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Veterinary Medicines Regulation
HIGHLIGHTS

News, views and interviews for the Veterinary Medicines Regulation.
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Editorial

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**Head of Veterinary
Medicines Division, EMA**

Welcome to the second edition of the newsletter for the Implementation of the Veterinary Medicines Regulation (VMP-Reg) programme.

Over the summer and early autumn, the programme and active projects have progressed on schedule in their delivery activities, including the go-live of an initial release of the data repository and application programming interface of the Union Product Database (UPD).

We have driven forward the discussions surrounding the detailed project planning for the UPD and EVVet3 to ensure a successful implementation of the legislative requirements within the short timeframe available. This has resulted in prioritisation discussions in both projects to determine the functionalities of the initial releases, and which functionalities would be added as system improvements after January 2022. You can find more information on the project pages.

Considerable progress has also been made in the change management workstream, with the

launch of the Regulators Change Liaison Network and the recruitment of our programme change manager.

I am also pleased to see the rising interest in our activities, measured in the subscriptions to this newsletter. We will continue to provide regular updates in this format over the next year.

> " *The establishment of the Union Product Database, as well as the Pharmacovigilance database would be paramount for the daily work of businesses, competent authorities, but also for European citizens.*
>
> **Eva Maria Zamora-Escribano, Head of Unit Animal nutrition, veterinary medicines, European Commission**

Programme update

Over the last few months, the VMP-Reg programme has focussed on pre-inception activities for any additional projects required for implementing the legislative requirements arising for IT systems laid down in Regulation (EU) 2019/6. More information on this is provided on the next page.

By providing easy access to data related to veterinary medicines, including their availability, safety, as well as sales and use of antimicrobials in the EU, the IT systems delivered under the VMP-Reg will increase transparency for the benefit of every European citizen.

These additional systems will be developed in alignment with guiding principles for the programme introduced in the previous edition of this newsletter.

- Where possible, feasible, and in line with the required functionalities, the new systems will be developed using already existing system components or system components currently under development in the EU Telematics network.

- The new IT systems will be developed avoiding duplication of data entry across systems within the programme scope to ensure that there is a single source for each type of information.

- A phased approach for development is applied in order to prioritise functionalities that enable legislative compliance first; and thereafter, prioritisation of additional improvements shall be considered in collaboration with the Member States and stakeholders.
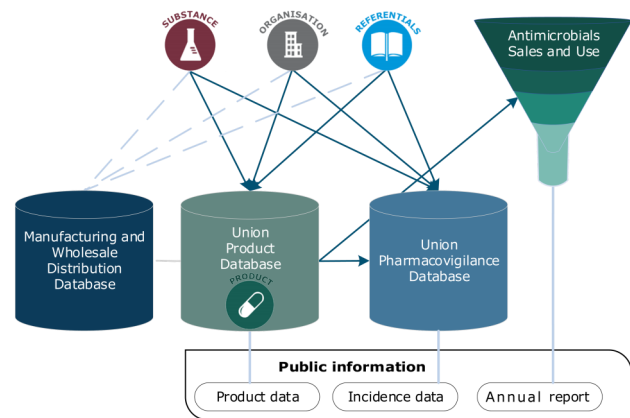
The **VMP-Reg Stakeholders meeting** held on 25 September 2020 provided a platform to exchange views with veterinary pharmaceutical industry, veterinary healthcare professionals and national competent authorities on programme, projects and change management activities. At the meeting, the objective of reducing administrative burden for all stakeholders was reiterated as instrumental to driving the design of the future IT solutions. The importance of appropriate transitional arrangements in the move to the VMP-Reg was highlighted.

For the change management workstream, in light of the extensive number and variety of changes that all stakeholders will face in a relatively short timeframe, the Agency was encouraged to consider offering tailored training and information to diverse stakeholder groups to facilitate the transitions.

The potential exists for an overall positive impact, provided that the Regulation is implemented in line with the initial objectives and on the basis of good dialogue and exchange with stakeholders.

Rick Clayton, Technical Director at AnimalhealthEurope; and Elsa Vecino, Technical Director at European Group for Generic Veterinary Products (EGGVP)

Collection of antimicrobials sales and use data

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 in animals. Member States will collate and send the data to the Agency. The Agency is tasked to analyse those data and publish an annual report.

