

Veterinary Medicines Regulation HIGHLIGHTS

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



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Welcome to the first edition of the newsletter for the Implementation of the Veterinary Medicines Regulation (VMP-Reg) Programme. As we have reached the halfway point in the preparations for the implementation of Regulation (EU) 2019/6 ('the Regulation'), it is an exciting time for the Agency and the [regulatory network](#), which is closely involved in translating the changes in the regulatory framework into a reality that is beneficial for all.

The Regulation will become applicable in January 2022 after a 3-year implementation period. In 2019, EMA focussed on preparing a number of [recommendations](#) in collaboration with Member States' experts and pre-inception activities to ensure that the VMP-Reg programme can start delivery of the changes in 2020. By now, the full governance structure for the programme has been endorsed and is operational, and two projects are actively delivering IT functionality required in the Regulation.

The delivery of this programme of changes constitutes a unique challenge for EMA, the network and our stakeholders and partners. I recognise the importance of not only delivering the legal requirements, but also ensuring that the solutions are efficient.

The short timelines for doing this demand a focus on what is essential and what can be introduced as improved functionality later. I will continue to pursue this approach in collaboration with the network and stakeholders to enable a timely and successful start of the new regulatory framework.

This newsletter introduces the various areas of activity. Future releases will provide updates on the progress of the different projects, and give a deeper insight into highlight topics.



The Commission relies on the Agency to deliver the IT projects on time and plays an active part in their governance.

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

Programme introduction

The Regulation calls for the establishment of a number of databases, at EU level, in order to support the intended benefits of the Regulation. The VMP-Reg programme intends, in collaboration with the Member States and stakeholders, to deliver the following systems (see illustration below):

- Union Product Database
- Union Pharmacovigilance Database
- Union Manufacturing and Wholesale Distribution Database
- Collection of sales and use data of antimicrobials in animals

Each one of these IT systems will be delivered as an individual project under the VMP-Reg programme and, at this time, only the Union Product Database (UPD) and Union Pharmacovigilance Database (EVVet3) projects are active. More information on these two projects can be found on the following pages. The IT systems within the scope of this programme will be developed in alignment with guiding principles such as the legal requirements arising from the Regulation and the supporting implementing act(s). 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

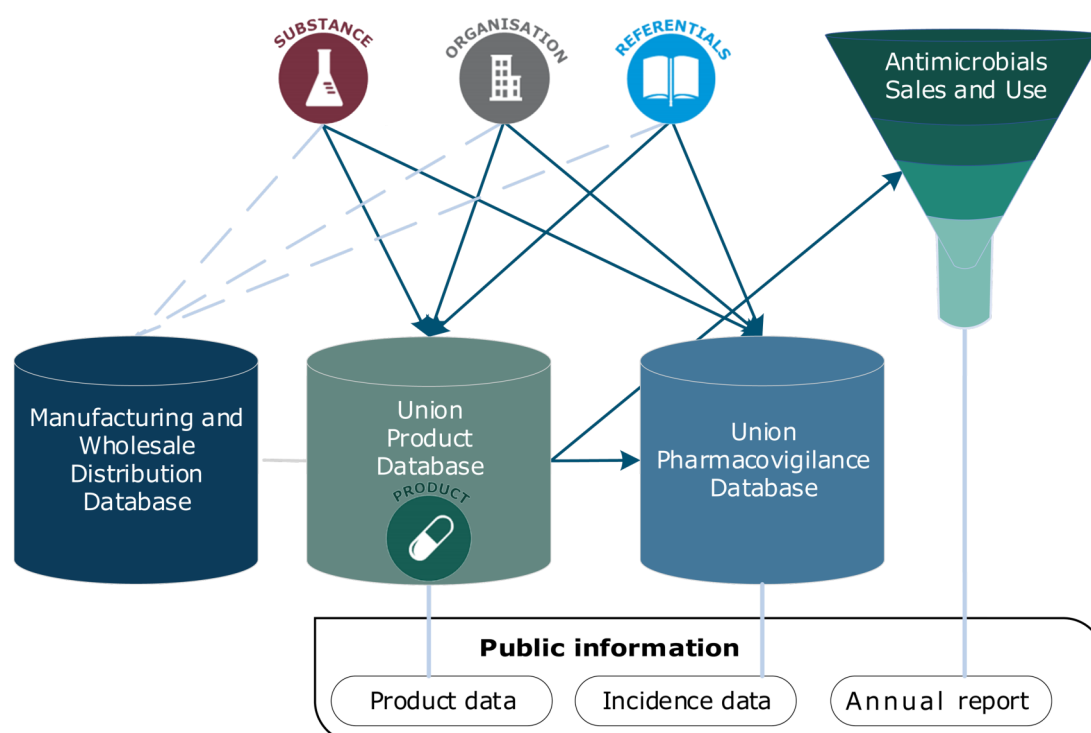
duplication of data entry across systems within the programme scope to ensure that there is a single source for each type of information. A phased approach for development is applied in order to prioritise functionalities that enable legislative compliance first; and thereafter, prioritisation of additional improvements shall be considered in collaboration with the Member States and stakeholders.

