Workshop for OIE National Focal Points for Veterinary Products

XVI Seminar on Harmonization of Registration and Control of Veterinary Medicines

Americas Committee of Veterinary Medicines (CAMEVET)

Cartagena de Indias, Republic of Colombia
September 20-25, 2010

Within the framework of the initiatives to reinforce the quality of the Veterinary Services, derived from the current OIE Mandate, the Workshop for the Training of the National Focal Points on Veterinary Drugs of the Americas is to be held in September 20-25, 2010, in the city of Cartagena de Indias, Republic of Colombia.

The Workshop is only intended for the National Focal Points on Veterinary Medicines appointed by the countries of the American continent, and its Agenda shall cover not only those subjects relevant to the OIE, but also the responsibilities entailed the functions of the Focal Points.

The Veterinary Service of Colombia, the National Association of Laboratories for Veterinary Products (APROVET) and the veterinary branch of the Colombian Traders Federation (FENALCO) have planned parallel activities to be carried out during the days in which the Workshop is to take place, which are open to the representatives of the Associations, companies and every participant from the private sector, which include the Plenary Session of the Veterinary Industry on Tuesday, September 21st.

The XVI Seminar of the CAMEVET shall take place from September 22nd on the afternoon, to September 24th inclusive, and shall include the revision of the status of the implementation of the documents harmonized by the Committee, the connections between the CAMEVET and the OIE and other organizations and regional and global projects.

During September 23rd and 24th, several technical topics shall be introduced, which include the continuity of the advances achieved on the working documents raised during the previous Seminars, related to the following topics:

- Piracy and illegal practices.
- Good Manufacturing Practices in ectoparasticides.
- Requirements for the registration of homeopathic and fitotherapic products, and veterinary dietary supplements.
- Guide for the registration of biotechnologically obtained subunit immunogens.
- Stability in veterinary pharmacological products.
- Glossary of terms and definitions.

On the other hand, the Seminar is the opportunity to present and discuss the CAMEVET's Strategic Plan, which shall define the objectives and goals for the committee in the forthcoming years.

Finally, the US Food and Drug Administration and the US Department of Agriculture have scheduled a technical workshop for September the 25th, which includes several topics of interest to the attendees.

The forthcoming announcements, the updating of the preliminary agenda and the information regarding the location of the event shall be available in the Regional Representation for the Americas website, www.rr-americas.oie.int, and the Colombian Agriculture and Livestock Institute webpage, http://www.ica.gov.co.

Draft Agenda

Workshop for OIE National Focal Points for Veterinary Products

XVI Seminar on Harmonization of Registration and Control of Veterinary Medicines

Americas Committee of Veterinary Medicines (CAMEVET)

Cartagena de Indias, Republic of Colombia
September 20 – 25, 2010

Representación Regional de la OIE para las Américas
Paseo Colón 315, 5to. Piso "D" (C1063ACD), Buenos Aires, Argentina
Tel: (54-11) 4331-3919 / 5158 - Fax: (54-11) 4331-5162
e-mail: rr.americas@oie.int Web: http://www.rr.americas.oie.int

