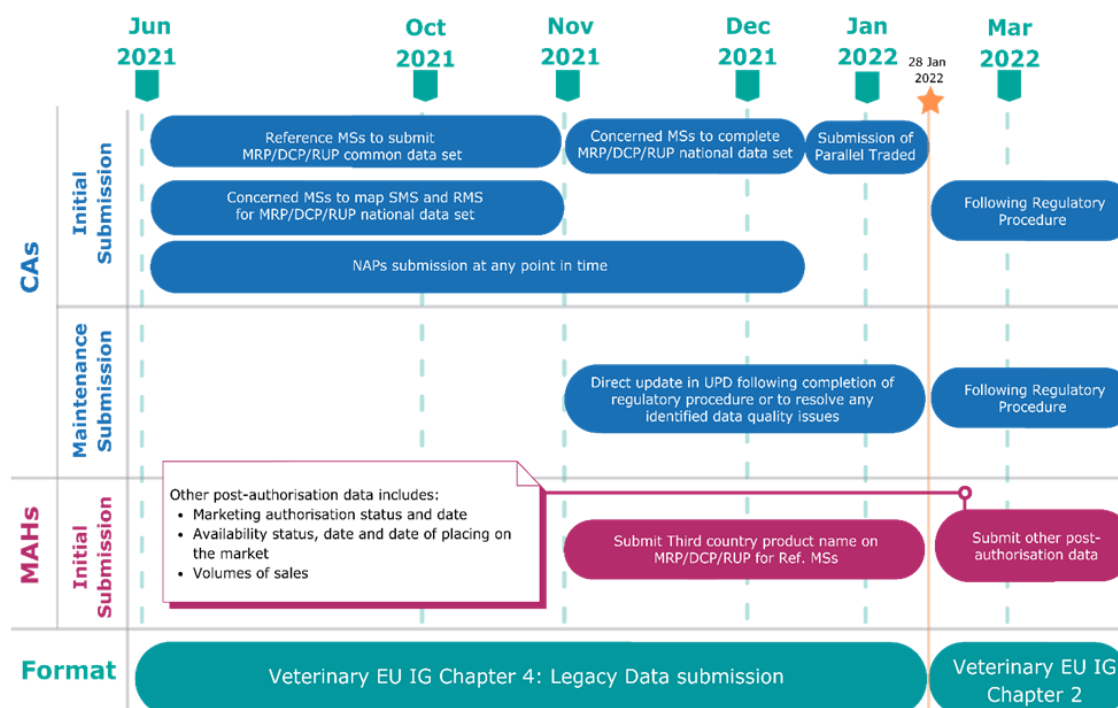
The functionality was demonstrated to industry during an **introductory webinar to the UPD** held on 15 September and attended by over 800 participants. The presentation, Q&As, and recording of the session are available on the [event page](#)

From November, the **UAT environment** will be made accessible to marketing authorisation holders. The **user acceptance testing** of the UPD will take place in October/November 2021 and will cover the great majority of the minimum viable product (MVP) functionalities. Volunteers from industry associations, NCAs using the UPD API and the UI, and the project team will participate. This UAT session will not include the UPD Public Website for which individual UAT sessions, involving representatives of the general public, are being planned.

After the finalisation of the analysis on the module on **variations not requiring assessment** in June, development started. The specific end-to-end user acceptance testing is scheduled for December.

Development of the **UPD public portal** is also progressing. The portal will be the go-to source for information on veterinary medicines, including availability in the EEA countries, for veterinary healthcare professionals and for all interested users.

Indicative timeline for submission of legacy data



Union Pharmacovigilance Database

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

The project team is revising the **EU AER VICH Implementation Guide** to address the comments received during the public consultation.

In September, the Project Group approved the final **requirements for pharmacovigilance inspection outcomes** and for **signal management**.

Development of the signal management and inspection outcomes modules has already started.

