Federal Decree by Law No. (21) of 2025
Regarding Veterinary Medical Products and Veterinary Pharmaceutical Establishments

We, Mohamed bin Zayed Al Nahyan, President of the United Arab Emirates,

- Having reviewed the Constitution,
- Federal Law No. (1) of 1972 Regarding the Competences of Ministries and the Powers of Ministers, as amended,
- Federal Law No. (10) of 2002 Regarding the Practice of the Veterinary Medicine Profession, as amended,
- Federal Law No. (7) of 2015 Regarding the Control of Prohibited Substances in the Field of Horse Racing and Equestrian Sports,
- Federal Law No. (9) of 2017 Regarding Veterinary Products, as amended,
- Federal Decree by Law No. (30) of 2021 Regarding Combating Narcotics and Psychotropic Substances, as amended,
- Federal Decree by Law No. (28) of 2023 Establishing the Emirates Drug Establishment,
- Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, and
- Upon the proposal of the Chairman of the Board of Directors of the Emirates Drug Establishment and the approval of the Cabinet,

Hereby promulgate the following Decree by Law:

Article (1)
Definitions

For the purposes of implementing the provisions of this Decree by Law, the following terms and expressions shall have the meanings assigned to each of them, unless the context requires otherwise:

State	:	The United Arab Emirates.
Ministry	:	The Ministry of Climate Change and Environment.

Establishment	:	The Emirates Drug Establishment.
Minister	:	The Minister of Climate Change and Environment.
Board of Directors	:	The Board of Directors of the Establishment.
Chairman	:	The Chairman of the Board of Directors of the Establishment.
Competent Authority	:	The local authority concerned with Veterinary Medical Products and veterinary pharmaceutical establishments in each Emirate.
Veterinary Medical Product	:	Devices, medicinal and medical products intended for use in or on an animal body as specified in Clause (1) of Article (2) of this Decree by Law.
Veterinary Medicinal Product	:	A substance, combination of substances or an input material prepared for the treatment or prevention of a disease, for the diagnosis of medical conditions, or for the restoration, correction, or modification of physiological functions or the structure of an animal.
Veterinary Biological Products	:	Veterinary Medicinal Product obtained through biotechnological techniques from a living organism or produced industrially in a way that mimics the biological origin. They consist of several categories such as vaccines, blood products and their derivatives, monoclonal antibodies, growth factors, plasma derivatives, cellular and gene therapy products, advanced therapy medicinal products (ATMPs), and allergy diagnostic products.
Active Substance	:	Any substance or group of substances responsible for the primary effects of the Veterinary Medical Product, which may be obtained from animal, plant, microorganisms, chemical, or other sources.

Veterinary Raw Materials	:	Active or inactive substances that are used in the manufacture of a Veterinary Medical Product, whether of chemical, biological, or natural origin.
Veterinary Complementary Products	:	Products used to improve the health condition of animals, support body functions, enhance digestion, and promote growth or performance, without having any therapeutic uses. Veterinary complementary products include: 1. Veterinary nutritional supplements. 2. Animal health care products. 3. Veterinary disinfectants.
Veterinary Nutritional Supplements	:	Complementary veterinary products taken orally in separate doses or added to feed (food) to support the animal's dietary system. and not intended to treat, diagnose, or prevent diseases. They consist of natural or partially or fully synthetic products such as vitamins, amino acids, mineral salts, living organisms, enzymes, or any other substances authorized by international organizations. They do not require a prescription for sale, nor do they require direct medical supervision for their use.
Living Organisms	:	Beneficial live microorganisms (Probiotics), such as certain types of bacteria (Lactobacillus, Bifidobacterium, Bacillus) and yeast (Saccharomyces cerevisiae), that are internationally permitted because of their safety and benefits in supporting digestion and immunity.