Workshop for OIE National Focal Points for Veterinary Products

Cartagena de Indias, Colombia, 20 – 22 September 2010

Day 1: Monday 20 September 2010			
Time	Theme	Duration	Speaker
08:00–09:00	Registration of participants		
09:00–09:30	Inauguration and Opening	30 min	Delegate of Colombia – Dr. Caicedo Lince Dr. L. Barcos – OIE
09:30–10:30	General presentation of the OIE	60 min	Dr. E. Erlacher Vindel
10:30–11:00	*Morning break – Coffee/Tea*		
11:00–11:20	OIE Reference Laboratories and Collaborating Centres	20 min	Dr. J. Oreamuno Toledo
11:20–11:30	Rights and responsibilities of Delegates and focal points	10 min	Dr. L. Barcos
11:30–11:50	o Good governance and the evaluation of Veterinary Services (OIE-PVS tool / PVS gap analysis)	20 min	Dr. L. Barcos
11:50-12:00	o International trade: Rights and obligations of OIE Members	10 min	Dr. L. Barcos
12:00–13:30	*Lunch*		
13:30–14:00	OIE Activities Linked to Veterinary Products o The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*	30 min	Dr. M. Minassian
14:00-14:20	o OIE Booklet on Standards for Veterinary Laboratories	20 min	Dr. M. Minassian
14:20-14:40	o OIE Procedure for the validation and certification of diagnostic assays	20 min	Dr. M. Minassian
14:40–15:00	Questions and answers	20 min	
15:00–15:30	*Afternoon Break - Coffee/Tea*		
15:30–16:10	Overview of Existing Structures Relevant for Veterinary Products o International structures ▪ VICH (description and expectation on the activities of focal points) ▪ CODEX (CCRVDF, Codex Task Force on Antimicrobial Resistance)	 20 min 20 min	 PaD + FDA G. Moulin
16:10–16:50	o Regional/structures ▪ EMEA (Europe) ▪ UEMOA (Africa) ▪ CAMEVET (America) ▪ Central American Customs Union	 10 min 10 min 10 min 10 min	 G. Moulin C. Lambert M.Minassian TBD
16:50–17:10	o The view of the European Commission	20 min	TBD
17:10–17:20	Questions and answers	10 min	
20:00	*Official Dinner or Cocktail (to be confirmed)*		

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Day 2: Tuesday 21 September 2010			
Time	Theme	Duration	Speaker
09:00–09:20	TORs and expected actions of OIE focal points on veterinary products	20 min	E. Erlacher Vindel
09:20–10:20	Areas of interest of focal points on veterinary products ▪ Antimicrobials (existing chapters, collaboration with WHO, etc) ▪ Other veterinary products ▪ Vaccines	 30 min 10 min 20 min	 G. Moulin P. Dehaumont P. Dehaumont
10:20–10:30	Questions and answers	10 min	
10:30–11:00	*Morning break – Coffee/Tea*		
11:00–12:00	Modalities (authorisation process, surveillance, distribution, control) o Assessment and authorisation of Veterinary Products ▪ Legislation framework (including OIE activities) ▪ Marketing authorisation and assessment procedures ▪ Quality assessment ▪ Safety assessment/residues ▪ Efficacy assessment ▪ Assessment of immunologicals	 10 min 10 min 10 min 10 min 10 min 10 min	 P. Dehaumont G. Moulin
12:00–12:30	o Surveillance ▪ Control laboratories (Quality/residues/antimicrobial resistance partly covered in a broader view at 9:20) ▪ Pharmacovigilance ▪ Residues	 10min 10 min 10 min	 C. Lambert
12:30–14:00	*Lunch*		
14:00–14:20	o Distribution and use	20 min	C. Lambert
14:20–15:00	o Inspection ▪ At manufacture ▪ Wholesaling ▪ Retailing ▪ Prescription ▪ Usage	 10 min 10 min 5 min 5 min 10 min	 P. Dehaumont
15:00–15:30	Introduction to the working sessions o Need for a good governance regarding Veterinary Medicinal Products o Preparation of the working sessions (election of rapporteurs)	 30 min	 P. Dehaumont

Day 3: Wednesday 22 September 2010			
Time	Theme	Duration	Speaker
09:00–10:30	Reports from Working Groups and discussion (plenary)	90 min	Each rapporteur
10:30–11:00	*Morning break – Coffee/Tea*		
11:00–12:00	Review of the Terms of Reference and final discussion	60 min	E. Erlacher Vindel
12:00–12:30	Conclusions and closing OIE Focal Point Seminar	30min	Dr. Luis Barcos

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XVI Seminar on Harmonization of Registration and Control of Veterinary Medicines - CAMEVET

