**CONCLUSIONS AND RECOMMENDATIONS**

**XXIX Seminar on the Harmonisation of the Registration and Control of Veterinary Medicines**
**Committee of the Americas for Veterinary Medicines (CAMEVET)**
**14 to 17 October**
**Lima, Peru**

**Opening Remarks**

Participants were welcomed by Ms. Vilma Gutarra García, Head of the National Agrarian Health Service; Dr. Catya Martínez, Sub-regional Representative of the OIE for Central America; and Dr. Maria Esther Pasco, Veterinary Products Focal Point for Peru and Chair of the Executive Board.

**Presidency Appointment**

Dr. Maria Esther Pasco, Focal Point for Veterinary Products for Peru, was formally designated as presidency of the Seminar.

**Status of Implementation of Harmonised Documents**

Ms. Ana Sgammini, CAMEVET Secretary, presented the results of a survey on the implementation status of harmonised documents within the Committee, with responses from 21 countries. Based on these results, a report was drafted, which is attached and will be distributed to all CAMEVET members and published on the website. The Secretariat will carry out periodic follow-ups with all countries to evaluate new implementations.

**Session – Review of Working Documents**

Ms. Sgammini presented a summary of the working group operational procedures and the various processing statuses. Documents in Process I status must have a concept note specifying the title, objectives aligned with CAMEVET's goals, a summary of the purpose, and regulatory background. The document enters Process II status after the first draft is completed, with a 60-day circulation period among CAMEVET members in the three official languages. After receiving comments, the document enters Process III for a second round of circulation. Following this, it advances to Process IV status and is presented as a final document during the seminar.

The Executive Board decided to continue holding periodic meetings with the coordinators of each working group to monitor the progress of the documents

**Regulations for Classification and Registration of Veterinary Products**

Dr. Wanderson do Reis, representing ALANAC, presented the progress on this document. The final draft circulated among the working group prior to the seminar with a deadline of 8th December. The working group now includes representatives from the official sectors of Colombia, Costa Rica, and Peru, and representatives from ALFA (El Salvador), APROVET (Colombia), and ASINVEP (Peru), with ALANAC (Brazil)

leading the coordination. The document, now in Process IV, will be presented at the next seminar for approval.

**Veterinary Product Labelling**

Dr. Tatiana Leal, Veterinary Products Focal Point for Costa Rica, presented the progress on the Process IV document. The document, which went through various stages and updates, was finalised by the working group, who met biweekly to discuss and refine it to be useful for all countries. Approved by unanimous vote, it will be reviewed every five years. Once translated into English and Portuguese, it will be distributed to all CAMEVET members and published on the website.

The document already agreed by the official members was put to a vote and approved unanimously, it was clarified that it is important that the document is reviewed every 5 years. The document after its translation into English and Portuguese will be shared, distributed to all CAMEVET members and published on the website. The document is included in **Annex I**.

**Good Practice Guidelines**

Due to changes in the coordination of the working group, it is now structured as follows: coordination led by Colombia (official), with the following official members: Brazil, Colombia, Costa Rica, El Salvador, the United States, Honduras, Mexico, Nicaragua, the Dominican Republic, and Uruguay. Additional participants include ADIPRAVE (Uruguay), AENSA (Ecuador), AFIRPROVA (Dominican Republic), ALANAC (Brazil), ANALAV (Mexico), ASIFAN (Costa Rica), CEV (Uruguay), CIA (Costa Rica), CIG (Guatemala), CLAMEVET (Argentina), and IINFARVET (Mexico).

The document will move to Process II status after the consensus first draft is prepared by the working group, following which it will be circulated for 60 days among all CAMEVET members.

**Biological Inputs**

Due to limited progress in the working group and the absence of coordination, this topic will remain inactive until reactivation is deemed necessary.

**Registration of Veterinary Medicines with Cannabis**

Dr. Angélica Barbosa, representing APROVET Colombia, presented the progress made during the circulation within the working group.

The document will be translated into English and Portuguese to begin the first round of circulation in Process II status among all CAMEVET members.

The working group is coordinated by APROVET (Colombia), and made up by representative of the official sector of Argentina, Bolivia, Chile, Costa Rica, Brazil, Curaçao, Guatemala, El Salvador, Ecuador, Honduras, Mexico, Panama, Paraguay, Uruguay, and the adherent members ABIQUIF (Brazil), AENSA (Ecuador), AFIRPROVA (Dominican Republic), ALANAC (Brazil), ALAVET (Chile), ALFA (El Salvador), ANALAV (Mexico), ANDIA (Panama), ASIFAN (Costa Rica), CAPALVE (Paraguay), CAPROVE (Argentina), CEV (Uruguay), CIA (Costa Rica), CLAMEVET (Argentina), FENALCO (Colombia), and INFARVET (Mexico).

**Efficacy Testing for Registration of Internal and External Parasiticides for Small Animals**

Dr. Patricia Millares, representing CAPROVE Argentina, presented the progress of the working document. After new additions to the working group, it is now structured as follows: coordinated by CAPROVE (Argentina) and made up by representatives of the official sector of Argentina, Colombia, Costa Rica, El Salvador, Mexico, Peru, and Uruguay, and the adherent members CLAMEVET (Argentina), ALANAC (Brazil), ALAVET (Chile), APROVET (Colombia), ASOVET (Guatemala), ANALAV (Mexico), and CEV (Uruguay). It was noted that the first draft will be circulated among the group members with a deadline of 180 days.

**Update of Certificate of Free Sale Models and Exclusive Export Authorisation**

Dr. Bunna Martis, representing SINDAN Brazil, presented the progress within the working group, which has been circulating in Process III status and will continue circulating until the end of the circulation period. The Secretariat will send reminders as further comments are awaited.

**Supplementary Studies to the Stability Guide**

Dr. Andrea Fraga, representing CAPROVE Argentina, presented the progress on the working document. During a virtual meeting of the working group, unresolved points were clarified, reaching an agreement to initiate circulation in Process III status, which began on 20th September and will conclude on 20th November. The comments received will be assessed with the aim of preparing a document in Process IV status.

**Guide to Establish Criteria for the Requirement of Residue Depletion Testing in the Registration and Renewal of Certificates for Veterinary Medicines with Known Active Ingredients in Non-Innovative Formulations**

Dr. Jorge Casim, representing CLAMEVET Argentina, presented the progress on the working document. The working group has welcomed new members, with CLAMEVET (Argentina) taking on coordination. The group now includes official representatives from Argentina, Brazil, Colombia, Costa Rica, the Dominican Republic, Ecuador, Guatemala, Mexico, Paraguay, Peru, and Uruguay, as well as participants from ALANAC (Brazil), ALAVET (Chile), ALFA (El Salvador), ANALAV (Mexico), APRIVET (Bolivia), APROVET (Colombia), ASIFAN (Costa Rica), ASINVEP (Peru), ASOVET (Guatemala), CAPALVE (Paraguay), CAPROVE (Argentina), CEV (Uruguay), CIA (Costa Rica), CLAMEVET (Argentina), FENALCO (Colombia), and INFARVET (Mexico).

**Good Manufacturing Practices | Guide for the Manufacturing of Veterinary Products**

Dr. Berta Chelle, Veterinary Products Focal Point for Uruguay, presented the progress on the document currently in Process II status. During a virtual meeting, the working group resolved previously unaddressed issues, reaching an agreement to start circulation in III status.

