XIX Seminar on Harmonization and Control for Veterinary Medicines
Americas Committee on Veterinary Medicines (CAMEVET)
Panama, Republic of Panama
September 24 - 27, 2013

Opening speeches

Professor Batista Gerardino, Deputy Minister of Agriculture, welcomed the participants, as Dr. Manuel Gonzalez Cano, OIE Delegate from Panama, Dr. Filiberto Frago Santamaria, OIE Sub-Regional Representative for Central America and the Caribbean, and Mr. Milson da Silva Pereira, SINDAN Executive Director.

Assumption of the Presidency

Dr. Marvin Yohan Vega Espinosa took the role as President of the Seminar.

Dr. Enrique Argento, CAMEVET Secretary, presented Ms. Ana Maria Sgammini, who has been hired to perform support tasks for the Secretariat.

Session I - Relations of CAMEVET and implementation of harmonized documents

Report of the 81st General Session of the OIE

Dr. Martin Minassian, Technical Assistant of the OIE Regional Representation for the Americas, presented the topics of relevance for the CAMEVET which were discussed at the 81st General Session of the OIE.

This included the presentation of the Technical topic I, entitled "Modern approaches and the use of new technologies for the control and eradication of aquatic and terrestrial animal diseases that fully consider animal welfare and minimize the impact on food security", as the Resolution No. 35 of the World Assembly of Delegates.

One of the conclusions of this study was that 75.9% of the countries responding to the survey support the use of DIVA strategies (Vaccines differentiating animals vaccinated from naturally infected) or high potency vaccines during an outbreak, and it is necessary for the OIE and countries to update their standards to the use of these and other new technologies.

Other topics presented dealt with the updating of the OIE list of antimicrobials of veterinary importance, and the OIE procedure for registration of diagnostic kits.

Finally, modifications adopted in the Terrestrial Animal Health Codewere presented. This included the adoption of definitions for "Good Manufacturing Practices" and "veterinary medicinal product", and also the update of Chapter 6.9, *Responsible and prudent use of antimicrobial agents in veterinary medicine.* He also reminded participants that Chapters 6.6, 6.7 and 6.10, also related to antimicrobial resistance, are under review. For that, it shall be important to be aware about the distribution of the reports of the OIE Commissions in order to provide comments via the Delegates.

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Paseo Colón 315, 5to. Piso Of. D Buenos Aires, Argentina
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Moreover, he urged Focal Points to intervene more actively in issuing comments to the modifications proposed in the OIE Standards.

Participants expressed their satisfaction with the inclusion of these definitions in the Glossary and the content incorporated into Chapter 6.9 of the Terrestrial Code, as they include a direct reference to the measures required to combat illegal practices in the marketing of veterinary products, as well as the inclusion of criteria for the manufacture of medicated feeds.

Status of implementation of harmonized documents in member countries.

Dr. Enrique Argento presented the status of implementation of harmonized documents. He remarked that necessary that everycountry send the proper answer to this survey , as this information helps to measure and characterize the impact of the work of the Committee.

It was noted that, in many cases, harmonized documents are not incorporated in national regulations without any change, but are used as a technical guidance, or are applied without being formally included in the regulations, so it is important to have such information.

On this basis, the Secretariat will include these options in the upcoming consultations to countries.

CAMEVET Strategic Plan: Status of advancement

Dr. Carlos Francia, Member of the Executive Board, and on behalf of CAPROVE, made a report on the progress of the CAMEVET Strategic Plan for 2010-2015.

He commented that although the full implementation of harmonized documents was not met, the implementation of technically equivalent regulations is a significant advance.

He also highlighted the participation in the VICH Outreach Forum and the requirement made by the OIE Headquarters to review the quality of translations of three VICH guidelines into Spanish, and the opportunity to participate in the review of the VICH guideline for stability testing, in order to include the assays for products to be commercialized hot weather climatic areas, which are not covered by the current guideline.

On the other hand, noted that the diffusion of harmonized documents to all OIE member countries, as well as the incorporation to the OIE Standards as a pending task. In this regard, it was considered that the participation in VICH is a possible way to meet these goals.

