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Veterinary Medicinal Products Regulation

HIGHLIGHTS

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

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INSIDE THIS ISSUE

Welcome to the 8th edition of the newsletter for the implementation of the Veterinary Medicinal Products Regulation (VMP-Reg) programme.

With only nine more weeks before the VMP-Reg becomes applicable and the related IT systems go live, national competent authorities and agency staff are collaborating to realise the upload of all legacy product data into the Union Product Database.

After the data submission started, challenges linked to the upload of large data sets were identified and are being addressed as matter of top priority for EMA and the network.

In parallel, activities to raise awareness and prepare all future users of the systems under development intensified. In this context, the Agency organised training activities for marketing authorisation holders and national competent authorities, webinars for animal health practitioners, and a second Info Day for industry in 2021.

The systems released in January will be further improved over the next years to best support all impacted stakeholders. The programme is defining the future governance that will prioritise the functionalities to be delivered after January 2022. The mandate and composition of the future governance group will soon be formalised.

The Agency will continue to provide dedicated support to all future users of the systems, to facilitate a smooth technical and business implementation.

Collection of Antimicrobials Sales and Use data

On 13 December, EMA and the Collection of Antimicrobials Sales and Use data (ASU) Project Group will **introduce the project** to the members of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) network. This will be the first of a series of meetings to update NCAs on the project progress and prepare them for the data submission. In 2023, they will have to start collecting the relevant data on antimicrobial sales and use for the first applicable species groups for submission into ASU in 2024. Essential information for NCAs is available in the European Commission Delegated Act on requirements; the implementing act on formats is expected for adoption in early 2022.

The **business case** for the ASU project was finalised and approved in November 2021. **Development** is expected to start in early 2022.

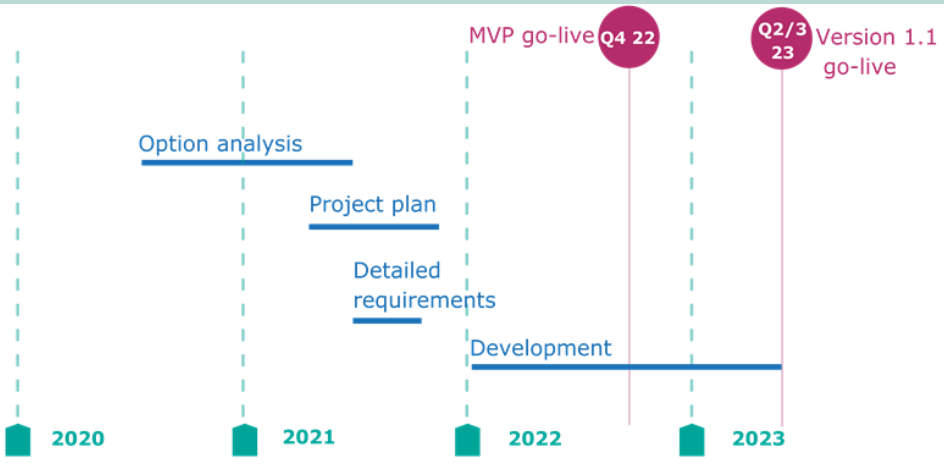
Upcoming activities include defining the approach to handle reference lists, finalise data mapping between ASU and the Union Product Database (UPD), and refining the use cases.

The ASU submission component and use data reports will be delivered in Q4 2022. A subsequent release including the sales data reports on the new platform will be made available in Q2 2023.

EMA will publish an **implementation guide** including information on the format and exchange mechanisms in Q2 2022. The Agency will also provide **user guidance and training materials** in Q4 2022.

Discussions have started on how to transition the current **ESVAC project** into the future IT governance structure that will support continuous improvement of the VMP-Reg IT systems.

> *The Project Group for the Collection of Antimicrobials Sales and Use data (ASU), with representatives from Member States competent authorities, has reviewed and prioritised the detailed requirements of the system which were signed off and approved by the project group at the end of October. The project is now ready to move on to the development phase and is on track to deliver the Minimum Viable Product (MVP) by end of 2022. The MVP will include the data submission components both for sales and use data reporting for the first applicable species and the analytical reports for use data. Subsequent releases will include additional analytical reports and other functionalities and will be made available by Q2 2023. This timeline will allow the delivery of the system to allow the submission, by Member States, of the 2023 data on the volume of sales and on the use of antimicrobial medicinal products which will take place by June 2024 and September 2024, respectively. To further support NCA preparedness, the Agency will develop a training programme including user manuals and an implementation guide, with detailed information on data format and reporting mechanisms as early as possible in 2022, taking into account the final requirements on data format contained in the Implemented Regulation to be published by the EC at the end of January 2022.*
>
> **Ana Vidal, EMA — Chair of ASU Project Group**



Manufacturers and Wholesale Distributors database

Development of the **Manufacturers and Wholesale Distributors database (MWD)** project is progressing according to plan.

