



**IX SEMINAR ON HARMONIZATION AND CONTROL OF
VETERINARY MEDICINES
BUENOS AIRES (ARGENTINA) 11-14 AUGUST 2003
ETOILE HOTEL RECOLETA**

ORGANIZATION: Coordinated by the OIE REGIONAL REPRESENTATION FOR THE AMERICAS, with the cooperation of CAPROVE (Chamber of Veterinary Products) of Argentina and FILASA

Jointly with CVM/FDA (USA):

**I WORKSHOP ON ACTIONS TO IMPROVE THE PARTICIPATION OF THE
AMERICAN COUNTRIES IN THE CODEX ALIMENTARIOUS COMMITTEE
ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVD) AND JECFA
BUENOS AIRES (ARGENTINA) 15-17 AUGUST 2003
ETOILE HOTEL RECOLETA**

OBJECTIVE:

IX SEMINAR

This Seminar has been organized with the purpose to follow 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 based on the experiences of the previous eight Seminars, and will continue the development of issues of last Seminar, hold in Merida, Yucatan (Mexico) in August 2002 (Peru) in August 2002.

To follow up proposals and conclusions of previous Seminars, during this IX Seminar several technical and operative subjects are to be continued as to reach institutionalization of harmonization of the registration and control of veterinary medicines in the country members of the Americas. 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. CAMEVET (Committee of the Americas of Veterinary Medicines), has been actively participating in concrete actions. This Seminar will serve to plan future actions, like to improve GMP, and also to get involved with other organizations to discuss concrete problems, to interchange opinions and promote better understanding among the countries of the Region.

As always this Seminar seeks, too, for the improvement of the Regional Representations web site, there is organizing a Veterinary Vademecum of Americas, for better diffusion of the products of the veterinary industry and the official registration service.

WORKSHOP: “ENHANCING THE PARTICIPATION AND EFFECTIVENESS OF LATIN AMERICAN COUNTRIES IN THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS”

This year in occasion of the IX Seminar, the CVM of the FDA is organizing a workshop to improve and define strategies to obtain better representation on the countries of the Region in the Codex Committee on Residues of Veterinary drugs in foods, and in the JECFA Committee. This is a very important subject for the register office of the countries, for the veterinary products industry for the animal health and public Health and because the technical and economical derivations for the countries. Up to the moment the American countries had not have enough and constant representation in the Codex meetings to bring up the problems of the region considering the current importance of drugs residues in food.

We hope that as from this workshop emerge proposals and strategies to allow a mayor participation and representation of the region countries for improving controls and the correct use of the veterinary products. The extraordinary experience of FDA in the organization of this workshop represents a great contribution to seek better participation and representation in the Codex and in the OIE of a great number of countries of the Region.

IX SEMINAR AGENDA

MONDAY AUGUST 11TH :

- 08:00-09:00 AM - Registration of participants
- 09:00-09:30 AM - Inaugural Session
CAMEVET President and Vice-president assumption
- 09:30-10:30 AM - TOPIC I: Adjustment of harmonization of guidelines for the pharmacological selected during VIII Seminar (see attached list)
Discussion on the Forums stipulated during the VIII Seminar.
 - 1.1 Use of Nitrofurans applying to Mexico
Dr. Miguel Angel Zamora (INFARVET)
- 10:30-11:00 AM - Coffee Break
- 11:00-12:30 AM - TOPIC I (Cont.)
 - 1.2 (11:00-11:30) Restriction in the use of veterinary products before milking or egg collecting Dr. B. Alpizar (Costa Rica)
 - 1.3. (11:30-12:30) Others Subjects pending on pharmacological from VIII Seminar.

- 12:30-02:30 PM - Lunch
- 02:30-04:00 PM . TOPIC II: Harmonization of Biological Products. Review of products selected during VIII Seminar (see attached list)
Discussion on Forums stipulated during VIII Seminar
2.1. Efficacy, safety and convenience of IBR vaccines of temperature sensitive strain, in bovines. Dr. Eduardo Puente (Technical service for Latin-America of Pfizer) (CAPROVE)
- 04:00-04:30 PM - Coffee Break
- 04:30-06:00 PM - TOPIC II: (CONT.)

