CONCLUSIONS AND RECOMMENDATIONS

XIII SEMINAR ON HARMONIZATION FOR REGISTRATION AND CONTROL OF VETERINARY MEDICINES

Santo Domingo, Dominican Republic, August 7 – 9, 2007

1. Executive Board Authorities

According to what was proposed and agreed during the Executive Board meeting, the designation for Dr Virginia Quiñones as Honorary Member for the official sector is decided by unanimity, in order to take advantage of her experience in the organization of the Seminar and participate in the organizational aspects for the next meeting.

It is agreed to establish the position of Honorary Member for all of the Presidents from finished Seminars, for a one year period, until being replaced by the following President.

Below are listed the executive Board authorities, according to what was determined during XII Seminar.

Presidents:
Dr. Richard Hill - Dr. Glen Gifford

Official Representatives:
Dra. Bertha Elizabeth Martínez - Nicaragua
Dra. Elia Muñoz - Uruguay
Dr. Néstor Fernando Guerrero Lozano - Colombia
Dr. Fernando Rivera Espinoza - México
Dra. Virginia Quiñones – República Dominicana (Honorary Member)

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

The charge of President will be in force until next Seminar, in September 2007. The 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 until the realization of the Seminar in 2008.

2. Report of the Secretariat activities

Executive Board activities

A report on the activities of the Executive Board was presented, for the sessions period accomplished in the actual Seminar.
A great improvement in the frequency and continuity for the Executive Board meetings is acknowledged, as the easiness obtained for communications through the use of teleconferences, as ten meetings were satisfactory accomplished.
The minutes of the Executive Board meetings are included in the final proceedings of the Seminar.

State of procedures for the working papers
A report on the situation of the working papers in process of analysis and review was made.
It is concluded that the tasks should be focused on those papers for which working groups could be formed and kept active.

State of implementation of CAMEVET harmonized guidelines
Results of the consultation made to the official representatives were presented.
As a general conclusion, a trend is observed, related to the beginning of the application process in order to implement the harmonized guidelines on the local regulations of the Member Countries.

State of CAMEVET harmonized guidelines at OIE
Dr. José Joaquín Oreamuno informed that the project related to Veterinary Products Labeling has been submitted to OIE´s Scientific Commitee for its reviewal.
Dr Oreamuno also reported that the project has also been proposed to the VICH (Veterinary International Committee on Harmonization).

It also was communicated that is necessary for the OIE Delegates to promote and take action in the presentation of the proposals for new sanitary standards of worldwide utilization.

The participation of the private sector is considered as necessary, supporting the Chief Veterinary Officers from the Member Countries in the process of application.

Organisation of contacts and Focal Points
According to what was informed by the Secretariat in the Executive Board meeting, it is communicated that the electronic distribution of the information will be only sent to the OIE Delegates as to the Veterinary Medicines Focal Points.
Veterinary Medicines Focal Points shall be responsible for the distribution of the documents to all of the interested parties from each Member Country.
It is considered that the Veterinary Products industry associations shall act as Contact Points for the private sector, assuming the responsibility for the distribution of the documents to the totality of the industries form each country.

Regarding its regional importance, OIRSA shall be included as a regional reference for the contact points from the Member Countries that take part of that Organisation, in order to promote and ensure their active participation.
In the same way, and related to the regional contacts belonging to the private sector in Central America, Dr. Menéndez will take steps toward their connection to the Executive Board, in order to attain their inclusion in the private sector contacts points and ensure their participation in the Committee activities.

3. Technical issues discussed during the Seminar

Guidance document on Good Practices for the use of veterinary products
The presentation of the draft document containing the results of the activities of the ad-hoc group, which is composed by representatives from the private sector of Argentina and Brazil (CAPROVE, CLAMEVET and SINDAN), and the official representatives from Colombia.
The ad-hoc group carried out the revision of the draft document which was initially presented during the XII Seminar, held in the city of Panama.
As the working paper was presented during the General Assembly (Step IV) without being distributed for opinions, it shall be considered in the status of Step III, for it is established that a 90 days time limit shall be considered as a deadline for the submission of commentaries.

It is remarked that this concept paper will be presented as a proposal for its inclusion in the Terrestrial Animal Health Code as its approval process in CAMEVET is finished.
It relates to the possibility of the extension 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.

Stability testing for veterinary products
The first draft was presented, related to the criteria for the establishment of shelf life for veterinary products. The document is the outcome of the duties taken by the working group coordinated by the official authorities of Uruguay.
In terms of the first circulation of the document, a 90 day deadline for the presentation of observations is be established.
Official representatives from Chile inform that will present a protocol model for the presentation of the information related to stability testing to the Working Group, for its distribution.

Good Manufacturing Practices for ectoparasiticides
The denomination “Ectoparasiticide veterinary product” is approved, replacing the use of the term “Pesticide” or “Pesticide for veterinary usage”.
That modification shall be applied to all of the CAMEVET harmonized guidelines, and all of the future documents.

First draft of the working paper was presented, which is related to the possibility of the application of the “Camevet Regulation on Good Manufacturing Practices – 2001” for the manufacture of ectoparasiticide veterinary products.

