Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure

Friday, 20 April 2018

European Medicines Agency
London, United Kingdom

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

About this event

The European Medicines Agency is holding this meeting to inform veterinary companies on Brexit regulatory preparedness for centrally authorised products and address any specific questions they may have further to the publication of European Commission and EMA questions and answers document and EMA procedural guidance. This event is targeting small and medium enterprises' needs (SMEs) and is also open to all companies and stakeholders developing veterinary medicinal products.

Arrival at the Agency and registration

On arriving for your meeting at 30 Churchill Place, please report to reception where you will be issued with an access pass. This pass will allow you to enter our industry lounge, which you are welcome to utilise during your visit. The industry lounge is located through the sliding doors to the right of the reception desk past the security turnstiles. Your EMA contact point will meet you there.
We strongly advise you to arrive up to 30 minutes before the start of the Info day, to allow you time for registration. Please note that the Agency requires all visitors to provide a valid photo ID on arrival, such as passport, identity card or driving licence. Participants without a valid photo ID may be turned away.

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Venue

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Agenda

Brexit regulatory preparedness for veterinary medicinal products in the centralised procedure

9:00-12:00, Meeting Rooms: 3A and 3M

Chair of the meeting : Ivo Claassen, Head of Veterinary Medicines Division, EMA

Registration and coffee ...../ *8:30-9:00*

1. Welcome and opening remarks ...../ *9:00-9:15*

- *Ivo Claassen, Head of Veterinary Medicines Division, EMA*
- *Christian Siebert, Head of Animal Nutrition and Veterinary Medicines Unit, European Commission, DG SANTE (E5) (via TC)*
- *Ariane Vander-Stappen, Policy officer, Veterinary medicines, European Commission, DG SANTE (E5) (via TC)*

2. Update on EMA Brexit preparedness activities ...../ *9:15-9:25*

Anthony Humphreys, Head of Scientific Committees Regulatory Science Strategy, EMA

EMA working group on committee operational preparedness for veterinary medicines.../ 9:25-9:35

Isaura Duarte, Head of Veterinary Medicines Department (ad interim), EMA

3. Impact of Brexit on veterinary applications/marketing authorisations ...../ *9:35-10:15*

▪ *EC/EMA Questions and Answers*

Sandra Vanlievendael, Head of Long Term and Special Projects Office, EMA

▪ *EMA Practical Guidance, including post-authorisation aspects and impact on manufacturing and supply*

- *Beyhan Mustafov, Veterinary Regulatory & Organisational Support, EMA*
- *Andrei Spinei, Manufacturing & Quality Compliance, EMA*

Coffee Break ...../ *10:15-10:35*

4. Perspective from EU Industry Trade associations ...../ *10:35-10:50*

Association of Veterinary Consultants (AVC), AnimalhealthEurope, European Group for Generic Veterinary Products (EGGVP)

5. Questions and answers ...../ *10:50-11.55*

Moderator : Marie-Helene Pinheiro, Industry stakeholders liaison, EMA

Additional panellists :

- *Patrick Costello, Head of Service of Parallel Distribution and Certificates, EMA*
- *Monica Dias, Crisis Coordinating Officer, EMA*
- *Emily Drury, Head of Veterinary Regulatory & Organisational Support, EMA*
- *Alberto Ganan Jimenez, Head of Service for Evaluation Procedures D, EMA*
- *Anne-Christine Lantin, Veterinary Regulatory & Organisational Support, EMA*
- *Anabela Marcal, Head of Department for Committees and Inspections, EMA*
- *Zigmar Sebris, Regulatory Affairs Officer, EMA*

6. Interaction with Industry Stakeholders - Next steps ...../ *11:55-12:00*

Marie-Helene Pinheiro, Industry stakeholders liaison, EMA

7. Closing remarks ...../ *12:00*