**Guide to Establish Criteria for the Use of Computational Models as Alternative Methods for Determining the Efficacy of Veterinary Antimicrobials**

Dr. Leonardo Viana, representing Brazil, along with Prof. Marcos Ferrante from the Federal University of Lavras, Brazil, presented the progress of the working group. During a virtual meeting, unresolved points were clarified, leading to an agreement to initiate circulation in Process III status.

**Efficacy Testing for the Registration of Internal Parasiticides for Ruminants and Swine**

Dr. Carlos Francia, representing CAPROVE (Argentina), presented the progress on the document currently in Process IV status. This final document will be available for general circulation for 60 days, during which comments and observations will be received. If no changes are made by the end of this period, the document will be considered approved. The Secretariat will inform on the approval status and circulate the document, which will subsequently be uploaded to the website.

**Guide for the Registration of Fixed Combinations**

Due to limited progress on the document, a reorganisation of the working group was decided. Following new additions to the group, it is now structured as follows: coordination led by ALFA (El Salvador), with official representatives from Brazil, Colombia, Costa Rica, Guatemala, Honduras, Mexico, Nicaragua, and Uruguay, and with participation from ALFA (El Salvador), ASIFAN (Costa Rica), ASINVEP (Peru), ASOVET (Guatemala), CAPROVE (Argentina), CEV (Uruguay), CIA (Costa Rica), CLAMEVET (Argentina), and FENALCO (Colombia).

**Antiparasitic Resistance**

Dr. Rocío Reyes, representing INFARVET (Mexico), presented the working group's progress. It was indicated that the document will begin circulating in Process III status among all CAMEVET members within the next 60 days for a 60-day period, aiming to finalise the document and submit it for voting at the next CAMEVET meeting.

**Residue Detection Kit for Edible Tissues**

Dr. Jorge Casim, representing CLAMEVET (Argentina), presented the concept note to approve the document title. Following unanimous approval, a Working Group was established, structured as follows: coordination by CLAMEVET (Argentina) and including official representatives from Uruguay, with participation from APROVET (Colombia), ASIFAN (Costa Rica), ALFA (El Salvador), CEV (Uruguay), CAPALVE (Paraguay), INFARVET (Mexico), and CAPROVE (Argentina).

**Session – Registration of Veterinary Products**

Dr. Maria Esther Pasco, Veterinary Products Focal Point for Peru, presented the changes in the registration processes for veterinary products in her country. She highlighted the regulatory framework established by SENASA, which provides clear access to current regulations. One key point is that, in Peru, the registration of veterinary products is valid for 10 years. For renewal, it must be requested 120 days before

the expiration date. Additionally, renewal does not require new information to be submitted, as long as the products retain the same characteristics as in the original registration, including labels, packaging, brochures, and containers.

**Session – Veterinary Pharmacovigilance**

Dr. Rocío Reyes, representing INFARVET (Mexico), gave a presentation detailing the progress in Mexico's regulatory framework under the Federal Law on Animal Health, specifically Articles 172 and 173, which establish programmes and procedures to monitor the efficacy and safety of registered products. Joint efforts between industry and government were undertaken, including training, workshops, and the revision of the pharmacovigilance guide. Collaboration with organisations such as the European Medicines Agency and the Committee of the Americas for Veterinary Medicines was highlighted, aiming to harmonise requirements and improve pharmacovigilance globally.

Additionally, the importance of training and collaboration between industry and government was emphasised to ensure the success of the veterinary pharmacovigilance system in Mexico. It was suggested that the CAMEVET Secretariat conduct a survey to identify which countries have an implemented pharmacovigilance system.

**Session – Veterinary Product Traceability System**

QFB Maria Elena González, Veterinary Products Focal Point for Mexico, gave a presentation on the Federal Animal Health Law of Mexico and its regulations, which establish the classification of veterinary medicines into three groups, each with different levels of risk associated with their active ingredients. According to Mexican Official Standards, veterinarians (MVZ) must issue different prescriptions depending on the medicine's group: quantified prescriptions for Group I and simple prescriptions for Group II.

The importance of traceability was highlighted as essential for tracking products throughout their life cycle, from production to administration to animals. This is particularly crucial for Group I products due to the risks associated with misuse. Furthermore, the draft of the new Mexican Official Standard proposes the inclusion of antibiotics in Group I, which will require stricter controls on their prescription. This modification aims to improve traceability and promote responsible use of these medicines.

The development of a digital system to facilitate the traceability and monitoring of high-risk products was proposed, which would enhance oversight and compliance with regulations. It was indicated that the pilot project is expected to be completed by November, aiming to establish a robust regulatory framework and implement effective measures to ensure the safe use of veterinary medicines.

**Session – Registration of Veterinary Products with Cannabis in Uruguay**

Chemist Isabel Alonzo, representing the Department of Veterinary Product Control, Division of Veterinary Laboratories (DILAVE) at the Ministry of Livestock, Agriculture, and Fisheries, presented an overview of the registration of veterinary products with cannabis in Uruguay. She highlighted the regulatory challenges despite the growing volume of publications and empirical use, noting that the regulatory framework is complex. The International Narcotics Control Board (JIFE) classifies cannabis as a narcotic,

restricting its use to medical and scientific purposes, which poses challenges for regulating its veterinary use.
In Uruguay, Law 19.172 of 2013 regulates cannabis, establishing a framework for its control and distribution through the Institute for Cannabis Regulation and Control (IRCCA). However, veterinary products must comply with specific regulations regarding active ingredients and substance control. Veterinary products with cannabinoids must be registered as any other medicine, adhering to strict requirements, including technical forms, certificates of origin, and quality testing.
The need to promote collaboration between regulatory entities and the industry was also noted to facilitate product development, ensuring that regulatory gaps do not impact the economy or production timelines.
It was noted that the variability in the application of regulations at the international level complicates the standardisation and access to cannabis-based products, making it crucial to continue developing appropriate control and certification methods.

Finally, the growing interest in the use of cannabis in veterinary medicine was highlighted; however, regulatory challenges, variability in effects, and the need for further research remain significant barriers.

**Conclusions from the Official Sector Meeting**
Dr. Carolina Marambio, representing the official sector of the Executive Board, presented the topics discussed during the official sector meeting. It was decided by consensus to submit the guide for veterinary product labelling for approval, and a review of guides requiring new coordination was conducted. Additionally, a request was made to establish a formal channel for registration alerts and specific inquiries from countries in the region. The need to issue authorisation letters for delegates was also highlighted, which are necessary for sharing information on registered, expired, cancelled, health-alerted, and suspended products, among other topics.
Furthermore, increased participation from the official sector was emphasised. To achieve this, focal points committed to following up with delegates to ensure maximum participation.

**Conclusions from the Industrial Sector Meeting**
Engineer Edith Gamarra presented the topics discussed in the meeting held by the veterinary product industry sector. She detailed issues such as the importance of continued collaboration with the official sector to prevent antimicrobial resistance, emphasising that the official sector should share initiatives to save efforts and optimise results.
The official sector was also requested to consider response times in registration procedures to avoid disrupting trade, accept certificates issued by Ministries from the product's country of origin if it is undergoing renewal, and ensure continuity of processes. In this regard, it was requested that Central American authorities apply the Central American Technical Regulation (RTCA) for medicines and related products in full, without halting imports due to observations made during the renewal process.
Concern was expressed regarding the new Andean Community (CAN) regulations, specifically Resolution 931, which introduces significant changes to the standards of each CAN member country.

