

Preliminary version - June 2007

XIII SEMINAR ON HARMONIZATION OF REGISTRATION AND CONTROL FOR VETERINARY MEDICINES

Americas Committee on Veterinary Medicines (CAMEVET)

Santo Domingo, República Dominicana August 7th - 10th 2007



Following the activities developed in CAMEVET since year 1992, and as a result of the 12th Seminar on harmonization of registration and control for veterinary medicines, which has been held in the city of Panama in 2006, next Seminar on Harmonization of Registration and control of Veterinary products will be held in the city of Santo Domingo, Dominican Republic from August 7th to 10th.

As a result of the proposals and conclusions from previous Seminars, many technical and operative items will be presented, and will focus on the actual situation related to the process of harmonization and application of the CAMEVET quidelines in the Member countries.

Technical guidelines on Audit Guides and protocols for evaluating the efficacy of products intended for internal parasites will also be discussed

Technical issues shall be discussed, as those related to the utilization of veterinary medicines in aquaculture, and the presentation of the proposals for working papers related to Good Manufacturing Practices for ectoparasiticides, as the criteria for stability tests in veterinary products.



XIII SEMINAR ON HARMONIZATION OF REGISTRATION AND CONTROL FOR VETERINARY MEDICINES

Tuesday, August 7th

10:00 - 13:00 Registration

(Registration will be available since August 6th)

14:00 - 15:30 Opening session. Assumption of CAMEVET's President and Vice-president

Opening speeches

Lic. José Manuel Mallén

President – Association of Manufacturers, Importers and Representatives of Veterinary Products

Dr. Luis Barcos

Regional Representative for Americas – World Organisation for Animal Health

Government Representative – Dominican Republic

15.30 - 16:30 Follow up of CAMEVET documents – Update and application of approved guidelines in the Member countries.

Dr. Martín Minassian - CAMEVET Secretary

Dr. Carlos Menéndez – Regional Coordinator of the Registration Officers for Veterinary Medicines and Animal Feedstuff – OIRSA

16:30 - 17:00 Coffee



17:00 - 18:00 Good Veterinary Practices related to the use of Veterinary Medicines

Presentation of the working paper prepared by the ad-hoc group

Dr. Carlos Francia – CAPROVE (Argentina)

18:00 - 18:30 Discussion

Wednesday, August 8th

O8:30 - O9:30 Criteria for the establishment of shelf life in veterinary products
 Presentation of the working paper (Step I)

 Q.F. Griselda Malán - DILAVE - Uruguay

09:30 - 10:00 Discussion

10:00 - 10:30 Coffee

10:30 - 11:15 Good manufacturing practices for ectoparasiticides

Presentation of the working paper (Step I)

Dr. Carlos Francia – CAPROVE (Argentina)

11:15 - 12:15 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

12:15 - 13:00 Discussion

13:00 - 14:00 Lunch

14:00 a15:30 Use of veterinary products in aquaculture



Ing. Birmania Martínez Gómez - Aquatic Animals Health Office - MAGFOR - Nicaragua

I: Use of veterinary products in aquaculture: Applications and regulatory aspects

II: Situation on residues of veterinary products in aquaculture

15: 30 - 16:00 Discussion

16:00 - 16:30 Coffee

16:30 - 18:45 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, August 9

08:30 - 09:30 Use of combinations of active pharmacological ingredients in fixed dosage products.

Dr. Benigno Alpízar Montero - Head of Department - MAG - Costa Rica

09:30 - 10:15 Discussion – Creation of a working group for the preparation of a working paper

10:15 - 10:45 Coffee

10:45 - 11:45 Sampling in biological products

Dr. Ricardo Rego Pamplona – Jefe de División de Productos Biológicos – MAPA - Brasil

11:45 - 13:00 Panel discussion: Regulatory aspects related to the registration of nutraceuticals, homeopatic and herbal medicines

Coordinator to be designed



13:00 - 14:00 Lunch

14:00 - 15:00 Registration Standards Project

This issue has the objective to present a project intended to establish minimal requisites for the worldwide products registration, using internationally recognized regulatory agencies as an example, and to propose the requisites that could be adopted or adapted for the situation in each country.

This project is being developed with the support of the industrial associations from United States

Bertha Giner – Technical and Regulatory affairs Manager for Latin America, Elanco.

15:00 - 16:00 Update on Bacterial Resistance

This presentation is directed to present the actual situation about the studies on antimicrobial resistance around the world and also the conclusions of international entities related to the fact that the ban on some drugs does not endorse any concrete benefit. Also focuses on presenting different alternatives for the administration of the OIE's critically important antimicrobial list, and proposed alternatives by international organizations (IFAH) which are different from prohibitions.

The presentation is considered to be useful for Latin American regulatory authorities, regarding next Codex Alimentarius meetings, which will be held in Rome (September, 2007) and North Korea (October, 2007).

Tom Shryock - Microbiologist PhD, Elanco USA.

16:00 - 16:30 Coffee

16:30 - 18:00 Conclusions and Recommendations

Activities related to the Seminar

Monday, August 6

18:00 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, August 10

Workshop: "Methodologies used for the calculation of meat and milk withdrawal periods"

Lecturers and schedules to be confirmed

Languages

Translation services (English - Spanish / Spanish - English) will be provided.

Accommodation

Seminar will be held at Hotel Coral Hamaca, Santo Domingo, Dominican Republic.

Recommended prices for participants are:

Single Room USD 420

Double Room USD 340

Triple Room USD 280

Prices include four nights of accommodation, food and snacks, drinks, aquatic sports and taxes.

Reservations and information

Turenlaces del caribe, s.a.

Calle "C" No. 32, Piso 2, Reparto Esteva - Santo Domingo - Republica Dominicana Tel: (809) 565-3500 - Fax: (809) 565-1221 - Email: congresos@turenlaces.com http://www.turenlaces.com/congresos.html

In order to make the reservation, download the reservation form at the web page, complete it and send it by fax.

Hotel reservations are not connected to the Seminar registration.

Registration

Registration fee will be 205 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.

(Spanish and English versions)

http://www.rr-americas.oie.int/es/proyectos/es camevet.htm http://www.rr-americas.oie.int/in/proyectos/in_camevet.htm