World Organisation for Animal Health
Founded as OIE

camevet
Comité de Las Américas de Medicamentos Veterinarios

**CONCLUSIONS AND RECOMMENDATIONS**

**XXVII Seminar on Harmonization of Registration and Control of Veterinary Medicines**
**Americas Committee for Veterinary Medicines**
**(CAMEVET)**
**9 to 11 November, 2022**
**San Salvador, El Salvador**

**Opening speeches**

Participants were welcomed by Mr. Néstor Odir Avendaño Romero, Delegate before the OIE for El Salvador, Ms. Stephany Claros, president of the Executive Board of CAMEVET, and Mr. Oscar Zelaya, Executive Director of OIRSA (International Regional Organization of Plant and Animal Health).

**Designation of President and Vice-president**

Ms. Stephany Claros, Focal Point for Veterinary Products for El Salvador, was formally designated as president of the Seminar.

**Session I – Pharmacovigilance Workshop**

The Seminar included training in Pharmacovigilance offered by Messrs. Camilo Giraldo and Gabriel Ardiles.

The scope of pharmacovigilance was defined, with an emphasis on the importance of notification as an essential element, and the role of veterinary doctors.

Mr. Mc. Allister, representative for the Andean Community, referred to the list of minimum competencies required of veterinary doctors by the OIE, and highlighted that pharmacovigilance has not been included in that list. Miss. Ana Sgammini, Administrative Secretary of CAMEVET, was tasked with presenting this issue to the Regional Office of the WOAH.

**Session II – Revision of Work Documents**

Miss. Ana Sgammini presented the work documents under Processing Status I.

**Efficacy tests for the registration of internal and external antiparasitics for small animals.**

Following the new additions to the work group, the latter is made up as follows: under the coordination of the representative for the Official Sector of Argentina, the official representatives from Colombia, El Salvador, Mexico, Peru, and Uruguay, with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), ALANAC (Brazil), ALAVET (Chile), APROVET (Colombia), ASOVET (Guatemala), ANALAV (Mexico), CADIN (Nicaragua), CEV (Uruguay).

**Update of models of free sale certificate and exclusive export authorization**

Following the new additions to the work group, the latter was made up as follows: under the coordination of SINDAN (Brazil), the official representatives of Belize, Chile, Colombia, Costa Rica, Cuba, Guatemala,



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

Mexico, Nicaragua, Peru and Venezuela, with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), APRIVET (Bolivia), ALANAC (Brazil), APROVET (Colombia), ASIFAN (Costa Rica), ALFA (El Salvador), INFARVET (Mexico), CADIN (Nicaragua) and CEV (Uruguay).

**Complementary Studies to the Stability guide.**
Following several additions to the work group, the latter was made up as follows: under the coordination of CAPROVE (Argentina), the official representatives of Argentina, Colombia, Costa Rica, Cuba, Ecuador, Guatemala, Mexico, Uruguay, with the participation of CLAMEVET (Argentina), APRIVET (Bolivia), ALANAC (Brazil), APROVET (Colombia), FENALCO (Colombia), ASIFAN (Costa Rica), CIA (Costa Rica), LABIOFAM (Cuba), AENSA (Ecuador), ALFA (El Salvador), ASOVET (Guatemala), ANALAV (México), CADIN (Nicaragua), CAPALVE (Paraguay), CEV (Uruguay).

**Veterinary Medicines Residue Studies**
Following several additions to the work group, the latter was made up as follows: the official representatives of Colombia, Costa Rica, Ecuador, Guatemala, Mexico, Paraguay, Peru and Uruguay, with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), APRIVET (Bolivia), ALANAC (Brazil), ALAVET (Chile), FENALCO (Colombia), ASIFAN (Costa Rica), CIA (Costa Rica), ASOVET (Guatemala), CADIN (Nicaragua), CAPALVE (Paraguay), ASINVEP (Peru) and CEV (Uruguay), under the coordination of the representative for the official sector of Argentina.

Following the new proposals under the topic, the work groups listed below were established:

1. **Guide for registration of fixed combinations.**

The work group is coordinated by El Salvador (official sector), and made up by the official representatives of Guatemala, Costa Rica, Honduras, Nicaragua, and Uruguay, with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), FENALCO (Colombia), ASIFAN (Costa Rica), CIA (Costa Rica), ALFA (El Salvador), ASOVET (Guatemala), CADIN (Nicaragua), ASINVEP (Peru) and CEV (Uruguay).

