CONCLUSIONS AND RECOMMENDATIONS

XII Seminar on harmonization of registration and control of veterinary medicines

Panamá City, Panamá, September 5 – 7, 2006

1. Executive Board Authorities

As a first conclusion, the modification of the executive board composition was unanimously approved. It will be composed as following:

President
The position for President will be proposed for the head of the Registration Area from the country which will host the Seminar following the actual Seminar. Position will be changed on a year to year basis.

Official Representatives
Four representatives will be nominated. Positions will be changed every two years.

Private Sector Representatives
Four representatives will be nominated. Positions will be changed every two years.

New Executive Board is listed below:

President:
Dra. Virginia Quiñones – República Dominicana

Official representatives
Dra. Berta Elizabeth Martínez - Nicaragua
Dra. Elia Muñoz - Uruguay
Dr. Néstor Fernando Guerrero Lozano - Colombia
Dr. Fernando Rivera Espinoza - México

Private Sector representatives:
Dr. Enrique Argento - Argentina
Dr. Milson Pereira da Silva - Brasil
Dra. Margarita Pinto - México
Dr. Carlos Rufrano - Argentina

President accepts the new position, which will be in force until next Seminar, in August 2007. Continuity in the charge will be for the Official Representative from the country which will host next Seminar.

All of the positions for the official and private representatives will be valid from September 5 until the 2008 Seminar.

2. Report of the Secretariat activities

State of working papers
A report on the situation of the working papers in process of analysis and review was made.

Listed below are the working papers in Step I phase (approved title, commitment for the development of first draft) in concordance with the commitments assumed during the X Seminar.

- application form for biological products containing Genetically Modified Organisms (Brasil, with cooperation from Cuba)
- *Efficacy and safety tests for antiparasitaries in companion animals (Brazil, with cooperation from Uruguay and Argentina)*
- *Good Practices for Clinical trials (Cuba, with cooperation from Argentina, Chile and Brazil)*
- *Setting of priorities for the evaluation of Technical Outlines (Cuba, Bolivia, Brazil and Uruguay*)
- *Definitions lexicon (Uruguay with cooperation from Bolivia, Paraguay, Argentina, Ecuador, Perú and Brazil)*

It is considered that all of these drafts have accomplished the Step I status (approved title), setting up a 120 days deadline from the seminar closing to the presentation of the draft papers, as defined in the guideline for the follow-up of CAMEVET guidelines.
Documents will be kept in the previous Step in the case of not receiving the draft papers in the established schedule and the relevance of their continuity as working drafts will be analyzed in the next meeting.

State of implementation of CAMEVET harmonized guidelines
Results of the consultation made to the official representatives were shown.
As a general conclusion, the low number of responses is highlighted, added to the fact that the implementation of harmonized guidelines is a process which encounters many difficulties in Member countries.

3. Technical issues developed during the Seminar

Guidance document on Good Practices for the use of veterinary products
A document containing the general outlines on good practices for the usage of veterinary products was prepared and *presented* by representatives from CAPROVE and SINDAN.
A working group was formed in order to develop a draft paper, which will be considered as a Step I document.
This concept paper will be presented as a proposal for its inclusion in the Terrestrial Animal Health Code as its approval process is finished,

It relates to the possibility of the expansion of the contents of the Article 3.9.3.1,which is related to the guidelines for the responsible use of antimicrobial products in Veterinary Medicine.

Style sheets for CAMEVET working documents
There are no observations for the document related to the style sheet for CAMEVET papers. The draft document was approved and changed to the Step VII status (Approved documents).
The codification system for documents was also approved, and will be included as an annex for the style sheet.

Audit guides for Good Manufacture Practices in Veterinary and Biological Products.
The review of the proposal for the modification of the guidelines was considered, keeping their status in Step III

Guidelines for efficacy tests for antiparasitic drugs
Based on the need of another revision on the document related to the evaluation of the efficacy of antiparasitary products intended for use in ruminants and swines, the document will remain in the Step III Status.