This system will be an important tool supporting the Regulation's objective to reduce the risks linked to antimicrobial resistance in the EU.

More detailed requirements on the format for the data to be submitted and the method of transfer of those data to the Agency are arising from the development of associated implementing/delegated acts, which are currently being drafted.

The initial outline of the requirements can be derived from the associated advices that the Agency prepared in collaboration with the Member States. However, the delegated act on requirements and the implementing act on formats are only expected for adoption for late January 2021 and January 2022, respectively.

The project to implement the collection system is being initiated and will contribute to the achievement of the benefits of the VMP-Reg by:

- Implementing an environment for the Member States to submit **defined variables for sales and use** of antimicrobials used in animals in a standardised template

- **Reinforcing data quality and prevent duplicate entry** of similar information in distinct IT solutions associated with the VMP-Reg by using the product data from the UPD in the template

- Providing functionality to perform **data analytics**, as well as making data available in a public interactive database to support analytical activities outside the remit of the VMP-Reg.

The system will be developed leveraging existing capabilities for collecting data on antimicrobial sales in the context of the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project, as much as feasible.

> " *Our members expect more emphasis on responsible use of antimicrobials while keeping the possibility for veterinarians to treat animals with antibiotics when needed, without increasing administrative burden.*
>
> *The veterinary profession works hard to fight AMR, reducing so far the overall sales of antimicrobials for animals by 32%. While staying committed to further promoting prudent and responsible use, it is also important to ensure veterinarians will keep being able to treat bacterial infections in animals.*
>
> **Nancy de Briyne, Deputy Director of the Federation of Veterinarians of Europe (FVE)**

Union Database on Manufacturers and Wholesale Distributors

Regulation (EU) 2019/6 also calls for the establishment of a Union Database on Manufacturing and Wholesale Distribution, which will include information regarding the granting, suspension or revocation by Competent Authorities of any manufacturing authorisation, wholesale distribution authorisation, certificates of good manufacturing practice, and registration of manufacturers, importers and distributors of active substances.

An analysis of the existing EudraGMDP database is ongoing to identify any gaps arising from the legislative requirements detailed in the VMP-Reg, and any required amendments of the system will be initiated in 2021.

Union Product Database

Development of the UPD started in January 2020. The high-level architecture of the database system to be delivered has been defined in collaboration with the project governance, and a **Product Owners group** with representation from some Member States competent authorities was established for the definition of detailed requirements of ongoing work packages. The components below are currently being developed:

- The **data repository** and **application programming interface**

- The **access management** component

- The **user interface** for the management of product data.

The next work packages to be initiated will focus on the management of variations not requiring assessment and 'other post-authorisation changes' to data contained within the UPD. As these work packages have impacts on veterinary pharmaceutical industry, the Product Owners group will now be extended to ensure adequate representation of the views of all impacted stakeholder groups. In addition, a workshop with participants from pharmaceutical industry was held on 15 October 2020 to gather initial high-level requirements on 'other post-authorisation data'.

The UPD project vision has been finalised and now guides the programme and project governance in their decision-making.

The UPD access policy has been drafted and defines the overall principles for providing access

Go-live of initial release of UPD data repository and API

On 24 September, the first components of the UPD, i.e. the UPD Repository and Application Programming Interface (API), were made available (see release notes). These components enable national competent authorities to connect their IT systems to the UPD to gain access to information on centrally authorised products. The functionality made available at this point is limited to reading centrally authorised veterinary medicinal product information and automatically creating product information from veterinary medicines authorised via the national, decentralised and mutual recognition procedures. More components and functionality will gradually be added until the complete system goes live on 28 January 2022.

to veterinary medicinal product information held in the UPD in line with the EU legislative framework, considering that the interest in and the use of the data may vary between stakeholders. The document underwent a public consultation over the summer and is scheduled to be adopted at the December meeting of the EMA Management Board.

The project is currently undertaking user research via surveys and interviews to ensure that the public UPD portal provides the required information and is easy to use.

