الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Veterinary Products Act and Regulation in GCC

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Chapter One

Interpretation

Article (1)

The following terms and phrases shall have the meanings assigned thereto unless the context indicates other meaning:

Inspector: the employee assigned by the competent authority to inspect locations of manufacture, importation, selling and storage of veterinary products and has the power of judicial control.

Technical team: the team assigned by the competent authority to ensure that the manufacturers of veterinary products adhere to good pharmaceutical manufacturing practice (cGMP).

License: a document issued by the competent authority which manufacturers and warehouses are licensed hereby for the wholesale trade of veterinary products.

Registration certificate: a document issued by the competent authority to register veterinary products, their companies and manufacturers.

Country of origin: country of the manufacturing company or the licensed to manufacture and market, which its regulatory authorities issue a Certificate of Free Sale or Certificate of Pharmaceutical Product (CPP).

Technical director: whoever obtained a degree for a minimum of a bachelor in pharmacy sciences, veterinary medicine with an adequate experience in pharmaceutical manufacturing.

Innovative drug: a new innovative of veterinary product that is lunched in the market for the first time by the company or the innovative manufacturer.

A generic multi-source veterinary product: a product that is identical to the innovative product in quality, safety, efficacy, concentration, dosage and method of use and intake.

OTC medicines: veterinary medicines that are sold to a consumer without a medical prescription from a healthcare professional.

Batch\Lot: a quantity of the veterinary products that are manufactured from the same substances and under the same conditions at once during a series of integrated manufacturing processes so that the final product is homogeneous.

Current Good Manufacturing Practice (cGMP): manufacturing practices that guarantee the product meets quality requirements when followed.

Good Storage Practices (GSP): part of the quality assurance that guarantee the maintenance of veterinary products quality during their storage.

Good Distribution Practices (GDP): part of the quality assurance related to the maintenance of veterinary products quality by monitoring the activities that take place during distribution.

Expiration date: the date specified on the veterinary product which should not be used after it expires.

Spoiled veterinary product: a veterinary product which its qualities have changed, and it is no longer usable.

Fraudulent veterinary product: a product which its content, form, or source have changed deliberately, whether it contains the same, wrong, or being without components, or contains ineffective, insufficient components, counterfeit containers, or contaminated materials, and that includes products of brand and generic names.

Withdrawal period: the period between the last dose of the drug being administered to the animal to the period in which it is permitted to consume its meat and products, so that this period is sufficient for the drug to be withdrawn from its body or its residues are within the permissible limit.

Contractual or cooperative manufacturing: the contract of a registered pharmaceutical company that is licensed to manufacture or market or which owns a patent of a product with a pharmaceutical manufacturer for manufacturing the product partially or fully, or for packing or packaging it.

Publicity or advertisement: any statement, whether written, readable, audible, visual, or otherwise, which is intended to publicize or directly advertise any veterinary product.

Chapter Two

Licensing and registering the veterinary products companies and its manufacturers

Article (2)

1. Considering what is stated in Article (16) of the Veterinary Products Act, it is prohibited for companies, manufacturers, and warehouses of veterinary products, registration applicants and individuals to import, market or circulate any veterinary product unless it is registered by the competent authority.

2. Clearance shall not be permitted (release) for veterinary products that are requested from abroad personally via the internet or by express mail without prior permission from the competent authority.

Article (3)

The competent authority in the country shall manage the following tasks:

1. Register the veterinary companies and its manufacturers.

2. Revoke and suspend the veterinary companies and its manufacturers registration.

3. Register the veterinary products.

4. Revoke and suspend the veterinary products registration.

5. Prohibit, recall and terminate the handling of veterinary products.

6. Issue licenses for manufacturers and warehouses of local veterinary products.

7. Take appropriate procedures and measures in light of technical reports issued by global authorities or organizations regarding veterinary products, their companies and manufacturers.

8. Monitor the veterinary products in the local markets.

9. Monitor the local veterinary manufacturers, including the assurance to the commitment of Good Manufacturing Practice (cGMP).

10. Inspect manufacturers of non-local veterinary products to ensure their commitment to good manufacturing practices (cGMP).

11 Monitor the warehouses of veterinary products, including the assurance to the commitment of good storage practices (GSP) and good distribution practices (GDP) of veterinary products.

12. Receive reports on the quality and safety of the veterinary products from hospitals, veterinary clinics, or livestock projects and take the necessary measures.

13 Receive reports on the quality and safety of veterinary products from breeders or individuals, and take the necessary measures.

14. Receive reports on the side effects of veterinary products from hospitals, veterinary clinics, livestock projects, breeders or individuals and monitor them, and take the necessary measures.

15. Issue and publish lists on veterinary products which are entirely banned, and lists of veterinary products that are banned from being used on specific animal species.

