THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

VETERINARY ANNUAL SYMPOSIUM 2011

ROMANO
Retaining Older Medicines and Accessing New Ones

Monday 17th October 2011

Crowne Plaza Hotel, Via Aurelia, Rome, Italy

Con il patrocinio del Ministero della Salute (with the patronage of the Ministry of Health)
Italy

Working Party
Ray Harding, Cyton Biosciences, UK (chair)
Guillaume Agède - Ceva Santé Animale, France
Rhona Banks, Triveritas, UK
Rick Clayton – IFAH-Europe
Virgilio Donini – Ministero della Salute, Italy
Melanie Leivers – European Medicines Agency
Mária Szabó - Central Agriculture Office, Directorate of Veterinary Medicinal Products, Hungary
Beata Truskowska, Fatro SpA, Italy

Veterinary Symposium
Monday 17th October 2011

08:30	***Registration, Coffee and Exhibition***
09.00	**Opening Remarks:** **David Jefferys – *TOPRA President*** **Virgilio *Donini - Ministero della Salute, Italy***

SESSION 1: The future in Europe and beyond

This session will examine 3 major initiatives to improve the availability of authorised veterinary medicines in Europe and beyond. Each initiative will address the problem from an entirely different perspective. The first initiative aims to support the efforts of OIE to improve the governance of veterinary medicines in transitional and developing countries, thus improving access to authorised products; the second initiative aims to improve the regulation of veterinary medicines in Europe; and the third initiative aims to bring improvements via the better coordination of research.

Chair: Rick Clayton, Member of TOPRA Symposium Working Party and IFAH-Europe

09.10	**VICH Global Outreach Programme**
	Jean-Pierre Orand - *Directeur de l'Agence Nationale du Médicament Vétérinaire, France (Collaborating Centre for Organisation International des Epizooties) and OIE representative to VICH*
	• Objectives • Proposed structures • Action Plan • How this project could improve availability of veterinary medicinal products
09:35	**Review of the veterinary medicines legislation**
	Martinus Nagtzaam - *Policy Officer, DG SANCO, European Commission*
	• Impact Assessment of the current legislation – key findings • Policy direction in key areas or 'Avenues to explore' • Next steps and timeline • How this project could improve availability of veterinary medicinal products
10.00	**Review of the veterinary medicines legislation: contribution from Industry**
	Brigitte Boenisch - *Merial, Chair of IFAH-Europe 1-1-1 Concept Task Force*
	• Objectives • Main proposals • How this project could improve availability of veterinary medicinal products
10.25	**DISCONTOOLS programme**
	Declan O'Brien - *Managing Director, IFAH Europe and Project Coordinator, DISCONTOOLS*
	• Aims and objectives • Plans and structures • Outcomes and future maintenance • How this project could improve availability of veterinary medicinal products
10:45	**Questions and Discussion**
	The speakers will take questions from the floor – this is your opportunity to explore the topics more fully.
11:00	**Break**

SESSION 2: Extending the availability of existing veterinary medicines

This session will cover current initiatives from regulators and industry to improve the availability of existing products

Chair: Melanie Leivers, Member of TOPRA Symposium Working Party and European Medicines Agency (EMA)

11:30	**Harmonisation of SPCs Project at CMDv**
	Nicolaj Donskov Nielsen - *Regulatory coordinator, Danish Medicines Agency, Denmark*
	• The CMDv SPC harmonisation project – Motivation and scope • Principles and challenges • Today and tomorrow (status and future)
11:50	**Industry engagement with the CMDv SPCs Harmonisation Project**
	Guillaume Agède - *Global Director of Pharmaceuticals Regulatory Affairs, CEVA Santé Animale, France*
	• Interest for industry • History • How harmonisation could improve availability of veterinary medicinal products
12:10	**Applying the principles of the 1-1-1 Concept to existing products**
	Erik de Ridder - *Elanco and Chair IFAH-Europe Technical and Regula*tory *Committee*
	• Maintaining MAs after company mergers • Handling variations to MAs • How these principles could contribute to a single market for veterinary medicines
12.30	**Questions and Discussion**
	The speakers will take questions from the floor – this is your opportunity to explore the topics more fully.
12.45	**Lunch**

SESSION 3: Authorising New IVMPs

This session will focus on veterinary immunologicals for the first time at Topra. The three presentations are on different aspects and will highlight some possibilities to licence different sorts of vaccines. Learn how to take advantage of novel regulatory opportunities and prepare for licensing of novel vaccines.

Chair: Rhona Banks Member of TOPRA Symposium Working Party, Triveritas, UK

13:45	**Biosimilar and Generic IVMPs**
	Maria Tollis - *Istituto Superiore di Sanità, Italy*
	• Clarifications on terminology • Scientific approach to define biosimilar/generic IVMPs • Applications for biosimilar IVMPs: future perspectives
14:05	**The MUMS Guideline for IVMPs**
	Jean de Foucauld - *CEVA Santé Animale, France*
	• General considerations: Key minor diseases and species • Recent lessons learned • Advantages and issues with 'MUMS'
14:25	**Taking IVMPs based on GMOs through the regulatory process**
	Ralph Woodland - *Head of Biological Assessments, Veterinary Medicines Directorate, UK*
	• Directive 2001/18: Obtaining permission for national release • ERAs for GMOs • Getting GMOs authorised
14:45	**Questions and Discussion**
	The speakers will take questions from the floor – this is your opportunity to explore the topics more fully.
15:00	**Break**

SESSION 4: Improving efficiency of key regulatory activities

This session will review three of the most important activities that confront regulatory professionals in their day to day work. The speakers will look at how experience is continuing to shape the way that variations are managed, progress in the preparation of electronic submissions and an update on pharmacovigilance activities, particularly concerning expected future changes to the requirements

Chair: Ray Harding Chair of TOPRA Symposium Working Party

15:30	**Variations Regulation: Update**
	Melanie Leivers - *European Medicines Agency*
	• Changes of ownership of MAs: managing Variations • Update on working of the Variations Regulation • Guideline on classification of Variations
15:50	**Experience and Progress on Electronic Submissions for Veterinary Medicinal Products**
	Michael Colmorgen - *Global Regulatory Affairs Manager, Bayer Animal Health, IFAH-Europe representative for the Telematics Implementation Group for e-submission (veterinary), Chair of Change Control Group for e-submission standards*.
	• Achievements and latest developments • Key objectives for efficient e-submission • Future perspectives and conclusions
16:10	**Pharmacovigilance: present and future**
	Marie-Odile Hendrickx - *Pfizer, Chair IFAH-Europe Pharmacovigilance WP, member of VICH expert working group*
	• Future Proposals • VICH Guideline • Pharmacovigilance inspections
16:30	**Questions and Discussion**
	The speakers will take questions from the floor – this is your opportunity to explore the topics more fully.
16:50	**Vote Of Thanks – Ray Harding, Chair of TOPRA Symposium Working Party**
17:00	**Close of Symposium**