KLIFOVET AG
ADDED VALUE TO ANIMAL HEALTH

Expectations of the Annex 2 proposal of Regulation 2019/6

February 6-7, 2020 Maritim Hotel Munich, Goethestraße 7

Day 1		
Time	Topic	Presenters
12:00	Registration and Snacks	
12:50	Conference Opening and Introduction	Klaus Hellmann Klifovet AG, Germany
13:00	Regulation 2019/06 – delegating and implementing acts ▪ Progress in timelines for CVMP to provide drafts ▪ Major challenges ▪ Approach taken by EMA and expert groups to tackle the requirements ▪ How is this implemented into the international activities within VICH, OIE and bilateral agreements	Ivo Claassen Head of Veterinary Medicines Division at EMA
	Session 1: CVMP activities and specific risks	Session Chair: Klaus Hellmann, Klifovet AG
13:30	CVMP activities to facilitate implementation of Regulation 2019/06 ▪ Priority areas of activity for 2020 ▪ Opportunities and challenges ▪ Looking beyond implementation of Regulation 2019/6	David Murphy, CVMP Chair, HPRA, Ireland
14:00	Specific requirements to Environmental Risk Assessment with special focus on: ▪ Requisites for generics ▪ SPC harmonization and ERA ▪ PBT substances ▪ Cascade use in aquaculture	Ricardo Carapeto, AEMPS, Spain
14:20	Specific requirements to assess the risk of resistance development ▪ What's new for antimicrobials and antiparasitics? ▪ Risk assessment in food producing and companion animals ▪ Consequences of revised data requirements on the availability of VMPs	Christine Schwarz, BVL, Germany
14:40	Q&A and Discussion	Session Chair
14:50	Coffee break	
	Session 2: Pharmaceutical and Biological VMPs other than immunologicals	Session Chair: David John, Animal Health Europe
15:20	Specific requirements to the quality of pharmaceutical products ▪ Organisation of the work of the expert group ▪ Changes in the part II of the dossier for pharmaceutical products ▪ Changes in the requirements in the dossier for the different legal basis	Marie Helene Sabinotto, ANSES/ANMV, France
15:50	Requirements to the safety of VMPs including aspects for certain novel therapies ▪ Expectations for safety aspects of non-biological products ▪ Expectations for safety of certain novel therapies ▪ Resulting challenges and ways forward	Paul McNeill, HPRA, Ireland
16:20	Specific requirements to the efficacy of VMPs other than immunologicals ▪ Expectations for efficacy for non-biological products ▪ Expectations for efficacy for certain novel therapies ▪ Resulting challenges and ways forward	Christina Munoz, AEMPS, Spain
16:50	Requirements to biological VMPs other than immunologicals ▪ Examples of products ▪ Quality and safety ▪ Resulting challenges and ways forward	Frida Hasslung Wikström, Lakemedelsverket/Swedish Medical Products Agency, Sweden
17:20	Q&A and Discussion	Session Chair
19:00	Networking Dinner	All invited

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Day 2		
Time	Topic	Presenters
08:00	Coffee and Snacks	
	Session 3: Immunological VMPs and particular VMPs	Session Chair: Regina Wolf, Klifovet AG
08:30	Requirements to Immunological VMPs ▪ Quality, safety and efficacy with specific focus on changes compared to Dir 2009/9 ▪ Resulting challenges and ways forward	Martina von Freyburg, Boehringer Ingelheim, France
09:00	Proposal: Particular Veterinary Medicinal Products and its applications ▪ Vaccine antigen master file ▪ Multistrain dossier ▪ Vaccine platform technology	Jacqueline Poot, CBG, The Netherlands
09:30	Industry view: Particular VMPS and options for innovation: ▪ Vaccine antigen master file ▪ Multistrain dossier ▪ Vaccine platform technology	David John, Animal Health Europe, Belgium
10:00	Q&A and Discussion	Session Chair
10:15	Coffee break	
	Session 4: Novel therapies	Session Chair: Klaus Hellmann, Klifovet AG
10:45	General requirements and approach to the development of Novel Therapies ▪ Quality, safety and efficacy testing ▪ Further guidance required ▪ Challenges remaining	Esther Werner, Paul Ehrlich Institute, Germany
11:15	Specific requirements and approach to the development of Gene Therapy ▪ Gene therapy; constructs and diseases ▪ Human experience ▪ Veterinary opportunity – or not?	Anja Holm, Central VetPharma Consultancy, Denmark
11:35	Specific Requirements and approach to the development of Regenerative Medicine, Tissue Engineering and Cell Therapy ▪ Autologous versus allogeneic stem cell therapies ▪ Mechanism of action ▪ Dose response ▪ Biodistribution	Jan Spaas, Global Stem cell Technology, Belgium
11:55	Specific requirements and approach to the development of Phage Therapy ▪ What are Bacteriophages? ▪ Challenges for use as veterinary medicinal product ▪ Regulatory requirements in the view of technical needs	Anne Wuensch, Klifovet AG, Germany
12:15	Specific requirements and approach to the development of RNA Antisense Therapy and RNA Interference Therapy Products ▪ Mechanism of action and advantages of technology ▪ Requirements ▪ Examples from human therapy ▪ Potential therapeutic areas for veterinary medicine	Dorothe Pfeifer, Klifovet AG, Germany
12:35	▪ Q&A and Discussion	Session Chair
13:00	Lunch & end of conference	