16. Pricing and re-pricing of the veterinary products per the pricing rules adopted.

17. Issue the necessary guidelines to guarantee the quality and safety of veterinary products.

18. Issue the approvals of the publicity or advertisement for the veterinary products.

19. Issue registration certificates for companies, manufacturers and veterinary products.

20. Issue permits to clear (release) the imported veterinary products.

Article (4)

Factories of local veterinary products shall obtain a license from the competent authority according to the following conditions and requirements:

First: general conditions and requirements:

1 Submit a license application.

2 Submit a copies of the licenses and approvals of the concerned bodies.

3 Submit a copy of the commercial registration.

Second: The local manufacturer license is obtained per the following procedures:

1. An application is submitted to the competent authority according to the following:

a) An application for obtaining a license.
b) A copy of the commercial registeration.
c) Manufacturer address and location coordinates.
d) Provide a scheme on all factory section, including production lines.

2. The competent authority decides on his\her application within a period not exceeding 60 days, and the application approved, a document shall be given to indicate the initial approval. The reasons shall be clarified if the application rejected by the authority.

3. When the initial approval is issued, the necessary approvals shall be obtained from the concerned bodies.

4. The competent authority shall grant the license after ascertaining the following:

a) The design of the building should be in accordance with the good manufacturing practices (cGMP).
b) The supervision of the factory, with all its departments and laboratories, shall be assigned to a gulf technical director.
c) A qualified and licensed person shall be assigned according to the requirements in each country to allow the launch of each veterinary product batch before allowing its marketing.
d) All means of vital security and safety in the factory shall be available.

Third: The license duration for veterinary products manufacturers is five years, and the license is renewed according to the following conditions:

1. The renewal application shall be submitted for a minimum of 180 days prior to the license expiry.

2. A copy of the establishment manager's valid license shall be submitted.

3. A visit to the establishment is required to ensure that it meets the licensing requirements.

Article (5)

1. The company or manufacturer registration shall be applied by:

a) Manufacturing company.
b) Its representative.
c) Local manufacturer.

2. The registration form prepared by the competent authority shall include the following basic information:

a) Company type and activity.
b) Number and addresses of manufacturers that are owned by the company.
c) Company relations with each of these manufacturers and the extent of its legal, technical and commercial liabilities.

3 The registration application shall be submitted to the competent authority accompanied by the following documents:

a) Registration certificate of the company.
b) A certified certificate issued by the concerned bodies in the manufacturer country proving it meets the current Good Manufacturing Practice (cGMP) including a proof that the competent authorities have periodically inspected it.
c) A valid manufacturer license issued by the concerned bodies in the manufacturer country to manufacture the veterinary products.

d) A list of the products which are manufactured by the company in his\her name, account, through a contractual manufacturing, or for other companies and the dates of their registration and marketing in the manufacturer country and the countries in which it is marketed.

e) A certified list by the company includes the countries where it is being registered with, attached by copies of the registration certificates.
f) An overview of the company activity in the field of research and development.
g) Provide a detailed file on the manufacturer (Site Master File).
h) Submit a registration file for the first product that the company desires to register and market according to the principles of the products registration referred to in the regulation herein.

4. The registration application for companies that do not own stand-alone pharmaceutical factories shall not be accepted, and the registration committee may exclude some companies that are licensed to manufacture or market some necessary products that have no registered and marketed alternative or generic in the country.

5. A technical team consisting of specialists shall inspect the manufacturer to ensure the application of the approved (cGMP), and the competent authority shall determine the fees for the inspection.

6. In the event of the manufacturer registration (production line) is not approved because the (cGMP) is not applied, the request for re-inspection of the manufacturer shall be considered after submitting what proves that the notes mentioned in the report of the technical team were avoided.

7. The registered company is obligated to inform the competent authority in writing of any sale, purchase, merger, or any legal or commercial procedure related to the company or one of its registered manufacturers within 90 days of completing the procedure.

8. The company and its registered manufacturers are obligated to provide an integrated system to follow up and monitor the side effects, and to identify Qualified Person Responsible for

Pharmacovigilance (QPPV), and record all the cases that are sent to the company by veterinarians, pharmacists, breeders, veterinary healthcare specialists, or that monitored by the marketing delegates of the product.

9. The company and its registered manufacturers are obligated to provide the competent authority with reports of monitoring the product side effects as follows:

a) Inform the competent authority within 72 hours of any hazardous symptom that appears or any symptom not mentioned in the Summary of the Products Characteristics (SPC).
b) Inform the competent authority about any issues related to the safety of the product that is discussed or reached by reviewing or analysing information of the side effects or during the benefit-risk assessment related to the product.
c) Inform the competent authority with Periodic Safety Update Report (PSUR) every 6 months during the first two years to register the product, and then annually for the following three years.

10. The company and its registered manufacturers are obligated to provide the competent authority with the reports of monitoring the side effects of the product and the decisions issued regarding the product from any competent regulatory authority or body, with stating the reasons that led to such a decision.

11. The company and its registered manufacturers shall deliver warning messages about the product to veterinarians, pharmacists and veterinary healthcare providers.

Article (6)

Before starting the veterinary product production with commercial quantities, the local manufacturer shall adhere to the following:

1. Registering the production line according to the measure specified by the competent authority.

2. The application for registering the veterinary product shall be submitted to the competent authority by the manufacturer or whoever he\she delegates according to the registration requirements stipulated in the regulation herein.