Through its scope, the VMP-Reg programme aims to realise specific benefits, some dictated by the Regulation and some inspired by the wish to reduce administrative burden for all partners and stakeholders, to increase the quality of the data underpinning the business processes and to improve the transparency of information on the safety and efficacy of veterinary medicinal products in the European Union.

The envisaged benefits are:

Support to the functioning of the Veterinary Medicines Regulation through stable and reliable IT solutions that support the regulatory actions relevant to the programme scope.

Support to the functioning of the single market through IT solutions that provide a central point of information on the availability and safety of





So far, the implementation programme of the Agency proceeds well and effectively addresses the requirements arising from the legislation.

While it is focusing on the implementation of the IT requirements, a lot of work has also been done on preparing the advice on the mandates given by the European Commission for the implementing and delegating acts. 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 'Product Database'.

The end product should be useful and be in line with the purpose of the revision of the legislation, namely to increase availability, stimulate innovation, reduce administration, facilitate the single market and fight antimicrobial resistance."

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

veterinary medicines marketed in all EU Member States, including veterinary medicines authorised in one or more Member State(s), registered homeopathic veterinary medicines, parallel traded veterinary medicines and veterinary medicines exempt from marketing authorisation, which are allowed for use in pets.

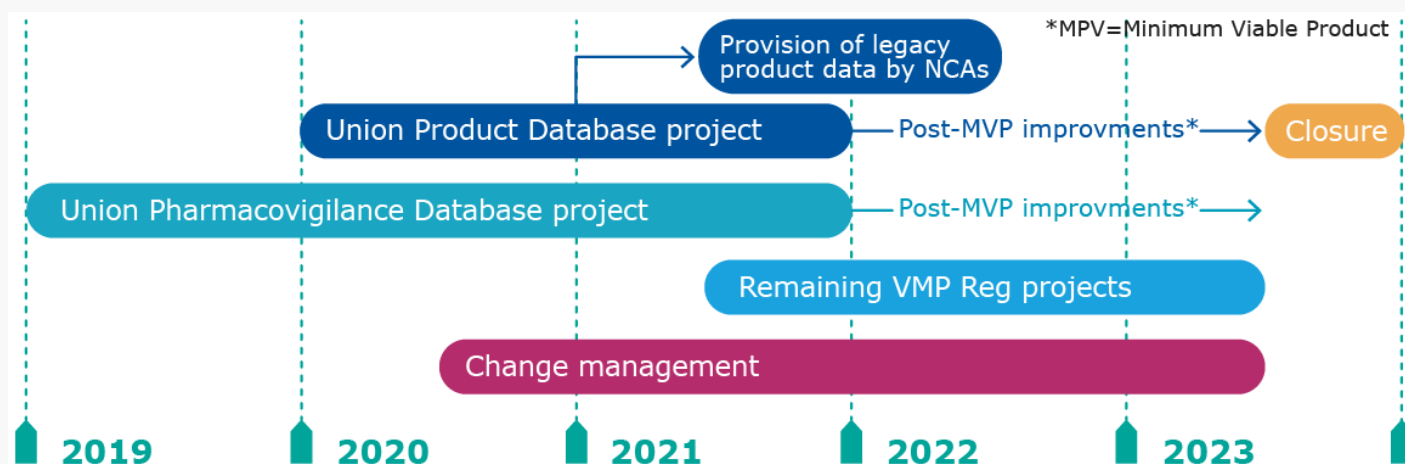
Support the harmonisation of veterinary medicinal product information through delivery of IT solutions that use, as much as possible, structured data and controlled vocabularies, so that information on veterinary medicinal products undergoing harmonisation procedures can be centrally identified and subsequently amended.

