Munich Conference on New EU Regulation on Veterinary Medicines and the Impact on Product Development and Life Cycle Management

January 31st – February 1st, 2019, Maritim Hotel Munich, Germany

DAY 1 – January 31st		
Time	Topic	Presenters
12:00-12:50	Registration and Snacks	
12:50-13:00	Conference Opening	Klaus Hellmann
13:00-13:30	Recap of the history and some new definitions	Rick Clayton
Session 1: Overview of the main changes (Chair: Rick Clayton, AnimalhealthEurope)		
13:30-14:00	The Regulation: pre-authorisation - The new procedures CP, DCP/MRP - Repeat use procedure - Packaging and labelling, - Limited markets, - Exceptional circumstances	Dries Minne (FAMHP, BE)
14:00-14:30	The Regulation: post-authorisation - Protection of technical documentation - Referrals - Variations - Pharmacovigilance - Databases x3 – products, PhV and GMP	Constance McDaniel (BVL, DE)
14:30-15:00	Q&A	Session Chair
15:00-15:30	Coffee break	
15:30-16:00	The Regulation: Manufacturing, Distribution and controls - Manufacturing - Inspection and controls - Distribution, retail and controls	Frank Verheijen (CBG-MEB, NL)
16:00-16:15	Q&A	Session Chair
Session 2: Impact on Product Development (Chair: Sabine Schueller, BfT)		
16:20-16:40	Impact on Innovation: enablers and disablers - Data protection - Limited markets - Restrictions and inhibitive requirements	Klaus Hellmann (Klifovet)
16:40-17:00	Impact on innovation: requirements regarding - Environmental safety - Antimicrobial resistance - Antiparasitic resistance	Brigitte Boenisch (Boehringer-Ingelheim / AnimalhealthEurope)
17:00-17:20	Impact on pre-authorisation procedures - Impact on administration - Impact on time to market Impact of product database and IT	Erik de Ridder (Elanco / AnimalhealthEurope)
17:20-17:45	Q&A and Discussion	Session Chair
18:00	Networking drinks and dinner	All invited

DAY 2 – February 1st		
Time	Topic	Presenter
Session 3: Impact on Life Cycle Management (Chair : Jean-Pierre Orand (Agence Nationale du Médicament Vétérinaire))		
09:00-09:30	Impact on post-authorisation procedures - variations, renewals, sunset clause, pharmacovigilance - Impact on administration Impact of databases	Kevin Yount (Bayer / AnimalhealthEurope)
09:30-10:00	SPC harmonisation and its Impact	David Murphy (CVMP/HPRA, IRE)
10:00-10:20	Q&A	Session Chair
Session 4: Transitional and Implementing measures (Chair: Ivo Claassen, Head of Veterinary Medicines Division, European Medicines Agency)		
10:20-10:40	Implication of transitional measures: - For new applications - Renewals - Variations	Jean-Pierre Orand (ANMV, FR)
10:40-11:00	Implementing measures - What is involved - What is the plan? Timelines and activities - Implementing act and delegated act adoption procedures and consultation of stakeholders	Ivo Claassen (European Medicines Agency)
11:00-11:30	Coffee Break	
11:30-12:00	Discussion on sessions 1 to 4	Session Chair
Session 5: Medicated Feed (Chair: Wolfgang Trunk (Animal Nutrition/Veterinary Medicines, DG Santé, European Commission)		
12:00-12:15	The New Regulation on Medicated Feedstuff - main goals and interconnection with the new VMP regulation	Wolfgang Trunk (DG SANTE, EC)
12:20-12:40	The New Regulation on Medicated Feedstuff – the view of the industry	Bob Cornez (Huvepharma / AnimalhealthEurope)
12:40-12:59	Questions & Discussion on MF	Session Chair
13:00	Conference Closure	Rick Clayton (AnimalhealthEurope)
13:00-14:00	Lunch available	