Another point raised as pending is the low perception of the importance of the topics related to veterinary products by the Delegates of the Veterinary Services, for which the continuity in their invitation to participate in the Seminars was proposed.

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The presence of the Mexican Delegate to the OIE Dr. Joaquin Braulio Alvarez Delgadillo was highlighted. He expressed the importance for his country to support the work of all National Focal Points, and also added that industry problems are also State problems, and responsibilities are always shared.

He expressed his congratulations to the participants by the results obtained in the forums linking the authorities and the industry in the Americas.

Proposal for the creation of the CAMEVET Training Committee.

The Executive Board informed the problem of the limited availability of specific training opportunities in the field of veterinary products was raised, for both public and industry sector staff.

Dr. Liliana Revolledo was convened to present the main problems in the registration of veterinary products from both the public and industry sector, which in many cases are based on the lack of personnel with sound knowledge in this topic

From that, she proposed the creation of an "ad-hoc" training commission in CAMEVET, in order to promote and develop training activities for public and private sectors. These will include both class room and virtual activities, using available communication tools. Moreover, these activities should be available in several languages, and include evaluation and certification systems. Moreover, these activities shall serve as an alternative source of funds for CAMEVET.

It was unanimously approved that the Executive Boards hall create a training committee, which shall develop its Terms of Reference, and begin planning training activities.

It was commented that the Veterinary Services in some countries provide training to private companies in order to reduce the frequency of errors, so it was proposed to integrate these activities in the planning.

Presentation of the results of the official sector meeting

Dr. Benigno Alpizar Montero presented the results of the meeting held by the representatives of the official sector, whose minutes are included as Annex.

Topics presented included the requirement of residue withdrawal studies, for which the relevance of performing such studies for each particular formulation was commented. Other topics regarding free sale certificates and the need for revision of the guidelines for Good Manufacturing Practices were also discussed.

The unavoidable responsibility for manufacturers to perform residue withdrawal studies was stated. However, it was emphasized that it is essential for producers to respect the withdrawal periods.

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Participants from OIRSA member countries member countries indicated on the availability of diffusion materials to promote good practices in the use of veterinary products, included in the materials distributed.

Presentation of the results of the meeting of the industrial sector

Dr. Carlos Menendez presented the results of the meeting held by industry participants. Topics included issues regarding the prescription of veterinary products, as well as the difficulties encountered in applying the Central American Technical Regulation. Countries were urged to unify their forms for the registration and the Free Sale Certificate models harmonized by the Committee.

After the request of support raised by the FIFVETCA representative regarding the ongoing negotiations about the implementation of regulations on residue depletion studies in Central America with the official sector, the Secretary made clear that the interaction between the government and private sectors is one of the objectives of CAMEVET, urging participants to continue their efforts in coordinating common positions.

CAMEVET participation in the VICH Outreach Forum

Dr. Enrique Argento made a presentation on his participation on behalf of the Committee, reviewing the history of the meetings celebrated, and reporting that next meeting will be held in November 2013.

He highlighted the participation of representatives from the Americas in such meetings, as the participation of CAMEVET in the Working Group formed by VICH to develop training activities, through Dr. Nestor Guerrero, the review of Spanish translations by Drs. Carlos Francia and Margarita Pinto, and the participation of Dr. Laura Sbordi in the Experts Working Group on residues in honey.

As for the revision of the VICH guideline on stability of veterinary products, the CAMEVET harmonized document shall be provided, considering that covers tropical climate zones not included in such guideline.

Participation in the Drug Information Association meeting

Dr. Argento reported on the invitation received to participate in the meeting of the DIA, whose member countries participate in VICH with IFAH, to present an overview of the impact of veterinary products in livestock production in the region.

Report on the OIE Global Conference on the Responsible and Prudent Use of Antimicrobial Agents for Animals, "International solidarity to fight against antimicrobial resistance"

Dr. Gloria Alarcon made a presentation on the World Conference, held in Paris, France, between 13 and 15 March 2013[1].

