Draft Agenda

XIV SEMINAR ON HARMONIZATION OF REGISTRATION AND CONTROL FOR VETERINARY MEDICINES

Americas Committee on Veterinary Medicines (CAMEVET)

Asunción, Republic of Paraguay

September 8 – 13, 2008

According to the activities developed in the CAMEVET since year 1992, and due to the agreements reached during the XIII Seminar in year 2007 in Santo Domingo, Dominican Republic, next Seminar is announced for September 8 – 13th.

As a result of the proposals and conclusions of the previous Seminars, various technical and operative issues will be discussed, especially analyzing the situation related to the application of the working documents harmonized by the Committee in Member countries, and the elaboration of worldwide standards through the chapters corresponding to veterinary medicines in the Terrestrial and Aquatic Animal Health Codes of the World Organization for Animal Health (OIE).

The technical topics to be discussed include the revision of the working papers related to the application of Good Manufacturing Practices for ectoparasiticides as well as the audit guides corresponding to pharmacological and biological products, the approaches for the establishment of shelf life in veterinary products, efficacy assays for antiparasitaries, and a reference document on illegal practices in the commercialization of veterinary products.

During the Seminar various presentations shall be carried out, on topics as the approval process for biological products based on genetically modified organisms, the approaches for bioequivalence tests in veterinary products, and a presentation on antimicrobial resistance, among other issues.

Finally, and as an associated event, a Workshop will be carried out by personnel of the US Food and Drug Administration Center for Veterinary Medicine and will focus on the update on human food safety requirements for antimicrobial veterinary drugs approval.

XIV SEMINAR ON HARMONIZATION OF REGISTRATION AND CONTROL FOR VETERINARY MEDICINES

Monday, September 8th

Registration

Meeting for Representatives from Veterinary Products Industry

Tuesday, Septiember 9th

Registration (continued)

Opening speeches

Session opening. Assumption of CAMEVET's President and Vice-president

Speeches carried out by official, industrial and OIE representatives.

Outcomes of the participation in the OIE Conference on Veterinary Products in Africa

Dr. Martín Minassian – CAMEVET Secretary

Evaluation of the CAMEVET activities related to the Terrestrial and Aquatic Animal Health Code.

Procedures for the participation of CAMEVET on the proposals for creation and modification of the OIE Standards

Dr. José Joaquín Oreamuno – OIE Subregional Representative for Central America

Presentation of the Central American Technical Regulation "Veterinary products: Facilities, Registration and Control"

Dr. Benigno Alpízar Montero–Head of the Departament of Registration and Control for Veterinary Medicines, National Secvices for Animal Health, Costa Rica

Follow up of CAMEVET documents – Update and application of approved guidelines in the Member countries.

Dr. Martín Minassian – CAMEVET Secretary

Wednesday, September 10th

Good Veterinary Practices related to the use of Veterinary Medicines

Presentation of the comments for the working paper (Step III)

Dr. Carlos Francia – CAPROVE (Argentina)

Milson da Silva Pereira – SINDAN (Sindicato Nacional da Indústria de produtos para Saúde Animal)

Criteria for the establishment of shelf life in veterinary products

Presentation of the comments for the working paper (Step III)

Lecturer to confirm

Good manufacturing practices for ectoparasiticides

Presentation of the document developed by the working group

Lecturer to confirm

Efficacy tests for antiparasitic products for ruminants and swines

Presentation of the modification proposals for the working paper (Step III)

Dr. Martín Minassian – CAMEVET Secretary

Unlawful practices in veterinary products trade

Presentation of the draft working paper

Hernan Cifuentes Sguerra – Asociación Nacional de Productos Veterinarios– Colombia

Good Manufacturing Practices in Pharmacological and Biological products.

Revision of the proposals for modification of the audit guides for pharmacological and biological products.

Presentation of comments to the working paper (Step III)

Dr. Martín Minassian – CAMEVET Secretary

Thursday, September 11th

Update on Good Manufacturing Practices

Dra. Berta Giner - Gerente de Regulatorio e Investigación. Elanco Animal Health Latinoamérica.