3. The application for registering a multi-source (generic) veterinary product shall be submitted, for a product whose data is protected or patented within the last year before the expiry of the protection at maximum.

Article (7)

1. The manufacture shall obtain the competent authority approvals before starting to produce any production line of a new pharmaceutical form.

2. The manufacture may manufacture veterinary products for third party after obtaining the competent authority approval.

Article (8)

1. The veterinary products manufacturers shall apply current Good Manufacturing Practices (cGMP) approved by the competent authority.

2. The application of (cGMP) by the manufacturers of veterinary products shall be ensured through a process approved by the competent authority.

3. The competent authority shall carry out the periodic inspection on the manufacturers of the veterinary products to ensure their commitment to (cGMP) per what is decided by the competent authority.

Article (9)

1. The veterinary products companies and manufacturers shall obtain a license for veterinary products warehouse from the competent authority per the following conditions and standards:

a) Submit an application to obtain the license.

b) Attach copies of the concerned bodies licenses and approvals.

2. The following technical conditions shall be provided in the warehouse:

a) The area shall not be less than 100^2m.
b) Its floor shall not be lower than the level of the public road, the land adjacent to it, or facing it in case it is on the ground floor.
c) The building and the roof shall be made of reinforced concrete or a non-combustible material according to the safety conditions determined by the competent authority.
d) A separate, sealed warehouse shall be allocated for the storage of hazardous materials and an airtight cupboard or a separate room for preserving products that contain narcotic substances.

e) Veterinary pesticides are kept in a separate place from the rest of the warehouse, with independent ventilation and a separate door from the veterinary products.

f) A suitable refrigerator for preserving veterinary products that need to be stored at a certain temperature, provided that it is equipped with a thermostat, an electronic register to monitor the temperature, and an alarm device in the event that the temperature falls or rises above the required temperature.

g) Adherence to Good Storage Practice (GSP) and Good Distribution Practice (GDP) of veterinary products approved by the competent authority.

h) The warehouse shall have an Act to provide the following data:

- Generic: the drug scientific and brand name, its concentration, pharmaceutical form, invoice number and date, batch number and validity date, the country of origin.
- Dispended: the quantity, the party to which it is dispended, the invoice number and date, batch number and manufacture date.
- The competent authority shall follow up on this Act on a regular basis.

3. When submitting the application to open a warehouse, the following shall be fulfilled:

a) Fill out and sign the establishment application form.

b) Attach the warehouse address and the location coordinates.

c) Appoint a pharmacist, veterinarian, or Gulf pharmacy technician licensed by the competent authority in the country to manage the warehouse.

d) In the event of narcotic substances trafficking, a Gulf citizen pharmacist licensed by the competent authority in the country shall be appointed to be the liable for it.

e) A copy of the valid warehouse lease contract or a copy of the title deed with the original for matching.

f) A copy of the company or institution’s registration certificate.

g) A copy of the pharmacist or the pharmacy technician’s license.

4. The duration of the warehouse license is five years, and the license is renewed according to the following conditions:

a) The renewal application shall be submitted within a duration not less than 180 days from the license expiry.

b) A copy of the establishment manager valid license shall be submitted.

c) Visiting the warehouse to ensure that it meets the licensing requirements.

5. The ownership of the veterinary products warehouse may be transferred according to the conditions mentioned in Paragraph (3).

6. Warehouse branches are considered independent warehouses, for which an independent license shall be obtained.
7. The approval of the competent authority shall be obtained when there is a desire to make any change in the activity, the name, address, location, or the liable manager of the warehouse.
8. It is not permissible for any warehouse to dispense any veterinary product unless the official price and the register number is printed on its outer cover without scraping or correcting in numbers except for what is excluded by the competent authority.
9. The warehouse should sell veterinary products to all establishments licensed to sell the veterinary products in a balanced manner that prevents monopoly or the availability of a specific variety in certain places.
10. The warehouse shall dispose spoiled or expired veterinary products through a company specialized in disposing medical wastes while keeping the disposal registers.

Article (10)

The company registration shall be revoked upon a proposal of the registration committee in the following cases:
1. If it did not market at least one of its registered products within a year of its registration.
2. If it is proven forgery or tampering with the submitted documents.
3. If the activity of the company or all of its products is banned.
4. If the company has tampered with the product content violating thereby the decision of registering the product.
5. If there is evidence that the company does not comply with the conditions under which the certificate of registration was granted, or that it does not continue to implement (cGMP).

Article (11)

1. The manufacturers and warehouses of veterinary products shall provide sufficient stock for local consumption, provide data on the generic, dispended and retained for all veterinary products available in the warehouse, and submit a copy of it to the competent authority.

2. If the manufacturer does not supply the veterinary product, then it is allowed to import according to the following conditions:

a) The competent authority may allow a licensed warehouse to import the product.

b) The competent authority shall issue an import permit specifying the name of the product, its pharmaceutical form, its concentration, the package size, the quantity imported, the manufacturer and the country of origin.
c) The competent authority shall determine the product sale price if the size of the imported package differs according to the pricing basis of the veterinary products.
d) The importer is obligated to sell the product at the official price, and the competent authority may exempt him\her from printing the registration number and price on the imported product.