2. **Registration of medication containing Cannabis**

The work group shall be coordinated by APROVET (Colombia), and made up by the official representatives of Argentina, Bolivia, Chile, Costa Rica, Curazao, Guatemala, Honduras, Mexico, Panama, Paraguay and Uruguay, and with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), ABIQUIF (Brazil), ALAVET (Chile), FENALCO (Colombia), ASIFAN (Costa Rica), CIA (Costa Rica), AENSA (Ecuador), ANALAV (Mexico), ANDIA (Panama), CAPALVE (Paraguay) and CEV (Uruguay).

3. **Biosupplies**

The work group shall be coordinated by Argentina (official sector) and made up by the official representatives of Chile, Colombia, Costa Rica, and Uruguay, with the participation of CAPROVE (Argentina), CLAMEVET (Argentina), ASIFAN (Costa Rica), CIA (Costa Rica), CAPALVE (Paraguay) and CEV (Uruguay).

Once the work groups had been made up, Miss. Ana Sgammini prepared a summary of the methodology for the work groups, noting that the preparation of a concept note is required for documents currently



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

under Processing Status I, indicating objectives –which shall be aligned with those of CAMEVET, a brief abstract indicating the purpose and, lastly, the regulatory background. Such documents shall advance to Processing Status II after the first draft has been drawn up and shall have a 60-day term for being circulated among all the members of CAMEVET in its three languages. Once the 60-day term has elapsed, documents shall advance to Processing Status III, and be circulated a second time with any observations made. When the second circulation has concluded, documents shall proceed to Processing Status IV, and shall be presented as a final document. This methodology is included in **Annex I.**

**Complementary Studies to the Stability Guide.**

Ms. Andrea Fraga, representing CAPROVE (Argentina), presented a summary of the contents of the Work Document, currently under Processing Status I.

It was noted that the guide is an extension of the guide already harmonized in CAMEVET for carrying out stability studies of veterinary medicines and which excluded other complementary studies. The objectives and scope of the guide were described.

The document shall begin to be circulated under Processing Status II upon completion of the draft and the corresponding translations into Spanish, English and

**Labels for veterinary products.**

Ms. Tatiana Leal, Focal Point for veterinary products for Costa Rica, presented a summary of the contents of the Work Document currently under Processing Status III.

A summary was presented of the stages this document has gone through.

It was noted that in 2021 the office of the secretariat circulated a survey which was answered by 19 countries. Subsequently, five meetings were held by the work group.

After gathering regulatory information from each country, it was decided to circulate the document among all the Industry Sector representatives under Processing Status III in its three versions, Spanish, English and Portuguese.

The document will additionally be sent to the international organizations that collaborated to achieve harmonization on the guide.

Miss. Ana Sgammini noted that, if required by the industry, a virtual meeting could be held with all the chambers and the coordination of the Work Group prior to the following CAMEVET meeting.

**Good Manufacturing Practices – Guidance on the Manufacture of Veterinary Products**

Mrs. Berta Chelle, Focal Point for Veterinary Products for Uruguay, presented a summary of the contents of the Work Document currently under Processing Status III.

A brief summary of the meetings held by the work group was presented.

It was agreed that certain points would be revised by the work group, with the subsequent circulation of the document to all the members of CAMEVET, under Processing Status IV.

**Efficacy Tests for the registration of internal antiparasitics for ruminants and swine**

Mr. Carlos Francia, representing CAPROVE (Argentina), presented a summary of the contents of the Work Document currently under Processing Status III.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

It was agreed that certain points will be revised by the members of the work group and subsequently circulated to all the members of CAMEVET under Processing Status IV.

**Regulation for the classification and registration of veterinary products**

Mr. Henrique Uchio Tada, representing ALANAC (Brazil), indicated that, in view of changes in Brazilian legislation, the coordination of the work group has been unable to make progress on this topic. It was decided that the document shall be submitted at the next seminar with the progress made.

