Joint EMA / HMA Workshop on requirements for the authorisation of veterinary vaccines in the EU

25 March 2015, European Medicines Agency (EMA), London

PROGRAMME		
OPENING SESSION		**Chair: David Mackay**
9.00 – 09.05	Introduction and welcome	Andreas Pott
9.05 – 09.10	Setting the scene	Anja Holm
9.10 – 09.15	Introduction on the background, rationale and expected outputs for the meeting	Jean-Pierre Orand
9.15 – 09.20	European Commission - The risk manager's perspective	Agnieszka Kasperek
SESSION 1:	**Requirements for marketing authorisation of vaccines in the EU and impact on availability**	**Chair: Esther Werner**
9.20 – 9.40	**1.1 Review of requirements for vaccines in the EU and their evolution since the start of Community legislation on medicines**	Carmen Jungbäck
9.40 – 9.45	Moderated plenary discussion	All
	1.2 National experience of application of the requirements for marketing authorisations and other ways of making vaccines available	
9.45 - 10.05	Small MS's perspective	Jiří Bureš
10.05 – 10.25	Large MS's perspective	Jean-Claude Rouby
10.25 - 10.30	Moderated plenary discussion	All
	COFFEE BREAK (10.30 – 10.50)	
	1.3 Perspective on challenges meeting the requirements for authorisation of vaccines in the EU	
10.50 – 11.10	Industry perspective	Jacques Léchenet
11.10 – 11.30	Perspective of veterinary SMEs	Rhona Banks
11.25 – 11.30	Moderated plenary discussion	All

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	1.4 Requirements for vaccines in other regions	
11.30 – 11.50	Licensing requirements for vaccines: US perspective	Larry R. Ludemann
11.50 – 12.10	Requirements for vaccines in other regions of the world: Industry considerations	Vaughn Kubiak
12.10 - 12.15	Moderated plenary discussion	All
	LUNCH BREAK (12.15 – 13.30)	
SESSION 2:	**Setting data requirements as part of balancing benefits and risks when authorising vaccines**	**Chair: David John**
13.30 – 15.00	Breakout groups of mixed composition will discuss the following topics 1. To what extent can the challenges to availability of vaccines be addressed within the existing legal framework (not just MAs but also other ways)? 2. What are the particular areas that present challenges to industry and to regulators? 3. How to define and promote an appropriate level of flexibility and pragmatism in application of existing guidance? 4. What measures could stimulate the authorisation of more vaccines (reducing data requirements? If so, in what area? Other measures?)? ***COFFEE BREAK*** (15.00 – 15.20)	Groups
SESSION 3:	**General discussion and conclusions**	**Chair: Anja Holm**
15.20 - 16.30	Feedback from the breakout session	Rapporteurs
16:30 - 17:00	General conclusions and recommendations addressing the question: 'Are requirements for marketing authorisation of vaccines in the EU proportionate to the benefits and risks of this type of product?'	David Mackay

List of speakers

Anja Holm	Danish Health and Medicines Authority; Chair of the Committee for Medicinal Products for Veterinary use (CVMP), EMA
Jean Pierre Orand	Head of ANMV – French Agency for Veterinary Medicines
Agnieska Kasperek	DG Sante – European Commission
Carmen Jungbäck	Head of Section Veterinary Virology 1 in the Veterinary Department at the Paul-Ehrlich-Institut (PEI), Germany; IWP member
Jiří Bureš	Institute for State Control of Veterinary Biologicals and Medicaments, Czech Republic; CVMP member
Jean-Claude Rouby	French Agency for veterinary medicinal products, France; CVMP member
Jacques Léchenet	Regulatory Affairs, MERIAL
Rhona Banks	Veterinary Biologicals Consultant at RA-Elect
Larry R. Ludemann	Section Leader, Bacteriology, Center for Veterinary Biologic, Policy, Evaluation, and Licensing - USA
Vaughn Kubiak	Responsible for Biological Regulatory Affairs, Zoetis Inc.

Session chairs

David Mackay	Head of Veterinary Medicines, European Medicines Agency
Esther Werner	Paul-Ehrlich-Institut - Chair of the CVMP Immunological Working Party (IWP-V) at European Medicines Agency
David John	Technical Manager at IFAH-Europe
Anja Holm	Danish Health and Medicines Authority; Chair of CVMP, EMA

Programme Committee

David Mackay	Head of Veterinary Medicines, European Medicines Agency
Anastasia Kesisoglou	Scientific Administrator, European Medicines Agency
Jean-Pierre Orand	Head of ANMV – French Agency for Veterinary Medicines
Anja Holm	Danish Health and Medicines Authority; Chair of CVMP, EMA
Esther Werner	Paul-Ehrlich-Institut - Chair of the CVMP Immunologicals Working Party (IWP-V) at European Medicines Agency
David John	Technical Manager at IFAH-Europe