

CONCLUSIONS AND RECOMMENDATIONS

VII SEMINAR ON HARMONIZATION OF REGISTRATION REGULATION AND CONTROL OF VETERINARY MEDICINES

Lima, Peru, 6-10 August 2001

During the present Seminar the following technical guidelines regarding pharmacological active principles were harmonized:

- **AMITRAZ**¹
- **IMIDACLOPRID**
- **DELTAMETRINA**
- **CIPERMETRINAS (Alfa, Beta, High, Cis, Low Cis)**
- **PRAZIQUANTEL**
- **PROPOXUR**
- **FLUAZURON**

The Brazil's proposed modifications to the BENCILPENICILINAS (ex PENICILINA G) technical guidelines will continue being analyzed, while Argentina and Colombia committed themselves to provide mayor information on the use of FEBENDAZOL in poultry as to complete the technical guideline already approved.

The following observations were made regarding biologicals:

- a. **VACCINE AGAINST EQUINE MUMPS:** The harmonization of this product will remain pending because is a biotechnological product of genetic modified strain. It is recommended that the country members shall submit to the OIE Regional Representation for the Americas the current legal rulings for this type of product as to further diffusion.
- b. **VACCINES AGAINST CLOSTRIDIUM WITH PARASITES, DIAGNOSTIC REAGENTS FOR EQUINE INFECTIOUS ANAEMIA, INACTIVE VACCINE AGAINST AVIAN MYCOPLASMOSIS:** The technical guidelines of mentioned products are submitted to the sectors involved so they may provide more information for better evaluation of same.
- c. **VACCINE AGAISNT RABIES (LIVE MODIFIED STRAINS), LIVE IBR VACCINE:** It is requested to the OIE Regional Representation for the Americas to make a survey among the country members as to define regulation on the use of this live vaccines.

¹All names of Pharmacologicals are in Spanish, from the original version
²Pan-American Center for fight against Foot and Mouse Disease

- d. FMD VACCINE: Its treatment remains pending until the conclusions of the Seminar organized by PANAFTOSA², to be hold in next September.

The following new products were proposed to be included in the Agenda of next year:

- Olaquinox
- Furazolidona
- Triclorfon
- Clorafenicol
- Dipirona
- Loperamida
- Ftalisulfatiazol
- Dimetilpolosiloxano
- Furosemida
- Carbaril
- Lidocaina
- Nandrolona
- Estanozolol
- Pilocarpina
- Neomicina
- Vitaminas liposolubles
- Somatotropina bovina
- Clenbuterol
- Vacuna contra parvovirus canina
- Vacuna contra 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

I. CAMEVET

- a. The Regulations of CAMEVET were approved (see ANNEX I)
- b. The Members of the Executive Board were elected. They are as follows:

President: Dr. Rómulo Sevilla (Peru)

Vice-President: Dr. Jorge Padilla Sánchez (Mexico)

Official Sector Member: Dr. Ricardo Pamplona (Brazil)

Private Sector Member: Dr. Mercedes Etcheverry (CEV³ - Uruguay)

³ Veterinary Specialties Chamber

Private Sector Member: Dr. Luis Mendoza (AVISA⁴ – Venezuela)

All these positions are in force since August 6, 2001 and until the next Seminar to be hold in 2002

- c. The GENERAL ASSEMBLY decides that the name of CAMEVET stands for COMMITTEE OF THE AMERICAS FOR VETERINARY MEDICINES, and this is the name that shall be used in the future. (see ANNEX II)
- d. The Secretariat “ex-office” informed that formal steps have been made in order that CAMEVET participates as observer in the Codex Alimentarius meetings. CAMEVET’s participation in these meetings has been accepted as co – observer of OIE.
- e. As well, formal steps as to CAMEVET’s participation as observer in the VICH’s⁵ meetings have been carried out. The mentioned organization has required more information regarding CAMEVET, because a confusion has come up. It was interpreted that CAMEVET was part of OIE. This situation was cleared up by a letter sent to the Secretariat of VICH. The VICH’S Secretariat is consulting the Steering Committee Members on the CAMEVET’s request to participate in VICH’S meetings. The American countries expressed their interest to integrate the mentioned organization.

II. INFORMATION SYSTEM (DATA BASE) ON VETERINARY MEDICINES

- a. The OIE Regional Representation for the Americas was congratulated because the development of the web page of CAMEVET inside the OIE Regional Representation for the Americas’s web site. It is recommended that the organisms and agencies shall continue including up dating information regarding Registration and control of veterinary medicines and of veterinary medicines residues in food.
- b. It is suggested to install new sections with pages for each country members, veterinary chambers and industry members of CAMEVET, to facilitate their participation in CAMEVET’s activities.
- c. It is recommended that the country members shall use the procedures previously determined in the web page as to sent their information. The system allows an efficient, fast and immediate communication with the country members.