Registration form for in vitro diagnostic products
Related to the presentation of the document containing the proposal for harmonization of the registration form for products intended for in vitro diagnostic, a 120 days time limit is established for the presentation of observations.
This document has to be adapted to the CAMEVET´s style sheet, and taking in account the observations made by the official representatives from Cuba, which are included with the working papers.

Veterinary products stability
A discussion forum regarding the regulations in force in CAMEVET member countries was developed
It is concluded that a Step I status will be applied, approving the title of the guideline, and establishing a 120 days period for the presentation of the first draft. Comments to this first draft will have to be submitted in 90 days after its reception.
Official authorities from Uruguay accept to coordinate the working group.

Focal point for veterinary medicines
The document related to the focal points for veterinary medicines was again presented.
Also the project elaborated by CAMEVET secretariat was distributed. That project details the procedure for the notification and distribution of new regulations put in force in the member countries.
A 90 days time limit is established for the presentation of observations to the document, which bill be in Step III status.

Heads of the registration offices are asked to confirm their designation as OIE focal points for veterinary medicines.

Consultation made by Uruguay related to closantel dosage
The consultation presented by the official representatives from Uruguay is included in the working papers.
The inquiry is related to the approved dosage for closantel in the Member countries, establishing a 60 days deadline for the presentation of the responses

4. Report on expenses, financial status and 2006/2007 budget

The report on the balance sheet and 2006/2007 budget was presented and approved.

Incomes

- XII Seminar signup fees (U$s 200/participant) **14.600**

Expenditures (Budget for the 2006/2007 term)

- Personnel 3.600
- Office expenses 1.800
- CAMEVET Secretary travels 3.000
- CAMEVET representative assistance – 18th OIE Regional Conference 1.500

Expenses **9.900**

Available resources **16.912.79**

Balance **7.012.79**

5. Other discussed issues

Communications
The update and change of the design of the Internet web page of the Regional Representation will be done, and also the links to the local regulations related to the registration and control of veterinary medicines will be updated.

Inclusion of harmonized documents in the OIE standards
It is agreed to set the priority for the presentation of the harmonized guideline related to labeling of veterinary medicines.

Workshop on the guidelines for the CAMEVET performance
A discussion was carried out regarding the guidelines for the operation of the CAMEVET. Two meetings were carried out, including the official representatives and the OIE, and the other meeting including the industry representatives and the OIE. Meetings were developed in order to elucidate the objectives and roles in the CAMEVET in the context of the OIE.
The following conclusions resulted from the discussion:

a. Connection of the CAMEVET with the World Animal Health Organization - OIE
It is recognized that OIE is the world reference organization for international standards related to animal health, animal products, and zoonoses.
CAMEVET will continue having the institutional support by the OIE.
As other improvement which were proposed for the working of the OIE, the future expansion of the supporting personnel and office facilities.

It was also informed that travel and lodging expenses for Regional Representative for the next Seminar in Republica Dominicana will be granted by the Regional Representation.

The participation of the experts in the fields related with the activities of the CAMEVET is extremely important, so the creation of a listing of experts is proposed. This listing should be available for consultation in for the formation of ad-hoc groups at the OIE.

Other way to improve the institutional status of the CAMEVET will be the participation in the OIE´s Regional Commission Meeting and the General Session, which will be held in Paris in May, 2007.

Another way to strengthen the activities will be based on the reception and submitting of proposals for the modification and update of the OIE´s standards and guidelines.

OIE will submit proposals for the Chiefs of the Veterinary Services in order to improve and reinforce the areas for registration of veterinary medicines.

OIE will encourage the participation of the heads of the Registration areas in CAMEVET annual meetings.

A recommendation regarding the reinforcement of the veterinary medicines registration departments will be made at the 18th Regional Conference. This will have the possibility of becoming a pronouncement from the OIE General Assembly in 2007.

b. CAMEVET Secretariat

An improvement in the communication is essential, related to the amount of information as its correct addressing.
Moreover, the update and improvement in the web page is essential. Among other things, the web page should include the actual state of the working papers (Approved / In process / No advances), as the minutes of the Executive Board meetings, and the expenses budget.
Another service to include in the web page should be the list of the Regional experts list.
Likewise, the contact information for the Seminar participants should be included.

c. Performance of the CAMEVET

it becomes clear for all of the participants that CAMEVET does not generate rules or standards, as it is a technical discussion forum which comprises industrial and official sectors, with the participation of public and private organizations, and promoting training and technical exchange and the production of technical harmonized guidelines for the Member countries. These guidelines can further be taken into national regulations, and proposals for regulations and international standards.