Additionally, it was requested to implement the necessary mechanisms to allow all registration documentation, including legal documents, to be submitted digitally. It was also suggested to evaluate and implement various traceability and control tools so that, using the existing antimicrobial databases, the prohibition of production and marketing would be a last resort.
Authorities were urged to advance and collaborate in the internalisation of harmonised and approved documents in all CAMEVET member countries, as well as to reconsider the repetition of tests and literature for product renewal. The minutes are included in Annex IV.

**Round Table**

Ms Ana Sgammini opened the round table discussion between the public and private sectors, where topics related to Antimicrobial Resistance were debated. This issue was introduced by Dr Rocío Reyes on behalf of INFARVET (Mexico), and the question was directed to all the officials present, with emphasis placed on antimicrobial resistance plans. Another topic was the Registration of Veterinary Products, where Dr Reyes raised concerns about registration delays. Regarding the Labelling of Veterinary Products, some countries were asked about the likelihood of adopting the recently approved CAMEVET guidelines. In terms of Residues, Dr Mercedes Etcheverry, representing CEV (Uruguay), enquired which countries conduct residue testing and whether these tests are conducted for all products. Additionally, the importance of participation from countries and veterinary services was stressed, with a note that qualified personnel should attend.
Moreover, the industry requests the implementation of necessary mechanisms to allow all registration documentation, including legal documents, to be submitted digitally. Likewise, it is proposed to evaluate and apply various traceability and control tools so that, using the existing databases of antimicrobials, the option to prohibit production and commercialisation becomes a last resort.
Authorities are urged to progress and cooperate in the adoption of harmonised documents approved by all CAMEVET member countries, as well as to reconsider the repetition of trials and bibliographic requirements for product renewal.

**Session – Antimicrobial Resistance**

Dr Delfy Góchez, representing the Antimicrobial Resistance Department of the World Organisation for Animal Health (WOAH), presented virtually the eighth round of data collection on the use of antimicrobial agents in animals via the ANIMUSE database, managed by WOAH. It was noted that during the 2013 Global Conference on the Responsible Use of Antimicrobial Agents, the need for harmonized data to monitor the use of antimicrobials in animals was established. In response, WOAH formed an ad hoc group to develop a global database (ANIMUSE), which serves as a critical tool for promoting transparency, scientific evidence, and global commitment to managing antimicrobial use in animal production.

The eighth round of data collection included the participation of 152 countries, with 81 countries contributing quantitative data between 2019 and 2021. A slight increase in the use of antimicrobials in animals was observed, breaking a previous downward trend. Tetracyclines remained the most widely used

antimicrobials, followed by penicillins and polypeptides. It was highlighted that in the Americas, Asia, and Europe, there is an ongoing need to reduce antimicrobial use, particularly those used as growth promoters. Collecting data on antimicrobial use in animals is essential to tackle the antimicrobial resistance crisis, especially within the “One Health” framework.

Dr Carolina Marambio, Veterinary Products Focal Point for Chile, representing the Permanent Veterinary Committee of the Southern Cone (CVP), delivered a presentation regarding the ad hoc group on Antimicrobial Resistance. The committee was clarified as an institution comprising the main authorities responsible for animal health and the safety of animal-origin food products in Argentina, Bolivia, Brazil, Chile, Paraguay, and Uruguay. Consequently, it was reported that the CVP has formed a working group on antimicrobial resistance with representatives from each member country. The CVP’s scheduled activities include a regional strategy for monitoring and raising awareness of Antimicrobial Resistance, the promotion of good practice guidelines for antimicrobial use, and the development of a regional stance in response to EU regulations. Additionally, efforts are being made to strengthen public-private partnerships to raise awareness about the consequences of improper antimicrobial use.

**Session - Substandard or Falsified Products**

Dr Andrés García Campos, representing the Department of Antimicrobial Resistance and Veterinary Products, gave a virtual presentation addressing substandard and falsified veterinary medical products and their global impact. He clarified that this issue represents a significant risk to animal health and antimicrobial resistance (AMR), posing a multi-sectoral challenge affecting public health and food security. The WOAH has identified falsified and substandard veterinary medical products as a global threat; these products, including medicines and other veterinary supplies, can undermine efforts to control animal diseases and prevent AMR. This issue has been addressed in various WOAH conferences and publications, highlighting the importance of stringent regulation and international cooperation. WOAH recommends that countries adopt international standards and strengthen their regulatory systems to ensure the quality of veterinary products in their markets. Various tools have been developed to assist countries in monitoring veterinary products, including information portals and training programs focused on product regulation. These initiatives aim to improve transparency and provide countries with reliable data on veterinary products within their borders, making strict regulation and international collaboration essential to mitigate risks and ensure the effectiveness of global animal health efforts.

Continuing the session on substandard and falsified products, Maria Elena González, Veterinary Products Focal Point for Mexico, presented the country's experience in implementing a tracking and monitoring system for substandard and falsified veterinary products, in collaboration with WOAH. This effort is part of the pilot phase of the VSAFE (Veterinary Surveillance and Alert for Fake and Substandard Products) program, initiated by WOAH. She introduced the alert and monitoring system designed to identify and mitigate the impact of low-quality or counterfeit veterinary products, which pose risks to animal health and public health. The system aims to detect and respond to unauthorised, counterfeit, or falsified

veterinary products, promoting stricter regulation and product safety in the Mexican market. Alerts are published on SENASICA's website, within the Directorate of Establishments, Products and Support Bodies Regulation (DREPOC) module, and these alerts help raise awareness among manufacturers, distributors, and consumers on the importance of purchasing and using quality veterinary products. Mexico aims to expand the coverage of this system by involving more supply chain actors and strengthening international cooperation with WOAH and other countries.

On the other hand, Dr Aida Rojas, Veterinary Products Focal Point for Colombia, presented her country's experience focusing on the marketing, inspection, monitoring, and control activities for veterinary products. The Colombian Agricultural Institute (ICA) oversees 2,197 establishments dedicated to selling veterinary products across different regions of the country, with supervision covering both the verification of commercial processes and compliance with regulations to ensure that products meet the required quality standards. Control is conducted in three main areas: Veterinary Medicines, Biologicals, and Animal Feed. Regarding the VSAFE program (Veterinary Surveillance and Alert for Fake and Substandard Products), it was noted that this is part of efforts to enhance the oversight and regulation of veterinary products in the country, aligning with international best practices.

**Application of Pharmacometrics in Veterinary Medicine**

Dr Gonzalo Suárez, a professor at the Faculty of Veterinary Medicine in Uruguay, presented on pharmacometrics—a science focused on simulating and modelling drug behaviour in the body, considering physiological and pathological aspects. He explained that Compartmental Models are used to study drug pharmacokinetics, examining distribution and elimination across different body compartments. He also highlighted the advanced PBPK Model (Physiologically Based Pharmacokinetic), which allows simulation of drug distribution in animals, adjusting dosages according to each species' physiological and pathological characteristics. This is key for veterinary medicine.

In terms of regulatory framework, it was noted that international guidelines regulate PBPK model use in drug development; both the FDA and other health agencies recommend using these models to optimize clinical study design, providing valuable data that continually enhance these models and support their application in new drug development. The application of pharmacometrics and PBPK models in veterinary medicine has proven to be a powerful tool for improving drug response predictions in animals, optimizing dosages, reducing adverse effects, and accelerating the development of new drugs, especially for special conditions or less-studied species.

**CAMEVET Strategic Plan**

Ms Ana Sgammini presented the draft of the fifth Strategic Plan, explaining that it was developed by the Secretariat, reviewed by the WOAH regional office and the CAMEVET Executive Board. The document is included in **Annex II**.

