

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

In 2020, the programme governance and project teams achieved considerable progress, despite the shift to virtual work due to the pandemic and the challenges this creates.

The active projects – Union Product Database and Pharmacovigilance Database – have advanced their delivery activities according to plan.

The VMP-Reg programme has also expanded with two additional projects, the Collection of Antimicrobial Sales and Use data and the Manufacturers and Wholesale Distributors database. More detailed information regarding all projects is provided on the next pages.

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. A clear overview of the change management activities and dependencies is

being produced to show which actions are required for national competent authorities and stakeholders, and all the activities ongoing to support a coordinated implementation and a smooth adoption of the new systems under development.

With only one more year to go until when Regulation (EU) 2019/6 will become applicable, even more than before, we will continue to promote active engagement of all stakeholders to ensure a successful delivery.



What is important for the veterinarians is to always keep a practical approach that considers the needs of veterinary practitioners in all aspects, whether talking about the categorisation of antimicrobials, pharmacovigilance or the Union Product Database.

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

Programme update

In spite of the challenges linked to the pandemic, in 2020 the Veterinary Medicinal Products Regulation Programme (VMP-Reg) made significant progress and paved the way to the work ahead until 28 January 2022 - and beyond.

Delivery of the Union Product Database (UPD) and the Union Pharmacovigilance Database (EVV) is advancing. The programme focuses on the development of robust and sustainable systems that satisfy the legislative requirements laid down in Regulation (EU) 2019/6, including the requirement for improvement after January 2022 to increase functionality for all impacted stakeholders.

One of the main priorities for 2021 is the **submission of legacy data on veterinary medicinal products** into the UPD which is planned to start in summer. Timely delivery of the UPD components to enable submission will be pivotal to achieve this goal. National competent authorities have initiated mapping the product data held in their national systems, supported by webinars hosted by EMA.

The dependency of other projects on the timely availability of legacy product data in the UPD is one more factor driving the network efforts to submit data in line with the deadline fixed in legislation. In particular, EVV will rely on the availability of all legacy data in the UPD to enable effective functioning of automatic recoding needed for signal detection and management.