[1]Presentations and conclusions are available at http://www.oie.int/eng/A_AMR2013/presentations.htm

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She detailed the topics discussed at the Conference, and presented the adopted recommendations. One of the relevant topics referred to the need for improved communication, collaboration and existence of agreements between all parties involved.

Also, stressed that one of the recommendations for OIE member countries refers that they "*develop or update appropriate legislation and regulation on import, marketing authorisation, production, distribution (including transport and storage) and use of quality veterinary medicinal products in interaction with other relevant competent authorities and private interested parties, and to ensure their efficient implementation*".

Sesion II –Working documents

Dr. Argento reminded the participants to respect the deadlines allocated for the submission, as this causes delays in the circulation and approval of the working papers.

Registration for homeopathic veterinary products

Dr. Germán Sarmiento Parra, representing Dr. Nestor Guerrero Lozano, presented the progress of the working document, in Step III status.

Based on the comments made by several countries, which raised doubts as whether the submitted document included the final comments, as the comments received after the deadline, a final circulation of the document including all of the comments received was approved.

A lapse of 60 days after the closure of the Seminar was established for the circulation of the compiled document, with 60 additional days for the reception of comments and its final adoption.

Guideline for the registration of biotechnologically obtained subunit vaccines

Drs Emigdio Lemes Anaya and Jesus Mena Campos made a presentation on the progress in the working document, in Step III status, detailing the changes made by the countries which submitted comments.

He clarified that comments were received after the deadline, which were presented and accepted, stating that these changes were not included in the Portuguese version. The document was approved and included as Annex.

The proposal made by SINDAN providing the Portuguese translation, which shall be available within 60 days, was accepted.

Guidelines for the establishment of withdrawal periods for veterinary products

Dr. Carlos Francia presented the progress in the preparation of the working papers related to the *guideline for conducting residue studies*, the *guideline for the calculation of withdrawal periods*, and the *guideline for the validation of analytical methods*.

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In this regard, he commented that the criteria applied in these guidelines is to consider as many scenarios as possible.

He noted that, although the basis for the preparation of these Guidelines have been the documents from VICH, the FDA and the EMA, they included new contents adapted to the reality of the continent, as in the case of the application of veterinary products through immersion.

According to the current procedure, the changeto the status of Step III was approved, and the drafts shall be circulated within a 90 days dead line fort he submission of comments.

Control of vaccines for infectious bovine rhinotracheitis (IBR)

Dr.Viviana Parreño presented the final document on potency testing for inactivated vaccines containing bovine herpesvirus (BoHV-1), in Step III status.

The document was approved unanimously, and is included as Annex

Guideline for potency tests in vaccines containing inactivated Bovine Parainfluenza 3 (PI-3) virus - guinea pig model

Dr. Viviana Parreño presented the progress in the working document, in Step III status, stating that no further comments were received to the final versions, and general comments provided too there related documents were used to improve their quality.

Dead lines for the submission shall be respected in order to provide comments.

Guideline for the registration of nutraceutical veterinary products/ dietary supplements

Dr. Jorge Dale, on behalf of the working group, presented the final version of the working document, in Step III status.

Existing problem was raised regarding the fact that in many cases theare as of registration of veterinary products have no concern in the document.

After the opinions of some participant sabout the need for a fur ther review by members of the Working Group regarding stability tests, it was agreed that they shall be included in a new version of the document, with a final distribution with additional 60 days for the reception of comments.

Proposal for new working groups

Recommendations for the design of safety tests for the development and registration of inactivated vaccines for cattle.

Dr. Maria Marta Vena presented the proposal for a working paperon safety testing for bovine inactivated vaccines, especially viral vaccines for non-vesicular diseases, usually in combination with bacterins.

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The propos alwas accepted. The Working Group will be coordinated by Dr. Maria Marta Vena, with the participation of representatives of the official sector from Chile, Mexico and Uruguay, as well as ADIPRAVE, CAPROVE and CEV.

Guideline for potency testing in vaccines containing inactivated bovine rotavirus.