Injectable Veterinary Supplements	:	Veterinary Medicinal Products administered intravenously or by other routes of injection, intended to correct or support the nutritional and metabolic balance of the animal in cases where oral nutritional support is impossible or insufficient. These products include solutions or formulations of vitamins, mineral salts, amino acids, or other internationally authorized substances. These supplements are used under direct veterinary supervision and may only be dispensed with an approved medical prescription.
Animal Health Care Products	:	Veterinary complementary products used for the general health care of animals and are not intended for the diagnosis, treatment, cure, or prevention of any disease, and do not require a medical prescription or direct medical supervision for their use.
Veterinary Disinfectants	:	Veterinary complementary products that are considered chemical preparations, products, or substances used to disinfect surfaces, tools, and equipment in veterinary environments or on an animal's skin to eliminate or reduce bacteria, fungi, and viruses, thereby preventing animal diseases or limiting their spread.

Veterinary Medical Device	:	A Veterinary Medical Product in the form of a substance, device, instrument, apparatus, implant, reagent, or system, including its accessories and operating software, including wearable devices and products based on artificial intelligence technology. It achieves its intended purpose for use in or on the body of an animal without having a pharmacological, immunological, or metabolic effect, and is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, mitigation, monitoring, or prevention of a disease, injury, or disability. 2. Detection, compensation for, or modification of an anatomical position. 3. Control of pregnancy and fertilization processes.
Marketing Authorization	:	The approval granted by the Establishment to a licensed legal person in the State to market a specific Veterinary Medical Product in the State in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.
Veterinary Consignment	:	All Veterinary Medical Products imported into, exported from, or transiting through the State.
Veterinary Establishments	:	Any establishment operating in accordance with the legislation in force in the State, such as a veterinary hospital, veterinary clinic, veterinary laboratory, commercial animal production farm, or an artificial insemination center for animals.
Veterinary Pharmaceutical Establishments	:	The establishments listed in Clause (2) of Article (2) of this Decree by Law.
Veterinary Medical Warehouse	:	A veterinary pharmaceutical establishment licensed to store and possess Veterinary Medical Products or Veterinary Raw

		Materials. The warehouse may be licensed for import, distribution, re-export, or wholesale.
Veterinary Medical Storage Facility	:	A veterinary pharmaceutical establishment licensed to store and transport Veterinary Medical Products.
Marketing Office	:	A veterinary pharmaceutical establishment licensed to practice the activity of promoting Veterinary Medical Products to veterinary practitioners and pharmacists.
Veterinary Medical Products Contract Manufacturing Organization (CMO)	:	A company contracted by pharmaceutical companies and entrusted with expanding the manufacturing operations of Veterinary Medical Products and providing comprehensive services ranging from development to the manufacture of the Veterinary Medical Product, which can assist in scalability, allowing the pharmaceutical company to focus on drug discovery and marketing. Its services include pre-development of the product, technical studies related to the product, materials, manufacturing methods, registration, and commercial production.

Contract Research and Development Organization (CRDO)	:	A company contracted to outsource and accelerate the innovation and development processes of Veterinary Medical Products, which includes: 1. Contract research Organizations (CROs): A company contracted to carry out one or more of the clinical research sponsor's obligations for the clinical trial. 2. Contract Site Management Organizations (SMOs): A company contracted to provide administrative services related to the management of clinical trial sites and does not assume any of the regulatory obligations of the sponsor for the clinical trials it manages. Its services include: identifying or managing principal and sub-investigators, hiring study staff, preparing submissions to institutional review boards and committees, and assisting in project feasibility, launch, or closure of the study site, or any other study activities related to the site.
Veterinary Biobank	:	A veterinary pharmaceutical establishment licensed to collect, preserve, store, and distribute biological samples including, but not limited to blood, tissues, and cells, and their associated information for future use. This includes, but is not limited to, independent and mobile blood banks and cord blood and stem cell banks. It does not include biological samples used for artificial insemination of animals.
Veterinary Pharmacy	:	A veterinary pharmaceutical establishment licensed to store, prepare compounding pharmacy, or conduct its activities, or to dispense, display, or sell Veterinary Medical Products directly to the public within the State. It is not permitted to import, export, or re-export.