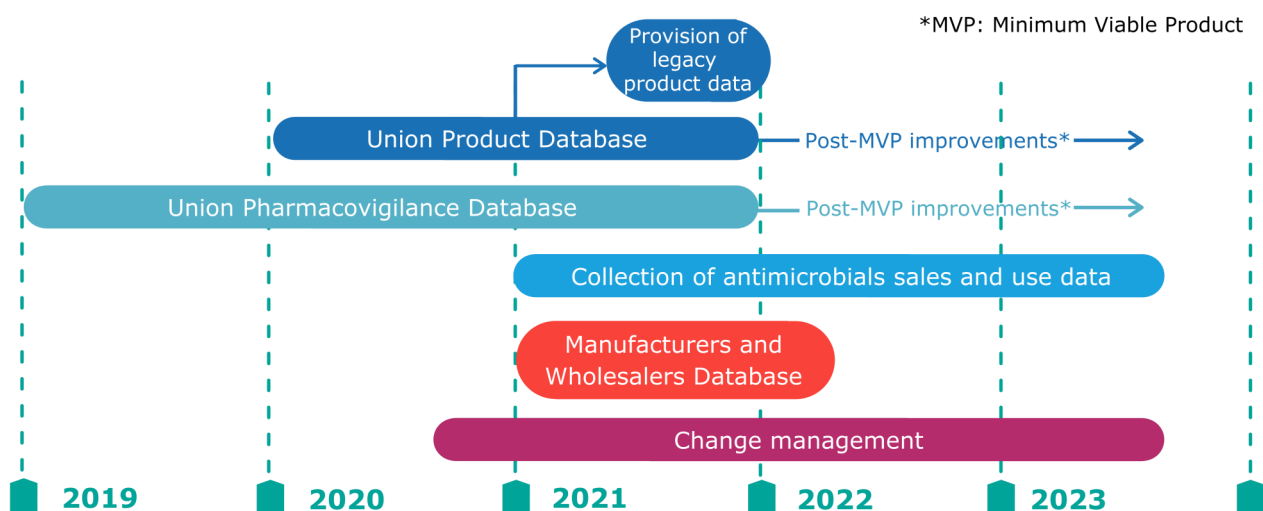
List of acronyms

- ASU:** Collection of Antimicrobial Sales and Use data
- DCP:** Decentralised procedure
- DEG:** Data Elements Guideline standard
- EVV:** Union Pharmacovigilance Database
- MAH:** Marketing authorisation holder
- MRP:** Mutual recognition procedure
- MS:** Member State
- 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

The rational approach agreed for the submission of legacy data will minimise the burden for all national competent authorities (see highlight box “Submission of legacy data” on page 4).

Two **additional projects** are now under the programme umbrella, the collection of Antimicrobials Sales and Use data (ASU) and the Union Database on Manufacturing and Wholesale Distribution (MWD) presented on page 3.

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



Collection of Antimicrobials Sales and Use data

The Collection of Antimicrobial Sales and Use data (ASU) project was kicked-off with the definition of its **mandate and governance**. The first Project Group meeting held in December 2020 defined the scope of the activity and the roadmap ahead.

The Project Group is currently working on the development of the project vision document and the business case.

Not only will the ASU play a pivotal role supporting the harmonised efforts to reduce antimicrobial resistance in the European Union in continuation of the successful ESVAC project, but it will also reinforce the quality and standardisation of national data and reduce workload by preventing duplicate entry of similar information in several IT systems. Product data from the UPD will be used in the template, in collaboration with the UPD project.

The final **technical specifications** of ASU will be laid down in the implementing act and delegated act expected for adoption in January 2021 and January 2022, respectively.

A **phased approach** to the types of data collected is foreseen in the VMP-Reg. The first deadline is the submission of antimicrobial sales data by 2022. Antimicrobial use data submission for the first

applicable species groups will start in 2024. The project delivery timeline will be drafted and made available soon.

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

For this, some representatives of the ESVAC network are part of the governance of ASU, ensuring a tight cooperation and effective communication between the projects.



The measures promoting prudent use of antimicrobials will help achieve one of the objectives of the recently published Farm to Fork Strategy, reduce overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030.

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

Manufacturers and Wholesale Distributors database

In the past few months, the VMP-Reg programme has worked on preparatory activities for the Manufacturers and Wholesale Distributors database (MWD) project. The existing [EudraGMDP](#) system is being analysed to identify the necessary amendments and additional features required by the VMP Regulation.

The MWD will be an important tool improving collaboration within the network. At the same time, it will increase transparency on manufacturers and wholesale distributors, certificates and importers information for the general public.

The MWD **project governance** will soon be set up, including representation of the national competent authorities. The project governance will agree on the detailed business requirements, plan, and change management approach.

Union Product Database

Kicked off in January 2020, development of the Union Product Database (UPD) considerably progressed last year. In September the first components were made available, with the UPD Repository and Application Programming Interface (API).

In January, the Commission Implementing Regulations on the UPD and the variations not requiring assessment were [published](#).

The **next go-live milestone** is scheduled for March 2021. It includes:

- the next version of the **UPD API**, also providing more advanced validation and document management;
- **document management** within the UPD data repository;
- first version of the **user interface** for competent authorities for the creation of centrally authorised products (CAPs) and nationally authorised products (NAPs).

The agreed technical solution for the interface to be developed for marketing authorisation holders will reduce administrative burden for industry.

The extended Product Owners Group now includes representatives of veterinary pharmaceutical industry, and is gathering the requirements for 'other post-authorisation changes' to data.

EMA's Management Board adopted the UPD [access policy](#) during its meeting in December.