Cartagena de Indias, Republic of Colombia, 22 – 24 september 2010

Day 1: Wednesday 22 September 2010			
Time	Theme	Duration	Speaker
10:00–14:00	Registration of participants		
14:00–15:30	Opening Session..... • Assumption of the Presidency and Vice- Presidency charges • Seminar opening speeches o OIE Regional Representative o Veterinary Industry Representative o Colombia Official Representative	90 min	TBD
15:30–16:00	*Coffee Break*		
	I Session - CAMEVET relations Implementation of the guidelines harmonized by the Committee		
16:00–17:00	Procedures for the participation of CAMEVET in the proposals for the creation and modification of OIE Standards Presentation of the Report of the OIE General Session. Responsibilities of CAMEVET in the follow-up of the discussed topics.	60 min	TBD OIE Regional Representation for the Americas
17:00–17:30	Results of the participation in the OIE Conference on Veterinary Medicinal Products in the Middle East "Towards harmonization and improvement of registration, distribution and quality control"	30 min	Dr. M. Minassian Secretary - CAMEVET

Day 2: Thursday 23 September 2010			
Time	Theme	Duration	Speaker
	I Session *(Continued)*		
09:00–09:45	Presentation of the CAMEVET Strategic Plan	45 min	Dr. E. Argento CAMEVET Executive Board
09:45-10:15	State of implementation of harmonized documents in Member Countries	45 min	Dr. M. Minassian Secretary - CAMEVET
10:15–10:45	*Coffee Break*		
10:45-11:15	Conclussions of the Veterinary Industry Plenary Session	45 min	TBD
11:15-11:45	Conclussions of the Workshop for OIE National Focal Points for Veterinary Products	45 min	TBD
11:45-13:00	Discussion.....	75 min	Official and private sector representatives
13:00-14:30	*Lunch*		

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Day 2: Thursday 23 September 2010			
Time	Theme	Duration	Speaker
	II Session – Working Papers		
14:30-15:00	Guideline for the registration of veterinary phytotherapeutical products..... Presentation of the working paper	30 min	Dr. Cristina Fischer Regner
15:00-15:30	Guideline for the registration of veterinary homeopathic products..... Presentation of the working paper	30 min	TBD
15:30-16:00	*Coffee Break*		
16:00–16:30	Guideline for the registration of veterinary nutraceutical products.....	30 min	TBD
16:30–17:00	Good Manufacture Practices for ectoparasiticide veterinary products..... Presentation of the final document developed by the ad-hoc group	30 min	Dr. C. Francia - CAPROVE
17:00-17: 30	Guidelines for efficacy testing for antiparasitic products – Ruminants and swine ..... Presentation of the revised document	30 min	TBD

Day 3: Friday 24 September 2010			
Time	Theme	Duration	Speaker
	II Session *(Continued)*		
09:00–09:45	Guideline for the registration of biotechnologically obtained subunit immunogens	45 min	TBD
09:45-10: 30	Presentation of the Glossary of terms and definitions.	45 min	TBD
10:30–11:00	*Coffee Break*		
11:00–11:45	Stability in veterinary pharmacological products.....	45 min	TBD
11:45-12:15	Good Distribution and Commercialization Practices for veterinary products..... Presentation of the working paper	45 min	Milson da Silva Pereira (SINDAN)
12:15-13:00	Piracy and unlawful practices in veterinary products trade..... Presentation of the working paper	45 min	Dr. H. Cifuentes Sguerra (APROVET)
13:00–14:30	*Lunch*		
	III Session – Technical Presentations		
14:30–15:30	(To be defined)		TBD
	IV Session – Conclusions and recommendations		
15:30–16:15	Presentation of training activities to be carried out by CAMEVET Approval of the proposal on location for next Seminars. Expenses report, financial status and budget	45 min	
16:15–16:45	*Coffee Break*		
16:45–17:45	Renewal of the CAMEVET Executive Board positions ..... Conclussions and reccomendations. Approval of the final document.....	45 min	
17:45	Awards for Committee participants Closing of the Seminar		

Parallel Activities related to the event

Monday 20 September 2010	
20:00	Official Cocktail

Tuesday 21 September 2010	
Time	Theme
8:00-14:00	Plenary Session of the Veterinary Industry Meeting for the representatives of the Associations and the participant companies, with the purpose of the exchange of proposals related to the CAMEVET activities and the production of a position paper.
14:00	Veterinary Industry Business Meeting Business meeting for the veterinary industry participants.

