**Technical regulation RTCA 65.05.51:18**



**ICS 65.020.30 IN CENTRAL AMERICA**

**1ra. Review**

**Veterinary drugs and related products. Requirements OF SANITARY REGISTRATION AND CONTROL**

**Correspondence:**This Regulation has no correspondence with any international norm.

 The Central American Technical Regulation, edited by:

-   Ministry of Economy, MINECO

•   Salvadoran Agency Technical Regulation, OSARTEC

•   Economic Development Secretariat, SDE

-   Ministry of Development, Industry and Trade, MIFIC

-   Ministry of Economy , Trade and Industry MEIC

-   Ministry of Commerce and Industries, MICI

**Report**

The respective Technical Committees for Standardization and Technical Regulation through the bodies of standardisation and technical regulation of the countries of the Central American Region and its successors, the agencies responsible for conducting the study or the adoption of technical regulations. They are formed by representatives from the academic, Consumer, private enterprise and government.

This document was approved as a technical regulation of Central America, Rtca

65.05.51:18 Veterinary Drugs and Related Products, establishments that manufacture, market or fractionated. Requirements of Sanitary Registration and Control, by the subgroup of agricultural inputs and the subset of standards-related measures. The formalization of this technical regulation, leads to the ratification by the Council of Ministers of Economic Integration (COMIECO).

Participating Member States

**By Guatemala**

Ministry of Agriculture, Livestock and Food (VISAR)

**By El Salvador**

Ministry of Agriculture and Livestock

**By Nicaragua**

Institute for the Protection and Agricultural Health

**By Honduras**

Secretariat of Agriculture and Livestock (SENASA)

**By Costa Rica**

Ministry of Agriculture and Livestock (SENASA)

**By Panama**

Ministry of Agriculture and Livestock Development

**1.   The subject**

To establish the provisions of health registration and control of medicinal products for veterinary use, related products and establishments.

**2.   Scope of Application**

Apply to veterinary drugs and related products, as well as the establishments that are logged, manufacture, market, shipped or sold, fractionated or stored in the States Parties.

With the exception of the scope of this regulation the health registry of the raw materials for veterinary drugs and related products, as well as the veterinary magisterial formulations, which is subject to the national legislation of each State Party.

Note 1. The provisions of this Regulation should be interpreted for the benefit and protection of human health, animal health, the environment and the livestock heritage in each of the States Parties, to comply with the institutional objectives that each Party has in its different bodies of law.

**3.   Definitions**

For the purposes of this Regulation, the following definitions are established:

**3.1 Storage:**Store establishments dedicated to veterinary drugs and related products, manufacturers or dealers duly registered and approved by the competent authority.

**3.2 marginal note or modification of sanitary registration:**change of a sanitary registration original, endorsed by the competent authority at the request of the holder.

**3.3 Competent authority:**Entity responsible for the implementation of this Regulation for its effective implementation by the sectors involved in the theme and activity that he understands.

**3.4 Certificate of analysis:**Document issued by the quality control laboratory of the manufacturer or other officially authorized, which certifies the results of the analysis of quality of a specific batch.

**3.5 Certificate of free sale:**Official document issued by the competent authority of the health registry, which certifies that a veterinary medicinal product or related product is sold freely in its territory.

**3.6 Certificate of sanitary registration:**Official document issued by the competent authority that gives faith that has complied with all the requirements established for the health registry.

**3.7 Packaging or packaging:**any container or wrapping intended to preserve the quality and safety of the veterinary medicinal product or related product, facilitating their manipulation.

**3.8 Packaging or primary packaging:**container within which is placed directly the veterinary medicinal product or related product in its pharmaceutical form completed with the purpose of protecting it from deterioration, contamination or adulteration and facilitate its management.

**3.9 Packaging or secondary packaging:**container within which places the primary container that contains the veterinary medicinal product or product in its pharmaceutical form affine finished, for distribution and marketing.

**3.10 State Party:**States which are party to the Protocol to the General Treaty of Integration

Central American Economic -Protocol of Guatemala.

**3.11 analytical standard: a**substance of known purity and quality, used as a pattern of comparison (primary or secondary) in laboratory tests for quality control.

**3.12 Primary Standard: a**substance that has been shown through a series of analyzes, be a high purity material obtained from an official source recognized and whose content assigned is accepted without require comparison with another chemical.

Note 1. Reference substances farmacopeicas chemistry are considered as primary standard.

**3.13 Secondary Standard: a**substance of quality and purity established, which is compared with a primary reference standard, used for routine laboratory analysis.

**3.14 Establishment veterinarian:**physical space where they are manufactured, sold, shipped or sold, fractionated, manage records or stored veterinary drugs and related products.

**3.15 Labelling:**any information that accedes, print or record in the container and packaging of commercial presentation of a veterinary medicinal product or related product.

**3.16 Excipient; inert ingredient; vehicle**: subject matter that is added to the active principles or their associations to serve as a vehicle, so as to enable its preparation, est ability, modify their organoleptic properties or determine the physical-chemical properties of the medicine and their bioavailability.

**3.17 Manufacturer:**any natural person (natural, individual) or legal legally constituted, which is dedicated to the elaboration or formulation of veterinary drugs and related products, being able to be maquiladora industry.

**3.18 Veterinary Pharmacy or dispensing**: establishment legally constituted dedicated to the commercialization of veterinary drugs and related products directly to the public.

**3.19 qualitative-quantitative formula:**full description of the composition and its contents, including active and inert ingredients, with simple elements or compounds, of a veterinary medicinal product or related product, issued by the manufacturer.

**3.20 Fraccionador**: Any person (natural or legal, individually), legally constituted dedicated to repack or repackage a veterinary medicinal product or related product following with good manufacturing practices.

**3.21 False Information:**Information that is presented with the objective of sustaining a health registry, which does not correspond to the true product information and that, with intention, it makes having authentic.

**3.22 inaccurate information:**that which is presented with the objective of sustaining a health registration and that without intention is not accurate*.*

**3.23 Insert or leaflet:**instructive form that accompanies each commercial presentation of a veterinary medicinal product or product akin, complying with the labelling provisions of this Regulation.

**3.24 recognized scientific literature or technical paper:**it is considered as a valid source that comes from journals indexed or reviewed by peers, sources or official guides, pharmacopoeias, books or monographs farmacopeicas whose appointments allow the traceability of the primary source, without detriment to the need to provide the primary source when required; studies conducted under internationally recognized guides, as well as private studies provided by the registrant made under international standards.

**3.25-Bond:**any natural person (natural, individual) or legal, legally constituted that provides services to third parties in formulation or elaboration of a product.

**3.26 Raw material**: substance, whatever their origin, active or inactive, used as a main component, the active ingredient or excipient which is used for the manufacture of veterinary medicinal products and related products, whether it remains unchanged as if you suffer from modification.

**3.27 Innovator:**is one drug that results from a research process, which is protected by a patent and is manufactured exclusively by the pharmaceutical laboratory that the development. They are called by the name of the active substance and by a name or trademark.

It is the product that was first authorised for marketing based on documentation of quality, safety and efficacy and has gone through all phases of the development of a new product.

**3.28 Generic Medication:**veterinary medicinal product which contains the same active principle/s/s, the same salt or ester of the active principle, that a product registered in advance and that it does not have patent protection, in the same concentration, pharmaceutical form, route of administration, dosage and therapeutic indications, destined for the same species and category, having to be bioequivalent with the product registered in advance and differ only in features relating to the size, presentation, period of validity, packaging, labeling, excipients or vehicles. As a consequence, they may show different biodisponibilidades, magnitudes and temporal profiles of their pharmacological activities.

**3.29 similar medication:**veterinary medicinal product, generic, which contains the same active principle/s/s of a medicinal product registered in advance with any country, to the same concentration and in the same pharmaceutical form, and may or may not vary the excipients, but respecting the specifications and quality standards recognized pharmacopoeias.

**3.30 veterinary medicinal product:**Any substance or their mixtures that can be applied or administered to animals, with therapeutic, prophylactic, immunological, diagnostics, eutanasicos or to modify the physiological functions and behavior.

**3.31 veterinary medicinal product in fixed-dose combinations:**mixture of two or more active principles that are in the same prepared, which are generally used in combination are more beneficial than individually**.**

**3.32 veterinary medicinal product and related product: a**set of alternative substances or mixtures that are not part of conventional medicine**.**

**3.33 Office Registrant:**establishment which has as its sole activity manage records of veterinary products and establishments, its renewal or modification to the competent authority.

**3.34 Withdrawal period or time of retreat:**is the period between the last administration or application of a drug and the collection of edible tissue or products from a treated animal that ensures the contents of residues in food is adjusted to the maximum residue limits for veterinary drugs (MRLS).

**3.35 preparations or magisterial formulations:**medicinal product developed by the pharmacist in a pharmacy to meet a prescription or prescription from your doctor, veterinarian in an individual patient or specific group of animals.

**3.36 Active Principle: A**substance that has one or more pharmacological effects or that without such effects, to be administered or applied to the animal body, acquires these effects after suffering changes in their chemical structure.

**3.37 Product:**veterinary medicinal product or related product, as appropriate.

**3.38 Related Product:**any substance, material of any origin and their mixtures that are used in animals or their way of life, for diagnostic purposes, health, hygiene and cosmetic.

**3.39 Biological Product**: veterinary product produced from bacteria, viruses, hyperimmune sera, toxins and similar products of natural origin, synthetic or biotechnological processes which include, reagents - diagnosis, antitoxin, vaccines, micro-organisms, dead microorganisms and antagonistic components or agencies immunising used in the diagnosis, treatment, or prevention of diseases in animals.

**3.40 Prescription controlled (on hold): a**prescription issued by a veterinarian approved by the competent authority to prescribe controlled drugs for veterinary use.

**3.41 Registrant:**physical person (natural, individual) or legal legally authorized by the owner or holder of a veterinary medicinal product or product akin to register with the competent authority . The registrant may be the same holder of the sanitary registration.

**3.42 Sanitary Registration: A**procedure in which the competent authority of a State Party approves the marketing of a veterinary medicinal product akin or operation of a veterinary establishment, then to comply with the requirements set out by this.

**3.43 Legal Representative:**physical person (natural or legal, individually) representing the holder or owner of the sanitary registration of a product or establishment veterinarian and answerable to the competent authority, as the case may be, in terms of their health registry.

**3.44 Regent veterinarian:**Medical professional veterinarian who, in accordance with the laws of each State Party, is authorized to comply with the responsibilities of the technical, scientific and professional of the various establishments veterinarians.

**3.45 holder or owner of the Sanitary Registration:**physical person (natural, individual) or legal entity that has in its favor the sanitary registration of a product, for marketing.

**4. Sanitary REGISTRATION OF ESTABLISHMENTS AND THEIR RENEWAL**

Every establishment veterinarian must be registered and authorized by the competent authority. The establishments are classified as:

A) Manufacturers

Fractionates b)

C) Traders (importers, exporters, drugstores or distributors). d) veterinary pharmacies or retail outlets

E) Storage

F) Offices Registrants

G) Holders of the record does not manufacturer h) Maquiladores

**4.1 General Requirements**

**(A)**possess the corresponding authorization to function, under the official rules in force in each State Party.

**(B)**have a legal representative in the country of the sanitary registration.

**(C)**In the case of representatives of foreign manufacturers, provide legal documentation that supports the authorization for representation in the country that is seeking to register.

**D) to**have a regent veterinarian.

**E)**legal documents that support the constitution of the company in the case of the legal person and documents of identity of the applicant in the case of the physical person (natural, individual).

**4.2 The manufacturers.**In addition to the general requirements must:

**(A)**Submit the certificate of Good Manufacturing Practices or the operating plan for compliance as set forth by the Agreement #3 of this Regulation.

**(B)**the services of a quality control laboratory of the manufacturer or other authorised by the competent authority and shall provide the certified copy of the authorization with the respective consular procedures.

**4.3 The maquiladora and crackers.**In addition to the general requirements, must submit the certificate of Good Manufacturing Practices or the operating plan for compliance as set forth by the Agreement #3 of this regulation

**4.4 Effect.**The sanitary registration of establishment shall remain valid for a period of 5 years and for renewal must comply with the requirements of sanitary registration set forth in this

Paragraph, as appropriate. Any such request must be made up to three months before its due date.

**4.5 Cancellation of the registration of health.**Health registries of establishments can be canceled prior to its expiration, to be checked for compliance with:

**(A) to**any of the conditions laid down for its granting.

**(B)**The violation of any specific rules in the field of each State Party.

**5. Sanitary REGISTRATION, RENEWAL AND OTHER CONTROLS FOR VETERINARY MEDICINES AND RELATED PRODUCTS**

All veterinary medicinal product and related product that is manufactured, import, export, shortening, store, marketed, dispatch or expend, you must be registered and authorized by the competent authority.

**5.1 Products subject to sanitary registration and control**

The competent authority of each State Party, you must register and control the following products:

**A)**pharmaceutical products or alternative medicine for veterinary use.

**B)**biological products for veterinary use.

**C)**Related Products for Veterinary Use.

**5.2 Classification of veterinary drugs and related products**

For the purposes of health registration and control of products, these are classified according to their risk level in four groups:

**I.**Restricted use veterinary medicinal products indicated in the list issued by the International Narcotics Control Board or by  States Parties, selling and shipping or exclusive outlets in veterinary establishments approved for that purpose by the competent authority through controlled prescription (on hold).

**II.**Restricted use products, sales and exclusive office or through controlled dispensing prescription (on hold) in approved veterinary establishments for the purpose by the competent authority.