Dr. Viviana Parreño made a presentation on the subject, on the basis of the importance of this virus associated with neonatal calf diarrhea.
The methodology fort he evaluation of potency in combined vaccines containing inactivated bovine rotavirus waspresented, using a guinea pig experimental model, which greatly optimizes the evaluation.

The propos alwas accepted. The Working Group shall be formed by the same members of the Parainfluenza-3 Working Group.

Veterinary products and aquaculture

The proposal to include issues related to the field of aquaculture was accepted, for which a working group was formed, coordinated by Canada, including Chile, Costa Rica, Mexico, Peru and the Cuban Center for Genetic Engineering and Biotechnology, representatives from ANVET, ALANAC, CAPROVE, FENALCO and SINDAN.

This working group will define the content and propose draft papers for the Committee, and also identify experts.

Minorspecies

Alter the discussion regarding the need for documents for that topic, a working group wasformed, under the coordination by SINDAN, with the participation of there presentatives from Chile, Cuba, Ecuador and Uruguay, as well as industry representatives from ADIPRAVE, ALANAC, CEV, CLAMEVET and FENALCO.

Growth promoters

SINDAN shall convene a speaker for the next seminar, and coordinate a working group composed by representatives from Ecuador, the Cuban Center for Genetic Engineering and Biotechnology, and industry representatives from ADIPRAVE, ALANAC, ANVET, AVISA, CEV, CLAMEVET, and the Chamber of Agricultural Products of Costa Rica.

Bioequivalence Working Group

The group will be coordinated by CAPROVE, and will aim to prepare a technical guideline for the design of trials. The groups hall include representatives from Chile, Mexico, Peru and Uruguay, as well as ADIPRAVE, ALANAC, CEV, CLAMEVET, FENALCO and SINDAN.

Instruction guides for completing the harmonized CAMEVET forms for pharmaceutical and biological products

Dr Federico Luna, in representation of Argentina, proposed him self for the coordination of the Working Group, with the participation of Ecuador, and representatives of CAPROVE, CLAMEVET, SINDAN, and of Dr. Liliana Revolledo.

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Labeling

Dr. Carlos Francia expressed the need for a document compiling the difficulties faced by the industry in terms of the different labeling requirements, which shall serve as a basis for assessing the need fort here vision of the harmonized document.

For that purpose, the Secretaria twill require the submission of the regulation spertaining to the labeling of veterinary products to the countries.

This document will be distributed 120 days before the celebration of the next seminar, only for information and with out requiring comments.

The Working Groups hall be coordinatedby CAPROVE and be formedby ALANAC, ANVET, AVISA, INFARVET/CANIFARMA, CLAMEVET, FENALCO and SINDAN.

Roundtable discussion: The present and future CAMEVET

Dr. Ofelia Flores, official representative of Mexico, stressed that the interest in CAMEVET is evident, given the continued and growing involvement of industry and the public sector in the annual meetings.

Dr. Carlos Francia mentioned that one of the needs for further progress in the Committee is to continue to develop the current and future strategic plans.

The formation of a Working Group with the role of drafting the CAMEVET Strategic Plan for the period 2015-2020 was proposed and approved. It shall comprise the official representatives of Argentina, Canada, Jamaica, Mexico, Paraguay and Uruguay, as well as representatives from ADIPRAVE, ALANAC, CEV and CLAMEVET.

The Working Group will make available a trilingual first draft within 180 days, which will be circulated for comments. In addition, the Secretariat will support the Working Group by asking each country to identify the three most important topics to be included in the Strategic Plan, with a deadline of 60 days for the submission of proposals.

It was commented that in some countries the register of veterinary products is under Health Ministry control for that reason, this kind of products moot be included in one Health concept.

Moreover, Dr. Argento added that the Committee's participation in international forums and the consideration of the opinions of the Committee are a sign of its increased visibility

The continuity in the participation in the activities of VICH was unanimously decided.

It was stated that technical documents are essentially guidelines, and the implementation is a decision of each country, so that each country must properly assess

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the risks, through the dialogue between the public sector and its industries, keeping the objective of raising the quality of our products to reach more markets.