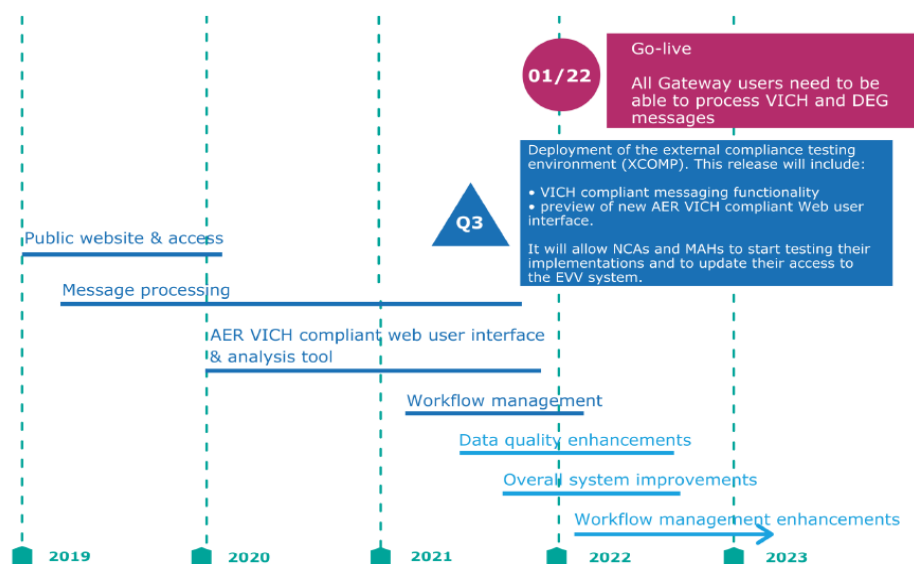
Work packages **currently under development** include:

- further development of the functionality linking active ingredients and authorised veterinary medicinal products to adverse event reports received in EVV, key to data quality;

- continued work on the implementation of the restricted area of EVWeb, the system user interface, and on an interim solution to support data quality;
- continued work on the integration of the data warehouse with the new database.

EMA published [two documents](#) containing respectively the field-by-field mapping from DEG to VICH standard, and the standard term lists mapping from DEG to VICH standard. These documents will help MAHs and NCAs to adapt their pharmacovigilance systems to support VICH messages by 28 January 2022 and should also support the development of the converter tool (see box).

The **test environment** will be made available to NCAs and MAHs from November 2021. Additionally, **training activities** for future users are scheduled from November onwards.



VICH format messages in EVV — action needed for NCAs and MAHs

NCAs and MAHs 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. Please see the highlight box on our [previous newsletter issue](#) (page 7).

From 28 January 2022 onwards, the following new business rules will apply to **DEG** format messages to ensure their compatibility with the VICH format:

- Species (DEG R.17.02 (species name)): Must exist in the VICH species list
- Breeds (DEG R.17.03.02 (breed name)): Must exist in the VICH breeds list
- AER ID (DEG R.05 (case number)): Must comply with VICH format (e.g. PRT-PRTDGVFV-...).

Change management

The programme change management activities currently focus on assisting NCAs in the **preparation and submission of legacy data into the UPD**.

Reference Member States have to enter the product common data by the end of October, to enable Concerned Member States to add their national data to the common data set by January.

EMA continues to provide weekly support sessions to NCA users who will submit data via the UPD API or the UI. A number of one on one coaching sessions have been offered to NCAs that will use the UPD user interface to submit their legacy data, or a part of the data. During these sessions, NCA experts create products in the UPD user acceptance testing and production environments, guided by the Agency's staff.

The SPOR team further increased its substantial support in **mapping substance and organisation data** for interested NCAs, and providing troubleshooting sessions to address NCAs challenges.

Change management activities at national level are led by the programme **Regulators' Change Liaison Network** (HMA TF CIVR), which ensures a two-way communication between NCAs and the programme to support the implementation activities within the impacted NCAs.

As changes to EudraGMDP arising from the implementation of the Manufacturers and Wholesale Distributors database project will impact NCAs in both the veterinary and human domains, the **GMP/GDP Inspectors Working Group** took the role of Regulators' Change Liaison Network for the project.

Activities to support **industry users** have started and will increase in the next months, in line with the IT systems development – see 'Upcoming activities'.