**III.**Veterinary products sold exclusively in veterinary establishments that acct an with a regent veterinarian and approved by the competent authority.

**IV.**Veterinary drugs and related products of free sale in any approved establishment.

**5.3 Types of sanitary registration**

Are considered two types of sanitary registration of veterinary drugs and related products

**(A)**Common health record.

**(B)**Sanitary Registration simplified.

**5.3.1 Common Sanitary Registry**

Applies to all veterinary medicinal products and related products, except for those who are not harmonized in the listing of products subject to sanitary registration simplified.

Interested parties must submit documentation and comply with the following requirements:

**(A)**Application of Sanitary registration (Annex A, form A1 or A2, as appropriate) duly filled and with supporting documents, signed and sealed by the regent and the registrant.

**B)**Power notary of the manufacturer or owner granted in favor of the registrant authorising it to carry out these activities before the competent authority.

**C)**Certificate of free sale according to normative Annex B, in original, issued by the competent authority of the country of origin.

**D)**Formula of qualitative-quantitative composition complete, in original, issued by the technician responsible for the laboratory or by the technician responsible designated by the manufacturer, that includes the name of the product, active ingredients and excipients expressed according to the International System of Units.

**(E)**Methods and methodology of  physical, chemical, and biological analysis, as appropriate, internationally recognized or validated by the manufacturer for the determination of the quality of the drug or related product.

**F)**Certificate of analysis from a commercial lot of the finished product, issued by the manufacturer or by the approved laboratory, in original, signed and sealed by the technician responsible for the same.

**G)**Project, tags, insert, packing material when appropriate, to be approved, and shall comply with the provisions established by the competent authority.

**H**) scientific studies or scientific literature recognized, to support the effectiveness, stability, security and quality, for each of the species requested for the pro pipeline to register, in accordance with the provisions set out in Annex C.

The owner of the registration must provide a summary of these studies or scientific literature recognized, as appropriate, noting the reference citations and attaching supporting documentation complete. Citations are not required for innovative medicines.

**(I)**a product sample to register, in the original container with the marketed in the country of origin, when required by the competent authority.

**J)**analytical standard (primary or secondary), as required by the competent authority.

**K)**when the veterinary medicinal product or related product is manufactured by a different company to the new holder of the sanitary registration, contract must be updated in the maquila, original or copy of the document duly legalized, in accordance with the provisions set out in Annex D to this Regulation.

**L)**The proof of payment for the service of sanitary registration where appropriate.

**5.3.2 Veterinary Drugs with active principles in fixed-dose combinations**

With the exception of this numeral multivitamins, multimineral supplement, vaccines, diagnostic kits, hyperimmune sera and related products. If any of these products combine with another type of medication, must comply with the requirements of this paragraph.

In addition to the requirements for the health registry, common combinations should comply with the following:

**5.3.2.1 Advantages that must demonstrate the combination.**Are accepted for the health registry the combinations of active principles, with recognized scientific literature or scientific studies specific to the combination you are requesting, to demonstrate significant pharmacological advantages of the combination in relation to each ingredient separately, without significantly increase the risks to animal health, human health and the environment, nor promote microbiological resistance factors. Therefore, these combinations must demonstrate at least one of the following advantages:

**A)**synergistic effect of summation or empowerment: when the action of different active principles are complemented by improving the therapeutic activity.

**(B)**Expansion of the spectrum: when the combination of active principles increases the range of action against causal agents of diseases or syndromes caused by a number of etiologic agents, so that the action of each ingredient is complemented to combat the disease process in its entirety.

**(C)**Better tolerability and safety: when the addition of an active ingredient decreases the adverse effects or side effects of other ingredient or where it has been demonstrated that, at doses lower than those normally used for each active ingredient, you get a therapeutic effect equal to or better.

**(D)**better clinical effect--pathological: when it is demonstrated that the addition of an active ingredient improves the clinical-pathological effect in specific situations, favoring the recovery of the animal.

**(E)**better pharmacokinetic profile: when adding an ingredient improves the bioavailability of the formulation, obtaining significant advantages in the intensity and duration of action.

**(F)**Better adaptation to the therapeutic regimen polifarmaceutico or ease of use of the disease.

**5.3.2.2 requirements they must meet the combinations**

**5.3.2.2.1 Indications for use.**Are only accepted as valid the directions in which the combination of the different active ingredients necessary to achieve the intended therapeutic effect, so that each active ingredient helps to achieve this effect.

**5.3.2.2.2 Dosage.**All the active ingredients must have the correct proportion in the formulation to obtain the desired effects, backed by studies that demonstrate the proportion; with studies of dose determination and validated methodology.

**5.3.2.2.3 Duration of action.**The duration of action of the various principles combined assets must be justified pharmacologically, so that the ingredients comply with all recommended uses.

**5.3.2.2.4 quality controls.**Because of that, by the pharmacopoeias of reference, the analytical methodology and quality standards are analyzed by the beginning of the individual assets, companies who wish to record these combinations must submit the validated analytical methods for the identification and quantification of the active ingredient is present in the combination.

**5.3.2.2.5 antagonisms.**Through scientific studies or scientific literature recognized specific to the combination that is being requested, it must be demonstrated that there is no antagonism between the ingredients of the formulation.

**5.3.2.2.6 periods of retreat.**Is set on the basis of the active principle to present the withdrawal period longer during the study, waste disposal site of the combination to register.

**5.3.2.2.7 implementation or administration.**The route of administration or application of the combination should correspond to the track approved for each ingredient separately, in the event that a new path must be provided the corresponding pharmacological studies or literature recognized scientific data specific to the combination you are requesting that demonstrate this new track.

**5.4 Simplified Health Record**

Applies to all veterinary medicinal products and related products that are on the list of products subject to sanitary registration simplified. Said sanitary registration does not imply that these products are of free sale. Interested parties must submit the documentation and comply with the following requirements:

**(A)**Application of Sanitary registration simplified (Annex A, form, A3 or A4, as appropriate).

**B)**Certificate of free sale according to normative Annex B, in original, issued by the competent authority of the country of origin.

**C)**Certificate of analyzes in a batch of finished product.

**D)**Formula of qualitative-quantitative composition complete, in original, issued by the technician responsible for the laboratory or by the technician responsible designated by the manufacturer, that includes the name of the product, active ingredients and excipients expressed according to the International System of Units.

In the case of diagnostic kits you must submit only the formula of complete qualitative composition.

**(E)**Methods of physical, chemical, and biological analysis, as appropriate, used and internationally recognized or validated by the manufacturer for the determination of the quality of the drug or related product.

**F)**Project, tags, insert, packing material when appropriate, to be approved, and shall comply with the provisions established by the competent authority.

**G)**analytical standard (primary or secondary) as required by the competent authority. It does not apply to products of hygiene and beauty.

**H)**notarized Power of the manufacturer or owner granted in favor of the registrant authorising it to carry out these activities before the competent authority.

**(I)**a product sample to register, in the original container with the marketed in the country of origin, when required by the competent authority.

**J)**when the veterinary medicinal product to be manufactured or affine, by a different company to the new holder of the sanitary registration, contract must be updated in the maquila, original or copy of the document duly legalized, in accordance with the provisions set out in Annex D to this Regulation.

**K)**The literals (e), (g) and (i) do not apply to diagnostic kits for veterinary use, however, must submit the specifications and components of the formula and technical specifications of the finished product.

**L)**Proof of payment for the service of sanitary registration where appropriate.

**5.5 Renewal of sanitary registration**

The renewal of sanitary registration is considered to be an update to the registration dossier according to regulations in force at the time of submitting such a request, therefore, additional to the following points, you must submit the documentation required in paragraph 5.3.1 and

5.3.2 if applicable and was not provided with prior to the file:

**(A)**Application for renewal (Annex A, form A5).

**B)**notarized legal document, issued by the manufacturer, which must indicate that the conditions under which it was granted the sanitary registration in force, have not suffered any modification legal, technical or scientific at the time of renewal.

**C)**Certificate of free sale according to normative Annex B, in original, issued by the competent authority of the country of origin.

**D)**analytical standard (primary or secondary), as required by the competent authority.

**E)**Proof of payment for the service of sanitary registration where appropriate.

**6.   General aspects of the registration, renewal, MODIFICATION, AND RECOGNITION OF SANITARY REGISTRATION**

A) Legalization of official documents. All documents issued by the official authorities of the country of origin of the product, as well as special powers that sustain the sanitary registration, renewal, modification, or recognition of the sanitary registration of veterinary drugs and related products, must comply with their legal and consular formalities.

(B) The validity of certificates of free sale and analysis, it is a period of not more than two years from the date of issuance or the date indicated by the GLC if it is less than two years and must be in effect at the time of the receipt of the request for registration, renewal, modification, or recognition of the sanitary registration.

C) The competent authority of the State party will be able to register veterinary drugs and related products developed exclusively for export, as long as the establishment manufacturer with registration and control by the competent authority of the country of origin; in addition the products must have the respective official health controls and the scientific basis of the medicine has no risk to human health, animal health and the environment.

D) The competent authority of the States Parties shall not register products that are in experimental phase in their country of origin.

E) veterinary drugs and related products must be registered with trade name only, not allowing multiple names for the same sanitary registration .

F) does not allow a product with the same number of sanitary registration aimed for different species is marketed with a packing material (labelling, commercial image) different for each species, weight or size of the animal.

G) You can register a product, renew or modify your sanitary registration provided that in their country of origin has not been canceled, prohibited its use for sanitary reasons, is in the process of registration or renewal.

(H) The renewal application must be submitted to the competent authority up to three months before the expiry date of the registration of health.

It also allows the importation and marketing of products which are in the process of renewing your registration and in compliance with the requirements requested by the competent authority.

Once the sanitary registration, if it is in the interest of the owner of the registration to keep your marketing, you must proceed to process a new record.

(I) The competent authority of the States Parties may request the official health certificates from the country of origin, related to the transmission of diseases or food safety.

J) veterinary drugs and related products derived from Genetically Modified Organisms (GMOS) or derived from biotechnology, require an assessment of the risk, in the event that this assessment is not satisfactory to the competent authority, will require a risk analysis.

K) biological products originating in countries with presence of transboundary diseases (exotic), require a risk analysis.

(L) The competent authority, with adequate justification technique, you can request the submission of additional documents that support the quality, safety or efficacy of the

Veterinary drugs and related products or clarification of any information contained in the registration dossier. If you require extra controls costs must be covered by the owner of the registration.

(M) The competent authority can request and monitor effectiveness testing in environmental conditions in the State Party where you intend to use a product. You can also order the re-technical evaluation of the chemicals, biological agents and formulated products previously registered when there is evidence of ineffectiveness, resistance or of adverse effects to human health, animal health or the environment.

N) The competent authority to check the falsehood of the information from the data entered or alteration of the documents presented, refused or canceled the health registry as the case may be.

N) When the veterinary medicinal product to be manufactured or affine, by a different company to the new holder of the sanitary registration, contract must be updated in the maquila, original or copy of the document duly legalized, in accordance with the provisions set out in Annex D to this Regulation.

O) for the products at the time of renewal of their sanitary registration do not have an accelerated stability study or natural (shelf), must be presented for renewal, the study of accelerated stability or, failing that, the commitment of the contribution of the accelerated stability study.

P) in the field of studies of stability will take the harmonized guide for the elaboration of studies of stability in veterinary pharmaceuticals of the American Committee for Veterinary Medicinal Products (CAMEVET) in its version in force, which must be taken by the States Parties through a resolution of the comieco.

Q) until the States Parties develop the respective laws and regulations in the matter, the stability studies referred to in this Regulation, related to biological products for veterinary use, must comply with the specific rules of the country of origin, or failing that, with a standard issued by a recognized charity or international agency.

R) When a product is produced by several manufacturers, must have an individual health record for each of the manufacturers, to comply with the procedure laid down in this Regulation.

S) States Parties may refuse registration, renewal, or recognition of the sanitary registration of products that do not have maximum residue limit (MRL) imposed by international bodies recognized in paragraph 17 of this Regulation.

T) States Parties may prohibit or restrict active principles for veterinary use, and shall publish them according to international procedures, cancel the

Records of those products containing prohibited substances that are in force at the time of its entry into force and order the withdrawal of the market of banned products established by each State Party.

Also, holders of registration of veterinary drugs with current health record, they must modify the tags to adapt them to the approved restrictions established by each State Party.

**7.   Exemption from HEALTH REGISTRY**

Exempt of the sanitary registration products in the following cases:

(A) in an emergency decreed, event or health protection to a national public interest.

(B) for research purposes, subject to compliance with the requirements set out in Annex F and in accordance with the clinical trial protocol established in the Agreement # 7 of this regulation, as appropriate.

C) for official health campaigns.

D) medical samples for the purpose of sanitary registration. e) Grants.

F) Veterinary drugs under veterinary prescription, intended for the treatment of a specific animal when there is no similar product registered in the State Party.

Do not allow the application for exemption of sanitary registration for active principles prohibited, for reportable diseases cross-border (alien) or that are restricted for target species the product, according to each State Party.

The competent authorities should analyze requests for exemption from registration, and may authorize the import requested, provided it complies with the provisions of this Regulation, the product does not constitute unacceptable risk to public health, animal health or environment and comply with the import formalities, when you apply. The authority must determine the amount to be imported and the requirements to be met according to what is established in each State Party.

**8.   Number AND CERTIFICATE OF HEALTH REGISTRY**

In the event that the competent authority shall approve the Sanitary Registration, Register the product as appropriate, assigning a number with which will identify the product for veterinary use in accordance with the harmonized coding.

