



## **VIII SEMINAR ON HARMONIZATION AND CONTROL OF VETERINARY MEDICINES**

**MERIDA, Yucatan (MEXICO). 12-16 August, 2002**

**HOTEL HYATT REGENCY MERIDA**

**ORGANIZATION:** Coordinated by OIE with the cooperation of the IICAB (Institute for International Cooperation on Animal Biologics), SAGARPA and FILASA

### **OBJECTIVE:**

This Seminar continues with the cooperation program developed by the OIE in Latin-America since 1992 regarding the harmonization of the registration and control of veterinary medicines. It is organized based on the experiences acquired in the previous seven Seminars, and to follow up the conclusions of last Seminar hold in Lima (Peru) in August 2001.

Considering the proposals and conclusions derived from the previously hold Seminars, during this VIII Seminar several technical and operative subjects are posted to reach institutionalization of harmonization of the registration and control of veterinary medicines in the American country members of OIE. This harmonization of veterinary medicines will be carried out not only to discuss the harmonization of technical guidelines but problems regarding administrative procedures as to facilitate the veterinary medicines import-export between countries of the Region. Another aspect of this Seminar is to work out effectively on the integration of the private Sector in the animal health programs throughout CAMEVET (Committee of Veterinary Medicines for the Americas), improve the GMP systems and also discuss on the solution of real problems to facilitate better understanding and interchange among the region countries.

This Seminar seeks, too, for the improvement of the Regional Representations's web site that allows a great diffusion of the Official Veterinary Services Registration of the veterinary products that are presented to the world from the Region.

## AGENDA

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### MONDAY AUGUST 12<sup>TH</sup>:

- 8:00-9:00 AM - Registration
- 9:00-9:30 AM - Inaugural Session  
CAMEVET's President and Vice-president assumption
- 9:30-10:30 AM - **TOPIC I:** Adjustment of harmonization of guidelines for the pharmacologics selected during the VII Seminar (see attached list)
- 10:30-11:00 AM - Coffee break
- 11:00-12:30 AM - **TOPIC I:** Harmonization of pharmacologics (cont.)
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - **TOPIC I:** Harmonization of pharmacologics (cont.)
- 4:00-4:30 PM - Coffee break
- 4:30-6:00 PM - **TOPIC I:** Harmonization of pharmacologics (continuation and finalization)

### TUESDAY AUGUST 13<sup>TH</sup>

- 9:00-10:30 AM - **TOPIC II:** Harmonization of Biologics . Revision selected in the VII Seminar (see attached list)
- 10:30-11:00 AM - Coffee break
- 11:00-12:30 AM - **TOPIC II** (cont.)
- 12:30-14:30 AM - Lunch
- 2:30-4:00 PM - **TOPIC II** (cont.)
- 4:00-4:30 PM - Coffee break
- 4:30-5:30 PM - **TOPIC II** (cont.)

## WEDNESDAY AUGUST 14<sup>TH</sup>

- 9:00-10:30 AM - **TOPIC III. CAMEVET MEETING**  
Development of the II Assembly  
Discussion on relations with other Institutions  
Projects for activities  
Budget discussion
- 10:30-11:00 AM - Coffee break
- 11:00 - 12:30 AM - **TOPIC IV:** Report on VICH activities. Progress in the Working Groups. Dr. Merton V. Smith (CVM-FDA-USA)  
Dr. Richard Hill (Director Development of Licenses and Policies – USDA, APHIS.
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - **TOPIC V. Adventitious agents in biologics products and biological materials.**  
2:30 - 3:25: - Dr. Linn Wilbur (APHIS-USDA) " Freedom from Adventitious Agents for US Veterinary Biologics Products  
  
3:25 - 3:45 Pawan Agrawal (Veterinary Biologics Section- Canadian Food Inspection Agency) " Materials of Animal Origin Used in the Preparation of Veterinary Biologics"  
  
3:45\_ 4:00 -Dr. James Roth, IICAB (Institute for International Cooperation in Animal Biologics) (AMES-IOWA-USA) OIE Collaborator Center.
- 4:00-4:30 PM - Coffee break
- 4:00-5:00 PM - **TOPIC VI:** Functioning of Web page  
Dr. Lieven Uytterhaegen
- 5:00-5:30 PM - “International Cooperation Project”  
**Margarita Arboix** (Spanish Agency of Medicines)