Chapter Three

Registration of veterinary products

Article (12)

I: All veterinary products are registered according to the registration form attached in the regulation herein.

II: Requirements of the veterinary product registration file:

1. Submit a registration application whose content is arranged according to the registration form referred to in (I).

2. Provide samples of the product as decided by the competent authority.

3. Provide a sufficient quantity for analysis of the reference substance or primary active substances, degradation results (breakdown), and other necessary analysis equipment.

4. Mention the basic product information on the internal and external packages, its internal leaflet and summary of product characteristics (SPC), as determined by the competent authority.

5. If the product submitted for registration is from veterinary vaccinations, it is required for its registration in addition to the above:

a) The presence of the disease in the state.

b) The vaccine strain isolated should be local.

III: The registration application file should be studied according to the following:

1. Evaluate the effectiveness of the product.
2. Evaluate the safety of the product for its intended use.
3. Evaluate the quality of the product.
4. The product required to be registered shall be marketed in the country of origin for a minimum period of one year before its registration with the same composition (except for vaccines and serums), and in the event of marketing failure, the reasons shall be clarified.
5. The veterinary product shall pass the analysis during its registration stages.
6. The product that does not pass the analysis for three consecutive times shall not be registered.

IV: Veterinary products are classified according to:

1. Prescription Only Medicine (PSUR).
2. Over the Counter (OTC).
3. Products dispensed under a controlled prescription.
4. Products dispensed according to prescriptions of narcotic products.
5. Products for use in specialized therapeutic institutions.

V: The competent authority issues a certificate of registration for the veterinary product upon the registration committee's recommendation, in which the following is determined:

1. The manufacturing company and country of origin.
2. Company registration number.
3. Trade name.
4. Scientific name.
5. Pharmacological form.
6. Concentration of the active substance (s).
7. Target animals.
8. Withdrawal period for the animal and its products.
9. Package size.
10. Validity period.
11. Storage conditions.
12. Price of the product.
13. Registration number of the product.
14. Registration date.

VI: When adding a new medical claim to a registered veterinary product, the following is required:

1. Approval of the competent authority in the country of origin or other regulatory bodies.
2. Pharmacokinetic and toxicological studies.
3. Field studies.

VII: Registration of the veterinary product does not mean acceptance of its registration in all its pharmaceutical forms and concentrations. Rather, an independent registration application shall be submitted.

VIII: The competent authority is entitled to postpone or reject the registration of any product while stating the rejection reasons. The applicant may submit his\her objection on the decision to the competent authority within 60 days from the date of notice.

IX: The competent authority publishes the veterinary products registered therewith through their website on the computerized network.

X: Veterinary products submitted for registration and manufactured contractually or cooperatively shall meet all registration conditions in addition to the following:

1.The multi-source (generic) products that are submitted for registration from local manufacturers and are manufactured in a city outside the country are only registered per the following conditions:

a) The company shall be one of the leading companies that market its products in developed countries.

b) Verify the application of (cGMP).

c) The product shall be one of the products that require manufacturing technology that is not available locally.

d) The local manufacturer shall undertake at least one industrial step.

2. If the company that implement the contract is registered with the competent authority, it shall:

a) Determine the basic steps of the manufacturing process, its stages, and the factory in which each step takes place.

b) A certified copy of the contracting agreement between the two parties, including the following clauses:

1) Commitment of the contractor to inspect the areas of production, control, storage, manufacturing methods, analysis, and batches registers, and to ensure the availability of all the technical capabilities.

2) Responsibility of both the grantor and the contract implementer for all matters related to the manufacturing and control steps with the necessity to specify the liable party of the final release for product's batch(s) – (Batch Release)

3) The contract term.

4) The licensing company and the local company shall inform the competent authority for a term of not less than 180 days before the expiry of the manufacturing license agreement in the event of non-renewing the agreement.

c) The name and position of the person responsible for releasing the batches, provided that the competent authority shall be notified on the replacement promptly in case he was changed by the party responsible for the final release of the product batches.

d) A letter shall be submitted from the contracting company stating its liabilities for the quality and safety of the product.

e) A pledge shall be taken by the technical director of the company granting the contract to inform the competent authority of any change with the information provided before making the change.

f) Manufacturing by third party shall not be restricted with marketing within the country, apart from the contracts executed by one of the local manufacturers.

3. If the implementing company is not registered with the competent authority, it shall:

a) Complete what was stated in paragraph (1).

b) Submit a pharmaceutical manufacturing license certificate to the company that executes the contract issued by the relevant authorities in the manufacturing country.

c) Submit a certificate of the (cGMP) for the implementing company issued by the relevant bodies in the manufacturing country and the manufacturer shall be subject to periodic inspection.

d) Companies authorized to manufacture for third party are subject to inspection prior to their registration and periodically by the competent authority to ensure their implementation of (cGMP).

