EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA retrospective: A year into the VMP-Reg

Veterinary Medicines Info Day 2023

Presented by Ivo Claassen on 16 February 2023
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Flashback to 2019

- VMP-Reg programme **established** to deliver on the IT systems required by Regulation (EU) 2019/6
- In the midst of a pandemic, the programme success remained a **priority** for EMA
- Excellent **collaboration** was key
  - National competent authorities (e. g. HMA Task Force on the Coordination of the Implementation of the Veterinary Regulation, HMA TF CIVR)
  - Pharmaceutical Industry (AnimalhealthEurope, Access VetMed, AVC)
  - Federation of Veterinarians of Europe

Programme vision (2019)

Regulation (EU) 2019/6 mandated that the European Medicines Agency ('the Agency'), in collaboration with the Member States, delivers the following IT systems:

- Union Product Database
- Union Pharmacovigilance Database
- Union Database on Manufacturing and Wholesale Distribution
- Collection of Sales and Use data of Antimicrobials in Animals

Programme vision (2019) – UPD

The Regulation calls for the establishment of a Union Product Database (UPD) to store and make available information on different types of authorised veterinary medicinal products, at Union level. Some of the key features to be delivered by the database are:

- Support the storage and management of product updates that may or may not require formal assessment by a regulator. This includes both variations not requiring assessment and certain variations requiring assessment.
- Provide information on the authorisation status and availability of veterinary medicinal products.
- Collect information on the annual volume of sales of veterinary medicinal products and make this information available to other systems for analytical purposes, such as calculation of incidence in the Union Pharmacovigilance Database.
- Enable the exchange of veterinary medicinal product information with other systems in a structured format, where possible, following recognised international standards and using controlled vocabularies.
- Make available an Application Programming Interface (API) and a Graphical User Interface (GUI) for users to view, create and manage product data.
- Support good data quality and data consistency across IT systems, especially between the UPD and regulator IT systems.

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Volume of sales & availability status reporting fully functional in Q1 2023 (VoS in Jan; AvS exp. 2 Mar)

Integration with UPhV scheduled for 2nd half of 2023 (legislative requirement for 2024)

Partially through validation rules/controlled data; support continuing in 2023 to improve data quality

Programme vision (2019) – EVV

Another system mandated by the Regulation is the Union pharmacovigilance Database (EVV), required to store and make available information of suspected adverse events for all veterinary medicinal products authorised in the Union. Its key features are:

- Support the storage and management of adverse event reaction reports, including reports on suspected lack of efficacy, as well as adverse effects on the environment;
- Store and make available the outcomes of the signal management process;
- Make available information on QPPV and Pharmacovigilance Master file;
- Make available results of pharmacovigilance inspections;
- Enable the exchange of information with other systems in a structured format, where possible, following recognised international standards.
- The system will be interconnected with the Union Product Database, making use of master data available in UPD and SPOR.
- Make available an Application Programming Interface (API) and a Graphical User Interface (GUI) for users to view, create and manage adverse event and signal management data.

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Programme vision (2019) – MWD & ASU

Union Database on Manufacturing and Wholesale Distribution (MWD) will store and make available information on manufacturing and wholesale distribution data in the European Union and will support the management of the information related to manufacturing authorisations and outcomes of inspections activities.

The Regulation also calls for the collection of data on Sales and Use of Antimicrobials in animals (ASU) and make available such information in the EU. It should enhance the quality and consistency of product data by using agreed standards and controlled vocabularies and enable users to view analytical data on the sales and use of antimicrobials.

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Union Database on Manufacturing and Wholesale Distribution (MWD) will store and make available information on manufacturing and wholesale distribution data in the European Union and will support the management of the information related to manufacturing authorisations and outcomes of inspections activities.

- completed & handed over to maintenance

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- on schedule to be delivered end 2023/beginning 2024, as required in legislation.

Programme vision (2019) – guiding principles

- The IT systems within the scope of this programme must be **developed in alignment with the legal requirements** arising from the Regulation, the supporting implementing act(s), as well as any other legislative requirements that apply.
- 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 must be developed **avoiding duplication of data input across systems** which are in scope of the VMP-Reg programme to ensure that there is a single source for each type of information.
- A phased approach for development, based on Agile principles, shall be considered in order to **prioritise functionalities that enable legislative compliance** first; thereafter, prioritisation of functionalities shall be done in collaboration with the Member States.

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not **all** legislative requirements have been delivered (some not due yet, very few delayed)

this principle was not entirely, rigorously applied

VMP-Reg implementation activities

- Extensive change management incl. frequent communications, events, webinars/trainings and targeted helpdesks/contact points
- Close contact with European Commission to obtain clarifications and provide guidance to the network and industry
- All procedures adapted to new/changed legislative requirements; procedural guidance on EMA website updated
- Most scientific guidelines have been updated, as necessary
- 12 technical/scientific advices delivered to European Commission, to support the development of secondary legislative acts (3 ongoing)
- Intense regulatory affairs support to all areas, internal and external stakeholders

Today

- Major regulatory changes → towards **"better administration"** in EU
- VMP-Reg programme delivered **on time** - three IT systems live since 28 January
  - **UPD**: Union Product Database is the first **central** database on veterinary medicinal products; also **first** network IT system compatible with ISO IDMP; improvements are ongoing
  - **EVV**: Union Pharmacovigilance Database connected to UPD, compliant with **VICH** standards, pilot of new procedure for signal management
  - **MWD**: EudraGMDP aligned with veterinary requirements
- First public website with information on **all veterinary medicines** authorised in EU/EEA

Today

- **Pharmacovigilance**: last PSURs for CAPs concluded in June 2022; signal management pilot is being reviewed and intended to be less resource-intensive, more effective process
- Increased monitoring in **antimicrobial sales and use**: project initiated and is delivering according to schedule; first submission under new rules in 2024
- Programme paved the way for continued **improvements in functionality and data quality**
- Reduction of administrative burden expected to materialize after current change/**transition** period

What’s next?