Bioequivalence Center	:	A licensed veterinary pharmaceutical establishment where research and comparative studies on the bioequivalence of a generic drug are conducted against an innovator drug.
Marketing Authorization Holder	:	The holder of a license to market one or more Veterinary Medical Products in the State in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof, and who is responsible for all aspects of its marketing, promotion, and follow-up in the State.
Veterinary Pharmacovigilance	:	The science associated with activities related to the identification of side effects, adverse or toxic reactions of Veterinary Medical Products, and the potential risks of their use, as well as the methods for their detection, monitoring, and surveillance, and the collection of reports for the purpose of their assessment, analysis, treatment, prevention, and identification of measures to prevent their occurrence.
Innovator Product	:	The first Veterinary Medical Product of its kind within its category, either because it contains new components or combinations that have not been used before, or is used in new ways, or because it has been developed and marketed for the first time by the developing company and has not previously obtained marketing approvals in the State, and an application has been submitted for marketing authorization to the Establishment by the innovator company or through its authorized representative for this purpose, while the product enjoys valid patents at the time of submission.
Orphan Product	:	A Veterinary Medical Product designated for the treatment, diagnosis, or prevention of a rare or emerging disease or condition.

Generic Product	:	A veterinary medicinal product similar to another veterinary medicinal product that has the same quality and quantity of active ingredients, the same pharmaceutical form, and is bioequivalent thereto. It may have a pioneer status, being the first generic Veterinary Medical Product to obtain marketing authorization in the State, similar to an innovator product that has not obtained marketing authorization in the State in terms of indication, pharmaceutical form, active substances, and bioequivalence, without prejudice to the intellectual property legislation in force in the State.
Veterinary Non-Clinical Research	:	Research conducted on Veterinary Medical Products in the laboratory or on non-target animal species, for the purpose of evaluating the safety, efficacy, and physical, chemical, toxicological, and pharmacological properties of the Veterinary Medical Products.
Veterinary Clinical Research	:	Scientific research conducted on target animals, for the purpose of using the Veterinary Medical Product thereon, to evaluate the efficacy and safety of Veterinary Medical Products under actual or simulated conditions of use, after the product has passed the non-clinical stage.
Target Animals	:	Animals intended for treatment, prevention, or diagnosis using the Veterinary Medical Product for research purposes.
Bioequivalence	:	The absence of any significant statistical difference related to the bioavailability of the active ingredient in a Veterinary Medical Product compared to another product with the same active ingredient when administered at the same dose and under the same conditions.
Bioavailability	:	The rate and extent of absorption and availability of the active ingredient in the Veterinary Medical Product or any of its active metabolites in the blood or at its site of action in the body.

Qualified Person	:	A natural person who is scientifically and technically qualified and licensed to perform a specific activity within the field of pharmacy, veterinary medicine, or another field related to Veterinary Medical Products and establishments in accordance with the legislation in force in the State.
Solvents, Preservatives, and Excipients	:	Inactive substances used to improve the appearance and properties of the Veterinary Medical Product.
Import, Export, or Re-export Approval	:	The approval granted by the Establishment to a facility or concerned entity for the import, export, or re-export of specific Veterinary Medical Products required for the performance of their duties, and not for commercial purposes, in cases determined by a decision of the Chairman.
Import, Export, or Re-export Permit	:	The permit issued by the Establishment to a licensed veterinary medical warehouse or a licensed Veterinary Medical Products manufacturing facility for the import, export, or re-export of Veterinary Medical Products, upon fulfilling the prescribed conditions in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.
Controlled Substances and Products	:	Veterinary products and materials whose medical and commercial handling require special regulatory controls, which are: 1. Toxic substances and plants. 2. Prohibited substances. 3. Narcotic drugs and psychotropic substances, whether in raw form or within a Veterinary Medical Product. 4. Hazardous medical products.