Once registered the veterinary medicinal product or related product, the competent authority shall issue the certificate of sanitary registration officer.

**9.   Sanitary Registration Deadline**

The Health Registry granted is valid for a period of five (5) years from its registration, and can be renewed for equal periods upon request. However, when it violates the provisions of this Regulation or prove to the original conditions of the sanitary registration have varied in terms of efficiency, indications or product safety, will proceed to demand any necessary corrections or the cancellation of the registration of health.

**10.   The import ban**

The competent authority of the State Party shall not authorize requests to import for commercial purposes of products that do not have the health registry duly approved and in effect, except those referred to in paragraph 7 (exemptions to the sanitary registration).

**11.   File OR DISMISSAL OF THE MANAGEMENT**

To sort the file or dismissal of the management, according to the administrative procedures of each State Party, when the applications submitted did not meet the requirements specified in this Regulation, the information submitted is incomplete or uncomfortable for the purposes required or for having been presented extemporaneously, provided that she had been properly prevented or required by the competent authority.

**12.     MARGINAL NOTE OR MODIFICATION OF THE SANITARY REGISTRATION**

The sanitary registration of a product can be modified at the request of the registrant and regent, payment of value when appropriate, only for the cases mentioned in Annex E (Normative) "Typology and Modification Requirements of Sanitary Registration".

For cases not covered by this Annex, it requires a distinct health record and individually for each of the variations.

Marginal annotations or modifications must be resolved (approved or denied) and notified in writing by the competent authority. They do not imply a new sanitary registration, provided that they are in force. In the event of not being approved, should indicate the reasons for denial.

**13.   Cancellation of Registration**

The sanitary registration of any product may be canceled by the competent authority, prior to its expiration, when:

(A) in writing by the owner of the sanitary registration.

(B) Does Not Comply in three consecutive sampling of three different lots with the quality standards established in its sanitary registration for the veterinary medicinal product or related product.

(C) The use and handling of the product represents unacceptable risk found for human health, animal health or the environment.

D) to detect irregularities, fraud or misrepresentation in the composition of the product or in the information provided for your health registry.

E) verify, through case studies or tests recognized by the competent authority of the

The State Party, that the product is ineffective for the purposes indicated in the health registry.

F) when any of the components of the product is prohibited by the State Party.

**14.   Labelling requirements and re-labeling**

The draft label or label, jewel case and insert that must accompany the application for sanitary registration, should be presented in English and another language, at the request of the person concerned.

**14.1 Obligation of the label and re-labeling**

Any unused veterinary medicinal product or related product that is manufactured, handled, stored, split up, distributed, marketed, dispatch, who dispenses or use in the countries of the Central American region, must contain the respective label that complies with the provisions of this Regulation.

Size must be legibly to the naked eye, not less than 1.5 mm (4 points Didot) and carry clearly printed and visible the following information on internationally accepted nomenclature, expressing the units in accordance with the International System of Units, not break off and maintain the quality of the specifications defined by the manufacturer:

**14.2 Contents of common label**

(A) the name of the product.

(B) Pharmaceutical Form.

C) Route of administration or application.

D)  Active Principles / biological agent and its concentration. e) Net Content.

F) Name and country of the manufacturing laboratory. In the event of production to third parties, must be

Specified (prepared by…to…).

G)  batch number, date of manufacture and expiration date, expressed in mm/yy

(Month/year).

H) expiration date or your Pictograph once opened the product, when you apply. i) Requirements for the storage and conservation.

J) Registration number of the State Party where the records, can be printed on the case (box) if it contains.

(K)  The phrase "prescription" (for controlled drugs)

(L) The phrase "veterinary use".

M) target species detailing each one of them.

N) The pictogram in the animal species for which it is intended (optional).

O) The phrase "Read the insert before using the product", when it contains. This information must come printed from the country of origin.

  It is not allowed to re-labeling, or the use of self-adhesive labels or autoadhesibles ("stickers") for any information on the final labels, except for the number of sanitary registration, subject to the approval of the competent authority.

**14.3 Contents of label for hygiene and beauty products**

(A) the name of the product.

(B) form of marketing (c) Instructions for Use.

D)  Ingredients (from highest to lowest concentration). e) Net Content.

F) Name and country of the manufacturing laboratory. In the event of production to third parties, it must be specified (developed by…...).

G)  batch number, date of manufacture and expiration date, expressed in mm/yy

(Month/year).

H) registration number of the State Party where the records. i) The phrase "veterinary use".

J) species of destination detailing each one of them.

K)  The pictogram in the animal species for which it is intended (optional).

(L) The phrase "Read the insert before using the product", when it contains.

In this type of product allows the re-labeling, without hiding the batch number, date of manufacture, expiry date, manufacturer, and country of origin; this information should come printed on the label or packaging from the country of origin.

**14.4 Contents of label for diagnostic kits**

(A) the name of the product.

B) Instructions for Use. See insert.

C) components and composition. d) net content.

E) Name and country of the manufacturing laboratory. In the event of production to third parties, it must be specified (developed by…...).

F) batch number, date of manufacture and expiration date, expressed in mm/yy

(Month/year).

G)   registration number of the State Party where the records. h) The phrase "veterinary use", when you apply.

(I) target species detailing each one of them.

(J) The pictogram in the animal species for which it is intended (optional).

K)  storage conditions.

In this type of product allows the re-labeling, without hiding the batch number, date of manufacture, expiry date, manufacturer, and country of origin; this information should come printed on the label or packaging from the country of origin.

**14.5 Contents of label for packaging or packaging that are less than or equal to fifty milliliters, 100 grams, collapsible and blister Blisters**

The labels of containers or packaging that are less than or equal to fifty (50) milliliters, one hundred (100) grams, collapsible and blisters blister, in its packaging or primary packaging must indicate at least the following information:

(A) the name of the product.

B) Net Content, it doesn't apply for blister.

C) storage conditions, it doesn't apply for blister. d) active principles and its concentration.

E) lot number and expiration date, expressed in mm/yy (month/year). In addition, date of preparation for packaging or packaging over fifty (50) milliliters and one hundred (100) grams.

F) registration number of the State Party where the logs for packaging or packaging

The age of fifty (50) milliliters and one hundred (100) grams.

G)  Name of the country and manufacturing laboratory. In the event of production to third parties, must be

Specified (prepared by…...). h) The phrase "veterinary use".

(I) Target species detailing each of them for packaging or packaging over fifty (50) milliliters and one hundred (100) grams.

(J) the withdrawal period, when you apply.

(K)  The phrase "See", insert optional for blister.

This information must come printed on the label, packaging or packaging from the country of origin.

The missing information according to Section 14.2, and the number of sanitary registration, must be contained in the secondary packaging (box) if it contains and the insert attachment.

Each unit must be accompanied by the corresponding insert.

**14.6 Contents of label for packaging or packaging that are less than or equal to fifty milliliters and 100 grams for ectoparasiticides for veterinary use**

The labels of containers or packaging that are less than or equal to fifty (50) milliliters and one hundred (100) grams, in its packaging or primary packaging must indicate at least the following information:

(A) the name of the product. b) Net Content.

C) Storage Conditions

D)  active principles and its concentration.

E) lot number and expiration date, expressed in mm/yy (month/year). In addition, date of preparation for packaging or packaging over fifty (50) milliliters and one hundred (100) grams.

F) registration number of the State Party where the registers, for packaging or packaging

The age of fifty (50) milliliters and one hundred (100) grams.

G)  Name of the country and manufacturing laboratory. In the event of production to third parties, must be

Specified (prepared by…...).

(H) The phrase "veterinary use".

(I) Target species detailing each of them for packaging or packaging over fifty (50) milliliters and one hundred (100) grams.

J) period of retreat, when applied. k) Class and type of ectoparasiticida.

L) Antidote(s) and indications for treatment in the event of poisoning in human beings. m) The phrase "See Insert".

This information must come printed on the label, packaging or packaging from the country of origin. The missing information according to Section 14.2, and the number of sanitary registration, must be

Contained in the secondary packaging (box) If the Contains or the insert attachment.

Each unit must be accompanied by the corresponding insert.

**14.7 Contents of the package or secondary packaging**

The container or secondary packaging (- blister) must contain the following information:

(A) the name of the product. b) Pharmaceutical Form.

C) Route of administration or application.

D)  Active Principles / biological agent and its concentration.

E) net content.

F) Name and country of the manufacturing laboratory. In the event of production to third parties, must be

Specified (prepared by…to…).

G)  batch number, date of manufacture and expiration date, expressed in mm/yy

(Month/year).

H) expiration date or your Pictograph once opened the product, when you apply.

(I) Requirements for the storage and conservation.

J) registration number of the State Party where the registers.

(K)  The phrase "prescription" (for controlled drugs). l) The phrase "veterinary use".

M) The pictogram on the species of animal(s) for which it is intended (optional). n) target species detailing each one of them.

O) The phrase "Read the insert before using the product", when contains it. p) pharmacological class.

Q)  indications.

R) Contraindications and restrictions.

S) Dose per animal species.

T) form and route of administration.

U)  Warning and precautions.

(V) the withdrawal period, when you apply.

W) The phrase "Keep out of reach of children and pets".

If the presentation of the product contains no secondary packaging, the totality of the information required in this section, must be printed on the packaging label or primary packaging.

This information must come printed from the country of origin.

**14.8 Contents of the insert**

When required to insert, this should always accompany the product to be distributed either at the wholesale or detail, included in the package or secondary packaging (case) or acceded to the product if the product does not contain box.

It must contain the following information:

(A) the name of the product. b) Pharmaceutical Form.

C) Route of administration or application.

D)  Active Principles / biological agent and its concentration. e) Presentations (optional).

F) Name and country of the manufacturing laboratory. In the event of production to third parties, it must be specified (developed by……to…).

G)  Requirements for the storage and conservation.

H) registration number of the State Party where the registers (optional). i) The phrase "prescription" (for controlled drugs).

J) pharmacological class. k) indications.

L) target species detailing each one of them. m) Dose per animal species.

N) form and route of administration. o) Warning and precautions.

P)  Period of Removal, if applicable.

Q)  The phrase "Keep out of reach of children and pets".

R) Contraindications and constraints. s) side effects.

T) adverse reactions. u) antidotes, if they exist.

**14.9 Contents of the insert to diagnostic kits**

When required to insert, this should always accompany the product to be distributed either at the wholesale or detail, included in the package or secondary packaging (case) or acceded to the product if the product does not contain box.

It must contain the following information:

(A) the name of the product. b) Instructions for Use.

C) components and composition.

D)  Net Content.

E) Technical Specifications of the finished product.

F) Name and country of the manufacturing laboratory. In the event of production to third parties, it must be specified (developed by ... to ...).

G)   registration number of the State Party where the registers (optional). h) The phrase "veterinary use".

I) species of diagnostic interest.

(J) The pictogram in the animal species for which it is intended (optional).

K)  Requirements for the storage and conservation. l) Warnings and Precautions

(M) The phrase "Keep out of reach of children and pets".

**14.10 Content of label, jewel case and insert for ectoparasiticides for veterinary use**

You must include, in addition:

A) Class and type of ectoparasiticida.

(B) terms and conditions of appropriate use is consistent with what is stated in the application for registration

Sanitary, specifying the common and scientific names of pests or parasites to

Combat, as well as the mode of use and application in animals, according to the pest in question.

C) method of preparing the final material applications, where appropriate.

(D)  methods for decontamination and disposal of used packaging, spills

Permanent and ectoparasiticides not used.

E) Warnings and precautions for use, relative to the toxicity of the ingredients for

Human beings and animals, symptoms of poisoning, first aid and measures applicable in the case of poisoning oral, dermal or inhalation when appropriate, antidote(s) and indications for treatment.

F) in uppercase and bold black color, the legend: "IN CASE OF POISONING

Talk TO YOUR DOCTOR AND GIVE THIS TAG".

G)  The legend "Stay away from children, domestic animals and food".

(H) The outstanding legend that says: "HIGH: Read this label before using the product."

(I) Indications on measures for the protection of the environment.

J) Indications of the protective equipment recommended for the implementation of the product, when you apply.

K)  The telephone number of the National Center of poisonings in the country where you register.

The toxicological classification of the ectoparasiticida must be carried out according to the World Health Organization (WHO), should be presented in the labelling in a visual way using a specific color and their identification must be made by a band along the base of the label and secondary case, if it contains, the width of which shall be not less than 15% of the height of the label and case.

To the center of the band must be printed in black letters or in a contrasting color text noting the toxicological category of the product "EXTREMELY DANGEROUS", "highly dangerous", "moderately dangerous" or "Slightly hazardous", as appropriate, in a size not less than one- third of the width of the band. In the Label and secondary case, if it contains, should be illustrative pictograms that support the proper use of the product in a size that does not exceed two thirds of the width.

The tones of the colors (PANTONES) as well as the symbols and words of warning to identify the toxicological category of the saes for veterinary use, must be done in accordance with the classification of the International Program on Chemical Safety (IPCS) of the World Health Organization (WHO).

The determination of the toxicological profile for saes band with an active ingredient or combinations must be done in accordance with the formulas recommended by the IPCS. In the same way you should use the DL50 recommended by the program.

The total surface area of the label may be of other colors, except the strip corresponding to the toxicological category. The contrast between the printed text and the Fund should highlight the legibility of the characters and not interfere with the color of the strip.

For blisters blister, collapsible and the contents of the label, packaging or primary packaging should be governed as indicated in paragraph 14.5 of this Regulation. For presentations that are less than or equal to fifty (50) ml or one hundred (100) grams, the contents of the label, packaging or primary packaging should be governed as indicated in paragraph 14.6 of this Regulation.