The draft will be circulated among all CAMEVET members for comments; after the first round of circulation, it will be translated, recirculated, and published on the website as the New Strategic Plan, effective from January 1, 2025, to December 31, 2029.

**Election of New Executive Board Members**

Ms Ana Maria Sgammini gave a brief overview of CAMEVET's regulations, informing attendees of the criteria for electing new Executive Board members.

Dr Carolina Marambio, representing outgoing official members of the Executive Board, announced the new official sector members:

- Colombia: Dr Aida Rojas
- Costa Rica: Dr Tatiana Leal
- Chile: Carolina Marambio
- Bolivia:
  President: Dr Maria Esther Pasco (Peru)

Ms Edith Gamarra, representing outgoing associate members of the Executive Board, announced the new industry sector members:

- CLAMEVET – Paraguay: Dr Jorge Casim
- CAPALVE – Paraguay: Ms Edith Gamarra
- ALFA – El Salvador: Dr Marien Gutierrez
- FLAIVET: Dr Ricardo Hoigjelle
  Alternates: ALANAC Brazil, ASIFAN Costa Rica, CAPROVE Argentina

**CAMEVET Budget and Resources – Financial Statement, Annual Balance**

Ms Ana María Sgammini presented the financial report, including annual expenses and revenue generated during this Seminar, as well as the budget forecast for the upcoming period and the procedure for financial requests developed by the Executive Board. The report is included as an annex. Special mention was made of CAMEVET's financial support for Focal Points who requested funding, including those in Costa Rica, Chile, Dominican Republic, Ecuador, Jamaica, Mexico, and Panama. The report is included as **Annex III.**

**Approval of Proposals for Future Seminar Venues**

Maria Elena González, Veterinary Products Focal Point for Mexico, expressed her country's interest in hosting the upcoming CAMEVET Seminar in 2025.

Before closing the Seminar, Peru was thanked for hosting, with appreciation extended to SENASA officials, ASINVEP (the Peruvian chamber), and all sponsors who contributed to the success of this CAMEVET seminar.

**Special Tribute**

A special tribute was made to Dr Emigdio Lemes Anaya, who served as the Veterinary Products Focal Point for Cuba and played a remarkable role in CAMEVET over the years.

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**List of acronyms of interest**

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| ABIQUIF | Brazilian Pharmaceutical Industry Association (Brazil) |
| ADIPRAVE | Association of the Agrochemical and Veterinary Products Industries (Uruguay) |
| AENSA | Association of Animal Nutrition and Health Companies (Ecuador) |
| ALANAC | Association of National Pharmaceutical Laboratories (Brazil) |
| ALANAV | National Association of Veterinary Laboratories (Mexico) |
| ALAVET | Association of Veterinary Product Laboratories (Chile) |
| ALFA | Association of Pharmaceutical Laboratories of El Salvador (El Salvador) |
| ANDIA | National Association of Agricultural Inputs Distributors (Panama) |
| ANIMUSE | Antimicrobial use in animals |
| APROVET | National Association of Veterinary Laboratories (Colombia) |
| ASIFAN | Association of the national pharmaceutical industry (Costa Rica) |
| ASINVEP | Peruvian Veterinary Industry Association (Peru) |
| ASOVET | Association of Distributors of Veterinary Products (Guatemala) |
| CAMEVET | Committee for Veterinary Medicinal Products of the Americas |
| CAPALVE | Paraguayan Association of Veterinary Product Laboratories (Paraguay) |
| CAPROVE | Argentine Association of the Veterinary Products Industry (Argentina) |
| CEV | Association of Veterinary Specialities (Uruguay) |
| CIA | Association of Agricultural Inputs (Costa Rica) |
| CIG | Association of Industry of Guatemala (Guatemala) |
| CLAMEVET | Association of Argentine Veterinary Medicinal Laboratories (Argentina) |
| CVP | Standing Veterinary Committee |
| DREPOC | Directorate for the Regulation of Establishments, Products and Support Bodies |
| FDA | U.S Food and Drugs Administration |
| FENALCO | National Federation of Merchants and Entrepreneurs (Colombia) |
| FLAIVET | Latin American Federation of Veterinary Industries |
| ICA | Colombian Agricultural Institute |
| INFARVET | Veterinary Pharmaceutical Industry (Mexico) |
| IRCCA | Institute for Cannabis Regulation and Control |
| JIFE | International Narcotics Control Board |
| WOAH | World Organisation for Animal Health |
| PBPK | Pharmacokinetics based on physiological compartments |
| AMR | Antimicrobial Resistance |
| RTCA | Central American Technical Regulations |
| SENASA | National Agricultural Health Service of Peru |
| SENASICA | National Service for Agri-Food Health, Safety and Quality |
| SG CAN | Secretary General of the Andean Community |
| SINDAN | National Union of the Animal Health Products Industry (Brazil) |
| VSAFE | Veterinary Surveillance and Alert for Fake and Substandard Products |

**List of Annexes**

Annex I - Guide to labelling of veterinary products (Spanish version)
Annex II - CAMEVET Strategic Plan (Spanish version)
Annex III - Financial Statement
Annex IV – Industry minutes

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**Annex I**

**CAMEVET**

**Cod: Rot 001**

**Status IV**

**October 17, 2024**

# VETERINARY PRODUCT LABELING

## Introduction

The unification of the criteria to be applied in the labeling of veterinary products is an essential part of achieving the harmonization of technical mechanisms that favor the quality, commercial exchange and traceability of products between member countries.

This is why the need to update the harmonized guide, which has been in the works since 2017, was raised at the XXII CAMEVET Seminar.

This document is the result of several circulations, surveys and virtual meetings of the official sector of the region carried out between 2017 and 2024.

## Objective and Scope

**Objective:** Harmonize the contents of the labeling on the packaging material of veterinary products.

**Scope**: Applies to all veterinary products that require registration.

## Terms and Definitions

**Packaging:** Set of operations that allow the adaptation of the packaged product to be marketed, including: labeling, case packing, coding, security heat sealing and placement of adhesives. The adhesive with the commercial information code is excluded.
**Official Authority**: Entity responsible for the registration and control of veterinary products in each of the countries that make up the Americas region.
**Blister:** Molded packaging that packages a certain finished product.
**Box - case:** Packaging made of paper, cardboard or other material that packages the primary packaging.
**Box-insert – Case-insert:** Packaging made of paper, cardboard or other material that packages the primary packaging and where all the information that the insert must contain is printed.
**Collective packaging – Hospital presentation:** Packaging that contains a defined number of units of a single product and from the same batch.
**Packaging:** Form of packaging, removable or not, intended to cover, contain and protect a product. Includes primary packaging and secondary packaging.
**Primary packaging:** Packaging that is in direct contact with the product.
**Secondary packaging:** Packaging that covers and protects the primary packaging.
**Label - insert:** This is the label where all the information that the insert must contain is printed.
**Label - tag:** Printed or lithographed identification, either as painted characters or engraved by heat, pressure or by another method, applied directly to containers, packages, wrappings or any other protector.
**Primary label:** Printed or lithographed identification that is placed on the primary packaging.
**Secondary label:** Printed or lithographed identification that is placed on the secondary packaging.