What EMA has learned since 2019

- **Scope management** - focus on must-have functionalities
- **Collaboration** – deliver together with network, industry & veterinary professionals
- **Expectation management** as a continuous exercise:
  - Not all benefits will be realized immediately
  - Everyone needs to learn how to operate in a new *normal*
- The VMP-Reg programme paved the way for **continued improvements** in functionality and data quality
  - Focus on usability & added value in prioritisation of ongoing improvements over the next years

New Agile Governance

Strategy

Agree the strategy and vision and the portfolio objectives, budget, Epic backlog

Define the strategic and portfolio objectives

Portfolio

Sequence the Epic backlog (work packages for execution) and provide technical guardrails for the work of the teams

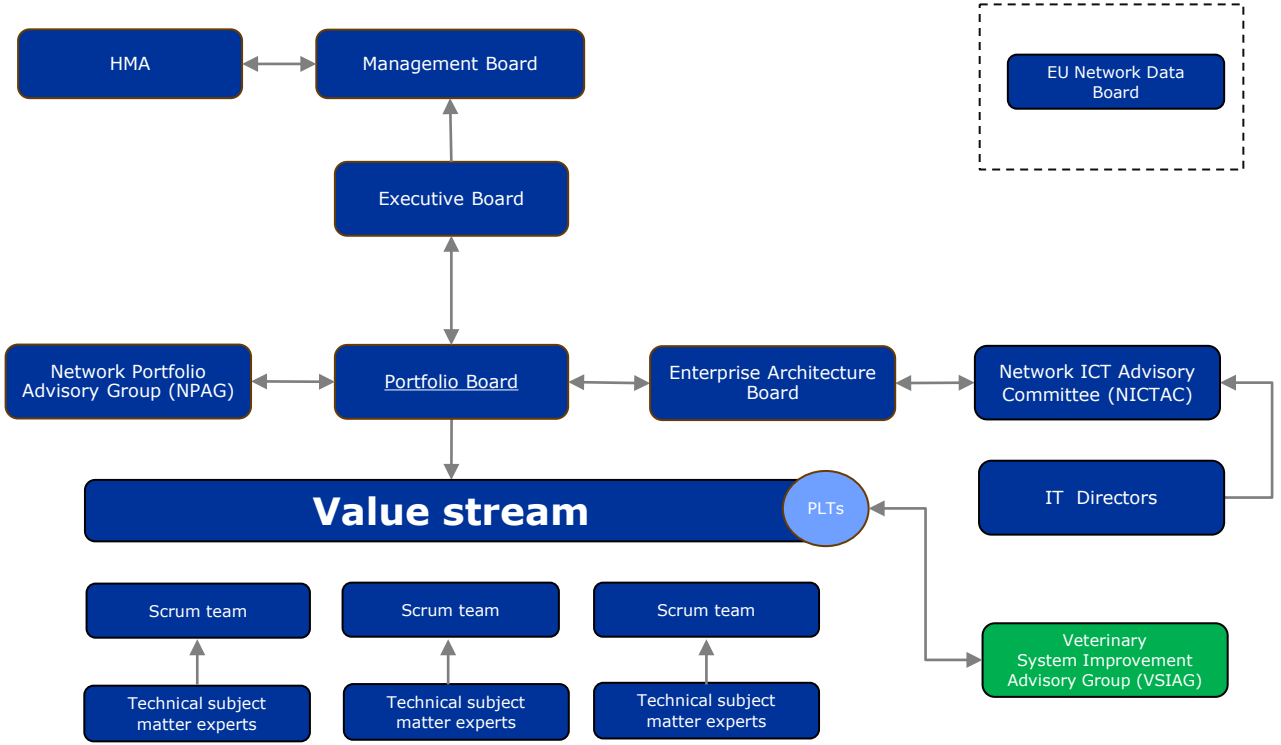
Teams organized into Value Streams

Execution

Deliver epics (work packages <12 months) sent down by Portfolio Board for delivery

MSs and Industry provide business requirements to support development of features and user stories, support UAT, etc.

THE HOW *(Work Done)*



PLTs – Product leadership teams

Veterinary IT systems improvements advisory group (VSIAG)

- **Group where stakeholders can raise and discuss requirements** (at functionality level) following the programme closure: kick-off meeting held in April 2022; fully operational since autumn 2022
- Outcomes are communicated to the Product Owners and Value Stream in time before the next quarterly planning cycle
- VSIAG members:
  - **MSs**: 8 representatives
  - **Industry:** C. Anton, T. Simon, B. Beutel, M. Colmorgen, R. Bhui and V. Vinot (AhE) S. Schwab and J. Petrič (Access VetMed)
  - **Animal Healthcare professionals:** 3 representatives
  - **EC:** 2 representatives
  - **EMA:** 2-3 representatives & participation of further EMA staff as needed

EU Vet Big Data: from strategy to action

Transposition of the EU Vet Big Data Strategy pillars into three actionable workstreams – watch this space!

Analytics discoverability

Governance & Literacy

Stakeholder engagement

Any questions?

Further information

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