**Session III – Activities of regional organizations**

Mrs. Ana Sgammini inaugurated the session by welcoming participants to a Roundtable with the dissertating international organizations.

Dr Ever Adalberto Hernández, of OIRSA, made a presentation on Traceability of Veterinary Medicines, indicating the importance of traceability of food, rations, and animals destined for food production. Examples of the traceability system used by the Ministry of Agriculture, Livestock and Food (MAGA) of Guatemala were presented.

The Permanent Veterinary Committee (CVP for its Spanish acronym), presided by Dr Ximena Melón, made a presentation on Antimicrobial Resistance, and indicated that one of the various ad-hoc groups of the CVP with different lines of work focuses specifically on antimicrobial resistance. The work of this group includes the existence of National Plans in each country and the progress achieved by each one, with an analysis of regulatory frameworks, priority pathogens, and monitoring systems.

Dr Helmer Alonso Esquivel, representing the Inter-American Institute for Cooperation on Agriculture (IICA for its Spanish acronym), made a presentation on the Antimicrobial Resistance Integrated Surveillance Program, emphasizing the countries of the region that are currently included in an integrated surveillance program. Additionally, reference was made to the countries that benefited from the Antimicrobial Resistance twinning project, which is based on the development of pilot surveillance programs.

Dr Mc Allister Tafur, representing the Andean Community (CAN for its Spanish acronym), made a presentation on Anthropic Factors and their relationship with antimicrobial resistance profiles detected in tilapias grown in the Betania dam in Colombia. This work was directed at determining the antibacterial resistance profiles of gram-negative bacillus strains present in the clinically healthy tilapias.

**Plenary meeting of the official sector**

Dr Gloria Alarcón presented the conclusions of the meeting held by the official sector, describing the topics dealt with, and aspects related to the notification of registry updates. In this regard, it was noted that Colombia has requested fluent communication among officers to notify the cancelation of registries in countries of origin. Topics related to the authentication with the Apostille of documents bearing digital signatures were also presented.

Links to the registration procedures of different countries in the region are included as **Annex II.**



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**Plenary meeting of the veterinary industry**

Ms. Edith Gamarra presented the topics discussed at the meeting held by the veterinary products industry sector. Ms. Gamarra described topics such as the Technical Regulation for Central America or RTCA, for its Spanish acronym, and requested a Discussion Group to be held within the sphere of CAMEVET in view of the existence of differing interpretations. Additionally, the issue of the requirements in the stability guide and in the labeling guide, and the recognition of the free sale certificate, was brought up in view of the differences between countries.

**Annual report of the OIE relating to antimicrobial agents destined for use in animals**

Dr Delfy Góchez, representing the department on antimicrobials resistance of the OIE, made a presentation on the data in the 6th. report.

It was indicated that the countries that participate in the gathering of data can provide quantitative or qualitative data.

It was noted that the 6th. round was published in May this year and received responses from 157 countries.

It was also noted that the reports published contain the results of the rounds, and a regional as well as a global report. The report also contains data on animal biomass and quantities of antimicrobials used in one year.

On the use of antimicrobials, 69% do not use growth promotors. In the Americas, 17 countries indicated that they use growth promotors.

With regard to the use of antimicrobials in aquatic animals, it was indicated that 25% of the countries were unable to answer due to the lack of cooperation by other entities or the private sector.

In relation to animal biomass, it was highlighted that bovines represent 43% of the biomass in the Americas.

A 27% worldwide drop in the use of antimicrobials in animals was noted.

The creation of a platform for facilitating the input of data was noted, in addition to the possibility of carrying out a training workshop for focal points next year.

**EU Project – Working together to fight antimicrobial resistance – project update**

Dr Maria Mesplet, officer of the tripartite project “Fighting Antimicrobial Resistance Together”, made a presentation under the framework of the update on project activities in the Americas, which involve 7 countries of the region.

A brief overview was made of the meaning of Antimicrobial Resistance and how the tripartite project with the FAO, OPS and OIE was established.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

Dr Mesplet described the four components of the project, noting that component 3 is based on promoting private sector participation in AMR control. Within this component is the fight against counterfeit products in the region.

The activities include the development of a mobile application that will make it possible to verify whether veterinary products containing antimicrobials are registered in the region and to access all product information. The prototype of the application was presented, and it was clarified that the application project is still under development.