XI: Veterinary products submitted for registration, manufactured and marketed with a license shall meet all registration conditions in addition to the following:

1. Manufacturing the product locally with a license from an international company:

a) If the company granting the license and the product were registered with the competent authority:

1) The company granting the license shall own the patent or the right to manufacture.

2) Submit a written approval from the company granting the license to allow the manufacturer or local company to manufacture and market its products locally.

3) After approving the registration of the product manufactured with a license, the registered product of the company granting the license shall be suspended after 180 days from the date of registering the local company product.

4) The company granting the license and the local company shall inform the authority within a period of not less than 180 days before the expiry of manufacturing license agreement in the event of non-renewal of the agreement.

5) The product registration shall be suspended for the licensing company, and the product registration shall be revoked for the local company in the event of the manufacturing license agreement termination with the local manufacturer \ company.

6) The active substances, their sources and the inactive substances included in the formulation of the product, the method of manufacture, the pharmaceutical formula, concentration, labelling and all the product standards should be the same as those made by the licensing company.

7) The local manufacturer \ company is accountable to the competent authority for the quality of the product and the issues that occur after marketing.

8) The local manufacturer \ company shall have all the potentials and equipment necessary for the production and analysis of the licensed product.

9) The trade name of the product manufactured with a local license should be the same as the trade name of the product manufactured by the licensing company and registered with the competent authority, and the package shall contain the phrase “made by the local manufacturer with a license from the licensing company”.

10) The registered products that require bioequivalence studies shall be excluded from these studies if they are manufactured by the local manufacturer \ company with a license from an international company, provided that:

a) The source of the active and inactive substances is from the licensing company or from an approved source and under its responsibility regarding bioequivalence.

b) The product does not have an extended-release pharmaceutical form (Sustained Release).

c) Comparative Dissolution Studies is submitted.

11) The product manufactured with a license by the local manufacturer \ company shall be given a validity period based on the stability studies, which is presented by the licensing company, provided that the local manufacturer \ company submits accelerated stability studies and static studies at specified storage conditions in the stability studies manual.

12) The manufacturing company is obligated to conduct all the analysis that the licensing company conduct on the product to ensure its quality on all the manufactured batches.

13) The licensing company is obligated to conduct all the required analysis on the product manufactured with a license by the local manufacturer \ company to ensure that it conforms to the approved manufacturing standards for the first three batches at least, produced by the local manufacturer \ company. The analysis results shall be sent to the competent authority accompanied with these batches that were performed by the local manufacturer / company.

b) If the licensing company is registered with competent authority and the product is not, the following shall be adhered to:

1) Registration of the product.

2) Application of what was stated in Paragraph (a)

c) If the licensing company and the product were not registered with the competent authority, the following shall be adhered to:

1) Registration of the licensing company.

2) Application what was stated in Paragraph (b).

2. Manufacturing the product externally with a license from an international company:

a) Innovative or multi-source (generic) products that manufactured with a license from companies that are entitled to market and are manufactured outside the country shall not be registered.

b) The competent authority may consider excluding some necessary products per the following conditions:

1) Fulfill the conditions stated in Paragraph (a) of (1).

2) Shall not be manufactured locally.

3) Their manufacture shall not be limited to the local market.

3. Manufacturing the product locally with other trade names of the same registered product: The local manufacturer \ company may agree with the licensing company to manufacture another product (Second Brand) under a trade name of the local manufacturer in addition to the company's innovative product, provided that the registration requirements are similar to those for registering the products according to the following conditions:

1) The registration file shall be submitted by the local manufacturer \ company.

2) The technical and legal liability shall be shared between the two manufacturers.

XII: Secondary packaging:

1. It is permissible for companies registered with the competent authority to do packaging (Secondary Packaging) for its products registered within the local manufacturers without any change made to the product.

2. The treatment of these products will continue to be treated as the registered product of the contracting company.

Article (13)

1. All veterinary products are subject to pricing. Exception of these products:

a) Veterinary herbal products.

b) Veterinary sanitary products.

c) Veterinary pesticides and disinfectants.

d) Veterinary cosmetic products.

e) Products and formulations prepared inside the pharmacy or veterinary clinic.

2. The veterinary product shall be priced according to the following pricing principles:

a) Factory price in the country of origin (Ex-Factory).

b) Whole price in the country of origin (Whole Sale).

c) Price of the product to be sold to the consumer (Retail Price) in the country of origin and countries in which it is marketed.

d) Cost, Insurance and Freight (CIF) proposed by the company to the country in the currency of the country of origin.

e) The export price to all countries in which the product is marketed at the time of its registration submission in the country, even if it is manufactured locally in any of those countries in which it is marketed.

f) The price of the product in the official price references, if any.

g) The therapeutic importance of the product.

h) Analogues prices registered in the country.

3. The price of the product should be determined according to the principles indicated in Paragraph (2) of this article, taking into consideration the cheapest prices offered.

4. The company or its agent shall inform the competent authority when the export price to any of its products registered in the country has decreased about the export price to the countries in which it is registered.

