

CONCLUSIONS AND RECOMMENDATIONS

VIII SEMINAR ON HARMONIZATION OF REGISTER NORMS AND CONTROL OF VETERINARY MEDICINES

Merida, Yucatan (Mexico), 12-16 August, 2002

During the Seminar technical guidelines for the following active pharmacological principles were harmonized: (*)

- CARBARIL
- CLENBUTEROL
- CLORANFENICOL
- DIMETILPOLISILOXANO
- DIPIRONA
- ESTANOZOLOL
- FTALILSULFATIAZOL
- LIDOCAÍNA
- LOPERAMIDA
- NANDROLONA
- OLAQUINDOX
- PILOCARPINA
- SOMATOTROPINA BOVINA
- VITAMINA A
- VITAMINA D
- VITAMINA E
- VITAMINA K

(*) The names of the Pharmacologicals are in Spanish

Modifications introduced to technical guidelines for BENCILPENICILINAS and FENBENDAZOL were also approved.

Regarding the guideline for CLORANFENICOL, even it was harmonized, it is recommended to the countries completely banning their use, to initiate the necessary procedures as to extend the prohibition only to animals for human's food production. The prohibition to use CLORANFENICOL in animals for company and in pharmaceuticals such as eyedrops, pharmaceutical syrup, or tablets, has no technical statement and encourage the use of patent medicines approved for human use that give rises to problems derived from the supervision of veterinary products.

The technical guideline for TRICLORFON it is sent again to the countries for their study.

It is decided to implement discussion forums with the purpose to harmonize pending specific issues concerning FURAZOLIDONA, FUROSEMIDA and NEOMICINA. The topics to be discussed in the forums and their members are shown in the following table:

Active principle	Subject	Members
FURAZOLIDONA	Potential genotoxicity use in animals for food production	Argentina Brazil Chile Guatemala Mexico
FUROSEMIDA	Dose	Colombia Cuba Uruguay
NEOMICINA	Intra-mammals use	Brazil Chile Cuba Mexico Uruguay

The operation of the Forums it is informed further in this document.

The following biological products were harmonized:

- REAGENTS FOR DIAGNOSTIC OF EQUINE INFECTIOUS ANAEMIA
- VACCINE AGAINST OVINE ECTHYMA (LIVE VIRUS)
- VACCINE AGAINST CANINE DISTEMPER
- VACCINE AGAINST CANINE HEPATITIS
- VACCINE AGAINST FELINE PANLEUKOPENIA
- VACCINE AGAINST CANINE PARVOVIRUS (INACTIVATED)
- VACCINE AGAINST PORCINE PARVOVIRUS
- VACCINE AGAINST FELINE RINOTRAQUEITIS
- VACCINE AGAINST MYCOPLASMOSIS (INACTIVATED)

Regarding other biological products the following comments are made:

- a) VACCINE AGAINST GLANDERS: Discussion concerning this product was postponed until Fort Dodge Animal Health presents more information.
- b) VACCINE AGAINST RABIES DISEASE: (LIVE ATTENUATED VIRUS) The guideline of this vaccine is sent to the Pan American Center for Foot and Mouth Disease and Zoonosis for consultation.
- c) VACCINE AGAINST BOVINE RHINOTRACCHEITIS (LIVE VIRUS): A forum to discuss the use of this type of vaccine it is opened. Argentina, Brazil, Colombia and Mexico will participate in this Forum. The operation of the Forums will be discussed later on in this document.
- d) VACCINE AGAINST FOOT AND MOUSE DESEASE: This guideline is approved, but it is necessary to obtain more information about detection of non-structural proteins.

The following vaccines technical guidelines are lived to the consideration of the next Seminar on Harmonization: VACCINE AGAINST BOVINE PARAINFLUENZA 3; VACCINE AGAINST BOVINE ROTAVIROISIS

It was received the proposal to include in the agenda of next year the following product:

- vaccine against canine parvovirus disease (attenuated virus)

Due to a SINDAN (Brazil) inquire, it is being recognized the value of the technical guidelines as elements for basic consultation and orientation, when registering of veterinary products, that do not alter the sovereign decision of the countries in cases regarding products for fight against priority national interest diseases.

I. CAMEVET

- a) The President and the Vice president of the Executive Board were elected according to CAMEVET's bylaws:

President: Dra. Mara Elma GONZALEZ ORTIZ (Mexico)

Vicepresident: Dr. Hugo Alberto QUEVEDO (Argentina)

The following official representative member was elected:

Dr. Ricardo PAMPLONA (Brazil)

The following representative members of the associated members were elected:

Dr. Mercedes ETCHEVERRY (Private Sector: Uruguay (C.E.V.)

Dr. Luis Mendoza (Private Sector Venezuela (AVISA)

This designations are in force since August 16th, 2002 and until date of the next Seminar on Harmonization to be hold in 2003.

- b) The Secretariat "ex – office" informed that CAMEVET has been accepted by the VICH (International Cooperation on the Harmonization of Technical Requirements for the Registration of Veterinary Medicinal Products), as "interested party" . As to access this mentioned status it is necessary to sign the Confidentiality Agreement. The General Assembly authorizes Dr. Emilio Gimeno, Coordinator of the OIE Regional representation for the Americas to sign this agreement on behalf of CAMEVET.
- c) Dr. Emilio Gimeno is assigned to attend the next VICH meeting to be hold in Tokyo, in October 2002.
- d) The General Assembly approved the Joint training Course on Quality and Audit Systems for the Official Sector members involved in Register of Veterinary Medicines and for Manufacturing and Import Companies of the Private Sector. It is recommended to the Secretariat ex – office to organize the mentioned course that will be hold in Argentina in March 2003.
- e) A formal invitation was received to attend a course in Barcelona, Spain, on Register of Veterinary Products procedures according to EU Norms.
- f) A proposal was received to organize courses on GMP. It will be coordinated together with FDA (USA) as to carried on this task.