**Labeling:** Packaging material that consists of a label – tag, box – case or insert.
**Inert ingredient – formulation agent – excipient – vehicle – support:** Substance without preventive or therapeutic action but a specific and particular function in relation to the designed formulation of the product. In general, when it comes to solid forms it is usually called excipient, while, for liquid forms, it is called formulation agent or vehicle.
**Instructions, insert, prospectus, brochure:** Printed material that accompanies a product with the technical, scientific and/or administrative information according to this guide.
**Diagnostic kit:** Package of articles, reagents or chemical, enzymatic, biological, natural or synthetic substances, used for *in vitro* diagnostic purposes of animal diseases in a specific test.
**Licensor:** Company that authorizes the distribution of a product to its subsidiaries around the world.
**Logo**: Mixed brand, composed of the logo and the name of the company, and that allows the consumer and official bodies to trace and identify the manufacturer, owner or legal representative.
**Printed packaging material (graphic labeling):** All material that makes up the labeling of a product. Packaging for external use is excluded from this definition.
**Commercial name of the product:** Commercial name of the product, whether brand or generic, plus a complement when appropriate.
**Presentation**: Way in which a product is presented for marketing.
**Finished product:** Product that has completed all the manufacturing stages.
**Bulk product:** Product that has completed all the manufacturing stages, except final packaging.
**Semi-finished product:** Product that has completed all the manufacturing stages, not including final packaging (labeling, leaflet and/or cartoning).
**Veterinary product:** Any chemical, biological, biotechnological substance or manufactured preparation whose use or administration is individual or collective, supplied or applied to the animal, mixed with food or drinking water, placed in its living environment for the purposes of prevention, diagnosis, control, treatment of diseases, restoration, correction or modification of physiological functions.
**Reconditioning:** Set of operations that includes the replacement of the primary or secondary labeling, box - case or insert with packaging material approved by the official authority.
**Archived veterinary prescription, retained veterinary prescription:** This is the one prescription that must be archived in the establishment where the product was acquired at the time of purchase.
**Envelope - Sachet:** Primary packaging made of paper or other material that contains a product.
**Sanitary registration holder or owner: Natural** person or legal entity that owns the veterinary product and has the sanitary registration of a product in their favor for its commercialization.
**Retail sales unit:** Modality in which a product is marketed to the final consumer.

**Procedure**

1. For the purposes of applying this guide, the texts of the materials are classified as essential information (I), necessary information (N) and optional information (O):

   **1.1. Essential information (E):** that which must be included in the packaging material indicated in this guide.

   **1.2. Necessary information (N)**: that which must be included in at least one of the packaging materials indicated in this guide.

   **1.3. Optional information (O):** information that may or may not be included in the packaging material indicated in this guide.

2. The distribution of the necessary information must be prioritized on the box over the inclusion in the insert. If the product does not contain a box or insert, all missing information must be contained on the primary label.

3. Every veterinary product that is manufactured, handled, stored, divided, marketed, dispatched, sold or used in CAMEVET member countries must have packaging material (graphic labeling) that complies with the provisions of this labeling guide.

4. **Essential information on the primary label of medicines, biologicals and ectoparasiticides for veterinary use.**

   **4.1. Blister**

   a) Trade name of the product.
   b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and their concentration.
   c) Lot, series, batch number or its equivalent term.
   d) Expiration date, expiry, use by date or its equivalent term.

   The necessary information must be included on the box-case or insert.

   **4.2. Vial or container less than or equal to 5 ml**

   a) Trade name of the product. In the case of diluent: Nature of the diluent, stabilizer or similar.
   b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.

c) Lot, series, batch number or its equivalent term.
d) Expiration date, expiry, use by date or its equivalent term.

The necessary information must be included on the box-case or insert.

**4.3. Containers larger than 5 ml and less than or equal to 50 ml or 100 g**

a) Trade name of the product. In the case of diluent: Nature of the diluent, stabilizer or similar.
b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.
Excipients: It is not mandatory to declare them, but at least “Excipients q.s.” must be indicated.

In biological products: Declare the name of the preservative/adjuvant.

c) Lot, series, batch number or its equivalent term.
d) Expiration date, expiry, use-by date or its equivalent term.
e) Net content.

The necessary information must be included on the box- case or insert. If these are not included, this information must be incorporated into the primary label.

**4.4. Containers larger than 50 ml or 100 g.**

a) Trade name of the product. In the case of diluent: Nature of the diluent, stabilizer or similar.
b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.
Excipients: It is not mandatory to declare them, but at least “Excipients q.s.” must be indicated.
In biological products: Declare the name of the preservative/adjuvant.
c) Lot, series, batch number or its equivalent term.
d) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
e) Net content.
f) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)”.
g) Withdrawal period/time, discarding period/time, when the product is intended for animal species producing food for human consumption.

The necessary information must be included on the box- case or insert. If these are not included, this information must be incorporated into the primary label.

**5. Essential information on the primary label of cosmetic products for veterinary use**

a) Trade name of the product.
b) Ingredients (from highest to lowest concentration).
c) Lot, series, batch number or its equivalent term.
d) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
e) Net content.
f) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)".

The necessary information must be included on the box- case or insert. If these are not included, this information must be incorporated into the primary label.

**6. Essential information on the primary label of hygiene products**

a) Trade name of the product.
b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.
c) Lot, series, batch number or its equivalent term.
d) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
e) Net content.
f) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)".

The necessary information must be included on the box- case or insert. If these are not included, this information must be incorporated into the primary label.

**7. Essential information on the primary label of infectious disease diagnostic kits**

a) Trade name of the product.
b) Lot, series, batch number or its equivalent term.
c) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
d) Net content.
e) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)".

The necessary information must be included on the box- case or insert.

8. **Essential information on the primary label of the diluent for injectable products (antigenfree biological or pharmacological)**
   a) Nature of the diluent, stabilizer or similar.
   b) Trade name: not required if the diluent is part of the product and is registered with it. If the diluent is used for several products, it must be registered separately in compliance with the provisions of this guide.
   c) Lot, series, batch number or its equivalent term.
   d) Expiration / expiry / use by date or its equivalent terms.
   e) Net content.
   f) The phrase “Veterinary use”.
   g) When it is distilled or bi-distilled water, it must be expressed as “Water for injection”.

9. **Essential information on the primary and secondary label of medical samples**
   Every veterinary product classified as a “medical sample” must contain the information required by this guide according to the product in question. In addition, the legends “FREE SAMPLE” or “VETERINARY MEDICAL SAMPLE” followed by the legend “PROHIBITED SALE” should be prominently displayed on both the primary and secondary packaging.

10. **Essential information on the primary label for imported bulk or semi-processed (semi-finished) products**
    a) Product name.
    b) Composition or equivalent term: Of active ingredients and its concentration.
    c) Lot, series, batch number or its equivalent term.
    d) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
    e) Net content. Volume, liquid weight or number of doses.
    f) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)”.
    g) Storage conditions (temperature, humidity, light, flammability as appropriate).
    h) The phrase "Not authorized for sale to the public".

11. **Essential information on the secondary label (box – case) of veterinary products.**
    a) Trade name of the product.
    b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.
    Excipients: It is not mandatory to declare them, but at least “Excipients q.s.” must be indicated.

In biological products: Declare the name of the preservative/adjuvant.

In cosmetics: Declare the ingredients from highest to lowest concentration. In diagnostic kits: Declare the components and composition.

c) Lot, series, batch number or its equivalent term.
d) Manufacturing/preparation date and expiration / expiry / use by date or its equivalent terms: expressed in month/year.
e) Net content.
f) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)".
g) Withdrawal period/time, discarding period/time, when the product is intended for animal species producing food for human consumption.
h) Sanitary registration number (in the country where it is registered).
i) Storage conditions (temperature, humidity, light, flammability as appropriate).
j) Animal species (of destination), of intended use or of diagnostic interest. Optionally, the pictogram of the destination species can be included.
k) Sales condition. For controlled products, include the phrase "Sale under controlled/retained medical prescription" or equivalent phrase.
l) The phrase "Read the information before using the product" / "Read the insert before using the product" or equivalent phrase.