It was mentioned that meetings have been held with the executive board and with the countries involved in the project, both in the official sector and in the industry. It is proposed to transfer the ownership of the application to CAMEVET to ensure its sustainability, and therefore we will continue to work together.

**Session IV– Presentation by countries of the region**

**Program for surveillance and monitoring in digital media – Electronic (virtual) commerce of veterinary medicines**

Ms. Rosina Leicht, representing SENASA Argentina, presented the summary of the program for surveillance and monitoring of veterinary medicines in digital media.

It was noted that work has been done on different platforms, such as Facebook, Instagram, Shoppe and Mercado Libre.

It was indicated that veterinary products are the ones most frequently found one these platforms, accounting for a total of 74.97% of publications reported throughout the country.

The monitoring program also includes web pages of veterinary practices and pet shops, it being noted that 98% of the domains notified adjusted their contents and operate within the regulatory framework.

It was noted that the project did not require expenses for the veterinary service, consequently, all the countries are invited to participate in the project.

**Mission, objectives and principles in the alliance for the use of antimicrobials**

Dr Santiago Vidal, representing Elanco, made a presentation on the alliance for the responsible use of antimicrobials, emphasizing the importance of public and private alliances.

The main objectives of the alliance were indicated, highlighting the importance of guaranteeing an aligned approach of all the interested parties in the development of antimicrobial policies.

It was noted that the alliance involves regulatory agencies, science, governments, producers, associations/chambers/industry, and non-government organizations.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

The alliance fulfills the purpose of the third component of the tripartite project funded by the EU, namely the promotion of public-private alliances.

A summary was provided of how the program began in Brazil, followed by Argentina, Colombia, Uruguay, and Chile.

**Mechanisms for expediting sanitary registration**

Dr Stephany Claros, Focal Point for Veterinary Products of El Salvador, presented the experience for expediting sanitary registration in that country.

The importance of training technical staff, updating systems, online registration and online payment services was noted.

The elimination of requirements was highlighted, as well as the need to provide an area for user attention and regular meetings with industry to gain first-hand knowledge of issues that arise.
The following were noted as improvements to be implemented: organization of registration dossier submissions, and creation of a supplies module in the system.

Dr Gloria Alarcón, Focal Point for Veterinary Products for Paraguay, presented the experience in expediting sanitary registration in that country.
A brief review was made of the different areas of SENACSA, indicating which areas are destined to registration.

It was noted that, within the veterinary product registration module, it is important to facilitate the process comprising the reception, registration, issue, control of and response to dossiers filed by users of the service; incorporate technological innovation to the process through the addition of useful and effective tools; full digitalization of documentation at every level of the establishment registration process; and enable external users to make online queries regarding the status of their dossier.

Following both presentations, gratitude was expressed for the content presented and a request was made to include in the agenda of future CAMEVET seminars the experience of different countries with regard to registration in order to fulfil the purpose of the Committee, namely, harmonization.

**Results of the survey – Level of implementation of harmonized documents**

Miss. Ana Sgammini presented the results of the survey conducted on the level of implementation of harmonized documents within CAMEVET, from which responses were obtained from 17 countries.

The commitment of officers was requested for future surveys in order to obtain a greater percentage of responses and, consequently, a more accurate statistical outcome.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

After this presentation, a request was made to Miss. Sgammini to make the questions in the survey simpler, asking only whether or not the guideline is being implemented.

**CAMEVET Budget and resources – Expense budget. Financial statement. Reading of the annual balance sheet.**

Miss. Ana María Sgammini presented the financial report, including the annual expenses and the income obtained during the current Seminar, together with the expense forecast for the following period. The report is included as **Annex III.**

The financial contribution made by CAMEVET to the Focal Points that requested financing was highlighted; these include Argentina, Bolivia, Colombia, Costa Rica, Ecuador, Guatemala, Honduras, Mexico, Nicaragua, and Peru.

A request was made for the Executive Board to consider financial support for the host country in the organization of future Seminars, as was the case with the current seminar. The need to assess the balance sheet in each case was highlighted to avoid hindering the stability of CAMEVET. The report was submitted to a vote and approved unanimously.