The **timeline below** shows the components or functionalities that will be launched in late 2021. In the future, additional improvements to the system — such as the ones listed below — will be routinely identified by and agreed in collaboration with all impacted stakeholders.
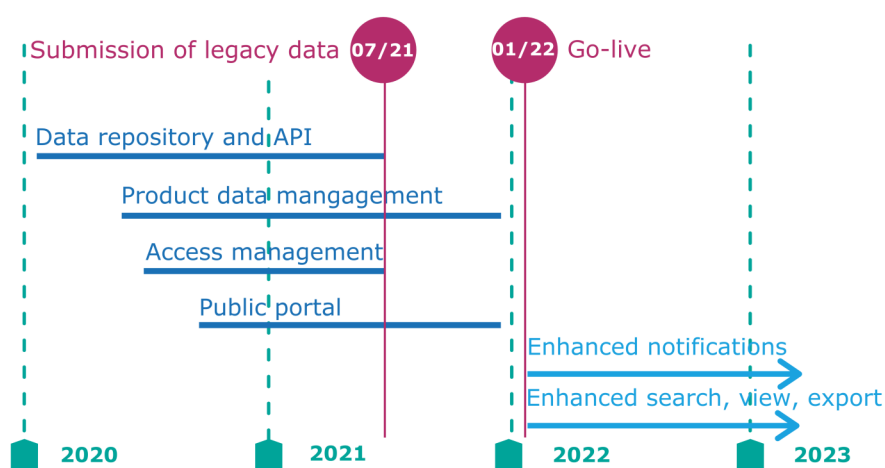
Union Pharmacovigilance Database

Development on the Union Pharmacovigilance Database has been ongoing since 2019. **Phase 1** of the implementation was completed in early 2020 and included:

- **Integration of existing EVVet2 system with Identity and Access Management module** of the Agency, which allows the organisation to directly manage the access of their affiliated users

- **Integration of the messaging platform with the existing ADR human platform**, initially only for the DEG standard; this component is now operational

- **Launch of www.adrreports.eu,** which integrates information on adverse events reported for centrally authorised veterinary medicines (see feature in first newsletter).

In 2020 the delivery methodology was aligned with the programme, and a Product Owners group with representation from Member States competent authorities was established to review and prioritise the detailed requirements of the existing design.

Work packages for the system under development in 2020 include:

- Continuation of the development of the messaging platform to also process **VICH compliant messages**

- Development of **EVWEB component**, which will provide a web user interface

Signal management

The signal management process is part of the workflow management that will deliver basic legislative requirements in the first release, and will be improved after the initial launch within the upgraded EVVet3 system in late 2021. The detailed requirements for this component will be further elaborated while the relevant implementing act on good veterinary pharmacovigilance practice is being drafted, discussed and adopted. The scheduling foresees that this implementing act will only be adopted around the launch of the EVVet3 system, which presents significant uncertainties for the development of this component. Therefore, more detailed requirements and improvements will be added only once the legal base is finalised.

- Development of **reports in the DataWarehouse** (DWH), including the streamlining of existing dashboards and reports and creating any new ones, to ensure that the DWH is also VICH compliant.