Special emphasis was placed on activities to promote the creation and strengthening of networks among the sectors involved, maintaining common goals.

Another accepted proposal refers that future Seminars shall include the reports of meetings where CAMEVET members participate, and promoting the participation on behalf of the Committee.It was also requested that efforts be made in order to include the reference to the actions and achievements of CAMEVET in the presentation made by the OIE at the Codex Alimentarius meetings.

Communications

The improvement in communications from the Secretariat was highlighted, being a pending task the update of the contents of the website, hosted under the OIE Regional Representation for the Americas.

In this regard, Dr. Minassian made the clarifications, being resolved that a partial solution shall be the use of a public folder hosting the documents, so that interested parties can access them. The Secretariat shall communicate the way to access such folder, after its creation.

The need for a directory of contacts was raised, and the representatives of the Associations were required to communicate any updates in their authorities and contact details to the Secretariat.

Expenses report, financial state and 2012/2013budget

Resources available to September 24, 2013	40.690,00 USD	
Income		
- Seminar registration XIX (USD 300 / participant)	30.000,00 USD	
Resources available at the end of the Seminar	70.690,00 USD	ARG 50,000.00
Budget for the financial year 2013 / 2014		
Expenditures		
Fixed expenses	8.400,00 USD	
Variable expenses		
- Support Fund for Focal Points	3.000,00 USD	
- Participation at meetings of the VICH	3.500,00 USD	
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Composition of the Executive Board

According to the CAMEVET Rules, Dr. Glen Gifford shall take office as Chair of the Committee by the end of the current Seminar, being current office until the end of next Seminar. Moreover, Dr. Marvin Yohan Espinosa Vega shall take the position of Honorary member from the official sector, in terms of being able to capitalize on his experience and participate in the organization aspects of the next Seminar.

Venue for the next meeting

The proposal to hold the next seminar in Ottawa, Canada, between August 27 and 29, 2014, following the Workshop for OIE National Focal Points for Veterinary Products is accepted.

The register mode will include an obligatory on line phase.
This registration will be used to send the invitations on time to let the needed official waivers and the Canadian VISA

Secretary wills verity the assistants confirmation 60 days before the seminar, in order to inform the assistants number to the organization committee.
The “on line” assistants will have a differential fee. The people inscription out of time will pay a higher fee.

In addition, it was accepted the Guatemala proposal to organize 2015 Seminar

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Annex:

1. Minute of the official sector meeting
2. Minute of the industry sector meeting
3. Harmonized Documents : Guideline for the registration of biotechnologically obtained veterinary products
4. Harmonized Documents: Control of vaccines for infectious bovine rhinotracheitis (IBR)
5. List of participants

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List of acronyms used in the document

ADIPRAVE: Industries Association of Agrochemicals Products and Veterinary (Uruguay)
ALANAC: National Association of Pharmaceutical Laboratories (Brasil)
ANVET: National Association of Veterinary Laboratories (Chile)
APROVET: National Association of Laboratories for Veterinary Products (Colombia)
AVISA: Venezuelan Association of Animal Health Industry

CANIFARMA: National Chamber of the Pharmaceutical Industry (México)
CAMEVET: Americas Committee on Veterinary Medicines
CAPROVE: Argentine Chamber of Veterinary Products Manufacturers
CEV: Chamber of Veterinary Specialties (Uruguay)
CLAMEVET: Argentine Chamber of Veterinary Medicinal Laboratories
EMA: European Medicines Agency
FDA: U S Food and Drug Administration
FENALCO: National Federation of merchants (Colombia)
FIFVETCA: Federation Central American of Industry Veterinary Pharmaceutical
ICA: Colombian Agricultural Institute
INFARVET: Veterinary Pharmaceutical Industry – Canifarma (México)
OIE: World Organisation for Animal Health
OIRSA: International Regional Organization for Plant and Animal Health
SENASA: National Agrifood Health and Quality Service (Argentina)
SINDAN: National Union of Industry Products for Animal Health (Brasil)
VICH: International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

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