**14.11 Labels of medical samples**

Any unused veterinary medicinal product or related product listed as "medical", you must have the legends "VETERINARY MEDICAL SHOWS" "PROHIBITED FOR SALE". The information included must contain at least the complete list of active ingredients, the form of proper administration and contraindications. It is forbidden the sale and trade of samples of veterinary drugs and related products, as well as the exposure of these establishments will commercialise.

**15.   CONTROL OF OPERATIONS AND VETERINARY DRUGS AND RELATED PRODUCTS**

**15.1 The**Member Countries should establish the measures and activities for the control and oversight on the establishments and products involved in the health registry, manufacture, fractionation, storage, import, export, re-export, re-packing, distribution, dispatch, dispensing, handling and use of veterinary drugs and related products.

**15.2 of advertising and its prohibitions**

Advertising for products in group III and IV in any medium of communication, must not contain ambiguities, omissions or exaggerations that entail the possibility to mislead the user, in particular with regard to security on the use, management, nature and composition of the product for veterinary use. Cannot contain different information that protects the health registration of the product.

Advertising must be done in accordance with the technical information, proven by the corresponding studies in your health registry.

It is forbidden to all advertising of veterinary drugs and related products in group I

And II.

Prohibits the advertising or publicity of those products that are not registered and the use of images that are injurious to human dignity.

**16.   Confidentiality AND SECURITY OF INFORMATION**

The staff of the entities responsible for the sanitary registration, you must comply with what is stated by the legal instruments of each State Party with respect to confidentiality and security in the management of the information object of processing, and must save administrative confidentiality on documentation as required in the performance of their duties.

The technical information provided for the health registry, treated as confidential, may be used by the competent authority for purposes of preservation of public health, animal health and the environment, as indicated by the local laws and regulations.

**17.   Analytical methodologies AND QUALITY SPECIFICATIONS**

The competent authority applies as a reference the analytical methodologies, specifications of safety, quality control and in veterinary medicinal products and related products referred to in:

1.   The Codex Alimentarius Commission.

2.   Code of Federal Regulations (CFR) of the United States of America, Titles 9 and 21.

3.   Food Safety and Inspection Service (SFIS), USDA.

4. World Organization for Animal Health (O.I.E.).

5.   Official Association of Analytical Chemists (AOAC).

6.   Pharmacopoeia of the United States of America (USP).

7.   Pharmacopoeia of the European Union.

8.  The Central American Technical Regulation RTCA 11.03.39:06 Pharmaceutical products. Regulation of Validation of Analytical Methods for the evaluation of the Quality of Medicines.

9.   Environmental Protection Agency (EPA).

10.  Methodologies for analysis validated by the manufacturer.

States Parties recognize the Maximum Residue Limits (MRLS) of veterinary drugs in their order of priority established by:

1. The Codex Alimentarius Commission.

2. Food and Drugs Administration (FDA).

3. European Medicines Agency (EMA).

4. Joint FAO/WHO Expert Committee on Food Additives (JECFA).

5.Other governmental agencies and/or research of international recognition.

**18.   Monitoring and Verification**

It is the monitoring and verification of this Regulation to the competent authorities of the United Party.

**19.   Bibliography**

1.  Committee for the Americas of Veterinary Drugs (CAMEVET - OIE), a. Approved Documents.

2.  CDM Compendium of Canadian drugs.

3.  FAO, Guidelines on veterinary medicines and related products.

4.  Laws of each State Party in the field of veterinary drugs

5. and related products.

6. OIRSA, Technical Requirements for the Sanitary Registration and Control of

7.  Veterinary drugs and related products and food for animals.

8.  Royal Decree 1246-2008 of Veterinary Drugs.

**20. References**

1.   Code of Federal Regulations (CFR) of the Food and Drugs Administration (FDA), titles 9 and 21.

2.   Food Safety and Inspection Service (SFIS), USDA.

3.   World Health Organization (WHO).

4.   Codex Alimentarius, Maximum Residue Limits (MRLS) approved for

Medications and ectoparasiticides for veterinary use.

5.   European Medicines Agency, Maximum Residue Limits (MRLS) approved

For medications and ectoparasiticides for veterinary use.

6.   United States Pharmacopoeia.

7.   European Pharmacopoeia.

8.   The International Conference of Harmonisation (ICH).

9.   Veterinary International Conference of Harmonization (VICH).

10.  World Organization for Animal Health (OIE).

11.  Organization for Economic Cooperation and Development (OECD).

**Annex A**

**Application form for SANITARY REGISTRATION**

**(Normative)**

**A1 - APPLICATION FORM OF SANITARY REGISTRATION FOR MEDICINES, CHEMICALS AND ECTOPARASITICIDES FOR VETERINARY USE**

**1. Commercial Product Name**

**2.   Classification (Official Use Only)**

|  |  |  |  |
| --- | --- | --- | --- |
| **3.** | **Establishment APPLICANT: OWNER LEGAL REPRESENTATIVE** | | **/** |
| 3.1. | Name. | |  |
| 3.2. | Exact address. | |  |
| 3.3. | Country. | |  |
| 3.4. | Number of the establishment registrant. | |  |
| 3.5. | Technical Manager: | |  |
| 3.5.1. | Professional identification number. | |  |
| 3.5.2. | Place or means to receive notifications. | |  |
| **4.** | **Manufacturing Facility** | |  |
| 4.1. | Name. | |  |
| 4.2. | Exact address. | |  |
| 4.3 | Country. | |  |
| 4.4. | Number of the establishment. | |  |
| **5.** | **Establishment FRACCIONADOR** | |  |
| 5.1. | Name. | |  |
| 5.2. | Exact address. | |  |
| 5.3. | Country. | |  |
| 5.4. | Number of the establishment. | |  |
| **6.** | **Pharmaceutical Form** | |  |
| **7.** | **Specifications AND METHODS OF CONTROL OF COMPONENTS OF THE FORMULA.** | | **The** |
| **8.** | **Methodology for developing** | **The product. (**Describe | |
|  | In a nutshell the manufacturing process). |  | |
| **9.** | **Specifications AND METHODS OF FINISHED** | **CONTROL OF THE PRODUCT** | |

List and describe the specifications and methods that are used in the assessment qualitative-quantitative determination of the components of the formulation in the finished product.

9.1. Biological methods

9.2. Microbiological Methods

9.3. Chemical Methods

9.4. Physical methods

9.5. Physical-chemical methods

**10.   The FORM OF PRESENTATION AND QUANTITY OF PRODUCT**

**11.   Packaging Specification AND CONTROL**

11.1. Characteristics of the container

11.2. System of inviolability

11.3. Quality Control of packaging

**12.   Validity period**(end of the lot)

**13. Evidence of effectiveness (**Bibliographic History and clinical evidence of effectiveness, where applicable).

**14.   Indications FOR USE AND MARKETING CATEGORY**

14.1. Main or supplementary.

14.2. For antimicrobial and antiparasitic products, specify the etiological agents susceptible.

14.3. Animal species and categories to which they intended, specific use in facilities,

Equipment, or others.

14.4. Official categorization: (free sale, prescription drugs, controlled and restricted

Or other types of sale).

**15. Track OF APPLICATION AND FORM OF ADMINISTRATION OR USE OF THE PRODUCT**

Parenteral, oral, facilities, equipment, instrumental or other.

**16.   Extemporaneous preparation products**

16.1 Preparation of the product for its correct use (PREMIXTURES, solutions, pre-

Emulsions, suspensions or other).

16.2 Validity Period After reconstitution, backed by studies of stability.

16.3 When the product is to be administered in rations or in the drinking water must be indicated its stability, compatibility and/or dwell time effective in the mixture or in the solution.

**17.   Dosage**

Indicate the quantities or or the active principles expressed in units of

Weight, Volume or International Units (IU) per kg live weight according to your indication of use for different species and ages.

17.1. Dose of the product according to its indication of use by live weight according to species and age.

17.2. Interval Between Doses.

17.3. Duration of treatment.

**18.   Security Studies**

Scientific studies to ensure the effectiveness, stability and quality of the product to record developed by the manufacturer. Should include bibliographic history food safety and security.

**19.   Pharmacokinetics OF THE PRODUCT - Bioavailability**

Routes of absorption, distribution and elimination of the active principles or their

Metabolites.

**20.   Pharmacodynamics OF THE PRODUCT**(Summary)

**21.   Possible side effects (local or general), incompatibilities and pharmacologic antagonism**

21.1. Contraindications and limitations of use (cases in which his administration can lead to harmful effects).

21.2. Precautions that should be taken before, during or after administration.

**22.   Intoxication AND OVERDOSE IN ANIMALS**

22.1 margin of safety and safety in the target species or destination.

22.2 Symptoms, conduct of emergency and antidotes.

**23.   Intoxication IN MAN**

23.1 toxicological category.

23.2 You must indicate treatment, antidote and data from toxicological centers of reference

In the country.

**24.    Unwanted biological effects.**

You must declare whether the active components in the conditions of use,

Do not produce adverse effects as mentioned below, should contribute, if it existed, the scientific literature in this regard.

24.1. Carcinogenesis

24.2. Teratogenesis

24.3. Mutagenesis

24.4. Resistance to pathogens

24.5. Blood dyscrasias

24.6. Neurotoxicity

24.7. Hypersensitivity

24.8. On the reproduction

24.9. On the normal flora

**25.   Controls ON WASTE MEDICATED FEEDINGSTUFFS**

25.1. Data on Acceptable Daily Intake (ADI)

25.2. Maximum residue limit (MRL) in tissues (muscle, liver, kidney, fat), milk,

Eggs and honey.

25.3. Time that must elapse between the last treatment and the slaughter

For human consumption.

25.4. Time that must elapse between the last treatment and the fate of the milk,

Eggs or honey for human consumption.

**26.   General Precautions**

26.1 Maximum and minimum temperature for its proper preservation.

26.2 Describe the appropriate form of storage, transportation and destruction of the product, as well as the method of disposal of packaging that constitute a risk factor for public health, animal and the environment.

**27.   Causes THAT CAN VARY THE QUALITY OF THE PRODUCT**Precipitation, DISSOCIATIONS DIMINUTION or loss of activity of the active principles, cold, heat, light, moisture, compression on pallets or deposits.

**28.   Labels AND BROCHURES DRAFT LABEL.**

**29.   Scientific papers or monographs.**

You must attach the scientific work or studies related to the product. You must include the translation of the summary and conclusions of such works at

Spanish language.

Are attached to this request the registration requirements laid down in this Regulation. All information attached to this request, it is an integral part of the same. We declare that the information submitted is true and any alteration or false information,

Invalidates this request, without prejudice to the criminal responsibility that implies.

**Name and signature of the regent Name and signature of the registrant**

**Place and Date**

**A2-   REGISTRATION REQUEST FORM FOR BIOLOGICAL PRODUCTS FOR VETERINARY USE**

**1.   Commercial Product Name**

**2.   Common name AND CLASSIFICATION - (Official Use Only)**

**3. Property owner/applicant: LEGAL REPRESENTATIVE**

3.1. Name.

3.2. Exact address.

3.3. Country.

3.4. Number of the establishment registrant.

3.5. Technical Manager:

3.5.1. Professional identification number:

3.5.2. Place or means to receive notifications.

**4.   Manufacturing Facility (for products produced in the country)**

4.1. Name.

4.2. Exact address.

4.3. Country.

4.4. Number of the establishment.

**5.   Establishment FRACCIONADOR**

5.1. Name.

5.2. Exact address.

5.3. Country.

5.4. Number of the establishment.

**6. Definition OF BIOLOGICAL LINE (**vaccine antigens, hyperimmune sera, reagents for diagnosis)

**7.   Pharmaceutical Form**

**8. Qualitative Quantitative FORMULA - - Biological and chemical constitution**

8.1. Antigen: identification, amount per dose (title, antigenic mass, protein or other)

8.2. Hyperimmune sera: concentration in I.u.

8.3. Conservative inactivating;;; emulsifiers, stabilizers adjuvants or other

Substances.

8.4. Thinner: chemical and biological constitution if it contains.

**9.   Product development methodology**

9.1. Describe briefly the manufacturing process. Describe all steps

Necessary for the development of the registration form.

9.2. Product control methods in the process.

**10.   The FORM OF PRESENTATION AND CONTENT**

**11.   Packaging Specification AND CONTROL**

11.1. Characteristics of the container

11.2. System of inviolability

11.3. Quality Control of packaging

**12.**Maturity PERIOD OF VALIDITY (**)**

**13.   Indications FOR USE AND CATEGORY OF MARKETING.**

13.1. Major indications or complementary.

13.2. Animal Species for which it is intended.

**14.   Track OF APPLICATION AND FORM OF MANAGEMENT OR USE OF THE PRODUCT. (**Parenteral, oral, dermal, spraying, scarification, ocular, nasal spray or other).

**15.   Extemporaneous preparation products.**

15.1. Preparation of the product for its correct use.

15.2. Indicate Validity Period After reconstitution backed by studies of

Stability.

**16.   Dosage.**

16.1. Dose of the product in preventive or curative application by body weight by species

And age.

16.2. Outline of Implementation recommended.

16.3. Time required to confer immunity and duration of the same.

**17. Possible side effects (local or general), incompatibilities and ANTAGONISMS**

17.1. Contraindications and limitations of use (cases in which his administration can lead to harmful effects).

17.2. Precautions that should be taken before, during or after administration.

**18.   General precautions.**

Maximum and minimum temperature for its proper preservation. Describe the

Proper storage, transportation and destruction of the product, as well as the method of disposal of packaging that constitute a risk factor for public health, animal and the environment.

