From collection to connection – the EMA veterinary data strategy

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ABSTRACT

In recent years, reflections have progressed on how medicines regulation could be enhanced by digital technologies. Although substantial advancements occurred in the use of such solutions in the regulation of medicines for human use, the use of digital technologies in the veterinary regulatory domain is an unexplored yet potentially fertile territory. This article offers an insight on the methodological model used by the European Medicines Agency (EMA) to develop a veterinary data strategy for the next five to seven years. The implementation of the Veterinary Medicinal Products Regulation has been a catalyst for the EMA Veterinary Medicines Division to investigate the convergence of the traditional systems development with the advancement offered by emerging digital technologies. This article provides a reasoned overview of the vision and direction that the EMA Veterinary Medicines Division intends to follow in developing a framework for the management of veterinary data resulting from newly available solutions and the use of these data to support key regulatory activities in line with the European medicines agencies network strategy to 2025, building on the recommendations defined by the HMA/EMA Big Data Task Force, such as the focus on data quality and data use to achieve business benefits.

Introduction

The Veterinary Medicinal Products Regulation (EU) 2019/6[1] (VMP-Reg) introduces revised legislation with the overall goal of simplifying the regulatory environment, reducing administrative burden, strengthening measures aimed at limiting antimicrobial resistance, stimulating the development of innovative veterinary medicines and improving the functioning of the internal market for veterinary medicines.

Driven largely by the implementation of the VMP-Reg, the Agency is revising its procedures, regulatory and scientific guidance documents and is also leading the implementation of IT systems. The implementation of such revised procedures, processes and systems offers an opportunity for the EMA to embrace a new data culture, to join VMP-Reg requirements with the use of new digital technologies, and to be the pioneer of digital transformation at the Agency and in the EU Medicines Regulatory Network.

For the implementation of the VMP-Reg IT solutions, the EMA established a VMP-Reg programme where several data management projects are under development.[2] Due to the short implementation period, most efforts are focused on point solutions that address specific regulatory requirements. The EMA vision is to establish an Agency-wide veterinary data framework for aligning these activities across each data management discipline in the veterinary regulatory environment in such a way that they complement and build one on another to power analytical capabilities and progressively deliver greater benefits in a more efficient way.

In implementing the new procedures and solutions, the Agency is joining the legislative requirements introduced by the new regulatory framework with the use of new digital technology as anticipated by the Heads of Medicines Agencies (HMA)-EMA joint Big Data Steering Group (BDSG) initiatives and the European medicines agencies network strategy to 2025.

The ultimate goals of this data strategy focus on increasing interoperability across regulatory systems to reduce administrative and economic burden and enhance consistency, transparency and responsiveness. The primary objectives are therefore:
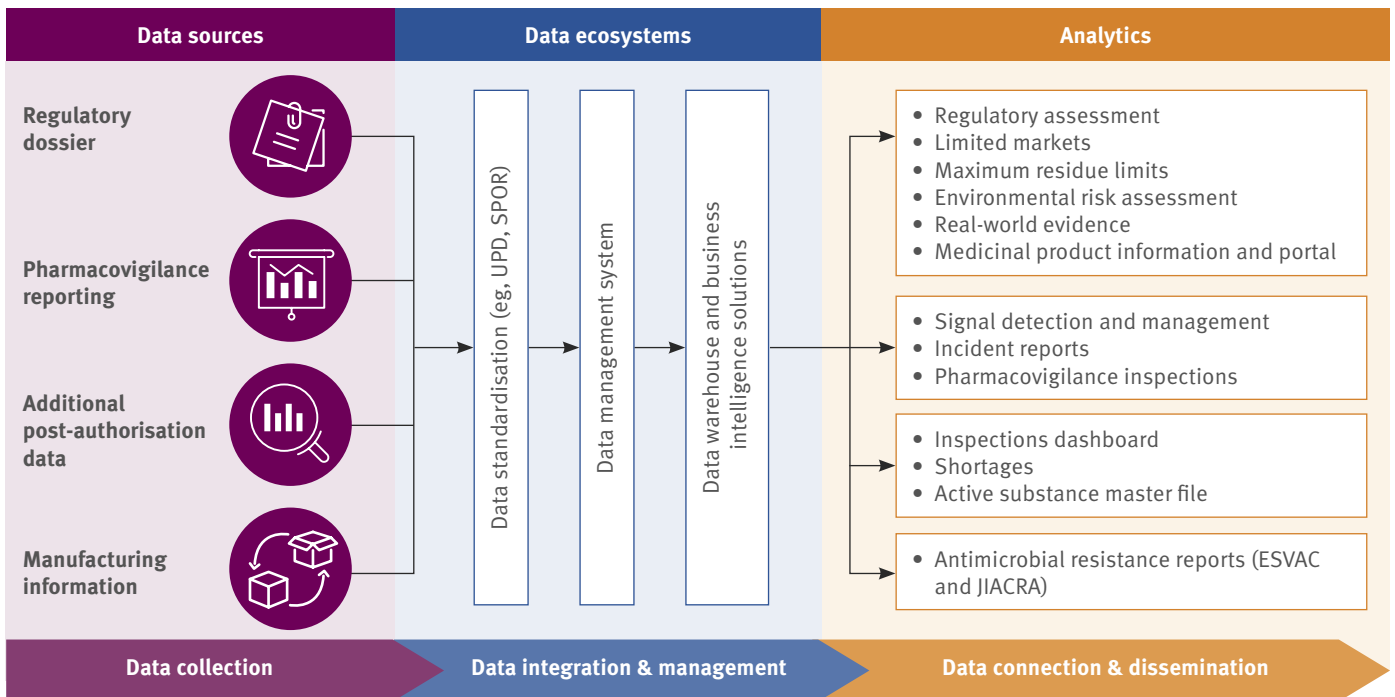
The pillars constituting workstreams in which detailed activities are to be planned and executed