**Election of new members of the Executive Board**

Miss. Sgammini made a brief overview of the CAMEVET Regulation, informing attendees of the rules for electing members to the new Executive Board.

A request was made to include an annex to the regulation that establishes the election of a fifth member in addition to the four members from the official sector and the industry sector to act as alternate member in the event of changes during the two-year mandate.

Ms. Aida Rojas, representing the official members of the outgoing Executive Board, announced the new members for the official sector:

-Paraguay: Dr Gloria Alarcón
-Mexico: Dr Maria Elena González
-Chile: Dr Carolina Marambio
-Honduras: Dr José Interiano
-Alternate member: Ecuador: Dr Jorge Berru

Dr Edgar Medina, representing the affiliated members of the outgoing Executive Board, announced the new members for the industry sector:

-CEV (Uruguay): Dr. Mercedes Etcheverry
-CLAMEVET (Argentina): Dr Carlos Rufrano
-ANALAV (Mexico): Dr. Rafael Raya
-ASOVET (Guatemala): Dr Jorge Santa Cruz
-Alternate: CAPALVE (Paraguay): Dr Edith Gamarra



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**Approval of proposed host countries for forthcoming Seminars**

Miss. Ana Sgammini presented a summary of the countries that have hosted seminars since the start of CAMEVET.

It was noted that the host country is required to guarantee the availability of a room with a capacity for 200 people, refreshments for all the participants, audio system and simultaneous interpretation service in Spanish, English and Portuguese (although the latter language is not mandatory, in view of the large number of participants from Brazil, it is considered important).

It was also noted that there are no restrictions on funds being provided solely by the official sector, or by local industry.

Since no country offered to host the 2023 Seminar, it was agreed that this issue would be followed-up during the year.

However, Peru indicated that every effort will be made to act as host for the year 2024.

Before concluding the Seminar, gratitude was expressed to El Salvador for acting as host country. This gratitude was made extensive to all the officers of the Ministry of Agriculture, the Association of Pharmaceutical Laboratories (ALFA for its Spanish acronym) of El Salvador and all the sponsors that helped organize the present CAMEVET Seminar.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**List of acronyms used in the seminar:**

| | |
|---|---|
| ABIQUIF | Associação Brasileira da Industria de Insumos Farmacéuticos/Brazilian Pharmaceutical Industry Association (Brazil) |
| AENSA | Asociación de Empresas de Nutrición y Salud Animal/Association of Animal Nutrition and Health Companies (Ecuador) |
| ALANAC | Associação dos Laboratórios Farmacêuticos Nacionais/Association of National Pharmaceutical Laboratories (Brazil) |
| ALANAV | Asociación Nacional de Laboratorios Veterinarios/National Association of Veterinary Laboratories (Mexico) |
| ALAVET | Asociación Gremial de Laboratorios de Productos Veterinarios/Syndical Association of Veterinary Product Laboratories (Chile) |
| ALFA | Asociación de Laboratorios Farmacéuticos de El Salvador/Association of Pharmaceutical Laboratories of El Salvador (El Salvador) |
| ASIFAN | Asociación de la industria farmacéutica nacional /Association of the National Pharmaceutical Industry (Costa Rica) |
| ASINVEP | Asociación de la Industria Veterinaria del Perú /Peru Veterinary Industry Association (Peru) |
| ASOVET | Asociación de Distribuidores de Productos Veterinarios/Association of Distributors of Veterinary Products (Guatemala) |
| CADIN | Cámara de Industrias de Nicaragua (Nicaragua)/Chamber of Industries of Nicaragua (Nicaragua) |
| CAMEVET | Comité de las Américas de Medicamentos Veterinarios / The American Committee for Veterinary Medicines |
| CAPALVE | Cámara Paraguaya de Laboratorios de Productos Veterinarios/ Paraguayan Chamber of Veterinary Products Laboratories (Paraguay) |
| CAPROVE | Cámara Argentina de la Industria de Productos Veterinarios / Argentine Chamber of the Veterinary Products Industry (Argentina) |
| CEV | Cámara de Especialidades Veterinarias / Chamber of Veterinary Specialties (Uruguay) |
| CIG | Cámara de Industria de Guatemala / Chamber of Industry of Guatemala (Guatemala) |
| CLAMEVET | Cámara de Laboratorios Argentinos Medicinales Veterinarios/Chamber of Argentine Laboratories of Veterinary Medicines (Argentina) |
| CVP | Comité Veterinario Permanente / Standing Veterinary Committee |
| FDA | U.S. Food and Drug Administration |
| FENALCO | Federación Nacional de Comerciantes y Empresarios/National Federation of Merchants and Entrepreneurs (Colombia) |
| IICA | Instituto interamericano de Cooperación para la agricultura / Inter-American Institute for Cooperation on Agriculture |
| OIRSA | Organismo Internacional Regional de Sanidad Agropecuaria /International Regional Organization of Plant and Animal Health |
| RTCA | Central American Technical Regulation |
| SINDAN | Sindicato Nacional da Indústria de Produtos para Saúde Animal/National Union of the Animal Health Products Industry (Brazil) |
| SG CAN | Secretaria General de la Comunidad Andina / General Secretariat of the Andean Community |
| WOAH | World Organisation for Animal Health |



