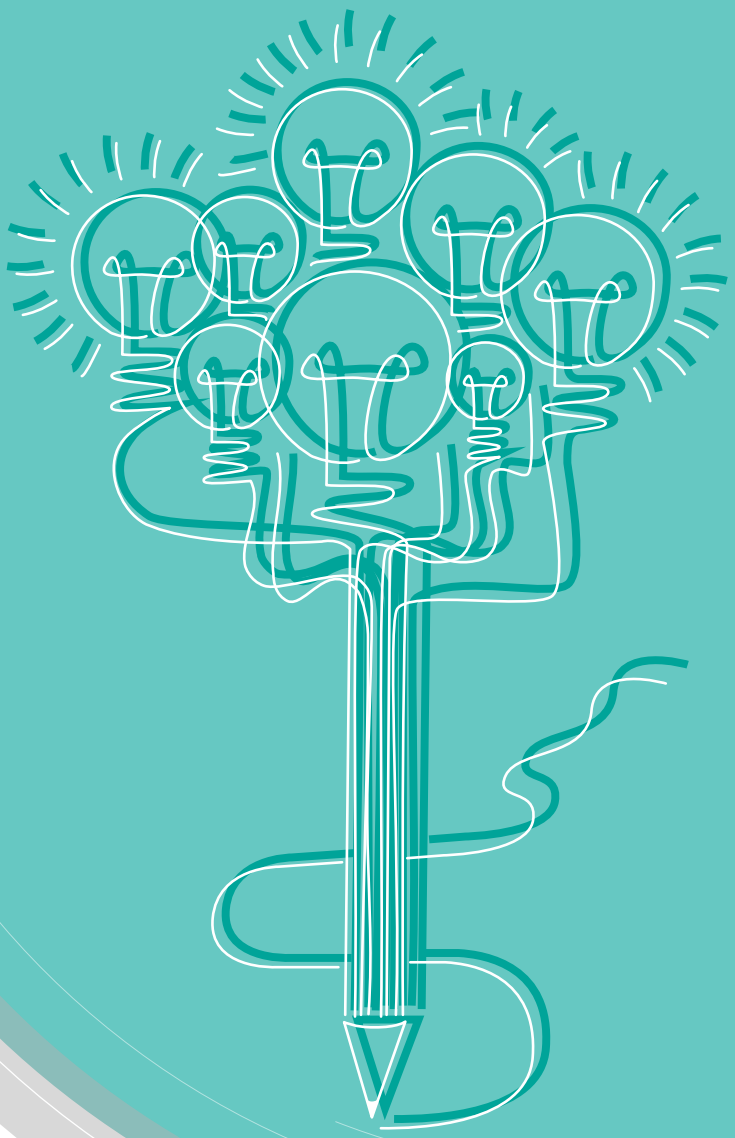

EMA Regulatory Science to 2025
Post-Public Consultation
Veterinary Stakeholders Workshop

5 – 6 December 2019

European Medicines Agency
Amsterdam, The Netherlands

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Objectives of the meeting

Further to last year's workshop and a very successful public consultation, we are pleased to inform you of the upcoming multi-stakeholders workshop entitled "EMA Regulatory Science to 2025" which will take place on 5th and 6th December 2019.

The objectives of this workshop are to:

- share the outcome and key messages from the analysis of the public consultation;
- reflect on the likely prioritisation of core recommendations EMA's Regulatory Science Strategy to 2025; and
- identify concrete actions in order to implement the key goals and core recommendations.

Please note that only a sub-set of core recommendations and actions across the strategic goals have been selected to be discussed within the workshop format. These have been selected primarily based on stakeholders' priority ranking of the core recommendations as well as the degree of comments/ suggestions received on the underlying actions and proposals for further actions. However, very constructive feedback has also been received on the remaining core recommendations and underlying actions. These will also be addressed post workshop such that the final RSS strategy document will present a holistic outcome of the public consultation as well as revised/extended action listings for all core recommendations.

Programme overview

Session 1	Overview of the outcome of the public consultation on EMA's Regulatory Science Strategy to 2025
Session 2	Develop new approaches to improve the benefit-risk assessment of veterinary medicinal product
Session 3	AMR & 3Rs – Breakout sessions
Session 4	Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance
Session 5	Promote and support development of veterinary vaccines
Session 6	Feedback from breakout sessions
Session 7	Transform the regulatory framework for innovative veterinary medicines

Organising Committee

Scientific Coordination Board (SciCoBo):

David Murphy	CVMP Chair, *Health Products Regulatory Authority (HPRA), Ireland*
Frida Hasslung Wikström	SAWPv Chair, *Swedish Medical Products Agency (MPA), Sweden*

European Medicines Agency (EMA):

