

## Conclusions and Recommendations

### **XIV SEMINAR ON HARMONIZATION FOR REGISTRATION AND CONTROL OF VETERINARY MEDICINES**

**Asunción, República del Paraguay, September 8 – 12, 2008**

#### 1. Executive Board Authorities

Asunción de la Presidencia del CAMEVET

Dr. Hugo Adolfo Corrales Irrazábal formally takes the charge as President for the actual Seminar.

According to the CAMEVET procedures, the positions of the official and private sector representatives are renovated. These positions will be effective by a term of two years, and will be in force until the conclusion of the 2010 Seminar.

Dr Corrales designates Dr. Primo Ricardo Feltes for the position of Honorary Member for the Executive Board, in order to capitalize on his experience for the organization of the Seminar and to participate in the preparation of next meeting.

Dr. Fernando Rivera Espinoza takes the position as President of the Committee by the closure of the current Seminar, being the charge of President in force until the end of the next Seminar, in 2009

Below are listed the executive Board authorities

#### **President:**

Dr. Fernando Rivera Espinoza – México

#### **Official Representatives**

Primo Ricardo Feltes (Honorary Member) - Paraguay

Adela Encinosa Liñero - Cuba

Luis Zamora Chavarri – Costa Rica

Marcos Vinicius de Santana Leandro - Brasil

Virginia Quiñones – República Dominicana

#### **Private Sector Representatives:**

Enrique Argento – CAPROVE (Argentina)

Carlos Rufrano – CLAMEVET (Argentina)

Margarita Pinto – INFARVET (México)

Milson da Silva Pereira – SINDAN (Brasil)

The formal notification for the Chief Veterinary Officers regarding the nomination of the official representatives in the Executive Board is considered necessary

## 2. Report on Secretariat activities

### **Activities of the Executive Board**

The report on the activities developed by the Executive Board was presented, remarking the continuity and the frequency of the meetings, as well as the facility obtained for the communication through use of teleconferences.

### **Status at the OIE of the CAMEVET harmonized documents**

Dr. Luis Barcos informs that the harmonized document regarding labeling of veterinary products shall be evaluated by the OIE Scientific Commission in the meeting that will be held in September 2008.

It was also remarked that it is necessary that OIE Delegates promote and take in charge the proposal of new worldwide sanitary standards produced by the Committee.

The participation of the private sector is also considered as imprescindible, supporting the Chief Veterinary Officers in the prosecution of these tramitations.

A remarkable point is that America is the only continent where there are active working groups based on public and private sector collaborative models.

The advantage for the generation of international guidelines must be taken by the Committee, since it is the only active group related to veterinary products within the OIE.

It is also proposed the analysis of the possibility for the generation of frameworks for the qualification of the Veterinary Services, through the use of the OIE Tool for the Evaluation of Performance of Veterinary Services (PVS Tool) on the aspects related to veterinary products.

Based on that, it is indispensable to redefine the objectives of the Committee, tending to the generation of international guidelines.

### **Participation of the Committee in extension activities with other organizations and working groups**

It is necessary to present the advances and actions taken by CAMEVET to the Regional Commission for the Americas, the Veterinary Permanent Committee (Comité Veterinario Permanente - CVP), the International Regional Agricultural Health Organization (Organismo Internacional Regional de Sanidad Agropecuaria - OIRSA) and the Andean Community (Comunidad Andina de Naciones - CAN).

### **Organization of the Focal Points**

It is imprescindible for the Veterinary Services to submit the formal communications in order to update the OIE database regarding the official representatives acting as Focal Points for Veterinary Medicines

### **CAMEVET participation on the OIE Conference on veterinary products in Africa**

The results of the participation of Dr. Martin Minassian as CAMEVET Secretary were presented..

Resulting from that presentation, the interaction and collaboration with African countries is proposed.

All of the presentations for the Conference as the conclusions and the list of participants shall be included with the memories for the present Seminar.