5. The veterinary product shall be re-priced every five years from the date of its registration per the procedures specified by the competent authority.

6. The competent authority may review the prices of veterinary products, if the need arises.

Article (14)

First: Importing unregistered veterinary products

1. It is permissible to allow the import of unregistered veterinary products according to the following conditions:

a) Obtaining prior approval of the import from the competent authority.

b) The product to be imported shall be within the important products and there shall be no substitute registered in the country.

c) The import shall be for the benefit of the veterinary hospital or the livestock project.

d) The product required to be imported shall be marketed in the country of origin, and the competent authority may make an exception from the marketing condition.

e) The import shall be from companies registered with the competent authority, and the competent authority may make an exception from the company registration condition.

f) It is banned to trade in unregistered products imported by veterinary hospitals or livestock projects.

2. Exception from the conditions stipulated in Paragraph (1) of this article are the samples submitted for the requirements of the product registration.

3. The competent authority may exclude the imported products for personal use from the conditions stipulated in Paragraph (1) of this Article per the conditions and controls set by the competent authority.

Second: Re-exporting the imported veterinary products:

1. Veterinary products may be allowed to re-export veterinary products according to the following conditions:

a) Obtaining prior approval of re-exportation from the competent authority.

b) Indicating the reasons of re-exportation.

c) Cases in which the competent authority allows for re-export per what is stipulated in Article (24) of the Veterinary Products Act.

2. Without prejudice to what was stated in (Second) of this article, the competent authority is entitled to order the re-export of the violative veterinary products per the provisions of the Veterinary Products Act.

Article (15)

Manufacturing unregistered veterinary products by the local veterinary manufacture is allowed for the purpose of export according to the following conditions:

1. Obtaining the approval of the competent authority.

2. Submitting the manufacturing justifications of the veterinary products that are not locally registered for the purpose of export.

3. The competent authority shall issue a certificate of origin for the veterinary products that are not registered and manufactured locally for the purpose of export only.

Article (16)

It is banned to import, trade or market any registered veterinary product if any change or amendment was made thereof unless after obtaining the prior approval of the competent authority.

1. The company that manufactures or markets the veterinary product shall obtain the approval of the competent authority for any change or amendment to the registered veterinary product.

2. The changes or amendments that require the prior approval of the competent authority include the following:

a) Country of origin.

b) Manufacturing location.

c) Manufacturing steps.

d) Inactive substances included in the product formulation.

e) Packaging materials.

f) The validity period.

g) Information contained in the internal leaflet and summary of product characteristics (SPC.)

h) Information on the inner and outer packaging, and the associated with the internal leaflet.

i) The product standards and its analysis methods.

j) The product trade name.

Other changes or amendments the competent authority deems necessary to obtain prior approval.

3. Inform the competent authority of any other changes or amendments.

4. Submit all required documents to support any change or amendment.

5. A change in the active substance, the pharmaceutical form, or the method of administration (Route of Administration) oblige the company to register the veterinary product.

Article (17)

The unregistered veterinary product may be imported for research purposes per the following conditions and controls:

1. An application to obtain an approval including the import objective shall be submitted.

2. Prior approval of import shall be obtained from the competent authority.

3. The product to be imported shall be registered in the country of origin, and the competent authority may make an exception from the registration requirement.

4. The competent authority shall specify in the import permit:

a) The name of the authority to which the approval was issued.

b) The quantity imported for research purposes.

Article (18)

The registrant of the veterinary product shall inform the competent authority about the following cases, whether they are in the country of origin or any country in which the product was registered and within a period not exceeding 15 days from the date:

1. Any warning has been issued about the product.

2. Manufacturing termination.

3. Product withdrawal.

4. Product suspension.

5. Prevention of handling the product.

6. Product registration revocation.

Article (19)

The application of Good Storage Practice (GSP) and Good Distribution Practice (GDP) for the veterinary products approved by the competent authority shall be adhered.

Article (20)

It is prohibited to advertise any veterinary product without the approval of the competent authority in accordance with the following conditions and controls:

1. The advertisement content shall be submitted to the competent authority.

2. The competent authority shall ensure that the ad content complies with the requirements it adopts.

3. The ad content shall not contradict with the internal leaflet and the summary of product characteristics (SPC).

4. The ad shall not contain information that leads to deceiving or misleading.

5. The ad shall not include any phrase affecting other veterinary products.

6. The ad target audience shall be determined.

7. The ad content shall be granted approval by the competent authority for the prescription and over the counter (OTC) veterinary products.

8. The approval of the ad for the prescription veterinary products shall be restricted to scientific journals, conferences and meetings designated for professional practitioners.

9. Whoever has issued the approval of the ad by his\her name is obligated to terminate advertising in the following cases:

a) The emergence of new updates indicating the existence of risks resulting from the product or its ineffectiveness.

b) The competent authority requests to stop the ad along with stating the reasons.

10. The advertisement decision number of the competent authority should be provided.

11. The form approved by the competent authority may be used for one year from the date of approval.

12. Any other requirements specified by the competent authority for advertising the veterinary products shall have adhered.