II. INFORMATION SYSTEMS ON VETERINARY MEDICINES – DATABASE- FORUM FUNCTIONING

- a) It is recommended to the country members to up date local norms concerning veterinary products as to include them in the Regional representation's Web site, that is an important source to interchange information.
- b) It is recommended to the country members to use the foreseen procedures to send any information throughout the Regional Representations Web site because it is a systems that allows an efficient, quick and immediate communication with other country members of the OIE.
- c) Functioning of the Forums: The Forums will remain open during 90 (ninety) days as from August 16th, 2002. The reports have to be sent to the Regional Representation for the Americas in electronic format as to be included in the Forums. At the end of the discussion period, the Regional Representation for the Americas will draw up a final document to be spread among the total country members and the conclusions will be discussed during next Seminar.

III. HARMONIZATION OF FORMS, IMPORT-EXPORT ADMINISTRATIVE PROCEDURES

- a) It is approved the necessity to drawn up an model of unique certificate for register of import products. The Private Sector Delegates from Brazil presented a draft document
- b) The country members commit themselves to send the items that a certificate as the proposed one should have. Each selected item should be based on. The proposal shall be submitted to the Secretariat "ex – office", before December 15th, 2002
- c) The proposals received by the Secretariat "ex office" shall be submitted to Brazil that is the country responsible for the proposals and coordinator of the working group. Brazil will draw up a final version to be put to the consideration of the country members, before April 30th, 2003 and then discussed in the next Seminar.

IV. VETERINARY MEDICINES CATEGORY

The country members will submit to the Secretariat "ex – office" the classifications of the active principles according to their risk level, as to increase the transparency principle, among the country members.

V. GOOD MANUFACTURE PRACTICE APPLIED TO VETERINARY PRODUCTS OF CAMEVET 2001.

- a) The General Assembly decides to adopt GMP Norms of CAMEVET 2001 and the Guidelines for Inspection of Establishments Manufacturers of Pharmacological of CAMEVET 2001 as documents harmonized. These documents were approved during the VII SEMINAR ON HARMONIZATION OF THE REGISTER NORMS AND CONTROL OF VETERINARY MEDICINES IN Lima (Per) in 6-10 August , 2001.
- b) The Harmonized documents will be permanently reviewed and the countries will made their formal contributions sending any information to the Secretariat "ex - office" not later than 2 (two) month prior to the date of annual Seminar.. This information will be forwarded to all the country members for their knowledge.
- c) During the IX Seminar a workshop on GMP will be carried out.
- d) The General Assembly decides to adopt as draft work the guideline for Inspection of Establishments elaborating biological products.

- e) It is set up that Colombia will continue implementing OMS 32 until any CAMEVET Norm is implemented within the country members.

VI. CATALOGUE FOR BIOLOGICAL PRODUCTS AND ACTIVE PHARMACOLOGICAL PRINCIPLES OF TECHNICAL GUIDELINES HARMONIZED DURING THE OIE SEMINARS

- a) It is adopted the project of catalogue drawn up by the Secretariat “ex - office” that was shown during the VII SEMINAR ON HARMONIZATION OF REGISTER NORMS AND CONTROL OF VETERINARY MEDICINES, in August 6-10, 2001 in Lima (Peru) that was improved with the collaboration of the countries.
- b) CAMEVET’S Catalogue will be reviewed permanently.

VII. CAMEVET’ S VADEMECUM

- a) The Secretariat “ex – office” will inquire the country members on the necessary data concerning each product, that should be in the Vademecum, taking into account the draft framework presented during the VIII Seminar on Harmonization.
- b) This issue will be discussed during the IX Seminar on Harmonization with the proposals received from the country members.

VIII. CAMEVET’S GLOSSARY

- a) The glossary presented by the Delegation from Uruguay it is adopted as draft work.
- b) The country members commit themselves to analyze the document and submit their proposals of modification to the Secretariat “ex – office” before 15th February, 2003.
- c) The proposals received will be sent to Uruguay, that will drawn up a final version to be put to the consideration of the country members before 30th May, 2003 and be discussed in a workshop during next Seminar.

IX. NORM FOR CONTROL OF RAW MATERIAL PROVIDERS FOR VETERINARY PRODUCTS MANUFACTURE

It was received the document presented by Mexico (INFARVET). With this document and jointly with the collaboration of the country members a draft document will be drawn up to be discussed in next Seminar.

X. TOPICS TO BE DISCUSSED IN NEXT SEMINAR

In addition to the subjects treated along this document the following subjects are considered:

- a) Procedures and register document harmonization (Argentina)
- b) Labeling norms harmonization (Brazil – Mexico)
- c) Food medicated (Argentina – Mexico)
- d) Clinic tests in Phase 3 (Cuba)

- e) Technical Guideline for vaccine against rabies combined with leptospire bacteria (Mexico)

XI. VENUE FOR NEXT SEMINARS

It was decided to accept the Argentina proposal as to organize the Seminar to be hold during year 2003 and the proposal from Brazil as to organize the Seminar for year 2004. Venue and dates will be established opportunely. USA and CANADA offer to the country members to bear jointly the organization of the Seminar for year 2005.