In concordance with that proposal, it is concluded that it is important to establish links with other OIE Regional Representations regarding the CAMEVET activities.

Due to this, it is proposed that invitations for the next Seminar shall be sent to all of the OIE Regional Representations from other continents

### **Vaccines provision for Haití**

Dr. Barcos described the actual situation in Haiti, related to the emergent sanitary problems affecting both human and animal health, and communicated the need for the provision of anthrax vaccines in an amount of 2.500.000 annual doses.

For that, the representatives from CAPROVE communicate that they will analyse the possibility of carrying out the provision. Also, the official delegation from Brasil shall study the possibility for their participation.

### **CAMEVET administrative secretariat**

According to the proposal made by SINDAN(Sindicato Nacional da Indústria de Produtos para Saúde Animal), it is agreed on the need of having a better administrative support in order to prosecute the activities developed by CAMEVET.

The administrative secretariat activities shall be principally focused on the follow up of the issues developed by the Committee, as for the management of the communications. CAPROVE will make available a professional from his staff, who will take that functions in a part time basis, without charge for the Committee.

### **Revision of documents harmonized in the CAMEVET**

It is considered that, in order to spread the works made within the Committee to all of the interested parties, the Secretariat will have to execute their revision and diffusion.

### **3. Technical issues developed on the Seminar**

#### **Reference document on Good Usage Practices for veterinary products**

The contents of the document including the results of the activities of the working group, formed by the representatives from the private sector from Argentina and Brazil (CAPROVE, SINDAN and CLAMEVET),and the Colombian official sector were harmonized.

According to the recommendation given by the Cuban official representative, Secretariat shall review the contents of the document, and compare it with a similar document developed by Codex Alimentarius Commission, in order to include the aspects covered by that document. Besides that, a style and contents revision shall be made taking in consideration the Annex 3.9.3.1 from the OIE Terrestrial Animal Health Code, related to the responsible and prudent use of antimicrobial agents in veterinary medicine.

It is considered that the harmonized document shall be distributed to all of the delegates participating in the OIE Regional Conference for the Americas and the OIE General Assembly, in order to achieve its inclusion in the OIE Terrestrial Animal Health Code.

For that, it is necessary that Chief Veterinary Officers from CAMEVET member countries shall be informed on the harmonization of the document by the Veterinary Medicines Focal Points and the heads of the veterinary products registration offices.

Besides that, it is considered as opportune that the member countries diffuse the contents of this harmonized document to all of the sectors related to the usage of veterinary products, including those related with the professional education.

A remarkable issue is the diffusion made in Brazil of the guideline on good usage practices for veterinary products, which printed version was distributed to the Seminar participants.

#### **Stability testing for veterinary products**

Due to the lack of observations presented after the first circulation of the working paper, and based on its crucial importance in the harmonization of the registration of veterinary products, a 120 days deadline is established for the presentation of observations for the draft document.

#### **Good Manufacturing Practices for ectoparasiticides**

Due to the task regarding the production of the first draft could not be fulfilled, it is considered on Step 1 status, establishing a 120 days deadline for the preparation of the first draft, by the working group initially set for the last Seminar.

#### **Audit guides for Good Manufacturing Practices for pharmacologic and biological products**

It is concluded on the need for analysing the observations made by the countries which presented observations for the audit guides, keeping the status of Step III.

A working group will be set up, formed by the representatives from CAPROVE, SINDAN and CLAMEVET, and the official sector representatives from Chile, Cuba, Mexico and United States, in order to accomplish the task.

#### **Batch codification systems for veterinary products**

Based on the proposal made by SINDAN, regarding the need of information about the systems used by Member Countries, it is agreed that Focal Points for Veterinary Medicines shall submit information on the systems actually in place for batch identification.

A 120 days deadline is established for the submission of the information, and the preparation of a paper to be distributed to the Member Countries.