Saturday 25 September 2010	
Time	Theme
8:30-17:30	FDA/USDA Workshop (See annex agenda)

Other relevant information

Translation services (English – Spanish) shall be provided.

Venue information

Seminar shall be held at Hotel Hilton Cartagena
Avenida Almirante Brion, El Laguito, Cartagena, Colombia 1774
Tel: 57-5-6650660 Fax: 57-5-6652211

The list of alternative hotels and the contact information for reservations is available at the Colombian Agriculture and Livestock Institute (ICA) webpage, www.ica.gov.co

Transportation

Official transportation for the event shall be provided by Avianca, offering special fares for the participants. For more information on the discounts available and flight reservations, please contact the ICA webpage.

Registration

Registration fee is 200 US Dollars, to be paid at the beginning of the Seminar.
The registration shall be free of charge for Government representatives.

Pre-registration for the Seminar is recommended, with no charge. Please confirm your participation by contacting the OIE Regional Representation for the Americas, tel/fax

(54-11) 4331-3919/4939/5158/5162/5165, or e-mail to rr.americas@oie.int, with copy to Dr. Martín Minassian, CAMEVET Secretary, secretaria@camevet.org. Pre-registration can also be made through the ICA website.

Hotel booking is not included in the Seminar registration.

More information and updates for this Agenda will be also available at the OIE Regional Representation and ICA web sites.
http://www.rr-americas.oie.int/es/proyectos/es_camevet.htm
www.ica.gov.co

Important – Visas for entering the Republic of Colombia

The Republic of Colombia requires an entrance permit for certain countries, for which the consult to the Republic of Colombia Foreign Relations Ministry or their consular delegations is recommended.

Listing of countries and requirements for migration procedures are available at the webpage http://www.cancilleria.gov.co/.

Plenary Session of the Veterinary Industry
Tuesday 21 September 2010

Time	Theme	Coordinador
8:00-14:00	CAMEVET achievements	(to be designed)
	Presentation of the CAMEVET Harmonized Documents to the OIE Scientific Committee	
	Problems in the marketing of veterinary products Unregistered products Illegal markets Lack of controls Unfair competition	
	Overlapping rules issued by different agencies	
	Requirements for traceability systems implementation	
	Analytical Techniques	
	Product – Package Interaction	
	Closing and conclussions	

Veterinary Industry Business Meeting
Tuesday 21 September 2010

Time	Theme
14:00	Veterinary Industry Business Meeting Business meeting for the veterinary industry participants.

FDA/USDA Workshop

Update on Approving Veterinary Drugs and Biologics

Saturday 25 September 2010

Sábado 25 de septiembre de 2010			
Hora	Tema	Duración	Disertante
8:30–9:30	The FDA in Latin America	60 min	G. Kopper, FDA
9:30–10:30	Implementing new VICH pharmacovigilance guidelines for biologics in the US	60 min	R. Hill, USDA
10:30	Break		
11:00-13:00	Special considerations for the approval of antimicrobial drugs o Update on the revision of the VICH guideline on impact of residues on human intestinal flora o How the assessment on effects on intestinal flora influences the ADI for a drug o Structuring the approved conditions of use to mitigate antimicrobial resistance during the approval of antimicrobial drugs	120 min	H. Fernández H. Fernández S. Piñeiro
13:00-14:15	*Lunch*		
14:15-15:30	Role of Residue Chemistry in the approval of animal drugs o Comparison of approval processes ▪ Pioneer products ▪ Generic products ▪ Generic products o Determination of withdrawal times	45 min	L. Friedlander
15:30-16:00	*Break*		
16:00-16:45	U.S. Drug Residue Programs	45 min	D. Cera
16:45-17:30	Discussion with attendees	45 min	
17:30	Closure and distribution of certificates		

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