The **timeline of the activities** planned for 2021 and beyond is shown below. It reflects the components or functionalities that will be launched in late 2021, and those that will be added after this initial release of the new EVVet3 system. This phasing has been agreed to enable timely delivery of a system compliant with legislative requirements in 2021. The improvements already scheduled for delivery in 2022 mainly relate to functionalities enhancing data quality.
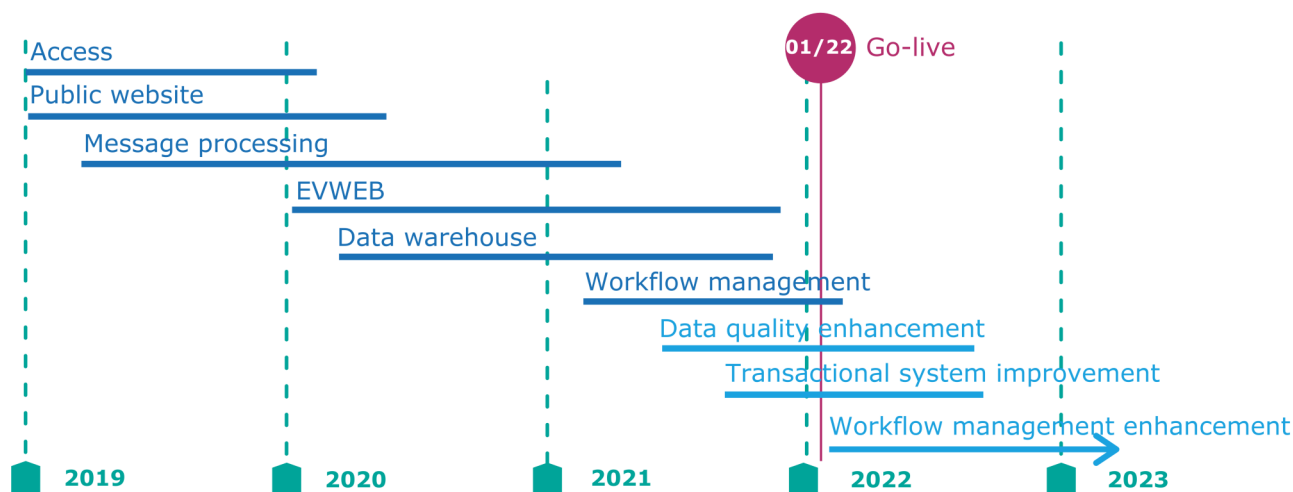
Change management

Activities within the Change Management workstream include the recruitment and onboarding of the Change Manager for the programme (see highlight box) and further elaboration of the change management plan.

The **Regulators Change Liaison Network**, a role that will be performed by the HMA Task Force on the Coordination of the Implementation of the Veterinary regulation (HMA TF CIVR) has been launched and the approach for tracking implementation of the VMP-Reg and integration with associated IT systems has been agreed.

The projects within the VMP-Reg programme are delivered in **'agile' development methodology**, meaning the detailed requirements are set while the delivery is ongoing. As such, agile projects are not conducive to defining the exact impacts on the business processes in the individual Member States, and the approach to change management has to focus on creating favourable conditions for change, so that, when the specifics of the change are known, the affected people can embrace and absorb it.

The Regulators Change Liaison Network has an important role in creating these conditions, as the change activities necessary in each Member State authority will depend on how the VMP-Reg is implemented in detail in the relevant authority. EMA's Change Manager will set the overall agenda of activities in collaboration with the HMA Task Force, will be available for advice, and provide supporting materials within the scope of the VMP-Reg programme.
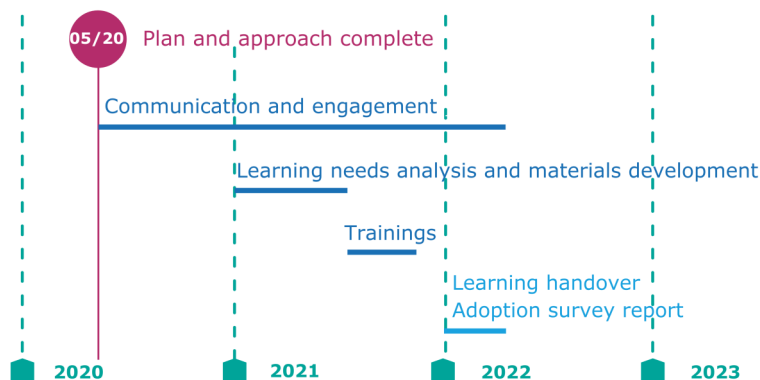
Upcoming activities include:

- **UPD**: technical webinar for NCAs on the data repository and API — **5 November**. Webinars organised in collaboration with the SPOR programme to prepare competent authorities for the mapping of product data (controlled vocabularies and organisation data) held in their national systems — **25 & 30 November**.

- **EVVet3**: a workshop with competent authorities to introduce the available information on the VICH standard its implementation in EVVet3 to enable preparations for the submission of adverse event reports in that format — **17 November**.

Outside the change network for regulators, information will continue to be channelled via the **VMP-Reg Stakeholders Group** to veterinary pharmaceutical industry and veterinary healthcare professionals, as well as on the EMA corporate website and this newsletter.