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**List of Annexes**

Annex I-Procedures work documents
Annex II- Links to registration procedures in different countries of the region
Annex III-Financial Statement



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

# Annex I

## Procedures work documents

**INTRODUCTION:**

In the course of the harmonization work developed by the Committee of the Americas for Veterinary Medicines (CAMEVET), documents that require adequate follow up and identification have been submitted, discussed and approved.

Likewise, it is essential to have a document circulation mechanism that clearly defines the steps that must be taken to reach harmonization, establishing deadlines for each step.

Thus, a system will be available that allows interested parties to know the stage in which the development of each document is.

**OBJECTIVES**

This procedure aims to:

1. Identify the different stages in the preparation of CAMEVET documents.
2. Establish the required deadlines for the circulation and receipt of comments prior to their approval.
3. Establish the document identification system.

**SCOPE**

The scope of this procedure covers all documents in the harmonization process, as well as documents already harmonized by the Committee.

**TERMS AND DEFINITIONS**

Group formed by Official Members or Adherent Members who show interest in working on a certain topic.

Work group Coordinator: Official Members or Adherent Members who assume responsibility for coordinating the actions of the working group in order to ensure compliance with this procedure.

Concept Note (Concept paper): Document that raises a possible topic of analysis and justifies the need for

**PROCEDURE**

**1. Documents in Step I status – "concept paper". it.**

1.1. CAMEVET members may pro pose the topics that need to be included in the work agenda of the Committee for their study, preparation, and harmonization of reference documents.

1.2. For the suggestion of a new topic, whoever initiated the proposal must be a member of CAMEVET and must submit to the Assembly a concept paper, in which the need to develop and propose a document for its harmonization must be substantiated. The must contain as a minimum:



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

- **Title:** the title must clearly ex press the subject covered by the document.
- **Document objective:** it must be in line with the objectives of CAMEVET.
- **Summary:** an explanation of the purpose and scope of the proposed topic should be developed.
- **Regulatory and scientific background:** must be submitted endorsing the relevance of the problem or subject, including the bibliography or regulatory information that supports it.

1.3. The subjects will be voted upon, requiring a simple majority of Members for the approval of their treatment.

1.4. For each one of the approved topics, a Work Group will be formed composed of a Coordinator and those CAMEVET members who wish to participate in the study of the subject matter

1.5. The Work Group must send the first draft of the document to the Secretariat within 120 days after the end of the Seminar in which the subject was approved. If the Project is not submitted within that period, the proposal on that subject will be excluded from the Seminar's schedule.

1.6. The documents drafts prepared by the work group will be sent to the Secretariat in the CAMEVET format and in the three languages used in the Committee (Spanish, English and Portuguese). The translations will be under the responsibility of the Work Group Coordination.

1.7. Once these requirements have been met, the documents enter the Step II - "First draft" status.

**2. Documents in Step II status – "First Draft"**

2.1. Documents in Step II status – "First draft" will be distributed through the Secretariat to all CAMEVET Members (Officers, Adherents and Collaborators) to receive comments. The deadline for receiving comments will be 60 days after distribution.

