



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 (MPA)

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

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8:30	Registration, Coffee and Exhibition
9:00	Opening Remarks: Henrik Holst - Associate Professor, Head of Veterinary Section, Medical Products Agency(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 – Technical Director, IFAH-Europe	
9:10	"Opportunities for improving legislation" HMA Reflection Paper: Progress since 2008
	Catherine Lambert - International Affairs, AFFSA, France <ul style="list-style-type: none"> • Background to the development of the HMAv Reflection paper • HMAv vision for the future legislation for veterinary medicinal products • Main drivers, issues and proposals • Next steps in the further development of HMAv reflections towards the 2010 review
09:35	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 <ul style="list-style-type: none"> • Impact Assessment Process • Key steps and timelines • Questions to be addressed by the impact assessment
10:00	Progress on HMA Strategy for an efficient European Medicines Regulatory Network
	Steve Dean – Director and Chief Executive, Veterinary Medicines Directorate, UK <ul style="list-style-type: none"> • The development and implementation of the HMA Strategy I • HMA Strategy Paper II - Task Force and timelines • Shaping the strategy to reflect the HMA global vision including future legislation
10:25	Questions
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 – Managing Director, Cyton Biosciences Ltd	
11:10	CVMP Oncology Guideline
	Fredrik Hultén – EWP delegate, MPA, Sweden <ul style="list-style-type: none"> • The motives, from a regulatory point of view, for forming a guideline for oncology veterinary medicinal products • The differences between such products and other VMDs that has to be taken into consideration when designing studies to explore and confirm the quality, efficacy and safety
11:30	CVMP Bioequivalence Guideline

	Karolina Törneke – CVMP Delegate, MPA, Sweden
	<ul style="list-style-type: none"> • Overview of the ongoing revision
11:50	Electronic Submissions
	Per Helboe – <i>Chair of HMA e submission sub group, Senior Director of Licensing Division, Danish Medicines Agency, Denmark</i>
	<ul style="list-style-type: none"> • Role of the Telematics Implementation Group on e-submission - Veterinary Sub-group (TIGes-Vet) • Revised guideline on e-submission • Preparations for 1 January 2010 - workshops May and December 2009
12:10	Antimicrobial Resistance – follow-up from the joint HMA/EMA workshop
	Valerie Thomas - <i>Intervet/Schering-Plough; Chair of IFAH-Europe Anti-infectives working party</i>
	<ul style="list-style-type: none"> • The objectives; why the workshop was organized • Prudent use in the veterinary context • Collecting sales volumes of antibiotics • Monitoring antibiotic resistance
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 – <i>Head of European Regulatory Affairs, Ceva Santé Animale, France</i>
13.45	CMDv Work Programme
	Esther Werner - <i>Chair CMDv, Paul-Ehrlich-Institut, Germany</i>
	<ul style="list-style-type: none"> • CMD (v) work programme
14:05	Packaging & labelling issues One year on - Authorities View
	Christophe Debruyne - <i>Federal Agency for Medicines and Health Products, Belgium</i>
	<ul style="list-style-type: none"> • Background to IFAH -Europe and CMDv Packaging Projects • Why rationalise the requirements of labelling? • View of the CMDv • Way of working in Belgium • Continue communication: tri-lingual is standard
14:25	Packaging & labelling issues One year on - Industry Feedback
	Veena Singh - <i>Manager, Veterinary Medicine Regulatory Affairs & Market Support, Pfizer Animal Health, UK</i>
	<ul style="list-style-type: none"> • Modern requirements vs. historical requirements • Constraints to harmonisation (Authority and Industry) • Progress on short and longer term goals • Future initiatives
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: Peter Ekström – MPA, Sweden
15:30	Variations: making the system work

	Melanie Leivers - <i>Deputy Head of Sector, Veterinary Marketing Authorisation Procedures, EMEA</i>
	<ul style="list-style-type: none"> • Status of the procedural and classification guidance documents • Preparations for 1 January 2010
15:50	Pharmacovigilance update
	Ton Kamphuis - <i>College ter Beoordeling van Geneesmiddelen, Netherlands</i>
	<ul style="list-style-type: none"> • NTA Vol. 9B, work-sharing PSURs • Work-sharing PSUR's
16:10	IFAH-Europe proposals for review of PV Chapter in 2010
	Sylvie Meillerais – <i>Technical Project manager, IFAH-Europe</i>
	<ul style="list-style-type: none"> • Why a review of the pharmacovigilance chapter of the veterinary medicines Directive is needed in 2010? • IFAH-Europe proposals for the review • IFAH-Europe views on the pharmacovigilance chapter of the HMA Reflection Paper on the improvement of the veterinary pharmaceutical legislation
16:30	Panel discussion
16:45	Closing remarks – Henrik Holst, MPA Sweden
	Thank you – Ray Harding, Chair of TOPRA Conference Working Party and Veterinary Special Interest Network
17:00	Close of symposium