Are attached to this request the registration requirements laid down in this Regulation.

All information attached to this request, it is an integral part of the same.

We declare that the information submitted is true and any alteration or false information, invalid, this request, without prejudice to the criminal responsibility that implies.

**Name and signature of the regent Name and signature of the registrant**

**Place and Date**

**A3 -   APPLICATION FORM FOR SANITARY REGISTRATION FOR HYGIENE AND BEAUTY PRODUCTS FOR VETERINARY USE**

**1.   Commercial Product Name**

**2.   Classification (Official Use Only)**

**3. Property   owner/applicant: LEGAL REPRESENTATIVE**

3.1. Name.

3.2. Exact address.

3.3. Country.

3.4. Number of the establishment registrant.

3.5. Technical Manager:

3.5.1. Professional Identification Number

3.5.2. Place or means to receive notifications

**4.   Manufacturing Facility**

4.1. Name.

4.2. Exact Address

4.3. Country

4.4. Number of the establishment

**5.   Establishment FRACCIONADOR**

5.1. Name

5.2. Exact address.

5.3. Country.

5.4. Number of the establishment

**6.   Form Of Marketing**

**7. Specifications AND METHODS OF CONTROL OF THE COMPONENTS OF THE FORMULA.**

**8. Product development methodology**(Describe briefly the manufacturing process).

**9. Specifications AND METHODS OF CONTROL OF THE FINISHED PRODUCT (**indicate and describe the specifications and methods that are used

In the qualitative assessment of the components of the formulation in the finished product).

9.1. Microbiological Methods

9.2. Chemical Methods

9.3. Physical methods

9.4. Physical-chemical methods

**10.   The FORM OF PRESENTATION AND QUANTITY OF PRODUCT**

**11.   Packaging Specification AND CONTROL**

11.1. Characteristics of the container

11.2. System of inviolability

11.3. Quality Control of packaging

**12.   Validity period**(end of the lot)

**13.   Instructions for Use**

**14.   Target species**

**15.   General Precautions**

15.1. Maximum and minimum temperature for its proper preservation

15.2. Describe the proper way to storage.

**16. Causes THAT CAN VARY THE QUALITY OF THE PRODUCT (**Rainfall, disassociation, cold, heat, light, moisture, compression in rammers or deposit).

**17.   Labels and booklets - DRAFT LABEL**.

Are attached to this request the registration requirements laid down in this Regulation. All information attached to this request, it is an integral part of the same.

We declare that the information submitted is true and any alteration or false information, invalid, this request, without prejudice to the criminal responsibility that implies.

Name and signature of the regent Name and signature of the registrant

Place and Date

**A4- REGISTRATION REQUEST FORM FOR DIAGNOSTIC KITS FOR VETERINARY USE**

|  |  |  |
| --- | --- | --- |
| **1.** | **Commercial Product Name** |  |
| **2.** | **Classification (Official Use Only)** |
| **3.**  3.1. | **Property Owner/LEGAL REPRESENTATIVE**NAME. | **Applicant:** |
| 3.2. | Exact address. |  |
| 3.3. | Country. |  |
| 3.4. | Number of the establishment registrant |  |
| 3.5. | Technical Manager: |  |
| 3.5.1. | Professional Identification Number |  |
| 3.5.2. | Place or means to receive notifications |  |
| **4.** | **Manufacturing Facility** |  |
| 4.1. | Name. |  |
| 4.2. | Exact Address |  |
| 4.3. | Country |  |
| 4.4. | Number of the establishment |  |
| **5.** | **Establishment FRACCIONADOR** |  |
| 5.1. | Name |  |
| 5.2. | Exact address. |  |
| 5.3. | Country. |  |
| 5.4. | Number of the establishment |  |

**6.   Specifications AND COMPONENTS OF THE FORMULA.**

**7.   Technical SPECIFICATIONS OF THE FINISHED PRODUCT**

7.1. Sensitivity

7.2. Specificity

7.3. Reproducibility

7.4. Detection limit, when applicable.

7.5. Limit of quantification, when applicable.

**8.   The FORM OF PRESENTATION (NET CONTENT)**

**9.   Validity period**(end of the lot)

**10.   Instructions for Use**

**11.   General Precautions**

11.1. Maximum and minimum temperature for its proper preservation

11.2. Describe the proper way to storage.

**12. Causes THAT CAN VARY THE QUALITY OF THE PRODUCT (**cold, heat, light, moisture, compression in rammers or deposit).

**13.   Labels and booklets - DRAFT LABEL**.

Are attached to this request the registration requirements laid down in this Regulation. All information attached to this request, it is an integral part of the same.

We declare that the information submitted is true and any alteration or false information, invalid, this request, without prejudice to the criminal responsibility that implies.

Name and signature of the regent Name and signature of the registrant

Place and Date

**A5-   RENEWAL APPLICATION FORM OF SANITARY REGISTRATION FOR VETERINARY MEDICINES AND RELATED PRODUCTS**

1. The name of the applicant company:

2. Number of sanitary registration of the company:

3. Name of the owner or legal representative:

4.  Renewal (No. of sanitary registration):

5.  Address:

6.  Telephone and fax:

7.  E-mail:

8.  Place or means for receiving notifications:

9. Brand name product:

10. Manufacturer:

11. Country of origin:

12. Code:

13. Status:

14. Name of the professional (Regent) requesting the sanitary registration:

15. Professional identification number:

16. Telephone

17. Mobile Phone:

18. E-mail:

Are attached to this request for renewal of registration requirements laid down in this Regulation.

All information attached to this request, it is an integral part of the same. We declare that the information submitted is true and any alteration or false information,

Invalidates this request, without prejudice to the criminal responsibility that implies.

Name and signature of the regent Name and signature of the registrant

Place and Date

**Annex B (normative)**

**Certificate of Free Sale (CLV)**

It should be issued by the competent authority of the country of origin, consist in original and in force, with the appropriate consular processing and contain the following information:

It is certified by the present, at the request of the Government of (name of the country), that the veterinary products listed below, in accordance with (law of the country of origin), is made(n) and markets(n) in (country) by (name of company), which was established (full address), with sanitary registration No. (sanitary registration number of the establishment), the owner of the sanitary registration, prepared by-for (in the event of a maquila), trade name, dosage form, formula of active ingredients, in accordance with the International System of Units, indications, target species (specify), no sanitary registration, validity of the sanitary registration, validity of the document (country, city, date), stamp and signature of the competent authority.

If the GLC from countries outside of Central American area does not contain all the information referred to in this Annex, the competent authority must issue a supplementary document with the missing information.

If the medication or product Akin does not possess Certificate of free sale because it is not marketed in the country of origin, the competent authority must issue a certificate of product intended for export containing at least the information mentioned above for the GLC and the reason(s) for which the same is not marketed in that country.

In the event that this document does not declare  the origin, the interested party must submit in addition a certificate of origin issued by the corresponding authority of the country of origin.

**Annex C (normative)**

**Technical information OF SUPPORT TO REQUEST A SANITARY REGISTRATION OF VETERINARY MEDICINAL PRODUCT AND RELATED PRODUCT.**

**A. Drugs, chemicals and ECTOPARASITICIDES FOR VETERINARY USE**.

**1.**Description of the process of elaboration.

**2.** Information on the origin of the raw materials, other ingredients described in a pharmacopoeia and packaging materials.

**3.** Pruebas for stability (specifications for the term of validity, description of the studies, results and conclusions).

**4.** Andstudios of waste disposal or verification of the withdrawal period and discard, the product to register.

**5.**For veterinary drugs generics, in addition to present bioequivalence.

**6.** Para medicines with innovative or new molecules, except products in alternative medicine, in addition to present:

6.1. Security testing in the target species, with their corresponding bibliographic references.

6.2. Clinical Documentation: studies of efficacy and dose determination.

6.3. Biological studies of unwanted effects

6.3.1. Carcinogenic

6.3.2. Teratogenic effects

6.3.3. Mutagenic

6.3.4. Resistance to pathogens, as appropriate.

6.3.5. Blood Disorders

6.3.6. Neurotoxicity

6.3.7. Hypersensitivity

6.3.8. On the reproduction

6.3.9. On the digestive flora, as appropriate.

6.4. Studies of environmental impact made by the manufacturer.

**B.   Veterinary biological products.**

**1.**Define and characterize the strains (master seed and production lines)

**2.**Degrees or sensitivity tests.

**3.**Information on the container and system of the inviolability of the container or packaging.

**4.**Studies and immunological properties when appropriate.

**5.**Production methods.

**6.** Protocolo manufacturing process (Preparation and incubation of the parent organization of planting, as appropriate); production of the Agency work planting, harvesting (handling and preparation, minimum and maximum period of time from inoculation to harvest), cultivation of plates, preparation of the pre-inoculum and inoculum, inactivation of the antigen, the antigen concentration, vaccine production, preparation of the product (composition of the preservative and adjuvant chemotherapy), method and degree of concentration, product information, method of packaging and desiccation, amount of antigen per dose, material evidence  (purity, safety, security, power and identity)

**7.** Information on the origin of the raw materials, other ingredients described in a pharmacopoeia and packaging materials.

**8.** Pruebas of control of the finished product (specifications for the term of validity, description of the studies, results and conclusions).

**9.** Pruebas stability and its protocol (specifications for the term of validity, description of the studies, results and conclusions).

**10.**For innovative biological product also present:

**10.1.**Security testing in the target species, with their corresponding bibliographic references.

**10.2.**Clinical Documentation: studies of efficacy and dose determination.

**10.3.**Biological studies of unwanted effects:

**10.3.1.**Carcinogenic

**10.3.2.**Teratogenic effects

**10.3.3.**Mutagenic

**10.3.4.**Blood Disorders

**10.3.5.**Neurotoxicity

**10.3.6.**Hypersensitivity

**10.3.7.**On the reproduction

**10.4.**Studies of environmental impact made by the manufacturer.

**-Appendix I OF ANNEX C-**

**Criteria FOR THE VERIFICATION OF THE WITHDRAWAL PERIOD AND/OR DISPOSAL OF VETERINARY DRUGS**

The States Parties agree to the implementation of the literal to numeral 4 of Annex C of the RTCA Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control, under the following criteria:

**1.**The verification of the withdrawal period and/or discard1 must be done to veterinary medicinal products used in food producing species for human consumption, once in the commercial life of the product and the study must be recognized by the other States Parties.

**2.**Compliance with the check should be carried out in accordance with the approved calendar of gradual implementation, for substances contained in the following table:

|  |  |
| --- | --- |
| **Timetable for the contribution of studies of checking times of withdrawal, and/or discard as active ingredients of most interest** | |
| **Present from the year** | **Veterinary drugs with the active principle** |
| 2018 | Enrofloxacin and Florfenicol |
| 2019 | Β lactam and Amidinas |
| 2020 | Sulfonamides and organophosphate pesticides |
| 2021 | Bencimidazoles |
| 2022 | Oxitetraciclinas |
| 2023 | Antibiotics of different groups to those previously included |
| 2024 | Internal and external antiparasitic different from above  Including |
| 2025 | Analgesics, hormonal and other drugs |

**3.**The check must be performed by product, not by active principle.

**4.**States Parties should review the lists of active principles and pharmacological groups most at risk in order to update them, in such a way that at the end of the process and, where appropriate, all veterinary medicinal products used in food-producing species with the respective study of checking of the withdrawal period and/or discard.

1 Thewithdrawal period and/or discard: it is understood by the withdrawal period the time interval between the last administration of a veterinary medicinal product to animals, under normal conditions of use and the time of sacrifice of that animal for human consumption or the period during which must be discarded milk, eggs and honey, required for the residue and metabolite of the veterinary medicinal product to achieve the internationally accepted safety levels.

**5.**When there is evidence of risk of a product can be pursue the reevaluation of the withdrawal period and/or discard approved, as recommended by Article 112(c) of the Guideline of Codex CAC/GL 71-2009 or that corresponds in its current version.

**6.**When you have expanded use of veterinary medicinal products toward other species for human consumption, the withdrawal period and/or discard that declares, is subject to a study for the new species, except when you apply the extrapolation.

**7.**When there are changes in the dosage of a veterinary medicinal product registered, the withdrawal period and/or discard is subject to a study by checking for the new dosage.

**8.**When there are changes of excipients in a veterinary medicinal product regist rado, the withdrawal period and/or Discard to declare is subject to a study, if the excipient modifies pharmacokinetic characteristics of the product.

**9.**In the case of combinations of active ingredients to fixed doses, the check should be done for that active substance that has the withdrawal period and/or discard longer period, individually.

**10.**The verification of the withdrawal period and/or discard is applicable to veterinary medicinal products of new health registration and subject to renewal that should not have made the studies at the time of the sanitary registration and in accordance with the schedule approved in paragraph 2 *above*.

**11.**In cases in which a same manufacturer makes a product with different trade names, but identical to that account with the study of the determination of the withdrawal period and/or discard, does not require an individual study for each of the products.

**12.**If you are prompted to extend the route of administration of a similar product authorized for the reference product, you must submit a study of waste disposal or verification of the withdrawal period and/or discard for that new track.

**13.**For the study of the withdrawal period and/or discard you must use the following tools:

A. Guide to the study protocol.

B. Procedure for the implementation of the Protocol.

**-End of document-**

**-Appendix II of Annex C-**

**Procedure TO IMPLEMENT THE GUIDE OF THE PROTOCOL FOR VERIFICATION OF THE WITHDRAWAL PERIOD AND/OR DISPOSAL OF VETERINARY DRUGS**

1.  The applicant must request in writing to the competent authority approval to carry out the verification trial of the withdrawal period and/or discard and submit the following documents:

(A) Request in writing .