#### **Guidelines for efficacy testing for antiparasitic products**

According to the successive circulations and revisions made on the working paper, where modifications made to the different chapters of the guideline were incorporated without observations, the content of the working paper identified as Technical Regulation: "Efficacy tests for the approval of anthelmintics for ruminants and swine"

Based on the existence of particular divergences on the chapter for hemoparasiticide products, the Secretariat shall contact the working group in order to make the needed amendments.

#### **Pending issues**

- Responsibilities and functions of Veterinary Medicines Focal Points

- Diagnostic reagents registration formularies
- Glossary of Terms and Definitions

Based on the actual status of Step III for these draft documents, the Secretariat shall make a new distribution for the Veterinary Medicines Focal Points for the presentation of observations.

### **Proposals on new working papers and formation of ad-hoc groups**

It is agreed on the usage of electronic working groups for the preparation of new drafts. In that fashion, the issues and the responsables for the coordination of the working groups are listed

- Good practices for distribution and commercialization  
SINDAN shall carry out the preparation of the draft reference document
- Controls on premixes and medicated feedingstuffs  
SINDAN will coordinate the working group, with the participation of INFARVET and ALANAC, and the official representatives from Chile.
- Guidelines for the approval of biotechnological products  
The official representatives from Cuba will prepare the first draft for the document
- Criteria for the approval of biological products containing genetically modified organisms  
INFARVET shall coordinate the working group.
- General guidelines for the establishment of shelf life for biological products  
CAPROVE will take charge of the coordination of the working group
- Nutraceutical, fitotherapic and homeopathic veterinary products  
The three issues shall be analysed separately.  
Fitotherapics: ALANAC  
Nutraceuticals: CLAMEVET  
Homeopathicals: The initial proposal shall be distributed, in order to receive the proposal to coordinate the working group

### **New issues and discussions to be included on next Seminar**

- Panel discussion on farmacovigilance activities carried out by CAMEVET member countries
- Presentation on the mechanisms applied by the European Medicines Agency (EMA) for the adequation of the registration systems in new European Union member countries

#### 4. Expenses report, financial status and 2008/2009 budget

The balance sheet, the financial status and the budget are approved.

**Available resources to 2008, September 8**

9.289,62

#### Incomes

- Participation fees (U\$ 200 / participant) 12.600

**Available resources by the Seminar closure** 21.889,62

#### **Budget for the 2008/2009 financial year**

#### Expenditures

- Personnel 4.800
- Office expenses 1.800
- CAMEVET Secretary travel expenses for XV Seminar 3.000
- Subtotal expenditures 2008-2009 budget 8.600

Estimated resources available by the beginning of the XV Seminar 13.289.62

The General Assembly considers that the budget shall take into consideration the participation of the Secretariat in international meetings.

#### 5. Other discussed issues

#### **Communications**

The importance of the constant updating of the CAMEVET contents at the OIE Regional Representation is stated.

Moreover, it is proposed and accepted the the production of an exclusive webpage for the Committee, for which the different alternatives shall be analysed and proposed.

It is considered as essential that the Committee shall have an OIE hosted e-mail address.

Related to the diffusion of the activities carried out by the Committee, it is considered as necessary to communicate the Veterinary Services on the results obtained throughout the actions carried out by CAMEVET, as the importance of the participation of the heads of the veterinary products registration offices from member countries.

It is considered that the communication shall be accomplished simultaneously by the OIE and the industry from member countries, and pointed to the Chief Veterinary Officers, the heads of the veterinary products registration areas, and the focal points for veterinary medicines.

It is recommended that the information produced by the Seminar shall be distributed to the Chief Veterinary Officers, so as the dispatch of acknowledgment notes regarding the participation from the official sector representatives, and special notes promoting the participation for those countries which could not participate in the present Seminar.

#### **Next Seminar Organization**

The official note sent by MVZ Enrique Sánchez Cruz, Director of the Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria, proposing Mexico as the hosting country for next Seminar is read and approved.

Due to the fact that the definitive date for the Seminar shall depend on many factors relative to the organization, it will be confirmed in brief.