2.2. Once the deadline for the receipt of comments has been met, the Work Group should evaluate the comments received. In the event that the suggestions are not incorporated into the document, the Work Group will have the responsibility to justify the reasons for the exclusion.

Should there be comments expressing disagreement, the Work Group may select the most pertinent one, or keep the disagreements for their resolution during the Seminar.

2.3. The Work Group will have a period of 60 days to review the comments, to prepare a document compiling the comments received and their translation into the three languages

**3. Documents in Step III status – "Draft with comments"**

3.1. The document containing the comments received will be identified as Step III – "Draft with comments" and will be circulated a second time by the Secretariat to all CAMEVET Members, with a period of 60 days for the issuance of comments. The same criteria applicable to the Step II status will be applied for the reception and incorporation of comments.

3.2. The Work Group will have a period of 60 days to review the comments, to prepare a document compiling the comments received and their translation into the three languages



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**4. Documents in Step IV status – "Final draft"**

4.1 The document containing the comments that have been received will be identified as Step IV - "Final Draft" and will be distributed by the Secretariat to all CAMEVET Members, for their final review prior to its discussion at the Seminar.

4.2 The Work Group Coordinator will have the responsibility of presenting during the Seminar only the most relevant points of the work document. This should include all comments received and the substantiation for acceptance or rejection, as well as the discrepancies that require discussion.

4.3 In the event that an agreement is not reached in the Assembly, the document will remain in the Step IV status, and will be circulated again, with a period of 90 days for the receipt of comments with their respective technical or legal basis allowing to reduce disagreements.

**5. Documents in Step V status – "Harmonized document"**

5.1. The documents that comply with all the steps mentioned above enter the Step V status – "Harmonized document".

5.2. Harmonized documents will be part of the Proceedings of the Seminars in which they will be considered as harmonized. In the same way, they will be distributed and published by the Secretariat on the CAMEVET website.

**6. Harmonized documents review**

6.1. Harmonized documents should be revised every five years

6.2. The Secretariat will keep the document revision schedule, requesting the formation of Work Groups with their respective Coordinators during the Seminar.

6.3. CAMEVET Members may request the revision of harmonized documents before the established deadline by sending a modification proposal to the Secretariat, detailing the points covered and the problem to be solved, including the respective bibliography. The Plenary will decide on the relevance of the proposals, where the inclusion in its work plan and the formation of a Work Group will be defined.

6.4. Documents under review will enter Step II status and will continue as a new document.

**7. Other provisions**

7.1. The Work Group Coordinators will be responsible for complying with the formats established in the Attachment. The Secretariat will be responsible for verifying that the documents prepared by the Work Groups comply with these requirements. In the event that the Work Groups do not comply with these rules, the Assembly may decide to postpone or suspend the discussion on the subject.

7.2. All documents that do not make progress will be removed from the work agenda of the Committee.



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**RESPONSIBILITIES**

**Work Group Coordinator**

- To receive and incorporate the comments that are made during the development of the Work Group notifying the Secretariat of its evolution.
- To meet the deadlines for project development.
- To report on the progress of the work group to the Executive Board every 90 days.
- To substantiate acceptance and rejection of comments.
- To submit documents in the three CAMEVET official languages.
- To carry out the presentations in the Seminars.

**CAMEVET Secretariat**

- To follow up on the evolution of the work of the groups.
- To distribute documents to be commented to CAMEVET members.
- To receive and circulate the comments that have been received.
- To follow up on the deadlines for project preparation and comments.
- To do the final design, distribute and publish the harmonized documents.

**REFERENCES**

- Procedural Manual – Codex Alimentarius Internacional
- VICH/96/002 Revision 13 October 2016 FINAL ORGANISATIONAL CHARTER OF VICH