Reduced administrative burden through integrated IT solutions with adequate data quality and minimal duplication of data entry activities.

Increased transparency through IT solutions that provide easy access to the general public to all non-confidential data related to veterinary medicines including availability and safety information.

The programme aims to realise these benefits for approximately 1000 pharmaceutical companies globally developing veterinary medicines that could potentially seek to interact with the EU network IT systems and close to 30 competent authorities within the EU regulatory network that authorise veterinary medicines and thereafter monitor their quality, safety and efficacy. In addition, there are over 200.000 veterinarians within the EU that would benefit from having access to information on authorised medicines in all Member States and their availability. Finally, a large proportion of the population of over 500 million EU citizens own or care for animals and would benefit from increased transparency on veterinary medicines.

The programme scope does not include the implementation of revised business processes to fit the Regulation, related IT solutions in Member State authorities or industry stakeholder entities, and the data quality assurance processes prior to submission to the systems.



Union Product Database

The Union Product Database (UPD) project was established at the start of 2020 to ensure timely implementation of the requirements arising from the VMP-Reg. The UPD will contribute to the achievement of the benefits of the VMP-Reg programme by:

- Improving transparency on veterinary medicinal products approved for distribution in the EU.
- Supporting the activities around the harmonisation of product information.
- Implementing a reliable tool that veterinary practitioners can use to elaborate treatment options, also in case of unavailability of a specific product in a particular Member State.
- Offering self-service access for industry for certain regulatory activities and enabling the management of variations that do not require assessment.
- Providing functionality to perform data analytics; as well as making data available that supports regulatory processes outside the remit of the UPD.



The Agency should make it as easy as possible to upload legacy data and to allow for gaps when data is not available. Please take into account the business processes, so that when new IT solutions are embedded in the processes, everyone should be able to deliver and use data as foreseen by the legislation. The Agency's efforts to ensure reliability and consistency of the variations processes will be appreciated. Our expectation is to have functioning and stable databases/systems for all areas to allow a smooth transition to the changing requirements in accordance with the new legislation at the dates set as deadlines.

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

The UPD will provide the following capabilities:

Access management component which manages the control of access to data or functionalities and ensures that all stakeholders have the appropriate access to the resources provided by the UPD and the proper permissions to perform actions in the UPD.

Data and document submission component which manages the requests for submission to the UPD of data and documents relating to new veterinary medicinal products in order to create a new dataset, variations and other post-authorisation changes to the datasets already existing in the UPD.

Application programming interface for the exchange of data and documents with the systems used by marketing authorisation holders, competent authorities, the Agency and the Commission.

Union product database portal which, through the use of data publishing, data searching, viewing and exporting, as well as data analytics, presents information to users and makes certain features available to them in accordance with their access rights.

Data and document repository component which manages all data and documents that enter into the Union product database.

Capability to manage variations that do not require assessment which allows the marketing authorisation holder to record a variation that does not require assessment and allows the relevant competent authority or the Commission, as applicable, to be notified and to approve or reject such variations.