Development of the Manufacturing and Importation Authorisation (MIA) and Registration of Active Substance manufacturers, Importers and Distributors (API-Reg) modules was completed, and the development team started working on the Wholesale Distribution Authorisation (WDA) module. **Changes to the GDP module** will be delivered in a post go-live release scheduled for Q1 2022.

Several NCAs that will use automatic upload of documents participated in a **preliminary user acceptance testing** (UAT) of the Good Manufacturing Practice (GMP) module. The team will work on the findings to implement needed fixes before the start of the UAT. The formal UAT for the GMP, MIA and API-Reg modules is planned for December.

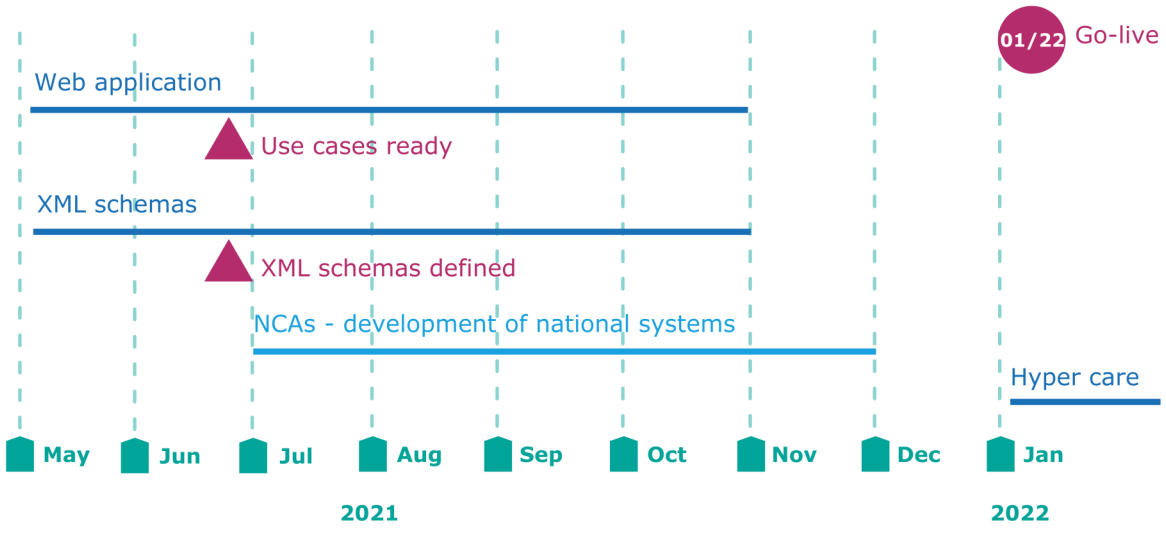
EMA continues to work on the **cleansing of EudraGMDP organisation data** as part of the integration of the EudraGMDP system with the Agency's Organisation Management Service (OMS).

After 28 January, all organisations in **EudraGMDP** – including EU and non-EU manufacturers, importers and distributors of human and veterinary medicinal products and active substances – must be registered in OMS.

As of 28 January 2022, before applying for a new/ updated manufacturing or wholesale distribution authorisation with national competent authorities, organisation have to check whether their **data is correctly registered in OMS**.

Dedicated **webinars** on OMS services and the **impact of the integration of EudraGMDP with OMS** were held respectively on 11 October 2021 (for NCAs) and 12 October 2021 (for industry), to support NCAs and industry preparedness. The recordings, presentations, and Q&As for industry users are available on the event webpage. Refresher sessions will be scheduled for January 2022.

> *The Manufacturers and Wholesale Distributors database Project Group was established in March 2021 with the nomination of experts from EU Member States national competent authorities. Very quickly, the Project Group started working and finalised the detailed requirements for the modules of EudraGMDP which will be updated, allowing development to start in July.*
>
> *The commitment and engagement of the Project Group members has been exceptional, especially in light of the tight timeline before go-live of the system in January 2022. The Group is now looking forward to participating in the user acceptance testing in December, to ensure the enhanced system to be released in January will be as robust as possible.*
>
> **Jana Schalansky, EMA — Chair of MWD Project Group**



Union Product Database

National competent authorities (NCAs) are progressing with the **upload of legacy data** into the Union Product Database (UPD), which currently amounts to over 2,500 product entries.

