



VII SEMINAR ON HARMONIZATION AND CONTROL OF VETERINARY MEDICINES

LIMA, PERU, 6-10 AUGUST 2001

ORGANIZATION: Coordinated by OIE/OPS with the cooperation of the IICAB (Institute for International Cooperation on Animal Biologics)

OBJECTIVE:

This Seminar continues with the cooperation program developed by the OIE in Latin-America since 1992 with the purpose to improve the harmonization of the registration and control of veterinary medicines.

As conclusions and proposals derived from the previous Seminars hold since 1992 in Buenos Aires, Bogota, Cancun, Brazil, Cuba and Costa Rica, during this Seminar several technical and operative subjects are specified 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 throughout the effective functioning of CAMEVET (American Committee for the Harmonization of Registration and Control of Veterinary Medicines).

At the same time, important technical subjects are updated, as the development of GMP applied to pharmacological and biologic production, to the improvement and harmonization of administrative procedures for the registration of veterinary medicines, to the better development homologous norms and rulings which facilitates the countries interchange and the effective run of the database in the web site.

AGENDA

MONDAY AUGUST 6TH:

- 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 VI Seminar (see attached list)
- 10:30-11:00 AM - Coffee break
- 11:00-12:30 AM - **TOPIC I** on Harmonization of pharmacologics (cont.)
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - **TOPIC II:** Harmonization of Biologics selected in the VI Seminar (see attached list)
- 4:00-4:30 PM - Coffee break
- 4:30-6:00 PM - **TOPIC II** on harmonization of biologics (continuation and finalization)

TUESDAY AUGUST 7TH

- 9:00-10:30 AM - **TOPIC III:** ORGANIZATION OF CAMEVET' functions. Definition of functions and responsibilities
Regional Representation for the Americas of the OIE as Secretary "ex -office" . Secretary ex – office" accomplished actions.
Official members, collaborators and joint members. Proposals and motions.
Project of Ruling and organization of an executive board.
- 10:30-11:00 AM - Coffee break
- 11:00-12:30 AM - **TOPIC III** (cont.)
- 11:00-12:00 AM - Lunch
- 2:30-4:00 PM - **TOPIC IV:** GLOSSARY. Proposal by the Delegation from Uruguay

Supervision plan of Uruguay. Presentation by the Delegation from Uruguay.

- 4:00-4:30 PM - Coffee break
- 4:30-5:30 PM - **TOPIC V:** Functioning of Web page
Dr. Lieven Uytterhaegen

WEDNESDAY AUGUST 8TH

- 9:00-10:30 AM - **TOPIC VI:** “Veterinary Drug Production Quality: The Regulatory Scheme”
Dr. William G. Marnane (Director Division Manufacturing Technologies (HFV-140))
(CVM-FDA-USA)
- 10:30-11:00 AM - **TOPIC VII.** GMP applied to biologic production
APIS-USDA Norms
Dr. Richard Hill (Director Development of Licenses and Policies – USDA, APHIS.
Dr. James Roth, IICAB (Institute for International Cooperation in Animal Biologics) (AMES-IOWA-USA) OIE Collaborator Center.
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - **TOPIC VIII:** Biotechnologies Rulings
IICAB (AMES-IOWA-USA) OIE Collaborator Center.
- 4:00-4:30 PM - Coffee
- 4:30-5:30 PM - **TOPIC IX:** Discussion on the Document about GMP presentation by the countries of the MERCOSUR in the VI Seminar.
Proposals and actions to follow.

THURSDAY AUGUST 9TH

- 9:00-10:30 AM - **TOPIC X:** Classification of Veterinary Medicines
discussion on the presentation by Mexico in the VI Seminar.

Mexican official regulation (061-ZOO-1999) on animal feeding products.- Dr. Raul Garcia Tinajero
- 10:30-11:00 AM - Coffee

- 11:00-12:30 AM - **TOPIC XI:** Quality Systems applied to the Veterinary Services.
Dr. Fernando Crespo León. OIE Scientific and Technical Service
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - **TOPIC XII:** Discussion on the presentation by Brazil about administrative problems in veterinary medicines export-import.
Dr. Mario Pulga – SINDAN (BRASIL)
- 4:00-4:30 PM - Coffee
- 4:30-5:30 PM - **TOPIC XIII** Discussion on the proposal by Chile, to organize an harmonized veterinary products catalogue.

FRIDAY AUGUST 10TH

- 9:00-10:30 AM - **TOPIC XIV:** Antimicrobial Resistance
Introduction. Dr. Emilio Gimeno
Survey on antimicrobial resistance : OIE Collaborator
Center – AMVM CNEVA, Fougères (France)
- 10:30-11:00 AM - Coffee
- 11:00-12:30 AM - **Continuation topic XIV.** Industry contribution on the antimicrobial uses and technical information about the microbial resistance.
Dr. Raúl Guerrero (Vice-President FILASA)
- Country presentation on Topic XIV
- 12:30-2:30 PM - Lunch
- 2:30-4:00 PM - Conclusions and recommendations

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

- 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)

LIST OF PHARMACOLOGICS TO BE HARMONIZED (names are in Spanish)

- AMITRAZ
- FEBENDAZOLE
- IMIDACLOPRID
- DELTAMETRINA
- CIPERMETRINAS
- PRAZIQUANTEL
- PROPOXUR
- FLUAZURON
- PENICILINA G

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RESERVATIONS MUST BE MADE BEFORE JULY 1ST, 2001

Private Organizations (Chambers, Federations, Industry) will pay a fee of USD 200 per Institution. This fee shall be paid at the registration in the Seminar.