- Implementing sustainable processes and systems
- Integrating the systems powering re-usability of the data across different areas and processes
- Delivering accurate and reliable information to promote public and animal health, as well as protection of the environment.

Vision of the EMA veterinary data ecosystem from a business perspective

Data sources	Data ecosystems	Analytics

Data collection → Data integration & management → Data connection & dissemination

The ambition is for the EMA Veterinary Medicines Division to act as a driver for the entire European veterinary network, leading and supporting stakeholders in the implementation, integration and connections of IT systems and data across the regulatory network. This is proposed to be achieved through collaboration focusing on providing excellence and expertise for the definition of principles and conventions on data activities and anticipating future data analytic needs. By following this strategic direction, the EMA's Veterinary Medicines Division will be well placed to take on the future challenges posed by emerging technology, changes in the VMP environment and the resource constraints that may arise.

The data strategy
The EMA veterinary data strategy is based on the following pillars (see Figure 1). The pillars constitute workstreams in which detailed activities are to be planned and executed.

Veterinary Data Hub
Considering the increasingly digital environment to which the Agency and the regulatory network are exposed, it is important to establish a data culture and data literacy that address future regulatory needs and demands. The Agency intends to establish a network of EMA vet experts that will define the methodology and infrastructure necessary to respond to data needs in a prompt, responsive, coherent and coordinated way: the Veterinary Data Hub (VDH).

The VDH will connect subject matter experts across the Agency for specific veterinary sub-domains to contribute to the design and performance of ad-hoc data management and analytic activities, providing a framework within which to react to data analysis requests ensuring legal and ethical compliance (eg, with EU regulatory legislation on data such as free flow of non-personal data[3]). Finally, the expectation is that the VDH will provide an interface with EMA stakeholders to engage in discussions with the common objectives of exploiting digital technologies for supporting regulatory decision-making in the veterinary domain.

The focal areas and business cases
The Agency data strategy identifies the sub-domains (so-called focal areas), where implementation of new digital solutions could be most beneficial in the next five to seven years. The identified focal areas include:
- Veterinary medicines information management, ie, implementing the Union Product Database (UPD)[4]
- Pharmacovigilance activities, which will be powered by the Union Pharmacovigilance Database
- European surveillance of antimicrobial sales and use in animals
- Environmental risk assessment
- Regulatory submission and evaluation
- Innovation of medicines
- Manufacturing/inspections coordination
- Innovative use of digital technologies.