To support NCAs in their upload, a new version of the system is deployed every three weeks, progressively improving and increasing functionalities. The **most recent release** was launched on 29 October (see the release notes).

The **user acceptance testing** (UAT) was completed in November, thanks to the participation of volunteers from industry associations, NCAs using the UPD API and the UI, and the project team. It covered the majority of the minimum viable product (MVP) functionalities.

This UAT session did not include the UPD Public Portal for which individual UAT sessions, involving representatives of the general public, are being planned. The end-to-end user acceptance testing of the module on **variations not requiring assessment** is scheduled for December.

EMA continues to provide NCA 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 offers to perform residual organisation and substances mapping to assist NCAs in the preparation of their legacy data for timely submission into the UPD.

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

> *It has been an honour to co-chair the Union Product Database Project Group (UPD PG) together with Paule Carnat-Gautier from the French national agency for veterinary medicinal products (ANSES-ANMV).*

At the project level this group provides strategic steering to the development of the UPD. The task itself was huge, even relying on existing technology and systems, as we agreed to do very early on.

The members of the UPD PG were nominated by the national competent authorities and the Agency as the body charged with developing the system. All members are hugely experienced with IT development or the underlying business processes, and most had previously contributed to the Agency's advice regarding Commission Implementing Regulation (EU) 2021/16, on the elements that should be part of such a system.

Tremendously committed, the group dedicated itself to overseeing the development of the system, always making time to contribute, even at short notice. Not always agreeing how processes should run to be efficient while enabling necessary connections and oversight at the outset, we found ways forward, and so far the development milestones have been met.

We are now supporting the work to address the difficulties that come with new systems and are looking forward to seeing the UPD in action next year.

Barbara Freischem, EMA — Co-Chair of UPD project Group

Union Pharmacovigilance Database

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

In November, the Project Group finalised and published the **EU AER VICH Implementation Guide** following the public consultation.

The team completed the data migration to EVWeb, executed the second deployment to production, and continued the work on stabilising the system.

In the next weeks, the team will **focus on**:

- further stabilising the system
- end-to-end user acceptance testing
- preparing for the go-live in January 2022
- analysis of duplicate management (post-MVP functionality).

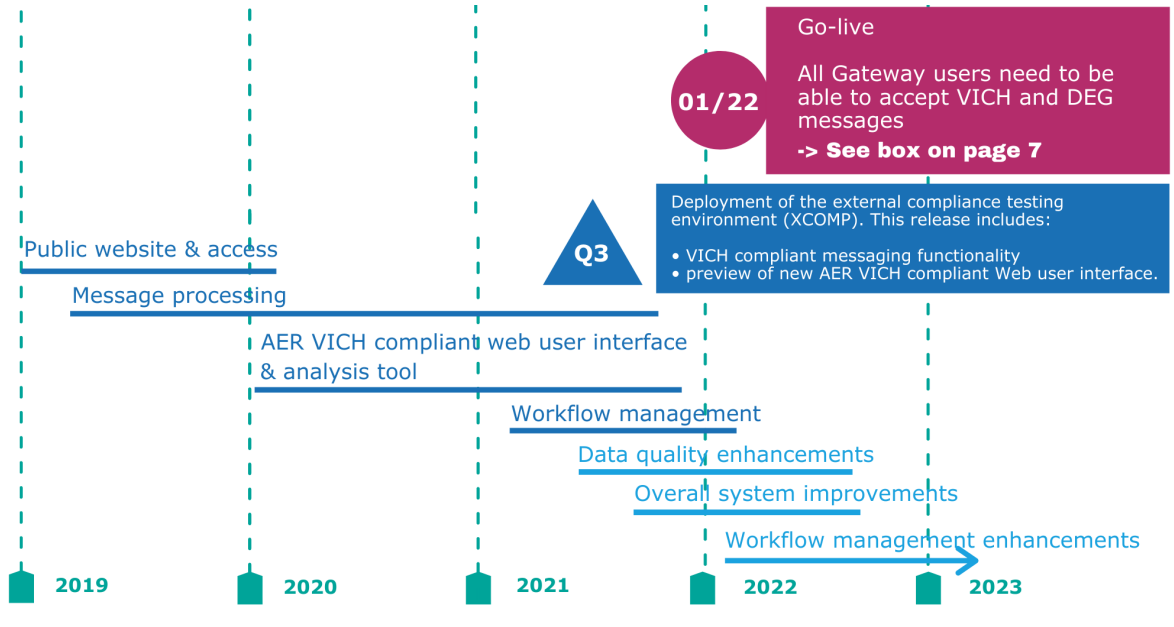
Access was given to several NCAs and MAHs to **test their gateway implementation**. Increased access for testing is being considered after the user acceptance testing is completed.

