EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3rd International Awareness Session

on science and regulation for animal health and welfare, public health and the environment

02-03 April 2020 - Amsterdam, The Netherlands

Chair: Ivo Claassen, EMA

Programme

Day 01
02 April 2020
Room 1D

Registration and welcome coffee / 09:00-10:00

01 A new veterinary medicines regulation: roadmap to implementation

***Speakers**: Sabine Jülicher (European Commission); Ivo Claassen (EMA); Agnès Saint-Raymond (EMA); Nancy de Briyne (Federation of Veterinarians of Europe, FVE)*

10:00-12:15

- Official welcome and opening remarks
- Roadmap to implementation of the New Veterinary Regulation
- EMA role and activities for veterinary medicines
- International cooperation for veterinary medicines

Lunch break / 12:15-13:00

02 Combatting the emergence of antimicrobial resistance
Support for innovation, including limited markets and collaboration with Academia

***Moderator**: Barbara Freischem (EMA)*

***Speakers**: Gérard Moulin (ANSES); Luca Guardabassi (University of Copenhagen); Noemi Garcia del Blanco (EMA)*

13:00-15:30

Introducing the Agency's contribution to fostering responsible use of antimicrobials in veterinary practice, the session will also provide information on Agency support to innovation in the development of novel veterinary medicines, the impact of those activities, and how one of the measures evolved from a policy to being written into legislation.

Coffee break / 15:30-16:00

03 Breakout sessions

16:00-18:00

03.1 Environmental risk assessment and aspects of veterinary medicines

Moderator

Ricardo Carapeto García (AEMPS)

Speakers

- *Damià Barceló (Catalan Institute for Water Research)*
- *Jordi Torren Edo (EMA)*

Introducing the potential impacts and the presence of veterinary medicines in the environment, this session will give an introduction on the development of the Environmental Risk Assessment of veterinary medicines and provide an overview of current policy, action plans, guidance and monitoring programmes.

03.2 Societal impact of animals

Moderator

Sabine Jülicher (European Commission)

Speakers

- *Carel du Marchie Sarvaas (HealthforAnimals)*
- *Nancy de Briyne (Federation of Veterinarians of Europe)*
- *Rory Breathnach (University College of Dublin)*

This session will focus on companion animals, discussing the impact to society of animals, the relation between owners and their pets, the contribution of veterinary medicines and professionals towards animal health and welfare.

Group photo
Networking event
18:00-21:30

Day 02
03 April 2020
Room 1D

Registration and welcome coffee / 08:00-08:30

04 Breakout sessions
08:30-10:30

04.1 Animal Welfare

Moderator

Marlies Halder (JRC)

Speakers

- *Catherine Milne (EDQM)*
- *Stefano Ponzano (EMA)*

Introduction to the role of veterinary medicines and the role of EMA in responding to ethical challenges, including information about the activities surrounding 3Rs (replace, reduce, refine) in animal testing in medicines development, the work of the European Commission Joint Research Centre (JRC), the European Directorate for the Quality of Medicines & HealthCare (EDQM) and initiatives to develop and validate quality testing approaches for both human and veterinary vaccines using non-animal methods.

04.2 Food producing animals and food security

Moderator

Hendrik-Jan Roest (Dutch Ministry of Agriculture)

Speakers

- *Nikolaus G. Križ (European Food Safety Authority)*
- *TBC*

This session will focus on the role that veterinary medicines play in ensuring the health and welfare of farmed animals in Europe. The European system is geared towards providing its population with sufficient, affordable and safe food. Veterinary medicines are essential to safeguard sustainable livestock production. Members states and European agencies work together to ensure food safety and security.

Coffee break / 10:30-11:00

05 Contribution of EMA and the EU network to veterinary medicines science and regulation

***Moderator**: David Murphy (HPRA)*

***Speakers**: Jean-Pierre Orand (ANSES), other TBC*

11:00-13:00

Reflecting on the EMA's vision "to foster scientific excellence in the regulation of veterinary medicines for the benefit of animal and public health", this session will look to the future and consider how the European regulatory network can engage with the opportunities and challenges presented by new technologies in order that they are translated into either new product development or facilitating 'better' regulation.

Lunch break / 12:15-13:00

06 Feedback from breakout sessions

***Moderator**: Ivo Claassen (EMA)*

13:45-15:45

Answer to questions on the parallel forum topics + Q&As

Closing remarks

Ivo Claassen and Agnès Saint-Raymond (EMA)

15:45-16:00

About this event

The European Medicines Agency (EMA) is pleased to hold its third two-day awareness session on science and regulation for animal health and welfare, public health and the environment.
This two-day awareness session will give an overview of the European regulatory system for veterinary medicines, on the role of the European Medicines Agency (EMA) and the European medicines regulatory network, as well as specific aspects of the new Veterinary Medicines Regulation.

Participants will have the opportunity to meet EMA staff and explore the Agency's work in detail. Time will be set aside during the sessions to discuss specific issues of interest to participants.

About the European medicines regulatory system and EMA

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the EEA countries, the European Commission and EMA. This network makes the EU regulatory system unique.

The network is supported by a pool of some four thousand experts drawn from across Europe, allowing it to source the best possible scientific expertise for the regulation of medicines in the EU and to provide scientific advice of the highest quality.

EMA and the Member States cooperate and share expertise in the assessment of new medicines and of new safety information. They also rely on each other for exchange of information in the regulation of medicine, for example regarding the reporting of side effects of medicines, the oversight of clinical trials and the conduct of inspections of medicines' manufacturers.

Venue

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More information on the event

How to find us

Welcome to EMA!