If the product presentation does not contain a box – case, this information plus the necessary information must be printed on the primary label or on the insert.

**12. Essential information on the insert**

a) Trade name of the product.
b) Composition or equivalent term: Of active ingredients or biological agents (name of the strain, if applicable) and its concentration.
In biological products: Declare the name of the preservative/adjuvant.

In cosmetics: Declare the ingredients from highest to lowest concentration. In diagnostic kits: Declare the components and composition.

c) Country name and company name of the manufacturer. In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)".
d) Withdrawal period/time, discarding period/time, when the product is intended for animal species producing food for human consumption.

e) If applicable: Toxicological aspects, warnings, contraindications, adverse reactions, precautions, restrictions, interactions, antidotes.

f) In diagnostic kits:
i. Technical specifications: sensitivity, specificity, reproducibility, detection and quantification limits (when applicable). ii. Interpretation of results.

If the product presentation does not contain an insert, this information plus the necessary information must be printed on the primary label or on the box - case.

**13. Required information to be included on at least one of the packaging materials, prioritizing its inclusion on the primary label or box- case over the insert**

**13.1. In general:**

a) Withdrawal period/time, discarding period/time, when the product is intended for animal species producing food for human consumption.

b) Sanitary registration number (in the country where it is registered).

c) Storage conditions (temperature, humidity, luminosity, flammability as appropriate).

d) Animal species (of destination), of intended use or of diagnostic interest. Optionally, the pictogram of the destination species can be included.

e) Sales condition. For controlled products, include the phrase “Sale under controlled/retained medical prescription” or equivalent phrase.

f) The phrase “Read the information before using the product” / “Read the insert before using the product” or equivalent phrase.

g) If applicable: Toxicological aspects, warnings, contraindications, adverse reactions, precautions, restrictions, interactions, antidotes.

h) In multidose, multipurpose or reconstitution products: Time span after opening the product or Validity of the product after being opened or reconstituted, expressed as a pictogram or as a legend.

i) Pharmaceutical form.

j) Route of administration, application or use. Described in prose, not in acronyms.

k) The phrase “Veterinary use”.

l) Indications, instructions for use or preparation:
   i. For antimicrobials, the common and scientific name(s) of the etiological agent(s) to be combated must be specified.
   ii. For ectoparasiticides: specify the method for preparing the final application material (if applicable) as well as the mode of use or application in animals.

m) Dose: by animal species

n) The phrase “Keep out of the reach of children and domestic animals” or equivalent phrase. For ectoparasiticides this phrase should be replaced by “Keep out of the reach of children, animals and food” or equivalent phrase.

o) The phrase “Consult a veterinarian” or equivalent phrase.

p) Pharmacological class.

q) The phrase “Empty containers, as well as any residual content, must be disposed of in accordance with current regulations at the nearest collection center” or equivalent phrase.

r) Warning and special precautions for use: Including those for the operator and personal protective equipment, if required. In ectoparasiticides, reference must also be made to the toxicity of the ingredients for humans, animals and the environment, to the symptoms of poisoning, first aid and measures applicable in the event of oral, dermal or inhalation poisoning; when applicable, antidote(s) and indications for treatment.

**13.2. In blister packs, vials of less than or equal to 5 ml, primary label of containers larger than 5 ml and less than 50 ml or 100 g:**

a) In biological products: Declare the name of the preservative / adjuvant.

b) Name of the country and company name of the manufacturer. In case of manufacturing for third parties: Specify "Made in (country) by (manufacturer's company name) for (owner's company name)”.

**13.3. In blisters and vials of less than or equal to 5 ml:**

a) Net content.

**13.4. For ectoparasiticides that are not administered orally, transdermally, percutaneously or otically and pesticides for use in livestock facilities.**

a) Toxicological classification.

b) In capital letters, in bold and in black or a color that contrasts with the background of the label, the legend: “In case of poisoning, consult a doctor and give him this label” or equivalent phrase.

c) Methods for decontamination (when applicable) and final disposal of the product.

d) The telephone number of the reference Toxicological Center of the country where it is registered.

**14. Optional information that may be included on packaging materials**

**14.1.** Generic name

**14.2.** Presentations.

**14.3.** Name of the Technical Director / Technical Advisor / Physician in Charge

**14.4.** Company name of the importer or semi-manufacturer.
**14.5.** Pharmacological or immunological properties, as appropriate

**9. General provisions**

**9.1.** In the event that the packaging, wrapping or labeling process is carried out by a third party, the third party shall not be mentioned on the label.
**9.2.** When the product is presented in collective packaging for retail sale, it is mandatory to include as many inserts as there are retail sales units. The establishment that sells products packaged in this way is obliged to deliver an insert together with each retail sales unit.
**9.3.** Printing of batch numbers, manufacturing date and expiration date or their abbreviation must be done in an indelible manner, visible to the public and easy to read, and the use of additional labels for this purpose is prohibited.
**9.4.** The texts on the packaging materials must be printed with the information approved by the official authority of the registering country. If said authority allows reconditioning in its country, the importer must guarantee that this process complies with the manufacturer's quality specifications and with the requirements of the official authority.
**9.5.** he texts on the packaging materials must be presented in the official language, and those terms in other languages may be accepted when for technical reasons they cannot be translated. In the case of bilingual packaging materials, the texts in the other language cannot contradict those approved in the official language.
**9.6.** The approval of the texts on the packaging materials in another language is the sole responsibility of the manufacturer and must be approved by the competent authority of the country of destination.
**9.7.** The characters used on packaging materials must be visible to the public and presented in dimensions that allow easy reading. The minimum acceptable size for printing texts will be 1.5 mm (four Didot points). Likewise, the information must be used in internationally accepted nomenclature, expressing the units according to the International System of Units (SI) or any other duly justified system.
**9.8.** In the case of ectoparasiticides, the toxicological classification must be carried out as indicated by the World Health Organization (WHO).
**9.9.** Vaccines intended exclusively for canines and felines may be presented with selfadhesive labels that can be easily removed from their packaging, to be transferred to the animal's health documentation.
**9.10.** The Health Authorities belonging to CAMEVET may accept any of the following terms for labelling as equivalent to what is established in their internal regulations:

a) For the manufacturer: "(Manufactured, prepared, produced) …by…" or any other phrase or term that clearly expresses to the user who the manufacturer of the product is.
b) For the manufacturing date: "manufacturing date", "processing date" or any other phrase or acronym that clearly indicates to the user the date of manufacture of the product.
c) For the expiration date: "(expiration, expiry, expires, use by) date", "Expiration", "Expiry" or any other phrase or acronym that clearly indicates to the user the expiration date of the product.
d) For batch identification: "batch", "batch number", "batch code", "Series" or "Batch".
e) For storage and preservation: "Store…", "Keep…", "Maintain…".
f) For the instructions: "insert", "prospectus", "leaflet", "instructions".
g) For the withdrawal period: "(withdrawal, safekeeping, disposal, suppression, suspension, waiting) Period/ Time".
h) For the phrase "(Keep, Preserve) …out of the reach of children and domestic animals".
i) For the composition: "formula".
j) Other terms that appear in the CAMEVET Synonym Agreement.

