

31 May 2017  
EMA/159266/2017  
Veterinary Medicines Division

## Programme - Focus group with invited stakeholders on field efficacy trials in the context of an EU authorisation for veterinary vaccines

Thursday, 22 June 2017, 13:00 – 18:00

Friday, 23 June 2017, 9:00 – 13:30

### Day 1, Thursday 22 June 2017 from 13:00 to 18:00 (Room 03-E)

Programme	Speaker	Time
<b>OPENING SESSION</b>		
– <i>Welcome remarks</i>	Dr Fia Westerholm (EMA)	13.00 – 13.05
– <i>Setting the scene: Steering Group introduction to focus group and objectives</i>	Dr Jean-Pierre Orand (HMA)/ Dr Faye Ioannou (EMA)	13.05 – 13.15
<b>SESSION 1: Identify specific challenges faced by industry in performing field trials to support efficacy claims</b>		
<b>Chair: Esther Werner (EU regulator)</b>		
– <i>Challenges faced by industry in performing field trials to support efficacy claims for food producing species</i>	Dr Frederic Descamps (IFAH- Europe)	13.15 – 13.30
– <i>Challenges faced by industry in performing field trials to support efficacy claims for small animals</i>	Dr Klaus Hellman (AVC)	13.30 – 13.45
– <i>Challenge models: under which conditions can the laboratory models be representative of field conditions to support the claims of veterinary vaccines - what are the pivotal parameters for defining the success of a challenge model</i>	Prof Etienne Thiry (University of Liège)	13.45 - 13.55
Moderated plenary discussion	All	13.55 – 15.10



Programme	Speaker	Time
Conclusions on session 1	All	15.10 – 15.25
<b>COFFEE BREAK (15.25 – 15.45)</b>		
<b>SESSION 2: Identify the value that field efficacy data may bring to the dossier for marketing authorisation of a veterinary vaccine</b>		
<b>Chair: Dr Jacques Léchenet (Industry representative)</b>		
– <i>EU Regulatory perspective and thoughts on field efficacy data</i>	Dr Jean-Claude Rouby (CADVVA, CVMP, ANSES)	15.45 – 16.05
– <i>Summary of interim results from analysis of field efficacy data for centrally authorised products</i>	Dr Martin Illott (EMA)	16.05 – 16.15
– <i>Requirements for field efficacy trials for the authorisation of veterinary vaccines in the USA and the rationale behind them</i>	Dr Paul Hauer (USDA - Centre for Veterinary Biologics)	16.15 – 16.30
Moderated plenary discussion	All	16.30 – 17.30
Conclusions on session 2	All	17.30 – 18.00

**Day 2, Friday 23 June 2017 from 9:00 to 13:30 (Room 03-E)**

Item	Agenda	Speaker	Time
<b>SESSION 3: Identify possible alternative sources of information on expected efficacy of a vaccine under field conditions</b>			
<b>Chair: Prof Kris De Clercq (Academic expert)</b>			
–	<i>Obtaining information on field efficacy for veterinary vaccines- challenges and solutions from an epidemiological perspective)</i>	Prof James Wood (Cambridge University)	09.00 – 09.15
–	<i>Alternative sources provided by recent system modelling in animal health for the upscaling of vaccine efficacy to the population level</i>	Dr Hans-Hermann Thulke (Helmholtz Centre for Environmental Research)	09.15 – 09.30
	Moderated plenary discussion	All	09.30 – 10.45
	Conclusions on session 3	All	10.45 – 11.00

Item	Agenda	Speaker	Time
<b>COFFEE BREAK (11.00 – 11.30)</b>			
<b>SESSION 4: Make recommendations on the need for field efficacy trials to support efficacy claims</b>			
<b>Chair: Dr David Murphy (CVMP Chair)</b>			
	Presentation of conclusions on session 1 and 2	Chairs	11.30 – 11.50
	Moderated plenary discussion	All	11.50 – 13.15
	Conclusions on session 4	All	13.15 – 13.30

## List of speakers

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Dr Jean-Pierre Orand (Head of ANMV – French Agency for Veterinary Medicines)

Dr Faye Ioannou (European Medicines Agency - Veterinary Medicines Division)

Dr Frederic Descamps (IFAH- Europe)

Dr Klaus Hellmann (Association of Veterinary Consultants - AVC)

Professor Etienne Thiry (University of Liège)

Dr Jean-Claude Rouby (CADVVA, CVMP, ANSES)

Dr Martin Illott (European Medicines Agency - Veterinary Medicines Division)

Dr Paul Hauer (USDA-Center for Veterinary Biologics)

Professor James Wood (University of Cambridge)

Dr Hans Thulke (Helmholtz Centre for Environmental Research-Leipzig)

## Session chairs

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Session 1 - Dr Esther Werner

Session 2 - Dr Jacques Léchenet

Session 3 - Professor Kris De Clercq

Session 4 - Dr David Murphy