III. HARMONIZATION OF FORMS AND ADMINISTRATIVE IMPORT-EXPORT PROCEDURES

⁴ Animal Health Industry Association of Venezuela

⁵ International Cooperation on the Harmonization of technical Requirements for the Registration of Veterinary Medicines Products

- a. The private sector delegation from Brazil has studied in depth this matter, which was presented in previous Seminars. An important simplification of import-export procedures is proposed as to facilitate trade between countries. It is concluded that the analysis of this proposal shall continue. This proposal is a matter of priority treatment because stands for non bureaucratic procedures and for the improvement of the efficiency of veterinary services. In this sense, it is agreed that the private sector delegation from Brazil shall prepare a guideline with a concrete proposal of modification. This guideline shall be submitted to the OIE Regional Representation for the Americas in order to be sent to the countries as to count with a draft for next Seminar.

IV. VETERINARY MEDICINES CATEGORY

- a. The delegation from Mexico has presented an important improved document, addressed during the VI Seminar. In this document the veterinary medicines are divided in three categories. Also suggestions from Costa Rica and Argentina were received, and in this case, the classification was made in four categories.

It is agreed that the analysis of this issue must continue.

- b. At this end, it is agreed that before November 30th of the current year the country members shall submit their opinion and comments to the New Projects section of the web page CAMEVET (OIE RR).
- c. The Executive Board is instructed to form a working group as to elaborate a document, upon the materials to be received, to be used as basis for discussion in order to promote harmonization on category.

V. GOOD MANUFACTURING PRACTICE OF VETERINARY PRODUCTS

It is recognized the need to encourage the implementation of GMP in the country members that do not have a norm on this matter. The General Assembly of CAMEVET recommends:

- a. To adopt as a working base document the GMP Norm and the Guideline for Inspection of Establishments elaborating pharmacological products that were presented in the VI Seminar on harmonization of Registration and Control of Veterinary Medicines in San Jose, Costa Rica, 7-11 August, 2000.
- b. To instruct the Executive Board of CAMEVET to form an “ad-hoc” working group on GMP in order to review and update the base documents and design a guideline for inspection of establishments elaborating biological products.
- c. To instruct the Executive Board of CAMEVET to organize Regional Seminars on specific GMP training so as to train the inspectors of the Official Sector and the veterinary industry

sector so as to facilitate them to initiate the transforming procedure as soon as possible.

VI. VETERINARY MEDICINES CATALOGUE

- a. The delegation from Chile has presented a valuable document which will be taken as base for the definition of the veterinary products catalogue.
- b. At this end, it is agreed that the country members shall submit their opinions and comments to the New Project section of the web page CAMEVET (RR OIE) before November 30th of the current year.
- c. The Executive Board is instructed to form an “ad-hoc” working group as to elaborate a document, upon the documents to be received, to be used as basis for discussion in order to carry out the practical application of the catalogue.

VII. ANTIMICROBIAL RESISTANCE

- a. It is recommended that the countries shall participate more actively in the OIE World Public Survey on Antimicrobial Resistance.
- b. In this sense, it is informed that the OIE draft documents and recommendations, as well as comments made during the survey can be accessed in the Web page of the OIE Collaborating Center for Veterinary Medicine: <http://www.anmv.afssa.fr/oiecc/abr>. Contributions shall be submitted by electronic mail to: oie.abr@anmv.afssa.fr and the document shall be titled OIE WORLD PUBLIC SURVEY.

VIII. NEW SUBJECTS FOR NEXT SEMINAR

- a. The treatment of the GLOSSARY is postponed for next year. The report was sent on time and form by the official delegation from Uruguay, but they were absent to this Seminar, and therefore this point was not treated.
- b. It was received from FILASA a draft document on SANITARY REQUIREMENTS FOR MANUFACTURES AND SUPPLIERS OF DRUGS USED IN THE ELABORATION OF VETERINARY MEDICINES
- c. As outcome of a proposal of the delegation from Chile, it was agreed to instruct the Executive Board to prepare a guiding document in order to norm the necessary control of imports as to prevent the importation of active principles without official control.

IX. COUNTRY HOST FOR NEXT SEMINARS

It was accepted and confirmed the proposal of Mexico to hold the next Seminar in August 2002 in Mexico, and also it was accepted the proposal of Argentina to organize the Seminar for year 2003. The venues and dates shall be notified opportunely.

ANNEX II

LIMA, PERU, 8 August, 2001

IN VIEW OF THE MINUTES of the VII Seminar on Harmonization of the Norms of Registration and Control of Veterinary Medicines, hold in Lima, Rep. of Peru from the 6th to 10th August 2001, and

CONSIDERING:

That the acronym "CAMEVET" has stood up differently in many documents

That therefore, is necessary to assign an unique name to the organism

THE GENERAL ASSEMBLY OF CAMEVET
RESOLVE:

Article 1°: To establish that CAMEVET stands for COMMITTEE OF THE AMERICAS FOR VETERINARY MEDICINES, This name shall be used from now on in all its activities.