The business case and the drivers for the applications of emerging digital technologies for each focal area need to be further developed in coordination with EU regulatory network experts, ensuring a strong connection with product lifecycle regulatory activities and identifying key benefits realisation.

The data landscape
The data landscape refers to the information that is needed by and managed within the Veterinary Medicines Division. This pillar aims to identify what data are managed and consumed. An in-depth knowledge of the data landscape will:
1. Enable identification of duplication of efforts in relation to data collection and management
2. Drive integration and power usability of existing data across different focal areas
3. Allow identification of key data sets that are used across different focal areas and for which specific data quality measures and data manipulation are required

Timeline of implementation of the principles and methodologies in the veterinary data strategy

**Short-term phase:
Data collection**

Focus on building the data framework
and identify new suitable data sources.

**Medium-term phase:
Data integration and analytic inception**

Build on previous phase to integrate data and develop
analytic reports and methods in key regulatory areas (eg,
pharmacovigilance, antimicrobials).

**Long-term phase:
Data connection and expansion of analytic capabilities**

Exploit data connection by means of new technical solution,
data sources and real-world data in key regulatory areas
(eg, farm management systems data for assessment and
evaluation of veterinary medicines).

2022   **2025**   **2027**

4. Allow the definition of a catalogue of data standards and common data models (CDMs)
5. Assist the identification of new data sources necessary to support the regulatory activities for the ongoing evaluation of VMPs.

The data ecosystem

While the data landscape addresses the question on 'what' data are managed at EMA, the veterinary data ecosystem aims at overseeing 'how' data sources and systems interact with each other to exchange, produce and consume data. Such ecosystems provide an environment for creating, managing and sustaining data sharing initiatives.

Figure 2 shows the vision of the EMA veterinary data ecosystem from a business perspective (ie, not accounting for the full set of IT systems in place or in development).

The veterinary data ecosystem should be expanded to manage the increasing number of new data sources and encompass the use of innovative digital solutions such as machine learning (ML), artificial intelligence (AI) and natural language processing (NLP) technologies with the primary goal of connecting and retrieving evidence from a complex variety of data to support regulatory decision making. One of the potential uses of these approaches has been recognised in providing prognostic information (what is going to happen), predictive information (what is likely to happen) and identifying trends and patterns based on real-world data (RWD) and evidence.[5] The processes to be established shall be based on advanced methods that are proven to fulfil the relevant regulatory requirements in a reliable, auditable and legal way.

Vision for the veterinary data strategy implementation: the operational activities

Although the regulatory framework defines precise requirements for the processes and systems to be implemented, it is pivotal that the Agency increases the integration and connection of the collected data across key

regulatory focal areas. This is to gain efficiency and reduce administrative burden. Moreover, augmenting systems integration will inevitably increase data utilisation, empirically improving its data quality.

The vision for the implementation of the principles and methodologies described in this veterinary data strategy is based on a phased approach with detailed activities covering the next five to seven years. The following key phases are presently envisaged:

1. Short-term phase: allow the implementation of systems and infrastructure for the collection of key underlying data and identify additional data sources to fulfil regulatory activities in the subsequent phases
2. Medium-term phase: implement the integration of specific data sets into targeted regulatory processes and systems to allow inception of key data analytics solutions and optimisation of the regulatory procedures
3. Long-term phase: power the data sharing, connection and information dissemination and expand analytic capabilities based on additional data sources and analytic methodologies.

The overall implementation timeline is summarised in Figure 3.