Ivo Claassen	Veterinary Medicines Division
Melanie Carr	Stakeholders & Communication Division
Anthony Humphreys	Scientific Committees Regulatory Science Strategy Division

DAY ONE

5 December 2019 – meeting room 1C

14:00 – 14:20 Welcome and introductions

***Guido Rasi**, EMA*

14:20 – 14:50 Session 1: Overview of the outcome of the public consultation on Regulatory Science Strategy to 2025

***Ivo Claassen**, EMA*

14:50 – 16:10 Session 2: Develop new approaches to improve benefit-risk assessment of veterinary medicinal product

Overview of underlying actions for the core recommendation

Discussion session to review underlying actions

***David Murphy**, CVMP*
***Jordi Torren Edo**, EMA*

16:10 – 16:30 Coffee break

16:30 – 18:30 Session 3: AMR & 3Rs

Parallel breakout sessions A & B[1]

Breakout session A: continue to promote the responsible use of antimicrobials and their alternatives

***Thomas Heberer**, BVL / **Christine Schwarz**, AMR Working Party*
***Helen Jukes**, EMA / **Javier Pozo Gonzalez**, EMA*

Breakout session B: reinforce and further embed application of the 3Rs principles

***Raffaella Corvi**, EC / **Ellen-Margrethe Vestergaard**, 3Rs WG*
***Nicholas Jarrett**, EMA*

18:30 – 20:00 Refreshments

[1] When registering for the workshop, please advise which of the breakout sessions you will be attending, as they will be running in parallel

DAY TWO

6 December 2019 – meeting room 1C

08:30 – 09:30 Session 4: Collaborate with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance

Overview of underlying actions for the core recommendation

Discussion session to review underlying actions

***Frank Verheijen**, MEB / **Gabriel Beechinor**, CVMP*
***Barbara Freischem**, EMA*

09:30 – 10:30 Session 5: Promote and support development of veterinary vaccines

Overview of underlying actions for the core recommendation'

Discussion session to review underlying actions

***Esther Werner**, IWP*
***Javier Pozo Gonzalez**, EMA*

10:30 – 10:45 Coffee break

10:45 – 11:15 Session 6: Feedback from breakout sessions

Feedback of Breakout session A

***Thomas Heberer**, BVL / **Christine Schwarz**, AMR Working Party*

Feedback of Breakout session B

***Raffaella Corvi**, EC / **Ellen-Margrethe Vestergaard**, 3Rs WG*

11:15 – 12:45 Session 7: Transform the regulatory framework for innovative veterinary medicines

Overview of underlying actions for the core recommendations

Discussion session to review underlying actions

***Jean-Pierre Orand**, ANSES / **Ivo Claassen**, EMA*
***Noemi Garcia del Blanco**, EMA*

12:45 – 13:00 Delivering the strategy

Practical information

Attendance in breakout sessions

You are invited to indicate your choice of breakout sessions when registering for participation at the workshop. Please note that breakout sessions A & B on Thursday 5th December 2019 will be held in parallel.

Live broadcast

- The workshop will be live streamed. Please follow the link in Multimedia tab on the event page. No registration or password is required.
- Please note that Remote participants are encouraged to submit comments by email to RegulatoryScience2025@ema.europa.eu or via Twitter on #RegScience2025.

Recording and Photography

The Agency records or broadcasts a number of its meetings, including some virtual meetings. This is part of the Agency's commitment to the principle of transparency as enshrined in the Treaty on the European Union. By attending this meeting you consent to any photographing, recording, broadcast and publication of presentations on the EMA website.

WiFI Access

WiFi is available throughout the EMA. Login details can be found on the back of your EMA access pass.

Getting to the Spark

EMA is located in Amsterdam Sloterdijk.

Please find below a map of the area.

Directions to European Medicines Agency and map of the area

Practical information

Contact

Should you have any questions, please contact Laetitia Kpenou via RegulatoryScience2025@ema.europa.eu

Physical disability

Let us know if you would like any specific help or information that would make your stay more comfortable. We will be very happy to help.

Registration

We advise you to arrive at least half an hour before the start of the workshop (i.e. at 12:30) to allow sufficient time for registration and settling down.

Meeting room

There is no seating plan in the room except for a number of reserved seats for the speakers, moderators and chairs of the workshop.

Presentations

We will not circulate printouts of speakers' presentations beforehand. However, a workshop brief including the details of the core recommendations for discussion as well as the underlying actions identified in the draft strategy document and in the public consultation will be circulated.

Catering

Refreshments will be provided at the end of day 1, on 5th December 2019 for all delegates and free of charge, to allow opportunities for discussion and networking.

Workshop venue

European Medicines Agency
Spark building
Orlyplein 24
1043 DP Amsterdam
The Netherlands
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