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

# Annex II

**Links to registration procedures in different countries of the region**

| | |
|---|---|
| Chile | https://www.sag.gob.cl/ambitos-de-accion/registro-de-productos-farmaceuticos-de-uso-veterinario |
| Colombia | Companies:<br>https://www.ica.gov.co/areas/pecuaria/servicios/grupo-de-registro-y-vigilancia-de-empresas-de-medi.aspx<br>Food product companies:<br>https://www.ica.gov.co/areas/pecuaria/servicios/alimentos-para-animales.aspx<br>Registration of biological drug products:<br>https://www.ica.gov.co/areas/pecuaria/servicios/regulacion-y-control-de-medicamentos-veterinarios.aspx |
| Costa Rica | https://sistemas.senasa.go.cr/hapi/Principal/Externo |
| Ecuador | https://www.agrocalidad.gob.ec/wp-content/uploads/2021/04/Manual-para-el-registro-de-empresas-y-productos-de-uso-veterinario-08_04_2021_APROBADO-WEB.pdf |
| Mexico | Authorization of food products and additives:<br>https://www.gob.mx/senasica/documentos/autorizacion-de-productos-y-aditivos-alimenticios-03-2020?state=published<br>Registration or authorization of pharmaceutical and chemical products:<br>https://www.gob.mx/senasica/documentos/elaboracion-del-expediente-de-registro-o-autorizacion-de-productos-farmaceuticos-y-quimicos-de-uso-veterinario-03-2020?state=published<br>Registration of biological products:<br>https://www.gob.mx/senasica/documentos/registro-de-productos-biologicos-para-uso-en-animales-03-2020?state=published |
| Nicaragua | They are in the process of adapting to the computer module |
| Paraguay | They are in the process of adapting to the computer module |



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

# Annex III

**Financial Statement in dollars**

| **Income** | | **30/12/2021 - 11/11/2022** |
|---|---|---|
| Resources available as of December 30, 2021 | | USD 95.884,80 |
| Purchase of USD | | USD 100,00 |
| CAMEVET Seminar Registration | | USD 28.750,00 |
| | **Subtotal Income** | **USD 124.734,80** |
| **Expenses** | | |
| **Fixed expenses (Salaries)** | | |
| Administrative Secretary (Ms. Ana Maria Sgammini USD 1,200/month) | | USD 12.000,00 |
| Administrative Secretary's bonus (June and December) | | USD 600,00 |
| | **Subtotal Fixed Expenses** | USD 12.600,00 |
| **CAMEVET Annual Meeting Expenses** | | |
| Focal Point Financing | | USD 12.985,00 |
| Participation of Ana Sgammini | | USD 1.307,00 |
| Payment of electricity strip during the Seminar | | USD 300,00 |
| Payment for seminar interpretation ESP-ENG-POR | | USD 8.356,00 |
| | **Subtotal** | USD 22.948,00 |
| **Other Expenses** | | |
| Internet (CAMEVET's domain) year 2021 | | USD 10,00 |
| Internet (CAMEVET's domain) year 2022 | | USD 10,00 |
| | **Subtotal** | USD 20,00 |
| **Variable Expenses** | | |
| Exchange dollars to Argentine Pesos | | USD 700,00 |
| | **Subtotal** | USD 700,00 |
| | **Subtotal expenses** | **36.268,00 USD** |
| | **Total balance at November 11, 2022** | **88.466,80 USD** |



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org

**Financial Statement in Argentine pesos**

| **Income** | | **30/12/2021 11/11/2022** |
|---|---|---|
| Resources available as of December 30, 2021 | | ARS 11.808,24 |
| Payments by participants from Argentina (3 participants/1USD-289 ARG) | | ARS 216.750,00 |
| Exchange US dollars to Argentine pesos | | ARS 199.500,00 |
| | **Subtotal** | **ARS 428.058,24** |

* Includes NC Interfly for US$ 8,272.00

| **Expenses** | | |
|---|---|---|
| **CAMEVET Annual Meeting Expenses** | | |
| Air ticket purchase expenses (Ms Ana Sgammini) | | ARS 387.186,00 |
| NC Interfly | | ARS 8.272,97 |
| | **Subtotal** | ARS 395.458,97 |
| **Other Expenses** | | |
| Purchase of USD | | ARS 28.500,00 |
| | **Subtotal** | ARS 28.500,00 |
| | **Subtotal Expenses** | ARS 423.958,97 |
| | **Total balance at November 11, 2022** | **ARS 4.099,27** |



COMITE DE LAS AMÉRICAS DE MEDICAMENTOS VETERINARIOS (CAMEVET)
Azopardo 1020- piso 1 - Ciudad Autónoma de Buenos Aires - Argentina ● Tel.: 54 11 5222 5876 ● secretaria@camevet.org