## Approval level

- XXIX Seminar on the Harmonization of Regulations for Registration and Control of Veterinary Medicines - 14 to 17 of October of 2024: General approval of the Guide text (Status IV)

### Effective date of this version

17 October 2024 to October 2029

## Review frequency

Every 5 years or when a member country officially requests it through its group.

**Annex 1. Summary of the essential (E) information, necessary (N) information and optional (O) information requested in each of the packaging materials**

| Ítems | Primary Label | | | | | | | | | | Box - case | Insert |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Blister | Vials ml ≤ | Label 5 ml - ≤ 50 ml | Label 50 ml | 100 g Cosmetics ^ | Hygiene products | Diagnostic Kits | Injectable diluent | Medical sample * | Imported in bulk or semi - processed | | |
| Trade name of the product<br>Note. In diluents: Nature of the diluent, stabilizer or similar | E | E | E | E | E | E | E | E | | E | E | E |
| Composition or equivalent term<br>a.- Of active ingredients or biological agents (name of the strain, if applicable) and their concentration<br>Note. Excipients must be expressed as "Excipients q.s." or similar | E | E | E | E | | E | | | | E | E | E |
| b.- In biologicals: declare the name of the preservative / adjuvant | N | N | E | E | | | | | | | E | E |
| c.- Ingredients from highest to lowest concentration | | | | | E | | | | | | E | E |
| d.- Components and composition | | | | | | | O | | | | E | E |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Lot, series, batch number or its equivalent term. | E | E | E | E | E | E | E | E | | E | E | |
| Manufacturing / preparation date or its equivalent term | O | O | O | E | E | E | E | | | E | E | |
| Expiration date / expires / use-by date or equivalent term | E | E | E | E | E | E | E | E | | E | E | |
| Net content | N | N | E | E | E | E | E | E | | E | E | O |
| Country name and company name of the manufacturer | N | N | N | E | E | E | E | | | E | E | E |
| In case of manufacturing for third parties: Specify "Manufactured in (country) by (manufacturer's company name) for (owner's company name)". | N | N | N | E | E | E | E | | | E | E | E |
| Withdrawal period/time, discarding period/time, when the product is intended for animal species producing food for human consumption. | N | N | N | E | | | | | | | E | E |
| Sanitary registration number | N | N | N | N | N | N | N | | | | E | N |
| Storage conditions (temperature, humidity, light, flammability, as appropriate) | N | N | N | N | N | N | N | | | E | E | N |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| The phrase "Not authorized for sale to the public." | | | | | | | | | | E | | |
| Species of destination or of diagnostic interest | N | N | N | N | N | N | N | | | | E | N |
| Sales condition. In controlled products, include the phrase "Sale under controlled / retained medical prescription" or equivalent phrase | N | N | N | N | | | | | | | E | N |
| The phrase "Read information before using the product" / "Read the insert before using the product" or equivalent phrase | N | N | N | N | N | N | N | | | | E | N |
| If applicable: Toxicological aspects, warnings, contraindications, adverse reactions, precautions, restrictions, interactions, antidotes - "See information in the insert" | N | N | N | N | N | N | N | | | | N | E |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| In multidose, multipurpose or reconstitution products: declare the time span after opening the product or Validity of the product after being opened or reconstituted | N | N | N | N | N | N | N | | | | N | O |
| Pharmaceutical form | N | N | N | N | N | N | | | | | N | N |
| Route of administration, application or use. Described in prose, not in acronyms. | N | N | N | N | N | N | N | | | | N | N |
| The phrase "Veterinary Use" | N | N | N | N | N | N | N | | | | N | N |
| Indications / Instructions for use or preparation | N | N | N | N | N | N | N | | | | N | N |
| Dose | N | N | N | N | N | N | | | | | N | N |
| The phrase "Keep out of the reach of children and domestic animals" | N | N | N | N | N | N | N | | | | N | N |
| The phrase "Consult a Veterinarian" | N | N | N | N | N | N | | | | | N | N |
| Pharmacological class | N | N | N | N | N | N | | | | | N | N |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| The phrase "Empty containers, as well as any residual content, must be disposed of in accordance with current regulations at your nearest collection center" or equivalent phrase | N | N | N | N | N | N | N | | | | N | N |
| **Ectoparasiticides that are not administered orally, transdermally, percutaneously or otically:** | | | | | | | | | | | | |
| a.- The phrase "Keep out of the reach of children, animals and food" or equivalent phrase | N | N | N | N | | | | | | | N | N |
| b.-Toxicological classification | N | N | N | N | | | | | | | N | O |
| c.- In capital letters, bold and in black or contrasting colour with the background of the label, the phrase: "In case of poisoning, consult a doctor and give him this label" or equivalent phrase | N | N | N | N | | | | | | | N | N |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| d.- Warning and special precautions for use: including those for the operator and personal protective equipment, if required. Refer to the toxicity of the ingredients for humans, animals and the environment, the symptoms of poisoning, first aid and measures applicable in case of oral, dermal or inhalation poisoning, where appropriate, antidotes and indications for treatment | N | N | N | N | | | | | | | N | N |
| e.- Methods for decontamination and final disposal of the product. | N | N | N | N | | | | | | | N | N |
| f.- The number of the reference Toxicological Center of the country where it is registered | N | N | N | N | | | | | | | N | N |
| **Infectious disease diagnostic kits:** | | | | | | | | | | | | |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Technical specifications (sensitivity, specificity, reproducibility, detection and quantification limits, when applicable) | | | | | | | | | | | N | E |
| Interpretation of results | | | | | | | | | | | N | E |
| Warning phrases and special precautions for handling or use | | | | | | | | | | | N | N |
| **Diluents:** | | | | | | | | | | | | |
| Nature of diluent: diluent, stabilizer or similar | E | E | E | E | | | | | | | E | |
| **Medical samples:** | | | | | | | | | | | | |
| The phrase "Veterinary medical sample" / "Free sample" | | | | | | | | | E | | E | N |
| The phrase "Prohibited Sale" | | | | | | | | | E | | E | N |
| **Optional:** | | | | | | | | | | | | |
| Generic name | O | O | O | O | | | | | | | O | O |
| Presentations | | | | | | | | | | | | O |

| | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Name of the Technical Director / Technical Advisor / Physician in charge | O | O | O | O | O | O | O | O | O | O | O | O |
| Company name of the importer or semi-processor | O | O | O | O | O | O | O | O | O | O | O | O |
| Pharmacological or immunological properties, as appropriate | | | | | | | O | | | | | |

Organización Mundial de Sanidad Animal
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Comité de Las Américas de Medicamentos Veterinarios

**Annex II**

# PLAN ESTRATÉGICO 2025-2029
**(Draft)**

## Misión

El CAMEVET es un proyecto regional de la OMSA, creado con el fin de armonizar normas de registro de medicamentos veterinarios entre los países de la región y miembros de la OMSA, a través de:

- La promoción de las guías de trabajo aprobadas y la aplicación de criterios comunes en la región, a través de la difusión de las guías y documentos aprobados por el CAMEVET, difundiendo los beneficios que estas guías aportan.
- La armonización de guías y documentos, incluyendo la creación de nuevos grupos de trabajo a partir de temas técnicos de relevancia y la revisión de guías adoptadas por más de 10 años de antigüedad.
- La difusión de guías CAMEVET con la finalidad de asegurarse que los objetivos y la armonización que se realiza en el marco del Camevet sea tenida en cuenta en los diferentes foros y/organizaciones internacionales

## Visión

El CAMEVET en el transcurso de su historia ha elaborado 30 guías armonizadas, las cuales se desarrollaron de acuerdo con los intereses de la región.