B) provide the test protocol, for each target species or by-product of consumption

Human being signed by the veterinarian responsible for the test.

(C) If the study is through a third party, submit the authorization or power of the manufacturer

For this purpose and the request in writing.

2.  The request must contain:

(A) the name of the product.

(B) active ingredient to evaluate.

C) species in which it applies. d) therapeutic use.

E) Route of administration.

F) dose and duration of treatment.

G) the  withdrawal period and/or Discard to check.

H) registration number of the veterinary medicinal product, when you apply. i) expiration date of the sanitary registration, when you apply.

J) Manufacturer and country of origin.

K)  where the trial.

L) Person to contact their phone numbers and e-mail address.

3.  The competent authority must then contact the applicant and set a date to coordinate everything related to the trial, according to established deadlines in each State Party.

4.  Veterinary medical officer and the veterinarian responsible for the field testing, must perform the inspection of the establishment where you are going to perform the test, by verifying the following:

(A) adequate facilities: poultry, chute (press), manga (chutra) and scales. b) the identification and registration of animals.

C) During the test you must guarantee to all animals animal welfare conditions, according to the laws of each State Party (management, food and health).

(D)  appropriate healthcare management plan.

5.  The veterinarian responsible for the essay should evaluate the health conditions of test animals, according to the Protocol.

6.  For the implementation of the veterinary medicinal product requires the obligatory presence of the veterinary medical officer, who should endorse by signing the appropriate form.

7. During the execution of the veterinary medical officer can perform verification visits, in coordination with the person concerned.

8.  Sampling.

8.1. The taking of samples is carried out by the veterinary medical officer in the establishment.

8.2. A mechanism should be established to ensure the custody and integrity of the sample until it is delivered to the approved laboratory. The same shall be entered in the respective protocol.

8.3. The applicant is responsible for removing the samples and deliver them to the approved laboratory while respecting the integrity of the same.

8.4. A mechanism should be established to ensure the custody and integrity of contramuestra, which must be stored in official custody, and must be entered in the respective protocol.

8.5. The interested party must develop the final report as set out in Annex 4, by providing all the support documentation to original for the record of the sanitary registration or renewal.

8.6. The analysis and interpretation of the results must be made as indicated in the guide of the Protocol.

9.  The competent authority must communicate in writing to the person concerned the results as the case may be:

(A) If the result is satisfactory, you must issue a resolution accepting the test.

(B) If the outcome is not satisfactory, you must issue a resolution communicating the rejection

Telling you that you must perform a study of waste disposal, according to international standards, you can assign its period of removal and/or discard. The applicant may appeal this resolution according to the internal mechanisms of each State Party.

C) does not comply with the requests contained in subparagraph (b), for products in the process of sanitary registration or renewal, the competent authority may cancel or deny your sanitary registration and inform the instances that correspond.

D)  essays must be countersigned by the competent authority where health care

Carry out.

E) After evaluation of the case the person concerned for the only time can reshape the formulation, without changing the principle(s) Active(s) nor concentration; only with the purpose of correcting the kinetics of the veterinary medicinal product and make a new verification trial of the withdrawal period and/or discard.

**-End OF TECHNICAL PROCEDURE-**

**-Appendix III OF ANNEX C-**

**A GUIDE TO THE PROTOCOL FOR VERIFICATION OF THE WITHDRAWAL PERIOD AND/OR DISCARD OF VETERINARY MEDICINAL PRODUCTS USED IN FOOD-PRODUCING ANIMALS FOR HUMAN CONSUMPTION IN THE UNITED PARTY**

**1. Introduction**

The study of verification of the withdrawal period and/or discard is a test in a single point of failure in the tissue marker taking technical validity, but limited to the comparison of the results of the withdrawal period and/or discard with the veterinary medicinal product of reference or BIOEQUIVALENT, which uses fewer animals and the result only indicates if the check is accepted. This test only sets, if residue levels even after applying a tolerance of 95% (UTL 95%), presents values equal to or less than the maximum residue limit (MRL) allowed in the point (in time) that has been selected for the test. It calculates the period of withdrawal, and/or discard, but if it confirms a specific period of retirement and/or discard, compared with the veterinary medicinal product of reference or bioequivalent.

**2. Background**

According to the laws of each State Party where you perform the study.

**3. Criteria for determining the need for a study of residues or a study of verification of the withdrawal period and/or discard**

The criteria for determining which veterinary medicinal products must be subjected to a study of verification of the withdrawal period and/or discard, depends on the type of veterinary drug product similar in question, of the active ingredient(s) present and indications of use, where you must take into account the specifications described below.

The competent authorities must assess the relevance and validation of the analytical methodologies used.

Residue studies or verification of the withdrawal period and/or discard, should be performed for veterinary medicinal products used in animals whose products and by-products are intended for human consumption.

**3.1 Veterinary Drugs that DO NOT REQUIRE verification studies of the withdrawal period and/or discard in a single point:**

Are excluded from this type of studies the following groups:

A) Veterinary drugs generics or similar with identical formulations, or with the same amount of active ingredient of the reference medicinal product; where it has been demonstrated bioequivalence.

B) Veterinary Drugs that demonstrate that the bioavailability of the active ingredient(s) in the(s) species(s) destination is less than or equal to the reference product and whose period of retirement and/or discard is 0 to 2 days.

**3.2 Veterinary drugs that require at least a study of verification of the withdrawal period and/or discard (in a single point):**

A) veterinary drugs in generic/similar where bioequivalence testing in the(s) species(s) of destination, the bioavailability of the active principle remains higher than that of the reference product, during the entire period of retirement and/or discard recommended for the reference product.

(B) similar veterinary drugs that have not shown bioequivalence with the reference product.

C) the veterinary medicinal products which have been modified any of the excipients and has security that alters the bioavailability of the active ingredient(s) in the kind(s) of destination in the tissues markers.

**4. Interpretation of the results of the verification of the withdrawal period and/or discard:**

(A) If the study demonstrates that the upper limit of the tolerance of 95% unilateral (UTL) presents residue values less than or equal to the corresponding MRLS, the check is accepted. The statistical test to be used is:

**Gkl**= Average + kSDm.

**Gkl**= upper limit of the Tolerance to the average in the single point.

**SDm**= standard deviation (typical) of the sample.

**K**= constant that is taken from the table in the Limit of unilateral Tolerance Factor

95% (75th percentile with a confidence of 95%), for a normal distribution.

: Statistical tool that Shapiro-Wilk test is used to determine the normality of the data obtained from the study of verification of the withdrawal period and/or discard.

When evaluating the data and these do not present a normal distribution according to the Shapiro-Wilk formula, the methodology described above for verification of the withdrawal period and/or discard is not applicable, therefore, you must use an alternative method is to increase the withdrawal period and/or disposal of the product of reference in a range between 10-30% depending on the risk of the product, according to EMA/CVMP/036/95, p. 11 and 12.

(B) If the study demonstrates the opposite, i.e. that the residues above the MRL then the test is not accepted and you cannot use the period established by the reference product so it should be a study of depletion of residues.

C) Methods of analysis and evaluation: This should include methods for the analysis and evaluation of the active principle. The methodology must be of reference (CODEX-FDA-EMA) or be validated scientifically (you must provide the complete analytical method with its corresponding validation).

(D)  The measurement point to consider is the last time (day, hours, among others) of the withdrawal period and/or discard of the veterinary medicinal product reference or bioequivalent.

E) Schedule of activities and implementation: schedule all activities that must be developed to comply with the objective of the study.

F) The number of animals or animal products should be as described in the following table:

**Table 1\***

|  |  |  |  |
| --- | --- | --- | --- |
| **Animal species/product** | **Product** | **State**  **Productive** | **Quantity**  **Minimal** |
| Of slaughter animals  (Ruminants/pigs/equines\*\*) | Marker tissue | Intended for slaughter | 6 animals |
| Cattle | Milk | Breastfeeding | 10 Animals |
| Birds | Marker tissue | Intended for slaughter | 12 (in mixtures  The tissue of two in two) |
| Birds | Eggs | -------- | 12 eggs of different birds |
| Rabbits/guinea pigs | Marker tissue | Intended for slaughter | 10 |
| Bees | Honey | -------- | 5 hives of the  Same apiary |
| Fish | Tissue  Bookmark | Ready for Harvest | 15-20 fish per  Pond Treaty |
| Shrimp | Marker tissue | Ready for Harvest  (The End) | 2 kg of shrimp  Integer by pond |

**\***According to the Committee's Technical Reference Guide of the Americas of Veterinary Medicinal Products (CAMEVET), for the conduction of studies of metabolism and kinetics of residues of pharmacological agents of Use

Veterinary in food-producing animals. Waste disposal studies to establish

Periods of withdrawal, and/or discard the veterinary medicinal product.

**\*\***In those States where the horses are intended for human or animal consumption.

**5.  General Report:**

Start date of the essay:

Date of completion of the test:

**Product:**

Brand name product:    Active ingredient and concentration:

Manufacturer:

Country of origin:

The importer and/or distributor:    Date of manufacture of the product:    Date of expiry of the product:    Number of lot:

Presentation:

Target species or by-products intended for human consumption:    Route of administration or application:

Dose and duration of treatment:

The withdrawal period and/or discard:

**Finca or exploitation:**

The name of the exploitation:   Country:

Owner:

Address of the owner:

Phone:

E-mail:

Geo-referenced address of the farm:

**Animals treated:**

Time of receipt of the product: (days, hours, among others).

Time of treatment: Date of application of product: No. of animals treated:

Date of shipment sacrifice:

\_ (Days, Hours, among others).

Way of application:

**Portion of the sample in slaughter:**

Date of receipt of animals at the slaughterhouse:

Date of slaughter:

Time:

Date of the samples:    No. samples collected:     Marker tissue where the sample is:    Person responsible for taking the samples:    Name of the veterinary medical officer responsible:

Responsible for the retirement and/or discard of samples:

Means of conservation of the sample:

Date of withdrawal and/or discard of samples:

**Lab:**

The name of the approved laboratory:    Institution to which the laboratory belongs:    Date and time of received from the samples in the laboratory:

Temperature of received of the sample in the laboratory.

**Analysis and interpretation of the results:**

Entity that conducted the analysis:

Professional who conducted the analysis:

The name of the person responsible essay:

Signature:

Approval of the competent authority:

Name Signature:

**6.  A guide for the implementation of the study:**

**6.1 Requirements for the verification tests of the withdrawal period and/or discard: General Aspects**

For the realization of the verification tests of the withdrawal period and/or discard it must comply with the following guidelines:

A) The protocol for the execution of the  test must be approved by the competent authority.

B) use methodologies that allow us to predict the behavior of the veterinary medicinal product in the target species.

(C) The laboratories or institutions, as well as the professionals responsible for the implementation of the analytical tests must be previously authorized by the competent authority, for the realization of that test and comply with the ethical principles in relation to the confidentiality and transparency.

D)  The institutions, laboratories or companies responsible for the implementation of the analytical test must have proven experience to the realization of the same, as well as installations and equipment in accordance with the methodology to be used.

E) must be performed as many studies of evidence of waste, such as species intended for human consumption have the veterinary medicinal product to analyze and if applicable, include the extrapolation of species.

F) The competent authority of the country where the trial is responsible for evaluating and approving the protocols of studies to test the withdrawal period and/or discard and must participate in the supervision of the evidence, at least the dates of application of the product and in the sampling of tissues or products.

**Objective**

To establish the criteria or principles for conducting verification of the withdrawal period and/or discard of veterinary medicinal products that require it in the States Parties.

**6.2 Methodology of the study**

**6.2.1 Reference Standards**

A) Technical Guide of the Committee of the Americas of Veterinary Medicinal Products (CAMEVET), for the conduction of studies of metabolism and kinetics of residues of pharmacological agents for veterinary use in food-producing animals. Waste disposal studies to establish periods of withdrawal, and/or discard the veterinary medicinal product.

B) Guide VICH GL48.

**6.2.2 veterinary medicinal product which is the subject of study**

Description of the veterinary medicinal product in study.

**6.2.3 Species(s) or product(s) in which the study is conducted**

According to the species(s) or product(s) of the test.

**6.2.4 Health Status of the animals and farms**

**6.2.4.1 Characteristics and sanitary conditions of animals which are the subject of the study**

A) representative animals of the species which is indicating the product. b) good health (clinical examination).

C) Animals without signs consistent with diseases.

D)  good body condition.

E) of slaughter animals or in different stages of production depending on whether the product

That is to check your withdrawal period and/or discard.

F) The animals submitted to the evaluation must not have received treatment with any

Veterinary medicinal product that interferes with the results of the study.

**6.2.4.2 Characteristics of the holding or the farm**

(A) adequate facilities: poultry, chute (press), manga (chutra) and scales.

(B) Identification and registration of animals. Animals must be identified in a way

Secure.

C) The farm must have a general management system that allows adequate nutrition

Of the animals on the basis of their nutritional requirements.

**6.2.4.3 Number of animals needed for the study**

The number of animals according to Table 1.

**6.2.4.4 veterinary medicinal product to evaluate**

Veterinary medicinal products to be used must be supplied by the interested party, ensuring that have been stored in accordance with the provisions of the product label.

**6.2.4.5 Implementation of the veterinary medicinal product**

(A) The animals should be weighed so that the dose of the veterinary medicinal product administered is accurate, according to the maximum recommended dose.

(B) The application of the product should be by a veterinarian responsible for the essay, by the route used to establish the maximum residue limit (MRL) of the product

 Reference, under the direct supervision of a veterinarian designated official.