Four months ahead of January 2022, the volume of queries sent to the functional mailbox vetchange.programme@ema.europa.eu keeps increasing. NCAs, industry, veterinarians and all interested stakeholders are welcome to email their questions and requests for clarification.

Recent activities:

- **16 September:** Usage of the UPD API – Second session. Content kindly developed by AGES (AT) for the Network, in collaboration with the UPD team. Recording and materials available to NCA staff on the EU NTC.
- **15 September:** UPD webinar for marketing authorisation holders. The UPD team demoed how to view and search data, and how to submit data on the volume of sales into the system. The presentation, Q&As, and recording of the session are available on the [event page](#).
- **4 August:** webinar on the usage of the API and NCA UI of UPD 01.03. Recording available to NCA staff on EU NTC.

Upcoming activities:

- **11 October:** webinar for NCAs on the integration of EudraGMDP and OMS. [Registration link](#)
- **12 October:** webinar for industry (manufacturers, importers and distributors of human and veterinary medicinal products and active substances) on the integration of EudraGMDP and OMS. [Event page](#)
- **21 October:** webinar for industry - Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities. [Event page](#)
- **28 October:** Veterinary SME Info Day. The event will address the needs of micro, small and medium-sized enterprises in relation with the implementation of the VMP-Reg. Registration by invitation, broadcasting available. [Event page](#)
- **10 November:** Adverse event collection and recording – webinar for NCAs and MAHs. Registration in October
- **24 November:** webinar for veterinary healthcare professionals on data collection on sales and use of antimicrobials

NCAs views

Following the release of the Union Product Database enabling NCAs to submit legacy data, we have asked NCAs to provide a status update.

Progress and constraints vary at national level, but their voices show the engagement and efforts to meet the deadline.

"The RMS terms are being cleansed and mapped and our database is going to be developed to fit the UPDs data structure. All the Hungarian Organisations are cleansed and matched with SPOR ORG and LOC IDs."

Directorate of Veterinary Medicinal Products (HU)

"We are getting ready to release the first part of the extension to our IT systems to support the use of UPD."

Danish Medicines Agency (DK)

"We are continuing data mapping and data improving as well as adjusting our national database to the EU Vet IG."

National Authority for Animal Health (PT)

"We are still testing in the UAT environment. We have found some issues and reported those to EMA. We expect to send data of products we are the RMS for in October."

Spanish Agency for Medicines and Health Products (ES)

"RMS products data preparation (enriched and transformed) is 90% ready for the API upload. On the API client program development, we have successfully uploaded tested data and documents to UAT 1.4.1."

Health Products Regulatory Authority (IE)

"We are currently finishing up SPOR mapping and data mapping and our IT experts are working on the implementation of data submission through the API directly from our database. No legacy data has been uploaded yet from our system."

Institute for State Control of Veterinary Biologicals and Medicines (CZ)

"Currently our main focus is the upload of the 40 RMS files in the UPD before November. We have set up a connection with the UPD application in the UAT environment. On 7th September, we managed our first successful upload of a small dataset into the UPD. The next step will be the upload of a full data package."

Federal Agency for Medicines and Health Products (BE)

"We have planned database structure changes in our national register to be compatible with UPD. The changes will be implemented soon."

Finnish Medicines Agency (FI)

"We have started to enter legacy data (manually via UPD UI). For the time being we successfully entered only few of our NAPs, but we are working together with the UPD team to overcome technical obstacles, and we are sure we will successfully enter all the needed data into UPD."

Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (SI)

"Work is in progress to submit data into the UPD, particularly with regard to mapping our data against SPOR data and with the preparations to select and deliver legacy data in FHIR format."

Healthcare Inspectorate (NL)

"We are adapting our solution and data structure to meet the latest requirements for UPD and to accommodate for UPD IDs in our internal medicinal product database. We will start the upload when some of the known issues are resolved by EMA."

Medical Products Agency (SE)

"Preparations for the implementation of the UPD API are nearing completion. Analysis and development work is scheduled to begin in October."

State Agency of Medicines (EE)

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

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

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