Submission of legacy data

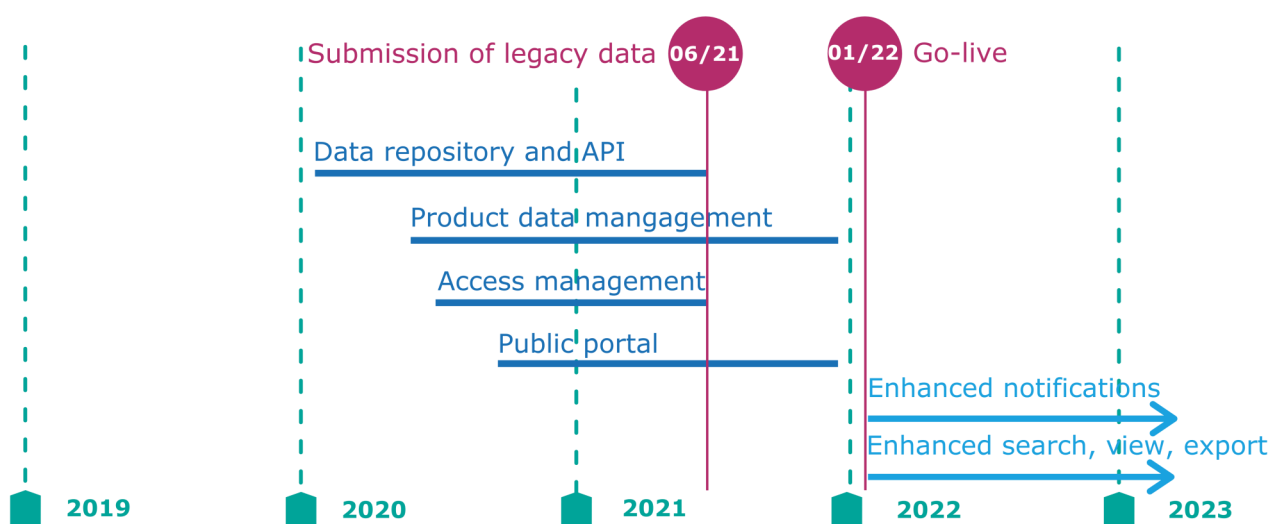
A common approach was agreed for the submission of data on products authorised through the mutual recognition procedure (MRP) or the decentralised procedure (DCP) into the UPD. First, Reference Member States will enter the product common data. They will be able to add their specific national data either at the same time or afterwards, when the Concerned Member States will add their national data to the common data set.

By reducing data duplication, the process will ensure high quality of the information available in the UPD. At the same time, it will radically decrease workload for national competent authorities since concerned MS will only have to map and submit national data for products authorised through MRP/DCP procedures.

The draft [EU Implementation Guide](#) on veterinary medicines product data was published for public consultation on 21 January and will be finalised in June 2021.

Cleansing of veterinary active substances in SPOR is being completed. A webinar for national competent authorities representatives on substance data will be held on 9 February to enable national competent authorities to progress the mapping activities of product data held in their national systems.

User research for the **public UPD portal** is ongoing. Initial wireframes have been developed and will be tested to make sure that the users can easily find the information they need on the portal.



Union Pharmacovigilance Database

Development of the Union Pharmacovigilance Database (EVV) started in 2019. **Phase 1** of the project was successfully completed in early 2020 and included the integration of the EVVet2 system with EMA's module for Identity and Access Management, the integration of the messaging platform with the existing ADR human platform, and the launch of www.adrreports.eu.

Work packages currently under development include:

- advancing the development of the **messaging platform**, including the automatic recoding functionality to improve data quality;
- further development of **EVWEB component**, providing a web user interface;
- development of **reports** in the DataWarehouse (DWH).

