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EMA/301003/2024
European Medicines Agency

Highlights - 1st EMA-AnimalhealthEurope annual bilateral meeting

01st July 2024 Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The Chair and the Deputy Executive Director of the EMA welcomed the participants to this first annual EMA-AnimalHealthEurope bilateral meeting, yet acknowledging the long and already established interactions over the past decades. Participants were invited to have an open dialogue on strategic priorities and challenges of mutual interest.

Similarly, AnimalhealthEurope acknowledged the importance of formalising the interaction, which is seen as an additional opportunity to continue the dialogue with the Agency at a more strategic level.

2. AnimalhealthEurope visions and priorities for the next 3-5 year

AnimalhealthEurope provided an overview of its current priorities which are expected to be reviewed in 2025. It was noted that, in line with its mission "being the voice of the European animal medicines industry", the key pillars driving AnimalhealthEurope current and future activities are one health, innovation and sustainability.

The importance of ensuring the availability of veterinary medicines, of supporting innovation through the regulatory environment and digitalisation, and of addressing the impact of horizontal legislation in Europe and beyond was also highlighted.

The activities included in AnimalhealthEurope workplan were noted.

3. European Medicines Agencies Network Strategy to 2028

The EMA informed AnimalhealthEurope of the current activities to update the European Medicines Agency Network strategy to 2028 and encouraged AnimalhealthEurope to participate to the upcoming public consultation expected to be launched in Q4 2024.

4. Veterinary Medicines Regulation implementation

AnimalhealthEurope provided an overview of the challenges experienced by its member companies in implementing the requirements of Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6).

The need to find pragmatic and simplified approaches to streamline the submission of variations and the importance of ensuring adequate support for the further development of the Union Product Database (UPD) in order to maximise its potential, ensure system robustness and data quality were highlighted.

The EMA noted the points raised, invited participants to acknowledge the progress made and welcomed the constructive AnimalhealthEurope representation in the ongoing discussions across multiple subject areas on possible improvements in line with legal requirements and allocated resources.

In this context, AnimalhealthEurope was invited to follow the discussion related to the reactivation of the Regulatory Optimisation Group (ROG), as presented at the last [Industry Standing Group \(ISG\)](#) meeting. For the Veterinary sector, the focus will be on improving IT systems and operations to streamline veterinary regulatory processes.

Post meeting note: A workshop with Industry stakeholders will be organised on the 10th October 2024 and invitation shortly sent.

5. Preparedness activities for vaccines availability in emerging diseases and emergency situations

AnimalhealthEurope highlighted the need to establish a structured dialogue with relevant parties on emerging diseases in order to ensure preparedness and rapid response in the event of a public health emergency.

The EMA noted the suggestion and asked to be kept informed. The need to become more agile in the response to emergencies was acknowledged.

6. Summary of follow-up items and close of meeting

Participants welcomed the open discussion and recognised the value of ongoing dialogue and engagement in order to understand each other's perspectives and confirmed the need to continue such bilateral meetings on an annual basis from now on.