



THE ORGANISATION
FOR PROFESSIONALS IN
REGULATORY AFFAIRS

VETERINARY ANNUAL SYMPOSIUM

Regulators and Industry – some common approaches to improving the regulatory environment

Thursday 8th October 2009

Clarion Hotel, – Ringvägen, Stockholm, Sweden

Organised in conjunction with

Swedish Medical Products Agency

Conference working party

Ray Harding – Cyton Biosciences Ltd - chair

Henrik Holst - MPA, Sweden

Rick Clayton – IFAH-Europe

Mária Szabó - Central Agriculture Office,
Directorate of Veterinary Medicinal Products,
Hungary

Melanie Leivers – EMEA

Guillaume Agède - Ceva Santé Animale

Veterinary Symposium

Thursday 8th October 2009

8:30	Registration, Coffee and Exhibition
9:00	Opening Remarks: Henrik Holst - Associate Professor, Head of Veterinary Section, MPA, Sweden
	Session I: Keynote presentations on the opportunities for re-organisation of the regulation of veterinary medicines in Europe
	<i>The first session will bring together the three main strings shaping the direction of the forthcoming review of the veterinary medicines legislation; the HMA Reflection Paper on opportunities for improvement, the European Commission's impact assessment on the legislative options, and the HMA Strategy to develop an efficient European medicines regulatory network.</i>
	Chairperson: Rick Clayton – IFAH-Europe
9:10	"Opportunities for improving legislation" HMA Reflection Paper: Progress since 2008
	Catherine Lambert - International Affairs, AFFSA, France
09:40	Review of Veterinary Legislation in 2010, Impact Analysis in 2009
	Martin Terberger- Directorate-General for Enterprise and Industry – Head of Pharmaceuticals Unit, European Commission, Belgium
10:10	Progress on HMA Strategy for an efficient European Medicines Regulatory Network
	HMA Management group representative - TBC
10:40	Coffee and Tea
	Session II: Outcomes of recent joint focus group meetings and joint workshops
	<i>This session will address how regulatory authorities foresee the implementation of recent scientific and administrative guidelines and the discussion that took place with industry on key issues</i>
	Chairperson: Ray Harding – Cyton Biosciences Ltd
11:10	CVMP Oncology Guideline
	Fredrik Hultén - MPA, Sweden
11:30	CVMP Bioequivalence Guideline (6 May 2009)
	Karolina Törneke - MPA, Sweden
11:50	Electronic Submissions workshop (7 May 2009)
	Per Helboe - Senior Director of Licensing Division, Danish Medicines Agency, Denmark
12:10	Antimicrobial Resistance – follow-up from the joint HMA/EMA workshop (20 May 2009)
	Valerie Thomas, Intervet/Schering-Plough; Chair of IFAH-Europe Anti-infectives working party
12:30	Panel Discussion
12:45	Lunch
	Session III: CMDv initiatives - bringing efficiencies to the system
	<i>This session will provide an update on the CMDv 2009 work plan and will be illustrated by the policy initiative on packaging improvement</i>
	Chairperson: Guillaume Agède - Ceva Santé Animale, France
13.45	CMDv Work Programme

	Esther Werner - <i>Chair CMDv, Paul-Ehrlich-Institut, Germany</i>
14:05	Labelling Initiative; view of CMDv one year on
	Christophe Debruyne - <i>Federal Agency for Medicines and Health Products, Belgium</i>
14:25	Labelling Initiative; view of industry one year on
	Veena Singh - <i>Manager Veterinary Medicine Regulatory Affairs & Market Support, Pfizer Animal Health, UK</i>
14:45	Panel Discussion
15:00	Coffee and tea
	Session IV: Better regulation - bringing efficiencies to the system
	<i>This session will cover the on-going and new initiatives and proposals for better regulation in the veterinary sector.</i>
	Chairperson:
15:30	Variations: making the system work
	Melanie Leivers - <i>Deputy Head of Sector, Veterinary Marketing Authorisation Procedures, EMEA</i>
15:50	Pharmacovigilance update
	Ton Kamphuis - <i>College ter Beoordeling van Geneesmiddelen, NL</i>
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16:10	IFAH-Europe proposals for review of PV Chapter in 2010
	Sylvie Meillerais - <i>IFAH-Europe</i>
16:30	Panel discussion
16:45	Closing remarks – Henrik Holst, MPA Sweden and Ray Harding, Chair of TOPRA Conference Working Party and Veterinary Special Interest Network
17:00	Close of symposium