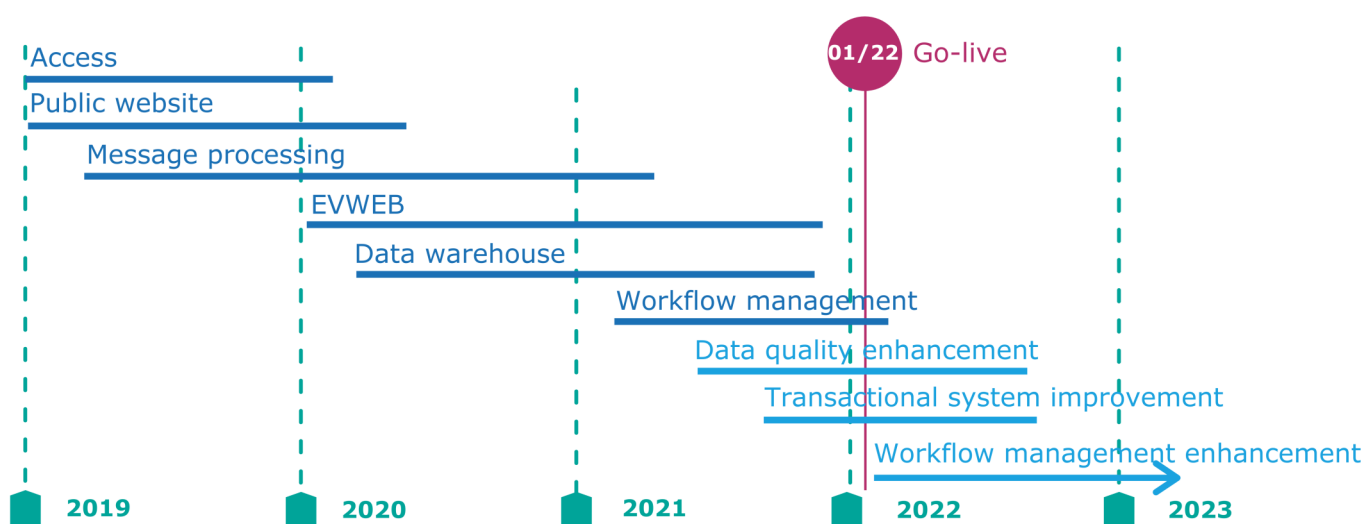
As of January 2021, EVV Product Owners Group has been expanded and now also includes **representatives of veterinary pharmaceutical industry**, thus ensuring that the views and needs of all stakeholders impacted are represented.

The EVV **access policy** will soon be published for a two-month public consultation, following a review with minor improvements that were identified in the implementation.

During the regular meetings with competent authorities and veterinary pharmaceutical industry representatives, it was highlighted that all national competent authorities and marketing authorisation holders will need to be able to read messages using the **VICH standard** as of the go-live of EVV (see highlight box "VICH messages in EVV" on page 6).

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 EVV system.

In view of the fact that the implementing act on good veterinary pharmacovigilance practice is scheduled for publication at the same time as the launch of the EVV system, more detailed requirements and improvements for the signal management functionalities will be added only once the legal base is finalised.



Change management

Activities within the Change Management workstream progressed with the further elaboration of the change management plan and the launch of training activities.

The **Regulators' Change Liaison Network** (a role performed by the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation) is showing their strong commitment to contribute to the change management activities by providing timely information on data held in the national systems. The analysis of national product data significantly supported the elaboration of proposals to structure the programme delivery.

Progress in the implementation of the VMP-Reg and the integration with the IT systems under development is monitored on a rolling basis.

Four **online webinars** were organised in November 2020 for national competent authorities, and around 80 participants joined each session:

UPD:

- A technical webinar on the data repository and the application programming interface (API).
- Two webinars were organised in collaboration with the SPOR programme to prepare competent authorities for the mapping of product data held in their national systems (controlled vocabularies and organisation data).

Recorded webinars available to NCA staff

The recordings of the webinars on the mapping of product data and on VICH standard are available to NCA staff who have an EU Network Training Centre learning management system account. NCA staff can request an account by completing the [request form](#).

EVV:

- A workshop to introduce the VICH standard and its implementation in EVV to enable preparations for the submission of adverse event reports in that format.

Upcoming activities include:

- **UPD:** webinar organised in collaboration with the SPOR programme to prepare competent authorities for the mapping of product data (substance data) held in their national systems — **9 February**.