05/20 Plan and approach complete

Communication and engagement

Learning needs analysis and materials development

Trainings

Learning handover
Adoption survey report

2020   **2021**   **2022**   **2023**

> *I am really excited to join EMA's VMP-Reg programme as Change Manager. We will all need to substantially change our current way of working to make the implementation of the legislation a success, and my role is to make that easier. I am looking forward to our change journey together, and to cooperating with colleagues in competent authorities, pharmaceutical industry, and the veterinary community.*

Irene Zanetti, Change Manager for the VMP-Reg programme

Stakeholder views

We asked our stakeholders how they are preparing for January 2022, when the VMP-Reg will become applicable. Their contributions are reflected below, and show the diverse viewpoints and focus areas for our different stakeholders. In future releases of this newsletter we will keep sharing views from our stakeholders on specific topic areas in the programme implementation or their own preparations for the implementation of the Regulation.

"The new Regulation will include important aspects for veterinarians such as veterinary prescriptions, the use of antimicrobials, the reporting of antimicrobials and online sales. To prepare our members, FVE created an infographic with the most important changes for veterinarians in practice. Many countries also organise information sessions for practitioners to prepare themselves, which prove to be very popular. This is important, because while the new legislation is a Regulation, still we see some differences in implementation in countries, e.g. which antimicrobials are classified as critical and how monitoring of antimicrobials is being done".

Nancy de Briyne, Deputy Director of the Federation of Veterinarians of Europe (FVE)

"The implementation of the VMP Regulation calls for the adoption of around 20 legal acts. The Commission's current focus is on 13 delegated and implementing acts which need to be adopted before or by 28 January 2022.

To ensure a holistic approach to AMR, work has also been initiated on other pertinent acts.

The Commission is working closely with the Member States to deliver all these delegated and implementing acts as foreseen by the VMP Regulation."

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

"Over the years, the Coordination Group for Mutual Recognition and Decentralised Procedures – Veterinary (CMDv) has been in close contact with the European Commission. Even when the text was under preparation, a letter was sent to EC with the CMDv's views and expectations.

Now, the CMDv legislation working group has been reactivated and all CMDv members are working on the update or preparation of CMDv documents. Upcoming questions will be continuously discussed with the Commission to develop clear and well-working processes."

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

"Internal reorganisation and external communication to all parties affected have been identified as key actions for operational preparedness. In 2019, BVL organized a large symposium to discuss upcoming challenges with stakeholders. Members of BVL actively participate in several working groups referring to the new VMP Regulation (e.g. the implementing and the delegated acts). Internal IT projects were initiated to update national databases and ensure data exchange between the national and the new EU databases.

Purposive organisational development activities include an internal reorganisation, a manpower requirement planning, and skill enhancement initiatives for staff members."

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

"Trade associations are working with their members to follow-up on the IAs and DAs through commenting on EMA advice and public consultations of draft implementing measures, particularly those that will have a major impact. This follow-up must also take into account the changes and projects happening in parallel and applicable to VMPs that may have an impact on the outcome of IAs and DAs.

Companies are preparing with internal communication and informative sessions so that staff are aware of the new requirements and what must be done to adapt.

Active planning, but concrete decisions, particularly those requiring major investments such as IT adaptations and increased capacity, cannot be made until the final IAs/DAs are in place."

Rick Clayton, Technical Director at AnimalhealthEurope; and Elsa Vecino, Technical Director at European Group for Generic Veterinary Products (EGGVP)

"The main role of the TFCIVR is to provide strategic support to the HMA on the implementation of the new veterinary regulation, to act as a forum for discussion providing recommendations and strategic direction into the development of IT systems, and to suggest initiatives and develop content for the EU Network Training Centre.

Until now the main role of the TCIVR has been to inform the NCAs of the progress of the programme and to promote their involvement in the different working groups set up by EMA. Member States (MS) have also the opportunity to exchange on their problems and the questions they may have concerning national implementation. MS can also share their best practices.

The TFCIVR will now have to continue raising NCAs awareness of all the work they will have to do before January 2022, particularly to be connected to European IT tools and develop adapted trainings for a harmonised understanding and implementation of the regulation."

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

NEXT ISSUE

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- Project status
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- Highlight features

Read the previous issue