Short-term: data collection phase

The short-term phase (covering around one to two years), emphasises the implementation of the systems as legally required. Focus is also placed on the completion of data within the established repositories. From a business standpoint and concomitantly with the development of integrated IT solutions, the objectives of the short-term phase are targeted at the collection of data in key veterinary systems such as the collection of VMP information in the UPD. Further integration and data consumption by key regulatory systems is envisaged such as in the implementation of the Union Pharmacovigilance Database, which will be one of the first systems to consume data from UPD. Focus will be given to the monitoring of data quality received and the implementation of adequate measures to
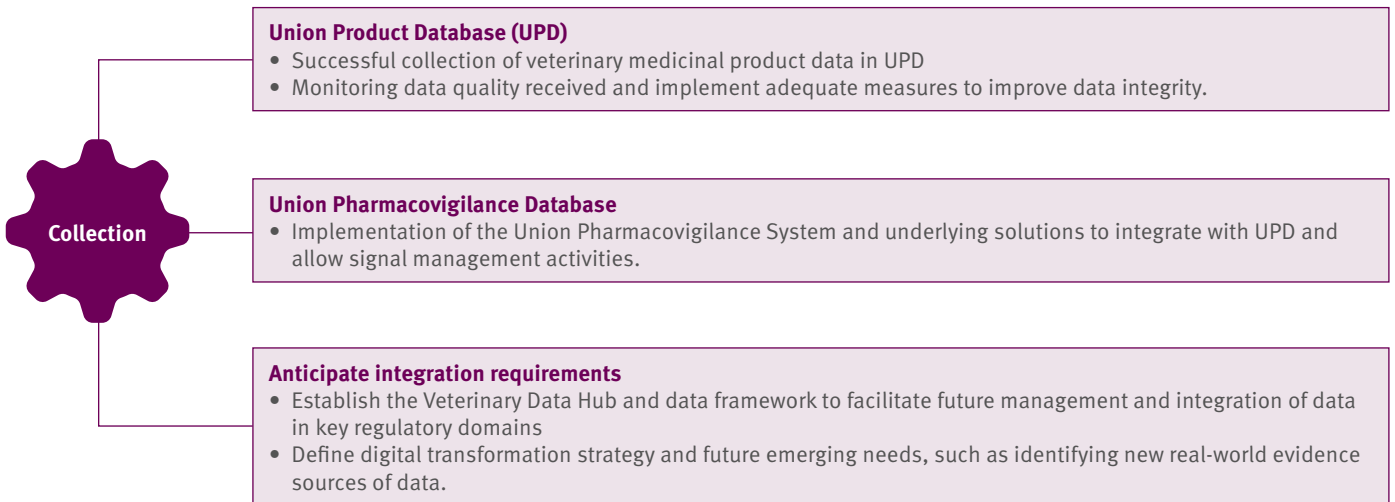
Collection phase

Collection

Union Product Database (UPD)
- Successful collection of veterinary medicinal product data in UPD
- Monitoring data quality received and implement adequate measures to improve data integrity.

Union Pharmacovigilance Database
- Implementation of the Union Pharmacovigilance System and underlying solutions to integrate with UPD and allow signal management activities.

Anticipate integration requirements
- Establish the Veterinary Data Hub and data framework to facilitate future management and integration of data in key regulatory domains
- Define digital transformation strategy and future emerging needs, such as identifying new real-world evidence sources of data.

Integration phase

Integration

Integration with key systems and processes
- Integrate the applicable subset of UPD data with:
  – Collection of antimicrobials sales and use data in animals
  – Regulatory application submission portal solution
  – EudraGMDP database
  – Improve data integrity.

Implement key set of data analytics and reports
- Dashboards for incident management, cross-border identification of veterinary medicinal products, Adverse Effect Reporting System website
- Implement the EU Veterinary Portal
- Implement new incident management processes and reports.

Anticipate analytic requirements
- Prepare for enhanced analytics and information dissemination
- Identify key external metadata and partnership, expertise and capacities on the network level, enabling scientific advice and method qualification for appropriate regulatory use of new digital technologies in the veterinary domain.

Connection phase

Connection

Expand existing analytical tools
- Expand connection of (internal) structured and unstructured data and processes automation in existing analytical tool.

Exploit data connection
- Establish methodologies on the use of additional digital technologies and data sources (eg, through farm management systems) for enabling regulatory activities (eg, [scientific] advice and assessment/evaluation of VMPs).