The VMP-Reg **Stakeholders Group** continues to be engaged and channels information to industry and the veterinary healthcare professionals community. The group meets regularly to discuss activities and challenges related to the implementation of the Regulation. In 2021, dedicated webinars and training activities will be organised to support stakeholder groups facing the transition to the new systems.

In 2021, this **newsletter** will be published every two months to ensure all impacted stakeholders receive timely updates.

VICH messages in EVV

The submission of adverse event reports in Data Elements Guideline standard (DEG) into EVV will be possible during a transition period, tentatively for at least six months. However, reports forwarded by EVV will be in the same standard that they have been submitted into the system (either the current DEG, or the new Veterinary International Conference on Harmonization standard — VICH). This means that only messages submitted in DEG format will be downloaded in this format.

For this, national competent authorities and marketing authorisation holders need to ensure that they are able to read VICH standard messages from the go-live of EVV onwards, which may necessitate temporary use of a conversion tool.

Stakeholder views

Last summer, we asked our stakeholders what they expect to be the biggest impact of the VMP-Reg on their institution. 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.

“This new legislation is a regulation and all Member States will have to review their national legislation to implement it. The impact at national level may be very different from one Member State to another. A first impact will be a better harmonisation that would improve and facilitate the circulation of veterinary medicines in the European Union. We can expect an increased availability in certain Member States, particularly in the ones which represent small markets.

Another expectation will be the development of new IT tools, especially a global Union Products Database and a pharmacovigilance database in compliance with VICH requirement for a tool for signal detection management.

Such IT tools should be very useful for crisis management, for improvement of vigilance and

availability for all stakeholders: agencies, industries and animal health professionals.

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

“The original objective is that changes in the management of post-marketing authorisation activities (pharmacovigilance, variations, end of renewals) should result in a reduction of administrative burden. But this depends on the final outcome of IAs and DAs and the adeptness of the network to implement them in a timely manner.

A high cost impact is feared for ERA/ECOTOX, for innovative and generic products, if the current requirement for unnecessary repeat ERA studies is not addressed, with consequential impacts on medicines availability.

Investments in IT structures are required, but hopefully this will bring benefits in the long-run provided that the systems are tailored to the needs and requirements of the vet sector and will enable the reduction of the admin burden.

The impact of the new Protection of Technical Documentation (PTD) rules on innovation and competition remain uncertain, with some elements remaining the same (first authorisation and major species) and some elements significantly changing (minor species and antibiotics, extended length of maximum possible PToD). At EGGVP there are concerns that the new PoTD rules will result in a significant delayed access to market of generic products.

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)

“The measures promoting prudent use of antimicrobials will help achieve one of the objectives of the recently published Farm to Fork Strategy, reducing overall EU sales of antimicrobials for farmed animals and in aquaculture by 50% by 2030.

The new rules on VMPs should bring more centralised authorisations facilitating access to products across the EU. The new rules on variations and pharmacovigilance will reduce administrative burden on authorities and businesses, with more streamlined procedures and processes.

The Union Product Database (UPD) and the Pharmacovigilance database will increase overall transparency, provide easier and faster access to data, ensuring faster and better-tailored decision making. The UPD should also enhance the single market by providing information on all veterinary medicinal products in the EU.”

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

“Our members hope the biggest impact is made in the following areas:

- Increasing availability of medicines. In veterinary medicine, practitioners are dealing with many species and indications. As a consequence, lack of availability of veterinary medicines and vaccines is a serious problem, especially for Minor Use/Minor Species (MUMS) and for limited markets. Practitioners are expecting that the new legislation will increase the availability of medicines and vaccines, such as through stimulating research in new medicines, keeping on the market old products, better use of the ‘cascade’ and through SPC harmonisation.
- Having a well-functioning “Product Database”. The development of the “Product Database” is important, as it will be the therapeutic tool available for veterinarians to find online which veterinary medicinal products are available in other Member States when they are lacking

products. This database must be user-friendly with easy and practical search functions. Competent authorities must also allow veterinarians to easily obtain the products identified in the database.

