XI SEMINAR ON HARMONIZATION OF REGISTER NORM AND CONTROL OF VETERINARY MEDICINES.
Montevideo, Republic of Uruguay, 12-14 September 2005

1. HARMONIZATION

A report on the status of each necessary formalities of CAMEVET, and also following general steps, concerning veterinary medicines labelling, were harmonized:

1.1. Labelling

The proposal on labelling which was previously distributed and discussed during last year Seminar, was presented and discussed now, too.
It was agreed that labelling shall be harmonized, based on items distribution required for labelling, considering place on the label, packaging and prospectus.
In addition, a list or priorities on placement of contents was defined, based on the possibility to include contents according to size and type of packaging. This list of priorities is in Annex I of this document.
This Document once harmonized will be identified according to CAMEVET's Identification of Norms.

2. CAMEVET

2.1. Executive Board
2.1.1. CAMEVET's Executive Board was appointed taking into account CAMEVET's ruling, as follows:

President: Dr. Elia Muñoz (Uruguay)

Vice-President. Dr. Luis Carlos Cigarruista (Panama)

Official Member: Dr. Adela Encinosa Liñero (Cuba)

Adherent Members:

Dr. Milson Pereira (SINDAN)
Dr. Enrique Argento (CAPROVE)

The Executive Board will be in force as from 14th September until next CAMEVET's Seminar will be hold in year 2006.

3. Venue of next CAMEVET's meeting

It was approved that the country hosting the Seminar will bear the local seminar expenses, (rent of conference room, simultaneous translation, secretaries, printing of seminar documents, folders for participants, etc). To bear these costs, the private sector will collect a registering fee. Because of this reason, resources coming out from these

private sector registering fees, will totally apply the Secretary ex-office of CAMEVET and to cover other CAMEVET's activities.

Panama's proposal to host and organize next Seminar was approved, and also the proposal of Central-America countries to host and organize CAMEVET's Seminar for year 2006 and Bolivia for year 2007

4. CAMEVET's 2005-2006 woking plan and future actions

Steps to follow up developing of CAMEVET's activities were approved.

The following CAMEVET's Working Plan was agreed:

- To set up in order and sort harmonized documents which came out from previous CAMEVET's Seminars as well as documents under discussion, according to CAMEVET's Identification Norms.
- Periodically distribution and follow up of information to be shared with CAMEVET's members.
- Up dating of information on American countries legislation and ruling concerning registration of veterinary medicines and other activities, placed on the Regional Representation for the Americas Web page

It was agreed that CAMEVET's Executive Board shall inform the American Country Veterinary Services on CAMEVET's important activities and its outcomes.

5. OIE Focal contact

It was agreed that CAMEVET's country members shall forward to the Regional Representation for the Americas and through this to the OIE, a proposal of action to be carried out by the OIE FOCAL CONTACT FOR VETERINARY MEDICINES

It was discussed that CAMEVET shall request the OIE to organize a technical area receiving presentations on countries information for knowledge and diffusion. Due date for receiving these presentation is 23rd September 2005.

6. Auditing of GMP Guidelines

Regarding presentation of modification on Auditing Guidelines it was agreed to maintain them in a step III status. Due date for presentation of remarks is March 2006.

7. Format of CAMEVET's documents – internal antiparasite efficacy assays – diagnostic kits.

Due date for receiving remarks to this document will be March 2006.

8. Veterinary Medicines inspection, verification and control

The importance of the veterinary medicines in food production, animal and public health and international trade, was pointed out. Taking into account this important role

of the veterinary medicines, it is necessary to strengthen and improve the veterinary medicines control and auditing.
Also it was discussed the relevance of education of producers and users.
CAMEVET's members interchanged ideas on inspection, verification and control of veterinary products. The following outcomes came out from the above discussion:
a) The Veterinary Products are key factors of the human food safety production line and in the zoonoses and other animal health control. For this reason, veterinary products inspection, verification and control, assuring veterinary products quality, are essential.
b) The development of these procedures may be done using Estate own resources, in the best way possible , and also taking advantage of other resources that the Society may dispose, as for example, the use of human resources by implementing agreements with other institutions or the analytical equipment capacity building.
c) Even general criteria for implementation of agreements with other institutions in the interior of the countries may be fixed, the countries differences make harmonization of procedures impossible.
d) It is necessary to acknowledge the country authorities on the importance and need of these activities.

So the following conclusion comes out:

I. A document shall be elaborated by the Argentine representatives as to set up criteria on regulation.
II. To request to the Regional Representation to communicate each countries Delegate, the importance of mentioned document, and need to improve its implementation, using available resources, assuring production of more safety food for the community and helping in zoonosis and other animal disease control.

9. CAMEVET' Secretary

It was decided to hire a Veterinary Doctor with great knowledge in veterinary medicines, in order to follow up pending activities of CAMEVET with base in the OIE Regional Representation for the Americas The the Veterinary Doctor tasks and his honoraries shall be supported with CAMEVET's resources.

	LABELING GUIDELINES			
	Letter size : 4 points			
	Range: PHARMACOLOGICAL VETERINARY MEDICINES - BIOLOGICALS			
	Table 1	Label	Case-box	Prospectus
	Item			
1	Product name and generic name - Pharmacological form	X	X	X
2	Volume or liquid weight and units	X	X	X
3	Production batch number	X	X	
4	Manufacturing date	X	X	
5	Date of expiration	X	X	
6	Name of Manufacturing laboratory - Country	X	X	X
7	Storing conditions	X	X	X
8	Dosage form	X	X	X
9	"Veterinary Use Only"	X	X	
10	"Read the prospect before using the product"	X	X	
11	Register Number	T	X	X
12	Importer name and address in the country	T	X	
13	"Sale with recipe" for controlled medicines	X	X	X

	Table 2			
	Item	Label	Case-Box	Prospectus
11	Qualitative and quantitative Formula / strain		X	X
12	Morphological type		X	X
13	Indications		X	X
14	Species to which the drug use is recommended		X	X
15	Dose indicated by animal specie		X	X

16	Administration indications		X	X
17	Warning and precautions – See additional information in the prospectus		X	X
18	Collateral effects – See information in the prospectus			X
19	Contraindications and restrictions – See information in the prospectus			X
20	Adverse symptoms – See information in the prospectus			X
21	Antidote (if exists) – See information in the prospectus			X
22	Period of retirement		X	X
23	Storage out of children and pets handling access	T	X	X
25	Telephone number for consumer (optional inclusion in labelling)			X
26	Technical Responsible		T	
27	Biological active and inactive agent		X	X
30	Name and identification of product owner and product manufacturer			X

Explanations:

1. Total items of Table 1 shall be included in the labelled product, and shall be included in the individual components (Label, case-box or prospectus) marked with "X" in the table.

2. Items of Table 2 shall be showed in the labelling, and may be showed in the individual components (case-box or prospectus), marked with "X" in the Table. The inclusion of these items in the case-box has a priority than in the prospectus.

3. Items market with "T" must accomplished with aforementioned, with the indication that could be excluded of the individual components (Label or case-box or prospectus) when its inclusion it is not possible because of lack of space for printing.