Nurture data literacy based on evolving digital technology
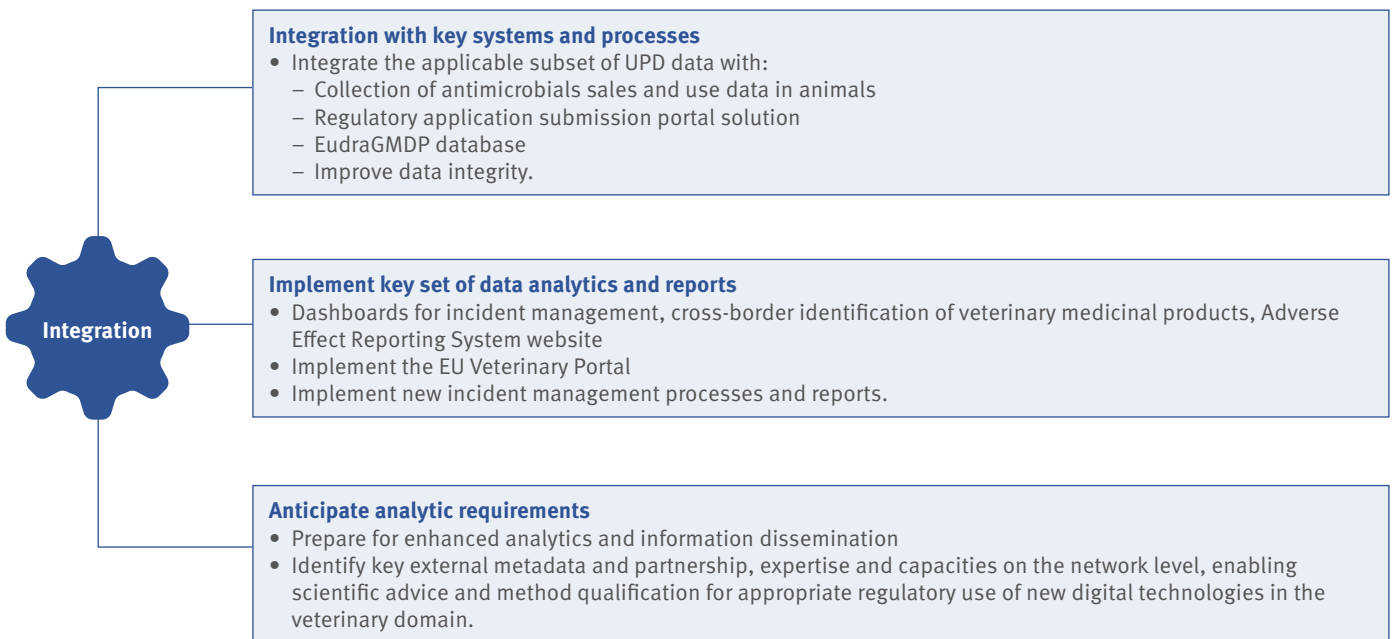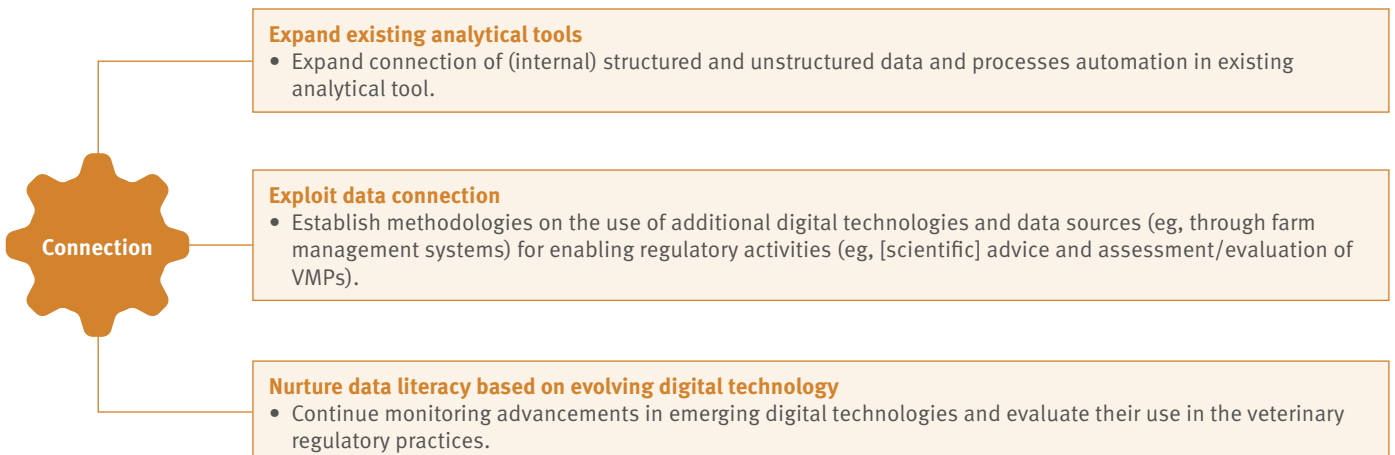- Continue monitoring advancements in emerging digital technologies and evaluate their use in the veterinary regulatory practices.

improve data integrity throughout.