C) You must apply the maximum dose stated by the manufacturer on the labelling, and must be the

Maximum duration.

D)  The containers used of the applied products should be in the custody of the

Competent authority, until the completion of the study.

**6.2.4.6 Duration of the test and collection of information**

A) The assay has a duration corresponding to the period of removal and/or discard the veterinary medicinal product .

B) During the test you must guarantee to all animals animal welfare conditions (management, food and health).

C) During the test must not be applied no veterinary medicinal product that may affect

The results of the test.

(D)  Any animal that present any  clinical sign during the test, you must be

Excluded from the same.

E) During the test, the information must be collected by technicians from the

The applicant laboratory of the study and endorsed by the veterinary medical officer designated by the competent authority.

F) The test must be carried out Monday through Friday, during working hours of the veterinary medical officer designated by the competent authority.

**6.2.4.7   Sacrifice and takes shows**

A) Animals should be slaughtered in a single day, process plants and by-products in establishments of primary production, where the samples and referee should be collected under the supervision of the veterinary medical officer.

(B) The identification of samples and the referee, must maintain traceability.

C) Type of tissue samples: marker or by-product, according to the veterinary medicinal product evaluated in accordance with Annex 3.

D)  minimum weight of the sample and contramuestra, required depending on the species and the trial.

**6.2.5 Results**

A) at the time of issuing the results, the laboratory must submit the original thereof to the person concerned and a copy to the competent authority.

(B) The applicant must develop the final report as set out in Annex 4, providing

All supporting documentation in original, for the registration dossier or renewal of the product.

**6.2.6 Trial Costs**

The costs associated with the test should be assumed by the interested party.

**Annex 1**

**List of ANIMALS TO TREAT**

**For THE VERIFICATION TEST OF WASTE**

**Date of the weigh-in:    Species:    Raza:**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Identification** | **Sex** | **Live weight**  **Kg.** |
| **1.** |  |  |  |
| **2.** |  |  |  |
| **3.** |  |  |  |
| **4.** |  |  |  |
| **5.** |  |  |  |
| **6.** |  |  |  |

The name of the veterinarian responsible for the manufacturer:    Signature:

Name of the veterinary medical officer: Signature:

**Remarks:**

**Annex 2**

**Application of the product**

Product name:   Therapeutic Use:     Active ingredient and concentration:    The withdrawal period and/or Discard to check    Presentation:

Lot Number: Date: Expiration date:    Number of registration: Laboratory Manufacturer:    Country of origin:

Date of administration of the product:    Veterinarian responsible for the essay:    Professional code:

Veterinary medical officer:

Provide the certificate of analysis of the batch of product to be used in the test.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Number** | **Identification of the animal** | **Dose applied** | **Route of administration** | **Date for sample collection** |
| **1.** |  |  |  |  |
| **2.** |  |  |  |  |
| **3.** |  |  |  |  |
| **4.** |  |  |  |  |
| **5.** |  |  |  |  |
| **6.** |  |  |  |  |

**Custody**: for the packaging of the product applied remain under custody of the competent authority until the end of the study.

The name of the veterinarian responsible for the essay:    Signature:

Name of the veterinary medical officer:

Signature:

**Annex 3**

**Registration, quantity, TYPE AND IDENTIFICATION OF THE SAMPLES**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sample** | | | | |
| Date of sampling: | | | The name and number of the establishment where the sample is: | |
| Name of the laboratory to which refers the sample: | | | Product name: | |
| Name of the veterinary medical officer: | | | Date of receipt of sample: | |
| **Shows**  **No.** | **Identification of**  **The sample** | **Type of sample** | | **Sample weight in**  **Grams** |
| **1.** |  |  | |  |
| **2.** |  |  | |  |
| **3.** |  |  | |  |
| **4.** |  |  | |  |
| **5.** |  |  | |  |
| **6.** |  |  | |  |

Name and signature of the official veterinarian:

   End Of Document

**Annex 4**

**Paragraphs TO DEVELOP IN THE FINAL REPORT OF THE**

**Check THE WITHDRAWAL PERIOD AND/OR DISCARD OF VETERINARY MEDICINAL PRODUCTS USED IN FOOD-PRODUCING ANIMALS FOR HUMAN CONSUMPTION IN THE UNITED PARTY**

The final report must contain the following sections:

1.  Title

2.  Author(s) of the study

3.  Summary in spanish and english or another language

4.  Introduction

5.  Materials and methods

6.  Results and Discussion

7.  Conclusions

8.  References

**Annex D (normative)**

**Items TO BRING WHEN YOU APPLY THE MAQUILA MANUFACTURING CONTRACT OR**

1.  Identification and legal capacity of the contracting parties.

2.  The duties and responsibilities of each party, in connection with the manufacture, handling, storage, release, labelling, re-packaging and/or re-packaging of the product, when you apply.

3.  The responsibilities of each party, in relation to the quality, safety and efficacy of the product.

4.  Express manifestation of the acceptance of the agreements reached by the parties with respect to the points mentioned in this Annex.

5.  List of each of the products, which should be annexd and can be modified when necessary.

**Annex E (normative)**

**Typology AND REQUIREMENTS FOR MODIFICATIONS TO THE HEALTH REGISTRY (ANNOTATIONS MARGINAL)**

**A.  Modifications that require prior approval of the competent authority**

**A.1. Modifications related with establishments**

|  |  |
| --- | --- |
| **Type of modification** | **Requirements** |
| A.1.1. Change of:  A) Manufacturer, preserving its origin  B) c) Bond Fraccionador  D) the  registration holder manufacturer and marketer of health)  F) Veterinary Pharmacy or dispensing Storer (g) | 1. Request signed and sealed by the registrant and regent.  2. Copy of the current operation granted by the  Competent authority stating the new social reason, in accordance with the laws of each State Party.  3. Legal status or constitution, updated, or document Identity of the person (natural, individual) (if the property is national).  4.  Proof of payment, when  Appropriate. |
| A.1.2. Change of the holder of the sanitary registration does not manufacturer | 1. Request signed and sealed by the registrant and regent.  2. Document issued by the competent authority stating the new   Social reason, according to internal regulations of each State Party.  3. Legal status or constitution, up-to-date, if the establishment is national.  4.  Proof of payment, when  Appropriate. |
| A.1.3. Change the registrant or office registrant. | 1.  Request signed and sealed by the registrant and the regent  2.  Legal status or constitution, up-to-date, if the  Establishment is national.  3.  Notarized power of the owner of the registration  Where you delete previous rights and |

|  |  |
| --- | --- |
|  | Indicates the new, with the respective consular procedures where appropriate.  4.  Proof of payment, when  Appropriate |
| A.1.4. Change or extension of legal representatives | 1.  Request signed and sealed by the  New(s) legal representative(s)  2. Power notarized and with respective consular procedures, where appropriate, attesting to the change or extension. If the owner of the registration and the new legal representative belong to the same establishment is within the discretion of each State Party the application of this requirement under its legislation  3.  Legal status or act of  Constitution, updated, or current document of identity of the natural person (natural, individual) (if the property is national)  4. Proof of payment, when appropriate. |
| A.1.5. Change of Registrant  Health workers by assignment or sale of registration, without altering the source | 1.  Request signed and sealed by the  The registrant and regent.  2. Legal document evidencing the assignment  Or Sale of the sanitary registration, where the change of the holder, with the respective consular procedures, where appropriate  3.  When the veterinary medicinal product or related product is manufactured by a different company to the new holder of the sanitary registration, contract must be updated in the maquila, original or copy of the document duly legalized, in accordance with the provisions set out in Annex D to this Regulation.  4.  Proof of payment, when  Appropriate |
| A.1.6. Change in the manufacturing site within the same country | 1.  Request signed and sealed by the registrant and regent |

|  |  |
| --- | --- |
|  | 2. Copy of the document of operation granted by the competent authority stating the new manufacturing site  3. Original or certified copy of the official document of compliance with  Good manufacturing practices or certificate of good practices  Manufacturing issued by a recognized entity  4. Proof of payment, when appropriate. |
| A.1.7. Change of fraccionador | 1.  Request signed and sealed by the  The registrant and regent  2.  Copy of the document of  Current operation granted by the competent authority  3. Original or certified copy of the official document of compliance with  Good manufacturing practices or certificate of good practices  Manufacturing issued by a recognized entity.  4.  When the veterinary medicinal product or related product to be manufactured, by a  Company other than the new holder of the sanitary registration, you must submit  Maquila contract date, in original or copy of the document  Duly legalized, in accordance with the provisions set out in Annex D of the  This Regulation.  5.  The competent authority shall, with due  Technical justification, you can request the realization of risk analysis.  6.  Proof of payment, when  Appropriate |
| A.1.8. Change or extension of the regent vet | 1.  Request for change or extension signed and stamped by the registrant and  Regent, complying with the requirements of the laws of each State Party.  2.  Proof of payment, when appropriate. |

**A.2. Modifications related to product registration**

|  |  |
| --- | --- |
| A.2.1. Currency risk group1. Request signed and sealed by the person concerned2. Technical or scientific documentation to justify the change or modification.3. Proof of payment, cuandocorrespondaA.2.2. Change of manufacturer1. Request signed and sealed by the registrant and indicating eltermino regent of the contractual relationship with the previous manufacturer and specifying thenew.2. Copy of the document in force of the new manufacturer ofoperation granted by the competent authority3. Original or certified copy deldocumento compliance officer of good manufacturing practices or Certificate of Good Manufacturing Practices issued by a recognized entity.4. When the veterinary medicinal product to be manufactured oproducto akin, by a company other than the |  |
|  | new holder of the sanitary registration, contract must be updated in the maquila, original or copy of the document duly legalized, in accordance with the provisions set out in Annex D to this Regulation.5. Legal document before a notary of the owner of the registration, which must indicate that the conditions under which he was awarded the health registration of the product has not been modified or scientific technique.6. Project of the packing, packaging and labelling with the new manufacturer7. Accelerated stability study or, failing that, the commitment of the contribution of the |

|  |  |
| --- | --- |
|  | Accelerated stability study and the implementation of the study of long-term stability.  8.  The competent authority shall, with due technical justification, you can request the  Realization of the risk analysis.  9.  Proof of payment, when appropriate. |
| A.2.3. Change or modification in the name  Commercial Product Name | 1.  Request signed and sealed by the  The registrant and regent with the justification of the change or modification issued by the holder of the health registration of the product.  2.  In the case of imported products, you must submit a document issued by the competent authority of the country of origin that declares the name change and that keeps the product specifications  3.  Project of the labeled with the new trade name.  4. Proof of payment, when appropriate.  Note 1. It allows the change of trade name for products intended for certain markets as long as they keep the technical specifications and is identified in the Certificate of Free Sale or an official document. |
| A.2.4. Change or extension in the  Commercial presentation  (Variation in the amount of unit packaging, weight or volume of filling) | 1.  Request signed and sealed by the  The registrant and regent with the justification of the change or extension issued by the holder of the health registration of the product.  2.  In the case of imported products, you must submit a document issued by the competent authority of the country of origin to declare the change or extension of commercial presentation and that keeps the product specifications.  3.  Project of the labelling of each new  Commercial presentation. |

|  |  |
| --- | --- |
|  | 4.  Stability study, when required.  5.  Proof of payment, when appropriate. |
| A.2.5. Changes or expansion in the  Technical product information and information from the labelling primary, secondary and insert  A. indications,  B. contraindications, precautions, c.  D.  Target species, e. dose,  F. route of administration, g. side effects,  H. side effects, i. period of removal,  J. toxicological band,  K.  The name of the active principle  Or the biological agent  L.  Others. | 1.  Request signed and sealed by the  The registrant and regent with the justification of the change or extension issued by the holder of the health registration of the product.  2.  In the case of imported products, you must submit a document issued by the competent authority of the country of origin to declare the change or extension of the product specifications.  3.  Provide recognized scientific literature or scientific studies that support the changes requested  4.  Draft of labelling with the changes  Requested.  5.  Proof of payment, when  Appropriate. |
| A.2.6. Change in the useful life period | 1.  Request signed and sealed by the registrant and regent with the justification  The change issued by the holder of the health registration of the product.  2.  In the case of imported products, you must submit a document issued by  The competent authority of the country of origin indicating and approve the  Change the useful life period.  3.  Study of long-term stability.  4.  Proof of payment, when appropriate. |
| A.2.7. Change in the conditions of  Storage | 1.  Request signed and sealed by the  The registrant and regent with the justification of the currency issued by the holder of the health registration of the product.  2.  In the case of imported products,  You must submit a document issued by the competent authority of the country of origin indicating and approve the |

|  |  |
| --- | --- |
|  | Changing the conditions of storage.  3. New accelerated stability study, with a commitment to submit  Subsequently, the study of long-term stability.  4.  Project of the tagged with the requested changes.  5.  Proof of payment, when appropriate. |
| A.2.8. Change or addition in the type of  The primary packaging material or container-closure system | 1.  Request signed and sealed by the  The registrant and regent with the justification of the currency issued by the holder of the health registration of the product.  2.  In the case of imported products,  You must submit a document issued by the competent authority of the country of origin indicating and approve the change or addition in the type of primary packaging material or system of container-closure.  3.  Accelerated stability study, with a commitment to subsequently to submit the study of long-term stability.  4.  Displays the new primary packaging material or system of container-closure  5. Proof of payment, when appropriate. |
| A.2.9. Change in excipients | 1. Request signed and sealed by the registrant and regent with the technical justification for change issued by the holder of the health registration of the product.  2.  In the case of imported products,  You must submit a document issued by the competent authority of the country of origin indicating and approve the change in excipients.  3. New formula of complete quantitative composition qualities, in original, issued by the technician responsible for the laboratory or by the technician responsible designated by the manufacturer, that includes the |

|  |  |
| --- | --- |
|  | Product name, ingredients and excipients expressed according to the International System of Units.  4.  Accelerated stability study, with a commitment to submit  Subsequently, the study of long-term stability, when you apply.  5.  Proof of payment, when appropriate. |
| A.2.10. Change of the material or dimensions  The secondary packaging | 1.  Request signed and sealed by the  The registrant and regent with the approval of the owner of the registration  2.  In the case of imported products, you must submit a document issued by  The competent authority of the country of origin Approving the change to the owner of the registration, authorizing the change.  3.  Draft of the packing material  With the changes requested.  4.  Proof of payment, when  Appropriate |
| A.2.11. To change the design (image) of the primary packaging and labelling  Secondary | 1.  Request signed and sealed by the registrant and regent with the approval of the  The registration holder  2.  In the case of imported products,  You must submit a document issued by the competent authority of the country of origin Approving the change to the owner of the registration, authorizing the change.  3.  Project of the tagged with the new design  4.  Proof of payment, when appropriate. |
| A.2.12 Changes made in the registry of the  Establishment  that must be updated in the product registration:  1.  Change of manufacturer.  2. Change of manufacturer, preserving its origin, in-bond, head of the health registry manufacturer, owner of the sanitary registration does not manufacturer, | 1. Request signed and sealed by the  The Registrant and the regent for each of the products associated with the establishment.  2.  Proof of payment, when  Appropriate, for the amendment made to the record of each product. |

 Registrant registrant or office.