As being considered as a concept paper, it was concluded to adopt the Step 1 status for the document, in order to elaborate the audit guide for the facilities used in the manufacture of ectoparasiticides.

A 120 days deadline for the preparation of the first draft is established.
Dr. Carlos Francia (CAPROVE) will act as the coordinator of the working group. Dr. Javier Carracedo (ALANAC), Dr. Carlos Rufrano (CLAMEVET), and the official representatives from Argentina are included in the working group.
Mr. Milson da Silva Pereira informs that SINDAN shall contribute with the participation of a specialized professional for the group.

Guidelines for efficacy tests for antiparasitic drugs
Based on the complete revision and modification of the chapters related to flukicides and products for hemoparasites by the working group formed by the official authorities from Uruguay and CAPROVE, a new revision of the working paper is considered as necessary, keeping the Step III status. A 90 days deadline is established for the submission of observations.

Technical Outlines for Pharmacological and Biological Products
Regarding the report made by Dr Adela Encinosa, related to the survey about the continuity of the activities on the Technical Outlines, it is decided to follow up on the activities.
For that, it has been agreed to refer the technical guidelines specifically for the active pharmaceutical ingredients in the case of pharmacological technical Outlines, and for the antigens in the Biological Technical Outlines.
The survey the proposal for the modification of the Guidelines format are included in the Seminar memories, for the presentation of comments in 30 days. Comments shall also include the proposals about the methodology to be applied for the revision of harmonized technical outlines, and which sectors of CAMEVET shall hold the responsibility for the rewiewal process.

Unlawful practices in veterinary products trade
A presentation related the problems due to illegal practices which are observed in the commercialization of veterinary products was made.
The status of Step I is established for the preparation of the draft document, being nominated Dr. Hernán Cifuentes (APROVET) as the coordinator for the working group.

Audit guides for Good Manufacture Practices in Veterinary and Biological Products.
The need for the revision of the observations made by those countries which presented observations for the Audit Guides is recognized, keeping their status in Step III.
Based on that, the updating of the “Camevet Regulation on Good Manufacturing Practices – 2001” is also considered.
The working group will be coordinated by Dr. Carlos Francia and Dr. Enrique Argento (CAPROVE), with the participation of the official and private sector from Mexico, CLAMEVET, SINDAN and ALANAC.

4. Report on expenses, financial status and 2007/2008 budget

The report on the balance sheet and 2007/2008 budget was presented and approved.

The expenses budget for the next period is presented

Incomes

• Participation fees (U$s 205/participant)	12.715	
Expenditures (Budget for the 2007/2008 term)		
• Personnel		4.800
• Office expenses		1.800
• CAMEVET Secretary travel expenses		3.000
Subtotal expenditures budget		8.600
Available resources	**22.839**	
Balance	**14.239**	

Budget includes the setting of the Secretary fees in 400 dollars monthly, which was approved by unanimity by the Executive Board.

5. Other discussed issues

Communications

The modification and updating of the CAMEVET web page that is hosted at the OIE Regional Representation is considered as an essential issue, as for the access to CAMEVET information and the regulations in force in the Member countries which apply to the registration and control for Veterinary Medicines.
It is considered that the information regarding all of the harmonized documents and the contact information for the Focal and Contact Points shall be included.
A recommendation is made, in order to include a direct link for accessing CAMEVET information directly from the OIE Regional Representation web page, due to the fact that many visitors may not be informed that CAMEVET is considered as a regional project, and accessing to its contents may be difficult.

It is also recommended that the Secretary should have an e-mail address under the OIE domain, due to the fact that all of the communications have been made under a personal e-mail.

It is necessary for all of the Sanitary Services to be notified about the results obtained by the actions developed by CAMEVET activities, as for the importance of the participation of the heads of the veterinary products registration departments.
That communication shall be made simultaneously by the OIE and the private representatives, and dispatched the Chief Veterinary Officers and the Focal Points.

It is recommended that the working agenda for the OIE 19th Americas Regional Meeting shall include a presentation about the advances and achievements obtained by the Committee.

Related to the communication activities, it is recommended that the information produced during the Seminar should be sent to the Chief Veterinary Officers, so as an acknowledgement note for the heads of the registration offices which have participated in the Seminar, and encouraging the participation in the case of those countries which had no possibilities to attend.

A special gratitude remark is made, related to the excellent role of the Dominican authorities in the organization of the present Seminar.

OIRSA member countries recommend that a appreciation letter regarding the support obtained should be sent to the local authorities.

Next Seminar Organisation

According to what was established in the XII Seminar, the organization of the next Seminar will be carried out by Canada and United States authorities, and it will be held at the city of Miami.

Dr. Richard Hill, Director of the Center for Veterinary Biologics (USDA), shall be the contact point for the organization of the XIV Seminar.

Proposed date for next Seminar in 2008 will be September 8 to 12, and the location for the meeting shall be defined as soon as possible in order to communicate all of the interested parties and allow the procedure for obtaining the required visas, transportation and lodgment reservations with the required anticipation.

The proposals made by Argentina for being the host in the 2009 Seminar (To be confirmed by the official sector) and Mexico for 2010 are accepted.