- 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 worked 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)

“A number of organizational and technical challenges such as the need to implement national IT solutions (databases and interfaces) and to adapt all relevant business processes in time.

The restructuring of the variation system including the refinancing/fee system will significantly impact the working processes, often resulting in an increased workload.

The substantial changes in the area of pharmacovigilance and inspections will have a huge impact on the surveillance of the safety of VMPs, and places the focus heavily on the signal management process which needs to be reinvented. National regulation needs to be adapted.”

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

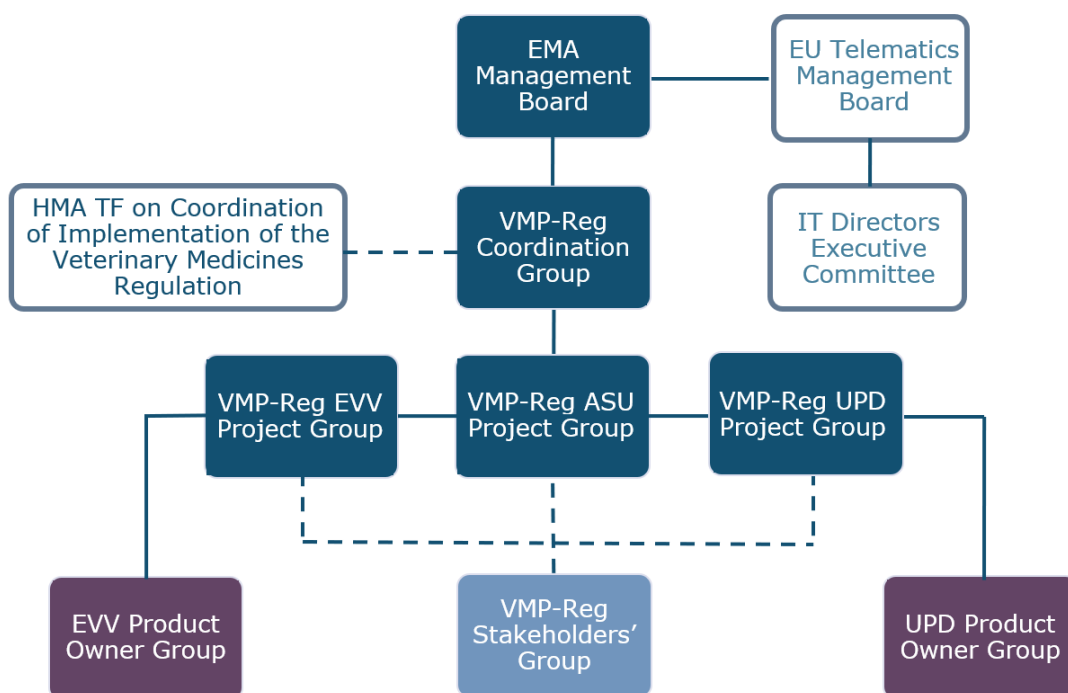
“The SPC harmonisation procedure was introduced in the Regulation 2019/6 and it will be one of the most challenging aspects for the CMDv. The CMDv must elaborate a procedure for the SPC harmonisation of authorised reference products and their generics.

The management of variations not requiring scientific assessment is also another big challenge for the network. Indeed, in January 2022 the new union product database should be ready for MAHs and for NCAs. In parallel, CMDv, EMA and NCAs should have agreed on the procedural aspects of the management of these variations intended to reduce administrative burden for both the competent authorities and the MAHs.

The transition period between current and new regulatory requirements is also another difficulty that the CMDv and NCAs will have to face. Whilst the European Commission and the CMDv have already started to work on already identified difficulties, I have no doubt that other questions will continually arise until the implementation date. The CMDv, alongside the HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation (TFCIVR) will continue to monitor the implementation of the Regulation within the network.”

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

Below is an overview of VMP-Reg programme governance structure, showing all the stakeholders involved and contributing:



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

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