Training activities for NCA and industry users started in November (see change management on page 6 for additional information).

The availability of accurate product data in the Union Product Database by January 2022 is crucial to enable effective signal detection and management via EVV. After NCAs upload products into the UPD, 2-3 months will be needed for the recoding of the AER reports against UPD products, which is needed to carry out **signal management activities**.

The new version of EudraVigilance Veterinary (EVVet3), consisting of EVWeb for recording and reporting of adverse events and the data warehouse for data analysis, is eagerly awaited by regulatory authorities and marketing authorisation holders alike. With this new version, not only will we fulfil legal obligations as stated in the Regulation (EU) 2019/6, but also put ourselves in a position to be able to access, analyse and assess the largest dataset of adverse event reports related to veterinary medicinal products in Europe. Over the past two years EMA has, together with Member States and industry representatives, put a considerate amount of work into setting up a system that is comprehensive and user friendly. It has to be highlighted that milestones such as compliance with the VICH standard for reporting and recording of adverse events as well as the setup of queries and dashboards for the signal management data analysis have been reached. Nevertheless, work will continue after the go-live in January to allow for continuing improvement of the system as it is being used.

Kathrin Schirmann, BVL (DE), Co-Chair EVV Project Group



Change management

The programme change management workstream currently focuses on supporting NCA in the timely **submission of legacy data** and on preparing the future users of the systems going live in January 2022 via training and assistance.

EMA continues to provide **weekly support sessions** to NCA users who will submit data via the UPD API or the UI, as well as one on one **coaching sessions** on the use the UPD user interface. EMA's SPOR team continues to **map residual substance and organisation data** upon NCAs request.

The results of the joint efforts of the programme Regulators' Change Liaison Network (HMA TF CIVR) are concrete: over 2,500 records have been uploaded in the UPD Production environment.

Q&As for industry on the UPD will be shortly published on EMA's website, and Q&As for EVV are under development.

The **training sessions** dedicated to industry users registered several hundred participants each. The questions raised during the events and the respective answers are made available in the events webpage.

The **functional mailbox** **vetchange.programme@ema.europa.eu** remains at the disposal of NCAs, industry, veterinarians and all interested stakeholders to email their questions and requests for clarification.

Upcoming activities:

- **8 December:** Webinar for NCAs and MAS on pharmacovigilance inspections, system, its integral quality management system and the pharmacovigilance system master file. Registration here
- **13 December:** ASU – Webinar for NCAs to introduce the project
- **13 January 2022:** EVV – Webinar for NCAs and MAHs on adverse event collection and recording (advanced)
- **18-19 January 2022:** EVV – Webinar for NCAs and MAHs on signal management (advanced).

Recent activities:

- **11 October:** MWD – Webinar for NCAs on the integration of EudraGMDP and OMS*
- **12 October:** MWD – Webinar for industry on the integration of EudraGMDP and OMS**
- **21 October:** Webinar for industry - Introduction to Organisation Management Service (OMS) / Referentials Management Service (RMS) services and activities**
- **28 October:** Info Day for veterinary SMEs**
- **8 November:** UPD – Webinar for NCAs on translations of RMS list terms*
- **10 November:** EVV – Webinar for NCAs and MAHs on adverse event collection and recording (principles)**
- **23-24 November:** EVV – Webinar for NCAs and MAHs on signal management**
- **24 November:** EVV – Webinar for veterinary healthcare professionals on data collection on sales and use of antimicrobials**
- **30 November:** Veterinary Medicines Info Day**

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

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

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

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

Therefore, national competent authorities (NCAs) and marketing authorisation holders (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 send and receive VICH format messages.

In addition, from 28 January 2022 onwards, the following **new business rules** must be applied to **DEG** format messages to ensure their compatibility with the conversion to 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

The following new business rule should also be applied to **DEG** format messages as soon as possible:

- AER ID (DEG R.05 (case number)): Must comply with VICH format (e.g. PRT-PRTDGVFV-…).
  Note: non-compliance will not generate an error message or submission failure.

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)
EMA: European Medicines Agency
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
UAT: user acceptance testing
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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