TUESDAY AUGUST 12TH:

- 09:00-10:30 AM - TOPIC III: CAMEVET functions.
III Ordinary Assembly
Discussion on intra-institutional issues
Discussion on the budget
Project on activities to be accomplished
- 10:30-11:00 AM - Coffee Break
- 11:00-12:30 AM - TOPIC IV: Activities regarding GMP. Course on Auditors hold in Buenos Aires Argentina, in 10-21 March 2003
Future activities.
- 12:30-02:30 PM - Lunch
- 02:30-04:00 PM - TOPIC V: Presentation by CMV of FDA (USA).
Up dates of VICH in pharmacologic control
Dr. Louis Thomas Mulligan CVM/FDA (USA)
- Introduction to the I Workshop “ Enhancing the participation and effectiveness of Latin American Countries in the Codex Committee on residues of Veterinary Drugs in Foods”
Dr. R. Ellis CVM/FDA (USA)
- 04:00-04:30 PM - Coffee Break
- 04:30-05:30 PM - TOPIC VI: PROJECT ON HARMONIZATION OF IMPORT-EXPORT ADMINISTRATIVE PROCEDURES
(SINDAN – Brazil)

WEDNESDAY AUGUST 13TH:

- 09:00-10:30 AM - TOPIC VII: Presentation by APHIS-USDA (USA)
Dr. R. Hill and others

- VICH up-dates on biological controls
- Proposed changes by USA on requirements for veterinary biologics
- Proposed changes to in vitro potency testing requirements for batch release of veterinary biologics

10:30-11:00 AM - coffee break

11:00-12:30 AM - TOPIC VII (Cont.)

12:30-02:30 PM - Lunch

02:30-04:00 PM - TOPIC VIII: 1. OIE Rules applied to Antimicrobial resistance
(Presentation by the OIE collaborator Center of Veterinary Medicines (Fougeres-France)
2. Advancing Global Food Animal Antibiotic Regulations and Policies Through Science Based Risk Analysis
Dr. Jacques Acar (Prof. Emeritus Microbiology- France)
(Elanco Animal Health - SINDAN)

04:00-04:30 PM - Coffee Break

04:30-05:30 PM - TOPIC IX : Harmonization of Labeling Norms
Report and Recommendations from an Animal Health Company Perspective on the advance for Label Harmonization within Latin America- Dr, Bruce Martin (Elanco Animal Health- SINDAN)

THURSDAY AUGUST 14TH:

09:00-10:00 AM - TOPIC X: Harmonization of Registration documents
(Presentation by CAPROVE)

10:00-11:00 AM - TOPIC XI: Electronic organization of the Veterinary Medicines Catalogue about VM harmonized.
TOPIC XII: Projected CAMEVET LATIN-AMERICAN VADEMECUM
Presentation of previous tests of the vademecum in the web site of the Regional Representation for the Americas
Dres. E. Gimeno, E. Argento, C. Francia, L. Uytterhaegen

11:00-11:30 AM - Coffee Break

11:30-12:30 AM - TOPIC XIII: Clinical tests in Phase three
(Presentation by Cuba)

12:30-02:30 PM - Lunch

- 02:30-04:00 PM - TOPIC XIV: Risk Analysis in the international trade of biological products
CAPROVE- Argentina
- 04:00-04:30 PM - Coffee Break
- 04:30-05:30 PM - CONCLUSIONS AND RECOMMENDATIONS

LIST OF PHARMACOLOGICAL PRINCIPLES FOR HARMONIZATION

TRICHLORPHONE (Presented during VIII Seminar)

DISCUSSION ON FORUMS STATED IN VIII SEMINAR

FUROZOLIDONE (potential Genotoxicity – use in human food of animal origin)

FUROSEMIDE (Doses)

NEOMICINE (intra-mammals use)

