EMA stakeholder workshop: advancing animal health through multi-stakeholder dialogue

The EMA vision

The aim is to continue fostering scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health, while facilitating and promoting innovation and access to novel medicinal products. To this end, four strategic goals were proposed, in line with those for human medicines. Each goal was accompanied by a set of core recommendations and underlying actions developed through horizon scanning and stakeholder engagement, and further consolidated in an initial workshop in November 2018. In keeping with EMA's usual approach, stakeholders and EU partners were invited to help refine and prioritise the goals, recommendations and actions via a public consultation that ran through the first half of 2019.

Four goals

Catalysing the integration of science and technology in medicines development

Novel developments by definition enter uncharted regulatory territory. The aim of the first goal is to foster a more proactive regulatory approach, so as to reduce uncertainty and help new science and technology be incorporated into the development of veterinary medicines, so that the needs of animal and public health can be met. The EMA has made four core recommendations:

- Transform the regulatory framework for innovative veterinary medicines
- Reinforce regulatory acceptance and further embed the 3Rs (replacing the use of animals with non-animal methods where possible; reducing the number of animals used to a minimum while still obtaining scientifically valid results; refining practices to minimise the stress and improve the welfare of study animals used for regulatory purposes)
- Applying the highest possible 3Rs standards when implementing the new veterinary regulation (https://eur-lex.europa.eu/eli/reg/2019/6/oj)
- Facilitate the implementation of novel manufacturing models.

Driving collaborative evidence generation – improving the scientific quality of evaluations

The second goal aims to provide regulators

In 2019, as part of its 2025 Regulatory Science Strategy, the European Medicines Agency (EMA) presented its vision for veterinary medicines regulation

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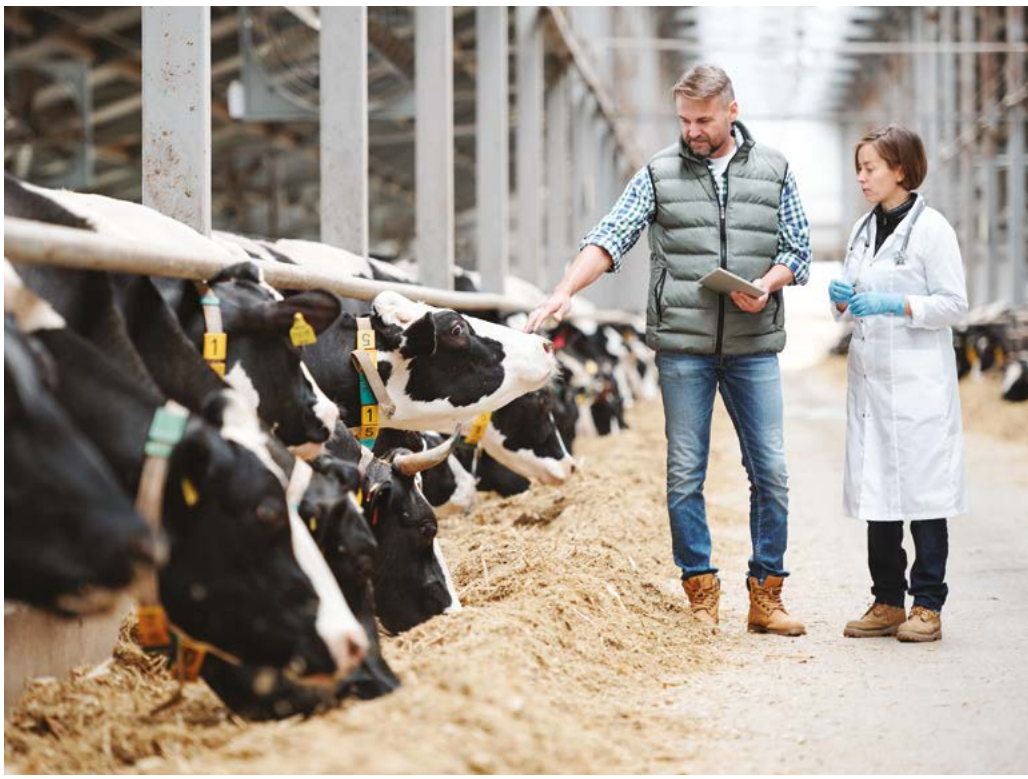

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Summary of European Medicines Agency workshop discussions