Both the public and industrial members must acknowledge the common benefits and accept the roles which are assigned to each other. This means that only those who have the responsibility for the implementation of harmonized guidelines are the countries, based on the proposals made by the heads of the registration offices.

It is considered that the parameters of the CAMEVET activity are the number of harmonized guidelines, the amount of guidelines which are taken into local regulations, and also the number of draft documents in the evaluation stage.

There must exist a commitment made by the heads of the registration offices for the information related to the process and terms for the implementation of harmonized guidelines at the national level.
The preparation of annual meetings, prior to the development of the Seminars, in which official and private representatives could discuss separately different issues is considered as a suitable activity

Another related point is the designation of "focal points" from the private sector, in order to simplify the diffusion of the information.

A claim is made for both the official and private sector representatives regarding that attendants must participate actively, being properly informed on the scheduled discussions and having enough faculties for taking decisions on behalf of their represented institutions.

It must be taken in account that guidelines harmonized in CAMEVET must be prepared taking in account the American reality. This is considered as a priority which must be considered for the continuity of the Committee

d. Proposals for the modification of standards and new standards to the OIE.
There is no agreement from the heads of the registration Offices related to this point
It is considered that documents which will be sent as proposals for the OIE have to be previously selected, and that those which have better possibilities could be the harmonized guidelines for veterinary products labeling, Focal Point and Good Practices for the Usage of Veterinary Products.

Another option which could be considered for the diffusion of the activities of the Committee is the printing and distribution of the harmonized guidelines and documents, Those publications should have the OIE´s logotype, as they achieve the technical qualities they need.

e. Evaluation and comments process for working papers
It is proposed to open the participation for the private sector from the beginning of the evaluation of the guidelines. This means that the Secretariat should receive comments from both the official and private representatives.

e. Member Countries arrogations
It is required for CAMEVET Member countries to formally inform about the process of implementation or application of harmonized guidelines.

Another necessary activity is that official authorities should formally submit as modifications as new standards related to CAMEVET harmonized guidelines to the OIE.

The importance of the communication of the drafts for new regulations to the CAMEVET member countries is considered, in accordance with the international regulations (OIE-OMC).

f. Executive Board
The new composition of the Executive Board is accepted, through the augmentation of the amount of members to five members from the Official sector (President and four representatives) and four representatives from the private sector.
Positions will be changed every two years, with the exception for the President, whose position will be changed on a year to year basis.
The position for President will be proposed for the head of the Registration Area from the country which will act hosting the Seminar

A crucial need for the performance of the Executive Board is to have the real institutional and economic support so as its Members can participate in the meetings.
The participation through videoconferences or teleconferences is also considered.

One of the responsibilities of the Executive Board is to act as the controlling body for the activities developed in CAMEVET.

6. Site for the Next Seminar.

The proposal from República Dominicana for hosting the next Seminar is accepted.

Dra Virgina Quiñones, Chief of Registration from Republica Dominicana Veterinary Services, will be the contact point and the responsible for the XIII Seminar organization.

The proposed date for the Seminar is August 6th – 10th, and the place where the Seminar will be held must be defined, in order to publish the information on

the web page as soon as possible and allow attendants to make the required hosting and transportation reservations.

The proposal for the organization of the XIV Seminar in the year 2008 in the city of Miami is also accepted, being organized collaboratively by United States and Canada.
The proposed date for the Seminar will be August 12th – 15th.

Hosting country must take charge of the local expenses (hall rental, translation services, secretaries, document printings, folders for the participants).
Registration fees will be 200 U.S. Dollars for participants from the private sector, and financial resources from this will be entirely assigned to the operation of the Secretariat of the Committee and other planned activities.

Both Republica Dominicana and United States must anticipate the aspects related to the need of visas for the participants, as the dispatch of the registration fees to the Buenos Aires OIE office.