General public portal

The public portal will be part of the UPD portal and will allow the general public to search and view all non-confidential data and documents on veterinary medicinal products referred to in Article 56 of Regulation (EU) 2019/6. It will enable veterinary healthcare professionals and the general public to find out in which Member State a specific veterinary medicine is available, or to find information on potential treatment alternatives. Providing a single source of up-to-date information on the availability of veterinary medicines in the EU Member States will enable a better functioning of the single market.

Union Pharmacovigilance Database

The Union Pharmacovigilance Database will be developed by amending the scope of the existing EudraVigilance Veterinary (EVVet3) project, which was initiated in 2018 to replace the current system for processing and managing veterinary pharmacovigilance messages.

The EVVet3 system will contribute to the achievement of the benefits of the VMP-Reg programme by:

- Improving transparency on the safety profile of veterinary medicinal products approved for distribution in the EU.
- Implementing a reliable tool that veterinary practitioners can use to consider the potential benefits and risks of a proposed treatment regime.
- Offering a platform for industry to perform their pharmacovigilance obligations.
- Providing functionality to perform data analytics; as well as making data available that supports pharmacovigilance processes outside the remit of EVVet3.

EVVet3 is developed with the aim to create a common platform for veterinary and human pharmacovigilance by leveraging existing capabilities of the human pharmacovigilance system as much as feasible.



The development of new IT tools, especially a global Union Product Database and a pharmacovigilance database in compliance with VICH requirements with tools for signal detection and management should be very useful for crisis management, for improvement of vigilance and availability for all stakeholders: regulatory agencies, veterinary pharmaceutical industry and animal health professionals.

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

Public access to adverse event information

As of February 2020, EMA is already making adverse events reports (AER) publicly accessible through the www.adrreports.eu website. The reports come directly from [Eudravigilance Veterinary \(EVVet\)](#), a database for processing pharmacovigilance reports which is used as one of several tools for regulators to monitor the benefit-risk balance of a veterinary medicine once it is authorised. The data published on the portal refers to approximately 250 centrally authorised veterinary medicines. It will be extended to include all veterinary medicines authorised in the EU by the end of 2021, and to include information on the incidence of reactions by 2024.

EVVet3 will provide the following capabilities:

Data submission, which includes the sending of AER messages either via a gateway or a user interface. It also includes validation, conversion, routing, loading and acknowledgement of messages, as well as supporting functionalities to search, view and download AER data.

Data quality management, which includes the processes of message recoding, duplicate management and transformation of data for the analytical tools.

Data analysis, which involves the tools for analysing AER data for signal detection, signal prioritisation, signal validation, signal evaluation and recommendation for action.

Signal management and pharmacovigilance (PhV) inspection outcomes, which provides for the processing of signal management activities carried out by the marketing authorisation holder and the storing of the results of pharmacovigilance inspections.

Data publishing, which involves making AER data and other information related to pharmacovigilance activities available to the public.

Integration points with other systems, such as user registration and management and management of organisation data, controlled terminologies, and product data.

Change management

When the implementation programme was established, it was understood that a planned, strategic approach to change management for the VMP-Reg programme is critical given the amount of change, the range and number of impacted partners and stakeholders, variation in impact to those groups and the environment against which changes will take place.

The VMP-Reg Coordination Group, in its role as the programme steering group, has therefore adopted a change management strategy describing the approach and principles for managing change throughout the programme's lifetime, with the aim of optimising the implementation and adoption of IT and corresponding business changes resulting from delivery of new IT systems as required by legislation.

To achieve this, the programme will leverage existing governance structures to support the change management effort across the stakeholder and partner network:

- The VMP-Reg Coordination Group will share the change sponsorship responsibility with Programme Accountable Executive.
- The HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation will coordinate the change network for national competent authorities (NCAs).
- The VMP-Reg Stakeholders Group will be engaged to channel information to industry and the veterinary healthcare professionals community.