The science that applies to the quality, safety and efficacy assessment of veterinary medicinal products and informs regulatory decision-making and processes in the veterinary field is advancing at a fast pace. Regulators must be able to address novel technologies, regulatory tools and methodologies in order to maintain the high standards that exist in the evaluation of veterinary medicines in Europe. The European Medicines Agency (EMA) has therefore determined regulatory science priorities for veterinary, as for human, medicines. A well-established multi-stakeholder consultative process comprising interviews, workshops and public consultation has helped gather feedback from stakeholders. The actions needed to progress in the veterinary regulatory science area were consolidated in a second workshop in December 2019.

with better evidence to underpin regulatory decisions, so that animals can gain more timely access to innovative treatments while they, the environment, and humans are all protected from medicines whose benefits do not outweigh their risks. The core recommendations proposed to achieve this goal are:

- To update the environmental risk assessment process, ensuring it incorporates the latest scientific knowledge
- To apply the latest scientific principles to the assessment of the safety of residues of veterinary medicines
- To collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance; to develop new and improved communication and engagement channels and methods to reach out to stakeholders
- To develop new approaches to improve and communicate benefit–risk assessment of veterinary medicinal products.

Addressing emerging health threats, availability and therapeutic challenges

With human health invariably taking priority, animal health, for which available treatments are more limited, is at greater risk of compromise during emerging health threats. The third goal therefore aims to ensure that the regulatory system can respond effectively to address the need for treatments for emerging health threats, and availability of medicines for existing ones. Recommendations for this goal are:

- To continue to promote responsible use of antimicrobials and their alternatives
- To coordinate regulatory network activities to improve data collection on antimicrobial use in animals
- To engage with stakeholders to minimise the risks of antiparasitic resistance
- To promote and support the development of veterinary vaccines.

Enabling and leveraging research and innovation in regulatory science

The Agency's final goal in the veterinary field aims to develop existing interactions between the EU regulatory network and academia in order to promote research on regulatory needs and challenges, as well as to increase knowledge exchange. Considered as key to delivering the other strategic goals and recommendations, this goal is also accompanied by four core recommendations:

- To develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- To leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- To identify, and enable access to, the best expertise across Europe and internationally
- To disseminate and exchange knowledge, expertise and innovation across the network, including EMA's stakeholders.

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Public consultation and second workshop

Following the initial EMA workshop, a public consultation ran through the first half of 2019 to refine, develop and prioritise the goals, recommendations and actions laid out in the draft strategy. As a result, stakeholders and EU partners contributed to shaping the final strategy.

In early December 2019, after analysing the feedback received through the public consultation, the Agency held a second workshop dedicated entirely to veterinary medicines. Workshop participants included veterinarians, representatives of academic infrastructures and trade associations, and regulators.

This second workshop allowed the EMA to share the outcome and key messages from the public consultation on the strategy. It also offered the opportunity to discuss the prioritisation of core recommendations with key stakeholders further, as well as identifying concrete actions to implement the strategy and addressing expertise development.

Topics for discussion during the second workshop were selected on the basis of the stakeholders' priority ranking of core recommendations, as well as the feedback received.

The main topics were new approaches to improve the benefit–risk assessment of veterinary medicinal products; stakeholder collaboration to modernise veterinary pharmacoepidemiology and pharmacovigilance; promoting and supporting the development of veterinary vaccines; the regulatory framework for innovative veterinary medicines, as well as antimicrobial resistance; and the 3Rs.

During the opening session of the workshop, the Agency emphasised the importance of veterinary science in the regulatory discussion. Science should be at the core of regulators' work and the implementation of the new veterinary regulation.

During the workshop, stakeholders expressed support for the identified recommendations, including new supporting actions identified from the consultation phase. The discussions, which were rich and extensive, included: identifying new data models to maintain old antimicrobial products; strengthening cooperation between all stakeholders and international partners to foster the uptake of 3R methods; developing new (and improving existing) benefit–risk methodology, including for non-conventional sources of data; further investing in a better understanding of disease progression to enable the use of biomarkers; and improving support for the development of veterinary vaccines through better, and perhaps earlier, dialogue with vaccine developers. In addition, participants expressed their commitment to continuing the multi-stakeholder dialogue during the implementation of the strategy to ensure it is successful.

EMA regulatory science strategy to 2025 encompassing veterinary medicines

The day ended with concluding remarks by Guido Rasi, EMA's Executive Director, who explained how EMA plans to support the new veterinary medicines regulation and its strategic aims through a new internal structure better adapted for the future.

Ultimately, the EMA's regulatory science strategy will become an integral part of the overarching and more operationally oriented EU Medicines Regulatory Network Strategy to 2025 and, in line with the new European Commission's priorities, the ambition is to develop a common and novel approach for the development of veterinary medicines. ■