An analysis of available and potential new data sources suitable for supporting regulatory activities in the veterinary domain is to be carried out. The identified new data sources will complement the data, standards and CDMs currently used in the veterinary domain at the Agency. Figure 4 summarises the data collection phase.

Medium-term: integration and analytic inception phase

The medium-term phase will continue for two to five years, with specific emphasis on the integration of the collected data with the focal areas to support the identified business cases and realise related regulatory benefits. In addition, analytic capabilities should be expanded for the dissemination of reliable information based on collected data.

Within the European regulatory network, respective expertise and capacities will have to be established in order to appropriately assess applications employing advanced data processing and analytics technologies. In order to ensure an innovation friendly environment, adequate processes and infrastructures should be established. Figure 5 summarises the integration phase.

Long-term phase: data connection and expansion of analytic capabilities

In the long-term phase (starting in five to seven years), analytic capabilities will be expanded, building on already developed solutions and making use of new data technologies with the ultimate goal of enhancing data connection and information dissemination to internal and external stakeholders.

Through the expansion of international and external cooperation to increase access, connection and sharing of data with additional sources, this phase will focus on two areas:

1. Extension of the analytical tools developed in the preceding phases by means of further integration of internal structured and unstructured data and internal process optimisation
2. Utilisation of big data and new digital technologies in regulation of veterinary medicines.

Business intelligence solutions already developed could be enhanced to include additional statistical, epidemiological and real-world data, as well as advanced analytics.

The long-term strategy aims at identifying solutions to access and analyse unstructured and new data sources not necessarily maintained internally at the Agency. Moving forward it is not sustainable to structure all unstructured data and maintain it prospectively. In addition, constraints in budget and resource capabilities, as well as lack of legal mandate requiring the collection of additional data, may prevent the Agency from receiving the sought-after data. The proposed approach is to explore the possibility to use new digital technologies and solutions to directly access and connect externally maintained data and evidence and transform these into reliable, traceable, auditable, legally acceptable and ethical information.

Processes and methodologies for use of new digital technologies and data (eg, through farm management systems) for enabling regulatory activities shall be developed. These should be based on scientific analysis and discussion[6] and developed in close cooperation with the relevant stakeholders.

Evolution of the EMA veterinary data strategy: the way ahead

Building on the solutions and the data gathered through the implementation of the Veterinary Regulation, it will be pivotal for the Agency to move from a "data collection" to a "data connection" practice. The importance of this ambition is emphasised by the increasing growth in volume of data that digital technologies make available (eg, from farm management systems, Internet of Things) and that regulators need to be able to take advantage of. In embracing this innovative data-path, opportunities specific to the veterinary data domain should be emphasised. For example, the use of data collected from animals does not pose the same ethical and legal issues of sensitive health personal data, and therefore it offers the possibility to streamline the data governance architecture for the experimentation with and roll-out of solutions.

As concrete next steps, an EMA veterinary data roadmap is to be defined to identify data gaps and additional sources to support veterinary regulatory activities. A change management plan will be developed, encompassing a systematic approach in assisting the experts with any changes that new digital technologies will bring.

Within the EU medicines regulatory network, the Agency is cooperating with HMA/EMA BDSG experts to define a pan-European Big Data Strategy. In this context, a Veterinary Big Data Stakeholders Forum is planned for 1 and 2 June 2021.[6] This is the first European event on big data for veterinary medicines regulation. It aims to initiate a concrete discussion with other regulators, industry, academia, farm management system providers and veterinary practitioners by sharing awareness of the latest initiatives making use of innovative digital technologies in veterinary regulation, to identify needs and ambitions, and to inspire future activities of the European Veterinary Big Data Strategy. ∎

DISCLAIMER

The views expressed in this article are the personal views of the author(s) and may not be understood or quoted as being made on behalf of or reflecting the position of the European Medicines Agency or one of its committees or working parties.

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