**B. Notifications. Modifications that do not require prior approval by the competent authority**

|  |  |
| --- | --- |
| **Type of modification** | **Requirements** |
| B.1. Discontinuation of recorded presentations | 1. Notification to the competent authority  2.  Request for updating the  Certificate of registration where appropriate |
| B.2. Change or extension of distributor | 1. Notification to the competent authority,  Complying with the requirements of the laws of each State Party |
| B.3. Update the method of analysis | 1. Notify and provide to the authority  The competent authority on the new method of analysis |
| B.4. Voluntary Cancellation of Registration  Health of a product | 1. Notification of the registrant and regent to  The competent authority on the voluntary cancellation of registration of a product. |

**Appendix F (normative)**

**Requirements TO APPLY FOR EXEMPTION FROM REGISTRATION OF VETERINARY DRUGS AND RELATED PRODUCTS FOR THE PURPOSE OF RESEARCH IN THE UNITED PARTY**

The applicant must provide the following documents to the competent authority:

1.  A written request with adequate justification technique that motivates the test to be carried out in the State Party concerned.

2.  Attach the test protocol as set out in the Agreement # 7 of this Regulation and the technical documentation .

3.  To comply with the provisions established by each State Party in relation to the use of experimental animals for research purposes.

4.  In the event that the product be imported, you must indicate in the test protocol the quantity of product to import and comply with the import formalities arranged in each State Party.

Once the application is approved and the test protocol, the interested party may start with the respective essay according to what is established in the same.

At the end of the essay, the interested party must submit a final report to the competent authority with the results obtained and the respective conclusions.

Related agreements to the RTCA 65.05.51:08 Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control, to be included in a resolution COMIECO.

**Agreement #1**

**List OF VETERINARY DRUGS AND RELATED PRODUCTS IN ACCORDANCE WITH YOUR RISK LEVEL**

The listing of products included in each one of the groups listed in the regulation RTCA 65.05.51:08 Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control, it is defined and published by the competent authority in each State Party and serves for the implementation of drug control and pharmacovigilance in accordance with the capacity and resources that possess each one of them.

**Agreement #2**

**Coding OF VETERINARY DRUGS AND RELATED PRODUCTS.**

The encoding of veterinary medicines and related products is detailed in the following way:

1.  For veterinary drugs put sequential number, the acronym MV-.

2.  For related products put the acronym AV sequential number.

3. Serial Number.

**Agreement #3**

**Code OF GOOD MANUFACTURING PRACTICES OF VETERINARY DRUGS AND RELATED PRODUCTS, VERIFICATION AND TIME TO DEPLOYMENT**

Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica and Panama agree to use as a reference for compliance, the approved Code of Good Manufacturing Practices for Veterinary Medicinal Products of the Committee for the Americas of Veterinary Medicinal Products of OIE, as well as your guide for verification; and at the same time agree to the States Party to the Central American region, to set a deadline of three years, renewable at the request of a State Party, according to the progress, for its implementation from the date of entry into force of the RTCA 65.05.51:08 Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control.

For veterinary biological products The United Party, agree to use as a reference for their compliance, standards of Good Manufacturing Practices for biological products issued by a

Entity recognized or recognized international body, until you develop the specific regulations on the subject.

For related products, shall apply the rules of good manufacturing practices that define each State

Part.

**Agreement #4**

**List OF VETERINARY DRUGS AND RELATED PRODUCTS SUBJECT TO SIMPLIFIED REGISTRATION**

The States Parties agree to adopt the following list and requirements for registration of veterinary drugs and related products:

A. Absorbents and adsorbents. b. Descornadores chemicals.

C. Deodorants and odorants. d.   Repellents do not pesticides.

E. Hygiene and beauty products. f. Obstetrical lubricants.

G.   Burning markers. h. Rubefacientes.

I. Topical ointments and creams that do not contain active principles of veterinary medicinal products to be sold through pharmacies.

The States Parties can update this list when technically necessary.

**Agreement #5**

**List of VETERINARY USE PRODUCTS NOT SUBJECT TO REGISTRATION**

The veterinary products listed below are not subject to sanitary registration in the United Party:

**1)**Accessories for pets

**2)**pet hygiene Arenas

**3)**Trainer for the control of animal behavior

**4)**crayon or marker for cattle

**5)**semen diluent without active ingredient

**6)**medical team and their reagents

**7)**stabilizers or indicators of water that is used for application of vaccinations

**8)**Medical Supplies

**9)**Equipment for hairdresser

**10)**Gel for palpation without active ingredient

**11)**surgical instruments or laboratory use

**12)**pet kennels

**13) rapid**kits of blood chemistry

**14)**liquid nitrogen for the conservation of biological, semen or embryos

**15)**patches for detection of heat

**16)**Products to preserve the quality of water in ornamental aquaculture species

**17)**Products for handling and transport of reproductive material

**18)**chemical reagents for laboratory use (does not include those used for diagnosis

Disease).

**19)**nipples sealers without active ingredient

**20)**Ink Tattoo

**21) wet**wipes for veterinary use without active ingredient.

The detailed list can be updated by the States Parties when it is technically necessary.

The exemption of sanitary registration does not imply the elimination of official health controls made by each State Party.

**Agreement #6**

**Basic information TO DEVELOP A TEST PROTOCOL OF VETERINARY DRUGS AND RELATED PRODUCTS**

The competent authority of the United Party, you should evaluate the clinical trial protocols submitted by manufacturers, for veterinary medicines and related products, containing the following basic information:

**I. Introduction**: description of the importance of the assay, relating the incidence in the country of the disease(s) (is) that controls or prevents the product to evaluate and the economic impact that this represents (theoretical bases of the trial).

**II. Product Features**: trade name, active principle, indications, pharmaceutical form, route of administration, dosage, target species, mechanism of action, product properties.

**III. Objectives of the trial:**

•   General:

   Specific •(s):

**IV. Hypothesis**(if any): Description of the assumptions of the product in respect to its efficacy or safety.

**V.  Materials and methods**: establishments where you will install the trial, species, category, number of animals, selection criteria, sampling methods, equipment and instruments to be used, evaluation and initial control of the animals, start and end date of the test, method of application, control and monitoring. Staff responsible in charge of activities. Analytical laboratories and technical sheets for registration. Statistical methods used for the evaluation, analysis and presentation of results.

**VI. Economic analysis.**Breakdown of costs of the test.

**VII. Schedule of activities:**Defined in stages to develop, with dates scheduled for execution.

**VIII. Bibliography.**

**IX. Name, signature and qualities of the researcher.**

**Agreement #7**

**Procedure FOR THE RECOGNITION OF SANITARY REGISTRATION OF VETERINARY DRUGS AND RELATED PRODUCTS IN THE CENTRAL AMERICAN REGION**

**1.   Scope of Application**

This procedure applies only to products originating in the United Party.

**2.   Requirements for the recognition of the Sanitary Registration**

**2.1.**Note of application for recognition of the person concerned to the competent authority.

**2.2.**Copy of the registration request form (Annex Regulatory Framework A1, A2, A3 or A4, as appropriate), submitted by the person concerned to the competent authority of the country where you initially registered, with the signature and seal of the responsible authorities.

**2.3.**Certificate of free sale, in original, with the appropriate consular processing, according to

Annex B Normative.

**2.4.**Having complied with the requirements requested in this Regulation for the sanitary registration of veterinary medicinal products in common including fixed-dose combinations or for the sanitary registration simplified, as appropriate.

**2.5.**Label, Jewel case and insert if this is the case, in the original, approved according to the requirements of this Regulation, with the signature and stamp of the competent authority and the date of approval.

**2.6.**Copy of the certificate and methodology of analysis for the finished product, submitted by the person concerned to the competent authority of the country where you initially registered, with the signature and seal of the responsible authorities.

**2.7.**When the manufacturing process involve two or more laboratories, you must specify the process involving each and provide the corresponding certification of compliance with good manufacturing practices of each laboratory in accordance with the provisions of this Regulation.

**2.8.**Payment for the service, when appropriate.

**2.9.**With technical reasons, the competent authority of each State Party, you can request the manufacturer testing for efficacy and safety.

**3   Renewal Requirements of recognition to the health registry**

**3.1**Application for renewal of the recognition of signed and sealed by the regent veterinarian and the holder or his legal representative, the competent authority of the State Party.

**3.2**Certificate of free sale, in original, with the appropriate consular processing according to

Annex B Normative.

**3.3**Legal Document before a notary, issued by the owner of the registration, which must indicate that the health registration of the product has not undergone any legal change, technical or scientific from the last request for modification approved by the competent authority.

**3.4**Proof of payment, if applicable.

**4   Requirements of the modifications to the recognition to the health registry**

**4.1**can be performed only in the country of origin, which can be recognized in the

States Parties through certification issued by the competent authority.

**4.2**are considered marginal annotations described in Annex E of the RTCA Policy 65.05.51:18 Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control.

**4.3 Requirements:**

**4.3.1**Application for the recognition of modifying the registry, signed and sealed by the regent veterinarian and the owner of the registration or his legal representative, the competent authority of the State Party.

**4.3.2 certified true**copy of the original document to support the change, signed and stamped by the competent authority, as well as their due approval and attach the packing material approved, if applicable.

**4.3.3**Proof of payment, if applicable.

**5 Procedure for the recognition of sanitary registration, renewal and its modifications or marginal annotations**

**5.1**Present the requirements established by the competent authority.

**5.2**The competent authority verifies the requirements presented.

**5.3**The competent authority resolves the request through resolution, and shall notify the interested in the middle pointed out. In the event of a refused, indicate the reasons therefor, and the interested challenge in accordance with the domestic legislation of each State Party.

**5.4**In the event of approval of the  recognition of sanitary registration, the competent authority assigns a registration number.

**5.5**The process concludes when the person concerned provides the end tag with the registration number assigned.

**5.6**Once registered the product for recognition, the competent authority extends the sanitary registration certificate.

**5.7**In the event of the adoption of the recognition, you must maintain the validity of the sanitary registration granted by the first State Party where you registered the product.

**6. Causes of refusal of recognition, its renewal and modifications or marginal annotations**

The recognition of registration of a veterinary medicinal product or related product should not be granted in the following cases:

A) Drugs, chemicals or biological agents and their mixtures banned in the country of destination.

(B) its use and manipulation represents proven risk to public health, animal health and the environment.

C) to detect any irregularity, fraud or misrepresentation in the information provided for the recognition of registration.

D)  substances with indications for use not accepted in the country of destination of recognition. e) does not comply with the requirements laid down in this Regulation.

**7.   Validity of the recognition of registration**

The registry recognized maintained that has the registration in the country of origin.

**8.   Other considerations**

**8.1.**If the competent authority of a State party cancels the registration of a product, you must communicate it in an official way and immediately to the other Party.

**8.2.**The applicant for registration, recognition must be registered with the competent authority in accordance with the regulations RTCA 65.05.51:18

Veterinary Drugs and Related Products. Requirements of Health Registration and

Control.

**8.3.**It is not permitted to market a product without having notified or approved, as appropriate, modifications to the original record.

**8.4.**Applications and approvals for the recognition is made by product.

**8.5.**The competent authority can request clarification on the dossier submitted when it deems necessary.

**Transitional article.**

1. For Costa Rica, Honduras, Nicaragua and Panama, the implementation of the requirement of paragraph 4, subparagraph A of Annex C of the Central American Technical Regulation, Rtca

65.05.51:18 Veterinary Drugs and Related Products. Registration Requirements

Health and Control is applicable to the medicines containing as an active ingredient ivermectin, doramectin, abamectin or moxidectin. The mutual recognition of records for these products among States Parties, applies only if they comply with what is established in the RTCA 65.05.51:18 Veterinary Drugs and Related Products. Requirements of Sanitary Registration and Control.

2. To comply with the agreement #2 is for a maximum period of 18 months from the registrant for stocks of the packing material.

**Purpose of the TECHNICAL REGULATION**