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Veterinary Medicines Division

Veterinary Big Data Stakeholder forum 1-2 June 2021
Key conclusions

Introduction

The first Veterinary Big Data Stakeholder forum was held on 1 and 2 June 2021. Over one and a half days and four sessions coordinated by eight moderators, the event presented the views of 21 speakers. The event was very successful with a high turnout of 300 to 350 attendees (via Webex and broadcast) on average.

The event offered an opportunity to engage and voice stakeholders' views expanding the current knowledge and understanding of the solutions, challenges and opportunities connected to the use of big data in the veterinary regulatory domain.

It also served as an opportunity for the EU Veterinary Regulatory Network to set the scene and share the strategic direction in implementing advanced analytic technologies to support veterinary regulatory activities in a more efficient and cost-effective way. This document summarises the reflections and conclusions of each session and presents the way ahead and next steps.

1. Session: stakeholders' perspectives on Big Data in the management of Veterinary Health

A comprehensive overview of the current investments, challenges and future opportunities from all the stakeholders' angles were presented. Key conclusions were as follows:

- It has been recognised as pivotal to establish an international multidisciplinary forum to discuss and implement Big Data in the veterinary regulatory domain with all stakeholders;

- It is important to identify business cases (additional to regulatory area such as Telemedicines) and new data sources and standards to leverage data variety, enable data connection and transform data into knowledge and regulatory action;

- Opportunities and challenges in using Precision Livestock Farming data were discussed as key additional data sources to power regulatory activities;

- Data governance is to be defined allowing data sharing and access in a sustainable environment e.g. EU Animal Data Space for sharing animal health data currently not covered by ongoing initiatives.

2. Session: Big Data in the monitoring of efficacy and risks

This session provided a deep dive into the application of Big Data in four key regulatory areas. The conclusions and reflections presented were as follows:

2.1. Antimicrobial Resistance (AMR)

- A high volume of data on antimicrobial use and AMR are already available and the amount of data on Biosecurity is increasing;
- Data standardisation is pivotal for enabling data collection and analysis;
- Aspects related to data ownership and availability needs to be resolved and open data practise should become the standard.

2.2. Environmental risk Assessment (ERA)

- Synergies between human ERA (i.e. PREMIER project) and veterinary domain were recognised as beneficial;
- Whilst Human & Veterinary data standardisation and systems are relatively mature and interoperable, methodologies of analysis applied to the human domain need to be adapted and developed to the veterinary processes and regulatory framework in the area of ERA.

2.3. Pharmacovigilance (PhV)

- New data sources to be explored to support PhV activities (e.g. farm management system);
- PhV data standards are relatively mature, but a dedicated workshop is to be organised to evaluate use of Big Data when new data and solutions (such as Eudravigilance Vet) will be available as part of the implementation of the Veterinary Regulation in 2022.

2.4. Real World Data in evaluation of efficacy and effectiveness of VMP

- Use of digital technologies in the evaluation of the efficacy and effectiveness of new medicines is beneficial but real challenge lay in how to make evidence generated by new digital solutions acceptable by the regulators and within the regulatory framework (e.g. specifically on auditability and validation of digital tool, models and results);
- Global harmonisation and cooperation are pivotal to exploit the use of new digital technologies and reduce administrative burden;
- Existing gold standards and guidelines will require revision, upgrading or further complementation.

3. Session: new data sources and advanced analytic solutions for veterinary regulation

The following conclusions were identified when presenting visionary principles on big data solutions in veterinary domain:

- It is pivotal for regulators to embrace a data culture and enable the utilisation and connection of data collected for secondary use to power regulatory decision-making and infer new sustainable policies;

- Data governance aspects are to be resolved: regulators have the potential to act as data brokers and intermediaries and explore business-2-government model for data access and ownership;

- Advanced analytics solutions were recognised to complement human analysis but not to replace it;

- Cooperation with other Agencies (e.g. EFSA) was recommended to adopt, adapt and cooperatively develop AI solutions for cross-agency regulatory activities (e.g. EFSA AI systemic Review of the dossier for scientific assessment and evaluation).

4. Session: The way ahead

A proposal for an EU Veterinary Big Data Strategy was presented and the following reflections were raised:

- Current efforts within the Veterinary EU Regulatory network are focused on the implementation of the Veterinary Medicinal Products Regulation;

- It is compelling for the EU regulators to be ready to accept/absorb digital innovation: EU regulatory network can achieve this via participation, cooperation, specialisation and transparency;

- Aspects to be resolved include:

    – Building data mindset and identify expertise;

    – Establish international cooperation forum;

    – Determine data governance;

    – Identify funding and resources.

Conclusions

The following conclusions and next steps were presented in the closing remarks:

- Big Data is already happening, and regulators need to be ready to exploit the benefits and manage the challenges that advanced digital technologies will bring;

- EU Veterinary Big Data strategy proposal is to be further developed and shared with the Head of Medicines Agencies in Europe (ideally in the course of 2022);

- Define the training curriculum and liaise with EU-NTC to reach all NCAs and possible thematic workshops with NCAs and stakeholders are to be organised as deemed necessary;

- Establish international cooperation forum on Veterinary Data;

- A second Veterinary Big Data Stakeholder forum to be organised in 2022.