A high-level change management plan has been drafted and is being finalised with the input of the governance structure. It includes the provisional planning of change management activities in two main areas:

- **Awareness raising and engagement**
Establishment of a network of change champions, establishment and operation of a central mailbox for the coordination of responses to stakeholder questions, planning of a regular newsletter on the programme and project progress, and other communication activities within the network and externally.

- **Training activities**

Detailed stakeholder impact assessments to determine learning needs supported by change readiness assessments, as well as the development of curricula and training materials and scheduling of the learning delivery.

While the plan is being finalised, change management activities have already started to support the programme delivery.

How companies are preparing for the change

"Trade associations are working with their members to follow-up on the IAs and DAs (implementing acts and delegating acts — ed.) 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)

Stakeholder views

We asked our stakeholders what their hopes and expectations in relation to the revised regulatory framework in the EU are. 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 share views from our stakeholders on specific topic areas in the programme implementation or their own preparations for the implementation of the Regulation.

"Some of the current European procedure guidelines require revision, others will have to be created from scratch whilst NCAs simultaneously adapt their national laws. However, the CMDv is diligently adhering to a comprehensive work schedule prepared at the date of publication of the Regulation (EU) 2019/6 in order to be fully compliant with the Regulation. Collaboration with the EMA and HMA is also important for the successful implementation of the Regulation as some procedures and IT systems will be common to the network.

So I hope that we will all be ready for the 28/01/2022 at both European as well as at a national level for the starting point of the work with this new Regulation."

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

Our biggest hope is that legislators and industry will manage to be ready by January 2022, so that the implementation of the Regulation can be applicable from that day."

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

"BVL expects more transparency, better harmonisation in authorisation procedures and regulations between MS (member states — ed.) (including SPC harmonization) and the same level of quality, efficacy and safety as well as surveillance standards for all VMPs irrespective of the authorisation procedure and the country. We also hope for positive effects with regard to the enforcement of the responsible use of antibiotics in veterinary medicine for food-producing and pet animals. Avoidance of redundant work through various work sharing programs/initiatives have positive effects on the total administrative workload. Incentives for products fulfilling conditions of limited markets may trigger the overall and national access to medicines for so far unmet needs in animal healthcare and species."

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

"The VMP Regulation provides for a modern, innovative and fit-for-purpose legal framework on veterinary medicinal products (VMPs). The VMP Regulation incentivises innovation for VMPs and aims to increase their availability with emphasis on new antimicrobials, limited markets and bees. Equally important, the VMP Regulation lays down specific measures to help fight antimicrobial resistance (AMR), notably by restricting the preventive use of antimicrobials and banning the use of antimicrobials for promoting growth and increasing yield. It delivers on the European One Health Action Plan against Antimicrobial Resistance by reserving certain antimicrobials for human use, drawing up a list of antimicrobials that cannot be used off-label and providing for gathering and reporting data on the sales and use of antimicrobials in animals."

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

"In June 2020, we have reached the halfway before the Veterinary Medicines Regulation 2019/6 enters into application. I note that a lot of work has already been done; thanks to the entire EMRN network (European medicines regulatory network — ed.). The roadmap is more or less respected even if the conditions were not optimal considering the BREXIT with the relocation of EMA and the COVID19 crisis that affects our work but not our willingness and our involvement. I hope that the objectives of the regulation will be reached and we have to keep in mind them during this period of drafting the delegated and implementing acts and development of IT tools.

I expect that with this new regulation, we will have useful tools:

- to reduce therapeutics gaps for a better animal health: better availability, more innovation and development of novel therapies;
- to increase the prudent use of antimicrobials for a better human health;
- to reduce the workload and administrative burden for industries but also for NCAs. This could be reached with well fit for purpose IT tools."

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

"HOPE - Innovation is stimulated for both new and existing products.

EXPECTATION – it is implemented in alignment with the initial objectives, in particular increase of availability and access to medicines, and reduction of administrative burden – driven by practical implementation and secondary legislation.

A successful outcome is dependent on the IAs and DAs being finalised in the same spirit as the original objectives of the Regulation, and through open dialogue and contribution from stakeholders."

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

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