Discussion on the application and the harmonization of the Good Manufacturing Practices in the CAMEVET member countries

Coding systems applied for lot numbers, manufacture and expiration dates on veterinary products

Presentation of the proposal for the draft document.

Milson da Silva Pereira – SINDAN (Sindicato Nacional da Indústria de produtos para Saúde Animal) - Brasil

Criteria applied for the approval of biological products containing genetically modified organisms

Presentation of the positions applied on USA and European Union

Lecturers to confirm

Bioequivalence and registration of generic veterinary products

Dr. Tomás Martín Jiménez – Profesor Asistente de Farmacología. Departamento de Medicina Comparativa, Universidad de Tennessee

Update on Bacterial Resistance to Antimicrobials

Dr. Tom Shryock – Microbiologist, Elanco USA.

FDA international extension activities, CAMEVET relations with VICH and Codex Alimentarius International

Dr Merton Smith - Special Assistant for International Activities – FDA Center for Veterinary Medicine

Conclusions and Recommendations

Other activities associated to the event

Monday, September 8th (Evening)

Meeting for Representatives from Veterinary Products Industry

An open meeting for all of the representatives from Associations and companies will be developed, in order to exchange opinions and positions related to the activities carried out by CAMEVET.

Friday and Saturday, September 12th – 13th

Update on Human Food Safety Requirements for Antimicrobial Veterinary Drugs Approval

Workshop developed by Dr Lynn Friedlander, Steve Yan and Haydée Fernández (Center for Veterinary Medicine, US Food and Drug Administration)

(see details below)

Accomodation

Seminar will be held at **Hotel Guaraní Esplendor**

Oliva esquina Independencia Nacional, Asunción, Paraguay.

Tel: 595 21 452099

http://www.guaraniesplendor.com/

Reservations: **reservas@guaraniesplendor.com**

Languages

Translation services (English – Spanish - Portuguese) will be provided.

Registration

Registration fee will be 200 US Dollars, which will have to be paid at the beginning of the Seminar. Government representatives' participation is free of charge.

Pre-registration can be made by confirming your participation to the OIE Regional Representation for the Americas, tel/fax (54-11) 4331-3919/4939/5158/5162/5165, or by e-mail to **rr.americas@oie.int** with copy to CAMEVET Secretary **m.minassian@gmail.com**

More information and updates for this Agenda will be also available at the OIE Regional Representation web site.

Hotel reservations are not related to the Seminar registration.

Updates for the working Agenda shall be available at the Regional Representation webpage. **http://www.rr-americas.oie.int/es/proyectos/es_camevet.htm**

Workshop

Update on Human Food Safety Requirements for Antimicrobial Veterinary Drugs Approval

September 12-13, 2008

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Sept.12 (Friday):

9:00 – 10:00	Overview of current human food safety requirements for antimicrobial veterinary drugs
10:30 – 11:00	Safety assessment of antimicrobial veterinary drug residues on human intestinal flora
11:00 – 11:30	Break
11:30 – 12:30	History and development of Guidance For Industry (GFI) #152
12:30 – 2:00	Lunch
2:00 – 3:00	Application of GFI #152 in the U.S. antimicrobial veterinary drug approval process
3:00 – 3:30	Break
3:30 – 4:30	Impact and experiences with GFI #152
4:30 – 5:30	Discussion with attendees

Sept. 13 (Saturday):

9:00 – 10:00	Setting withdrawal times
10:00 – 11:00	Role of different components of human food safety on the final approval of an antimicrobial drug
11:00 – 11:30	Break
11:30 – 12:30	Discussion with attendees

IMPORTANT-Participants of the official sector

The participation costs for the FDA Workshop (hotel expenses and daily per diem corresponding to 77 dollars) will be covered for the representatives of the official sector.

Since the financing is limited to 30 participants (not existing a limit to participate in the workshop), it is important that those attendees notify of their participation **before August 22** to the Secretary of the CAMEVET-Dr. Martin S. Minassian (m.minassian@gmail.com) and Dr. Haydée Fernández (Center for Veterinary Medicine - US Food and Drug Administration - haydee.fernandez@fda.hhs.gov)