## THURSDAY AUGUST 15<sup>TH</sup>

- 9:00-10:00 AM - **TOPIC VII:** GLOSSARY: Proposition of plan by Uruguay. Delegation
- 10:00-10:30 AM - **TOPIC VIII :** Classification of Harmonized technical Guidelines from previous Seminars
- 10:30-11:00 AM - Coffee break

11:00-12:30 AM - **TOPIC IX:** Classification of Veterinary Medicines, based on Risk Level. Continuation of discussion of the presentation made in the VI and VII Seminar. Proposal of countries

12:30-2:30 PM - Lunch

2:30-4:00 PM - **TOPIC X:** Discussion on the proposal by Chile, to organize an harmonized veterinary products catalogue

4:00-4:30 PM - Coffee break

4:30-5:30 PM - **TOPIC XI :** Continuation of discussion of the VII Seminar on the presentation by Brazil about administrative problems in veterinary medicines export-import.  
Dr. Mario Pulga – SINDAN (BRASIL)

#### **FRIDAY AUGUST 16<sup>TH</sup>**

09:00-10:30 AM - **TOPIC XII:** Discussion on the Document about GMP presentation made by the countries of the MERCOSUR in the VI and VII Seminar.  
Proposals and actions to follow.

10:30-11:00 AM - Coffee break

11:00-12:30 AM - **TOPIC XIII:** Project of Mexico on regulations for requirements to be achieved by the Industry, distributors and drug suppliers to produce veterinary products

12:30-14:30 PM - Lunch

14:30-16:00 PM - Conclusions and recommendations

## **LIST OF BIOLOGIC TO BE HARMONIZED** (names are in Spanish)

Pending from VII Seminar

- VACUNA ANTIAFTOSA
- VACUNA CONTRA ADENITIS EQUINA
- VACUNAS ANTICLOSTRIDIALES CON ANTIPARASITARIO INTERNO.
- VACUNA ANTIRRABICA PARA HERBOVIROS
- VACUNA CONTRA IBR ( a virus vivo)
- REACTIVOS PARA DIAGNOSTICO DE AIE
- VACUNA CONTRA MICOPLASMAS (OLEOSA) (PROPUESTA CUBA)

Proposed for this VIII Seminar

- Vacuna contra la parvovirus canina
- Vacuna contra la parvovirus porcina
- Vacuna contra el moquillo canino
- Vacuna contra la hepatitis canina
- Vacuna contra la panleucopenia felina
- Vacuna contra el ectima contagioso
- Vacuna contra la parainfluenza 3 bovina
- Vacuna contra la rinotraqueitis felina
- Vacuna contra rotavirus bovina

## **LIST OF ACTIVE PHARMACOLOGICALS PRINCIPLES TO BE HARMONIZED**

Pending from VII Seminar

- BENZIL PENICILINA G (Brazil's report)
- FEBENDAZOL ( Argentina and Colombia report)

Proposed for this VIII Seminar:

- Olaquinox
- Furazolidona
- Triclorfón
- Cloranfenicol
- Dipirona
- Loperamida
- Ftalilsulfatiazol
- Dimetilpolisiloxano
- Furosemida
- Carbaril
- Lidocaina
- Nandrolona

- Estanozolol
- Somatotropina Bovina
- Pilocarpina
- Neomicina
- Vitaminas liposolubles
- Somatotropina bovina
- Clenbuterol

## TURIST INFORMATION AND HOTEL RESERVATIONS

### **Executive Advisors on Events S.A. of CV**

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### **INFORMATION ABOUT HOTEL Hyatt Regency Merida**

Hotel fee	Mexican pesos	USD
Single room ( 1 person)	\$ 1.390,00	139,00
Double room (2 persons)	\$ 1.645,00	164,50

#### Includes:

- Accommodation according to type of room
- Breakfast buffet
- Buffet lunch
- Two drinks during lunch (beers, sodas and juices)
- Two coffee breaks (during days of Seminar)
- Taxes
- Tips of waiters during lunch and breakfast (tips not included will be charged to the room account)
- Bellboy (per person) (check -in , check-out) \$30,00 3,00
- Room maid (per room, per night) \$15,00 1,50

### **Hyatt Regency Merida**

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