Chapter Four

General Provisions

Article (21)

1. Registration committees of veterinary companies, their manufacturers (production lines) and products shall be formed by a decision of the Head of the competent authority.

2. The decision to form the committee specifies its tasks and work method.

3. Among the committee tasks shall be the following:

a) Recommend the registration of the veterinary products companies and manufacturers (production lines).

b) Decide on objections related to the registration of the veterinary products companies and manufacturers (production lines).

c) Study the updated reports on the registered veterinary product, its uses, warnings and side effects, and raise its recommendations.

d) Recommend the adoption of the registration principles of the veterinary products companies and manufacturers (production lines)

e) Recommend the adoption of detailed rules for pricing veterinary products.

f) Recommend the suspension, withdrawal or revocation of the registered product.

g) Determine the method of dispensing the product and the place of dispense.

h) Suspend or revoke the registration of companies and manufacturers (production lines) of veterinary products.

i) Study the topics referred to it by the competent authority.

4. The registration committee members' remuneration shall be determined by a decision of the Head of the competent authority.

Article (22)

The competent authority is entitled to prohibit the import, cease the handling, suspend, revoke the registration, or order the recall or withdrawal of the veterinary product in the following cases:

1. If any changes or amendments are made to the veterinary product stipulated in Paragraph (1) of Article (16) of this regulation without the approval of the competent authority.

2. If the competent authority has reports regarding its toxicity, or if serious side effects appear.

3. If the competent authority has reports about the existence of a defect in the product quality or efficiency.

4. If its use was ceased based on the recommendation of the relevant international regulatory authorities or organizations.

5. If its registration is revoked or its production ceased in the country of origin.

6. If it is not marketed or imported within one year from the date of its registration.

7. If it is proved that the information related to the veterinary product provided in the registration file is incorrect.

8. If the company or its agent fails to submit a request to renew the product registration before a minimum of 180 days from the date of the registration certificate expiry.

9. If the veterinary product fails to study the bioequivalence.

Second: veterinary products whose handling is ceased, suspended, or its registration is revoked, or ordered to be recalled or withdrawn shall be acted according to the following:

1. In cases where the competent authority decides to dispose the product, the company or the manufacturer is obligated to dispose it per the disposal measures stipulated in this regulation.

2. In cases where the competent authority allows products to be re-exported, this shall be done per the measures stipulated in this regulation.

Article (23)

First: The registration of veterinary companies and manufacturers shall be renewed in the following cases:

1. Before the registration certificate expires for a minimum of 180 days.

2. When any radical change is made to the manufacture building or production lines according to what is decided by the competent authority.

The applicant shall fulfill all the conditions and requirements stipulated in Article (5) of this regulation.

Second: The registration of the registered product shall be renewed 180 days before the end date of its registration per the following:

The applicant to renewing the registration of the veterinary product shall submit the following:

1. A certificate of pharmacist product (CPP) or free sale certificate from the country of origin issued by the competent authorities.

2. A list of the countries names that allowed the product to be handled, and another list of the countries names in which the product was submitted for registration, in addition to the countries that the registration of the product was refused with indicating the reasons for rejections.

3. A list of the product prices in the countries in which it is marketed.

4. The approved internal leaflet or the summary of product characteristics (SPC) in the country of origin written in the English language and certified by the competent authorities.

5. A list of the changes or amendments approved by the competent authority from the date of registration or the last renewal arranged according to the date of the change.

6. Update the stability studies section and provide stability study on at least two production batches that cover the entire validity period.

7. Submit any amendments made to the clauses required in the technical contract in the contractually manufactured products.

8. If the product contains plasma products, the (Master Plasma File) shall be submitted for the product or an acknowledgment from the manufacturing company indicates that there is no change in the plasma source approved by the competent authority.

9. A sample of the product that is handled in the local market.

10. A statement of the names of the substances from the animal origin, which are included in the formulation of a product, its source, and the certificates related thereby.

11. All available information about the monitoring of the drug side effects since the date of its registration or the renewal, in addition to any proposed changes to the approved bulletin.

12. Any other requirements the competent authority deems necessary.

Article (24)

1. The veterinary product that is counterfeited, spoiled, expired, violated of the registration standards, or stored under violative storage conditions shall be disposed.

2. The competent authority shall form one or more committees to supervise the disposal of veterinary products of those with experience and competence.

3. The process of disposing of veterinary products is carried out by a company specialized in disposing of medical wastes according to the scientific principles followed.

4. The violator shall bear the costs of the disposal process.

Article (25)

In cases where the competent authority seizes a violation to the provisions of the Veterinary Product Act and its implementing regulation in places licensed by other parties, they may request to revoke the license from the licensing authority, along with a statement indicating the reasons and justifications for the revocation request, providing such authority with the decisions or judgments issued against the violator.

Article (26)

1. The inspecting authority may assist the Veterinary Products Act and its implementing regulation on the veterinary products to ensure:

a) Safety.

b) Insurance.

c) Quality.

d) Effectiveness.

e) Storage methods and transportation.

f) Their conformity with the registration file.