LIST OF BIOLOGICS TO DISCUSS HARMONISATION

VACCINE ATTENUATED AGAINST CANINE PARVOVIRUS

ISSUES DERIVED FROM VIII SEMINAR

VACCINE AGAINST RABIES WITH ATTENUATED STRAINS

VACCINE AGAINST IBR (LIVE VIRUS)

VACCINE AGAINST PI3

VACCINE AGAINST BOVINE ROTAVIRUS

COST

Official Organisms: none

Private Organisms and Laboratories: USD 200 per organism or laboratory

WORKSHOP

Enhancing the Participation and Effectiveness of Latin American Countries in the Codex Committee on Residues of Veterinary Drugs in Foods

August 15 – 17, 2003
Buenos Aires, Argentina

Friday, August 15

8:30 AM	Greetings and Introduction	Drs. Ellis and Gimeno
8:45 AM	The Codex and Codex procedures	Dr. Fernández
9:45 AM	Consultant perspective on residue control program in Latin America	Dr. Montes Niño
10:15 AM	Coffee break	
10:45 AM	Industry role in working with Codex	Dr. Guerrero
11:15 AM	Impact of Codex on food production and food trade for Latin America	Dr. Costa Guedes
11:45 AM	Activities concerning the use of antimicrobial drugs in food producing animals	Drs. Fernandez and Ellis
12:30 AM	Lunch	
1:30 PM	Human food safety evaluation by JECFA Introduction Toxicology requirements Residue chemistry and metabolism requirements	Dr. Friedlander Dr. Mulligan Dr. Ellis
3:30 PM	Break	
4:00 PM	Derivation of an MRL from toxicology and residue chemistry data	Dr. Fernández and Ellis
4:45 PM	Round table discussions	All speakers
6:00 PM	Adjourn	

Saturday, August 16

9:00 AM	Additional comments or pending questions	All participants
9:30 AM	Summary of comments and questions from questionnaire distributed to LA countries	Drs. Ellis and Fernández
10:00 AM	Break	
10:30 AM	Development of priorities for CCRVDF	Dr. Ellis
11:00 AM	Discussion of priority issues of interest to LA countries concerning CCRVDF	All participants
12:00 AM	Discussion of veterinary drugs of interest to LA countries for CCRVDF and JECFA	All participants
1:00 PM	Lunch	
2:00 PM	Formation of working groups <u>Group 1</u> : Development of priority issues of interest related to priorities to LA countries <u>Group 2</u> : Development of priority drugs for CCRVDF and JECFA evaluation	
3:30 PM	Break	
4:00 PM	Continuation	
5:30 PM	Adjourn	

Sunday, August 17

9:00 AM	Discussion of working group papers Group 1: 9:00 - 10:00 Group 2: 10:00 – 11:00	All participants
11:00 AM	Break	
11:30 AM	Development of a network of LA countries for CCRVDF issues	All participants
12:30 AM	Conclusions and workshop evaluation	
1:00 PM	Closing	

**VENUE OF THE EVENTS AND
SUGGESTED HOTEL FOR ACCOMODATION**

RECOLETA ETOILE HOTEL

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Buenos Aires

Argentina

We have chosen for this event a Hotel of exceptional characteristics located in a very important tourist zone of Buenos Aires (Recoleta). All room options include breakfast (Buffet), access to the covered and warm swimming pool, Health Club, and garage. We have accorded an institutional price, as follows:

Standard room: \$ 145 plus 21% (IVA) USD 56 aprox. 1 plane room of 27.62 m2 with 1 double bed or two single beds. Balcony, mini- bar, TV, cellular telephone, internet and telephone with DDI

Executive room: \$ 154 plus 21% IVA USD 60 aprox. 1 bedroom with double bed or two single beds, and a room with sofas, one is bed , and a table (46,58 m2) Includes Mini-bar, TV, cellular phone, internet and DDI telephone, balcony and Jacuzzi.

Diplomatic Suite: \$ 198 plus 21% (IVA). USD 74 aprox.

1 room with a double bed, a table, sofas, a reception room with sofas, bar and a table (78,26 m2). Includes min-bar, TV, cellular phone, internet, balcony and DDI telephone, and double Jacuzzi.