Este compromiso con las metas generales y regionales no ha cambiado, el CAMEVET continúa esforzándose por desarrollar guía de interés entre los países, considerando nuevos productos y desarrollos tecnológicos. Este nuevo Plan Estratégico tiene como objetivo principal ***armonizar normas de registro de productos veterinarios*** y de este modo facilitar el comercio seguro, desarrollando mecanismos que permitan crear criterios comunes para evitar la duplicación de ensayos y la disparidad en las aprobaciones, estimulando la comunicación entre los sectores oficiales y privados.

## Acciones

**Internalización:**
- Difundir las guías y documentos aprobados por el CAMEVET.
- Realizar reuniones con los Sectores oficiales al más alto nivel posible.
- Difundir los beneficios de generar y adoptar las guías y documentos armonizados

**Armonización:**
- Desarrollo de temas técnicos de relevancia
- Desarrollar nuevos grupos de trabajo
- Revisión de guías adoptadas
- Continuar con los seminarios anuales CAMEVET

**Participación internacional:**
- Participar e involucrar en los trabajos de CAMEVET a organismos como el VICH, OMSA, CODEX, como así también CVP, CAN, OIRSA, CAFSA, CARICOM.

## Misión

promoción de las guías de trabajo aprobadas y la aplicación de criterios comunes en la región

armonización de guías y documentos, incluyendo la creación de nuevos grupos de trabajo a partir de temas técnicos de relevancia

difusión de guías CAMEVET en el marco del Camevet para quesea considerada en los diferentes foros y/organizaciones internacionales

## Visión

***Armonizar normas de registro de productos veterinarios***

Facilitando el comercio seguro desarrollando mecanismos que permitan crear criterios comunes para evitar la duplicación de ensayos y la disparidad en las aprobaciones, estimulando la comunicación entre los sectores oficiales y privados.

**Annex III**
**Dollar balance**

| **Revenue** | | **30/12/2023 31/10/2024** |
|---|---|---|
| Resources available on 30 December 2023 | | USD 84.609,60 |
| Registration for the CAMEVET Seminar | | USD 53.000,00 |
| | **Subtotal Income** | **USD 137.609,60** |
| **Expenditure** | | |
| **Fixed costs (Salaries)** | | |
| Administrative Secretariat (Srta. Ana Maria Sgammini USD 1.200/mes) | | USD 10.800,00 |
| Aguinaldo Administrative Secretary (June and December) | | USD 600,00 |
| Gastos Admin. Por uso de las Oficinas de la OIE (150/mes) | | USD 0,00 |
| | **Subtotal Fixed Costs** | USD 11.400,00 |
| **CAMEVET Annual Meeting expenses** | | |
| Funding to Focal Points | | USD 7.567,00 |
| Participation of Ana Sgammini | | USD 3.146,00 |
| Payment of per diems for CAMEVET seminar lecturer | | USD 1.835,00 |
| Payment for seminar interpretation ESP-ENG-POR | | USD 10.443,00 |
| | **Subtotal** | USD 22.991,00 |
| **Other Expenditure** | | |
| Google Workspace Business Starter JAN-SEP | | USD 71,54 |
| Reimbursement to Ana Sgammini for payment of receipt book | | USD 30,78 |
| | **Subtotal** | USD 102,32 |
| | **Subtotal Fixed Costs** | **34.493,32 USD** |
| | **Total balance as at 31 October 2024** | **103.116,28 USD** |

**Balance in Argentine pesos**

| **Revenue** | **30/12/2023 31/10/2024** |
|---|---|
| Resources available as at 30 December 2023 | ARS 0,00 |
| Currency exchange Panama to $ (change ticket Administrative Secretary) | ARS 6.000,00 |
| **Subtotal** | **ARS 6.000,00** |
| | |
| **Expenditure** | |
| **CAMEVET Annual Meeting expenses** | |
| No costs so far | |
| **Subtotal** | ARS 0,00 |
| | |
| **Expenses for Participation in Other Events** | |
| No costs so far | |
| **Subtotal** | ARS 0,00 |
| | |
| **Other Expenditure** | |
| No costs so far | ARS 0,00 |
| **Subtotal** | ARS 0,00 |
| | |
| **Subtotal Expenditure** | ARS 0,00 |
| | |
| **Total balance as at 31 October 2024** | **ARS 6.000,00** |

**Annex IV**

MINUTES OF THE XXIX CAMEVET INDUSTRY MEETING, LIMA, PERU

1. It is necessary to foster joint collaboration between the public and private sectors in developing strategies to combat antimicrobial resistance.
2. A review of response times from official entities for regulatory procedures in different countries is requested to ensure they do not hinder trade.
3. We need to focus on achieving One Health through an integrated approach across all sectors.
4. Regarding labelling, Central American countries are urged to recognise and harmonise labelling standards across the region, particularly during product renewal processes.
5. Central American authorities are required to apply the RTCA for medicines and related products literally in cases of registration recognition, without imposing additional requirements.
6. We request consideration of the approved terminology in technical regulations to enable harmonised labelling across different countries.
7. There is significant concern over the new CAN regulation, Resolution 931, which introduces radical changes to national regulations without transitional periods or consensus with the industry for proper implementation. These changes include drug combinations and residue studies, referencing Central American regulations. Since 2011, this region has struggled to harmonise implementation across all countries, leading to trade imbalances and serious obstacles for the industry. APROVET Colombia reports that three other guilds in their country, along with those from Ecuador, Peru, and Bolivia, have sent joint communications to governments and regulatory entities. These communications highlight the drawbacks of various aspects of the current Decision Project in CAN, which could directly affect not only the veterinary pharmaceutical and biological industry but also primary animal protein producers, thereby endangering food security in the region.
8. Mechanisms must be implemented to allow all registration documentation, including legal documents, to be submitted entirely in digital format.
9. We propose evaluating and applying various traceability and control tools so that, based on existing antimicrobial databases, the prohibition of production and marketing is used only as a last resort.
10. Regarding the application of the RTCA for Veterinary Medicines and related products in Central America:

- a. During the renewal process, authorities are urged to apply paragraph h of point 6 literally, which allows the marketing of products undergoing registration processes if submitted in a timely and proper manner.
- b. Regarding requirement 5.3.2 related to Drug Combinations, joint lists between official sectors and the industry are encouraged to determine prohibitions. This would facilitate the review of files, reduce registration times, and prevent the requirement from being ambiguous or subject to individual discretion.
- c. For point 5.3.1 of the common sanitary registration requirements, we request acceptance of literary evidence and the suspension of residue studies or residue verification in the absence of regional infrastructure. Current issues include: restricted indications, off-label uses in species without studies, lack of products, increased illegal trade of products outside the law, and obstacles to regional trade, all of which harm national industries.

11. Authorities are requested to intensify collaborative efforts with the industry to advance and support the internalisation of harmonised documents approved by CAMEVET in all member countries.
12. We urge authorities to evaluate and analyse the consequences of excessive regulations, taking other continents as examples where high costs of implementing regulatory standards negatively affect the development and sustainability of the productive chain. Transferring this problem to our continent would directly impact economies that rely primarily on livestock production.

CONCLUSIONS:

It is requested through the Camevet secretariat to raise these requests from the Industrial sector to the highest authorities such as, WOAH, Ministers of Agriculture and Livestock and Official Heads of the Veterinary Services of the different countries, as well as to provide an attentive response to this document.