2. Inspection of veterinary products shall be carried out in accordance with the inspection procedures manual approved by the competent authority.

3. The Head of the competent authority shall determine the official employees who have the powers of judicial control.

Article (27)

1. The inspector, after proving his\her official status, is entitled to enter and inspect places that deal with veterinary products or substances that are subjected to the provisions of the Veterinary Products Act and its regulation.

2. The workers who are present in the veterinary products places should enable the inspector to carry out his duties and provide him with all the facilitation that enable work performance.

3. The inspector may withhold or seize any product, register, or document to prove the violation.

4. In the event that any violation is seized, the inspector shall write a seizure report approved by the competent authority and hand over a copy of the form to the responsible person for the place where the violation occurred.

5. The inspector may seek the assistance of security when needed.

Article (28)

The agricultural cooperation committee is entitled to interpret, propose and amend this regulation, just as every country has the right to propose an amendment to this regulation.

Article (29)

This regulation shall be implemented after 180 days from Veterinary Products Act came into force.

Abbreviations:

cGMP current Good Manufacturing Practice.

CIF Cost, Insurance and Freight.

CPP Certificate of Pharmaceutical Product.

GDP Good Distribution Practice.

GSP Good Storage Practice.

OTC Over the Counter.

POM Prescription Only Medicine.

PSUR Periodic Safety Update Report.

QPPV Qualified Person for Pharmacovigilance.

SPC Summary of Product Characteristics.

Annex (1) Registration Form of Veterinary Products

Table 1: Folder Structure for an Electronic Application for a Pharmaceutical Product

Root Folder	
Additional Information	
Part 1	**Summary of the Dossier**
1a	**Administrative Information**
1b	**SPC and Product Literature**
1c	**Critical Summaries**
1c1	Quality
1c2	Safety and residues
1c3	Efficacy
Part 2	**Quality Documentation**
2a	**Qualitative and Quantitative Particulars**
2a1	Qualitative particulars
2a2	Usual terminology
2a3	Quantitative particulars
2a4	Development pharmaceutics
2b	**Description of the Manufacturing Method**
2c	**Control of Starting Materials**
2c1	Active substances
2c2	Excipients
2c3	Container closure
2c4	Substances of biological origin

2d	**Control Tests at Intermediate Process Stages**
2e	**Tests on the Finished Product**
2e1	General characteristics of the finished product
2e2	Identification and assay of active substance(s)
2e3	Identification and assay of excipient components
2e4	Safety tests
2f	**Stability Tests**
2f1	Active substances(s)
2f2	Finished product
2g	**Other Information**

Part 3	**Safety and Residues Tests**
3a	**Safety Tests**
3a1	Precise identification of product and active
3a2	Pharmacology
3a3	Toxicology
3a4	Other requirements
3a5	URA
3a6	ERA
3b	**Residue Tests**
3b1	Identification of product
3b2	Metabolism and residue kinetics
3b3	Residue analytical method
Part 4	**Preclinical and Clinical Trials**
4a	**Preclinical Requirements**
4a1	Pharmacology
4a2	Resistance
3a3	Target animal tolerance
4b	**Clinical Requirements**
4b1	Clinical trials

Table 2: Folder Structure for an Electronic Application for an Immunological Product

Root Folder	
Additional Information	
Part 1	**Summary of the Dossier**
1a	**Administrative Information**
1b	**SPC and Product Literature**
1c	**Critical Summaries**
1c1	Quality
1c2	Safety and residues
1c3	Efficacy
Part 2	**Quality Documentation**
2a	**Qualitative and Quantitative Particulars**
2a1	Qualitative particulars
2a2	Usual terminology
2a3	Quantitative particulars
2a4	Product development
2b	**Description of the Manufacturing Method**
2c	**Production and Control of Starting Materials**
2c1	Starting materials listed in pharmacopoeias

2c2	Starting materials not listed in a pharmacopoeia
2d	**Control Tests During the Manufacturing Process**
2e	**Control Tests on the Finished Product**
2e1	General characteristics
2e2	Identification of active substance(s)
2e3	Batch titre or potency
2e4	Identification and assay of adjuvants
2e5	Identification and assay of excipient components
2e6	Safety tests
2e7	Sterility and purity test
2e8	Residual humidity
2e9	Inactivation
2f	**Batch to Batch Consistency**
2g	**Stability Tests**
2h	**Other Information**

Part 3	**Safety Documentation**
3a	**General Requirements**
3b	**Laboratory Tests**
3b1	Safety of one dose
3b2	Safety of an overdose
3b3	Safety of the repeated administration of one dose
3b4	Examination of reproductive performance
3b5	Examination of immunological functions
3b6	Special requirements for live vaccines
3b7	URA
3b8	Study of residues
3b9	Interactions
3c	**Field Studies**
3d	**ERA**
3e	**Assessment of Products Containing or Consisting of GMOs**
Part 4	**Efficacy Documentation**
4a	**General Requirements**
4b	**Laboratory Trials**
4c	**Field Trials**