Narcotic Drugs and Psychotropic Substances	:	Medical, pharmaceutical, and other products containing any of the active substances listed under the aforementioned Federal Decree by Law No. (30) of 2021, as amended, or any other law that supersedes it.
Semi-Controlled Substances and Products	:	Veterinary substances or medicines that are not classified as narcotic drugs or psychotropic substances, but whose movement within the State must be monitored because their misuse may cause harm to public health.
Chemical Precursors	:	A chemical substance used at any stage in the manufacture or production of veterinary medicines or medicinal products, and classified as a chemical precursor according to the schedules attached to Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that supersedes it.
Prohibited Veterinary Substances	:	Prohibited Veterinary Medical Products and any other prohibited materials related to the veterinary field that are not permitted for circulation in the State, which shall be designated pursuant to a decision issued by the Board of Directors.
Restricted Substances	:	Substances that are used in specific areas but are prohibited from use in others, and for which a decision shall be issued by the Board of Directors.
Side Effects	:	A set of signs and symptoms documented in the package leaflet of the Veterinary Medical Product, expected to occur in some target animals during the use thereof in accordance with the uses, doses, and routes of administration documented on the outer packaging or label of the Veterinary Medical Product or its package leaflet and specified in the marketing authorization.

Adverse Reaction	:	Any unintended and undesirable effect or symptom observed in an animal treated with a Veterinary Medical Product, within the doses documented in the package leaflet and the uses authorized under the marketing authorization, which occurs as a result of effects other than the primary effects of the Veterinary Medical Product.
Adverse Event	:	An undesirable medical occurrence in an animal receiving a Veterinary Medical Product or exposed to a specific medical intervention, which does not necessarily have a causal relationship with the Veterinary Medical Product. It is also referred to as an adverse reaction if the product is a veterinary medical device.
Unexpected Adverse Reaction	:	An adverse reaction occurring during the use of the Veterinary Medical Product that was not expected and whose nature or severity exceeds that documented in the marketing authorization.
Genetically Modified Organism (GMO)	:	A living organism that possesses a novel combination of genetic material different from its original composition, obtained through the use of modern biotechnology.
Genetically Modified Organism (GMO) Products for Veterinary Medical Use	:	Substances prepared from genetically modified living organisms or containing genetically modified living organisms, their derivatives, residues, or other products containing or incorporating a proportion of the genetically modified component and intended for veterinary medical use.
Approved Pharmacopoeias	:	Official scientific references that specify the technical standards for quality, purity, and testing of substances and medicinal products, and that are recognized by the Establishment as binding regulatory references.

Non-Clinical Research Entities	:	Licensed research establishments in the State, conducting laboratory or experimental research on Veterinary Medical Products, excluding research on target animals for therapeutic use.
Veterinary Clinical Research Entities	:	Licensed research establishments in the State, conducting clinical research on target animals for therapeutic use, to evaluate the safety and efficacy of Veterinary Medical Products.
Certificate of Free Sale	:	An official document issued by the Establishment confirming that the Veterinary Medical Product is authorized for circulation in the local market and permitted for export.
Certificate of a Pharmaceutical Product (CPP)	:	An official document issued by the Establishment, in accordance with the World Health Organization model, confirming that the Veterinary Medical Product is registered and licensed in the State, and setting out its regulatory data, quality, safety, and efficacy.
Reference Authorities	:	National, regional, or international regulatory authorities recognized by the Establishment as a reliable reference in the areas of registration and approvals for veterinary medical manufacturing facilities and products, and in the evaluation of their quality, safety, and efficacy.
Emergency Use Authorization	:	The authorization granted by the Establishment temporarily for the use of a Veterinary Medical Product that has not obtained marketing authorization, or for the expanded use of a Veterinary Medical Product that has obtained marketing authorization in areas other than those for which it was approved, in order to address a public health, epidemic, or environmental emergency that threatens human health, animal health, or food security.

Grey Market : The trade of Veterinary Medical Products through unlicensed channels in the State, or without obtaining the necessary approvals and authorizations in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.

Batch : A defined quantity of raw material, packaging material, or a Veterinary Medical Product processed in a single process or series of successive processes, expected to be homogeneous within the specified limits of quality standards.

Article (2)

Scope of Application of the Decree by Law

The provisions of this Decree by Law shall apply to the following Veterinary Medical Products and veterinary Pharmaceutical Establishments:

1. Veterinary medicinal products:
    a. Veterinary medicinal products, including veterinary biological products and injectable veterinary supplements.
    b. Veterinary raw materials.
    c. Veterinary complementary products.
    d. Veterinary medical devices.
    e. Genetically modified organism (GMO) products for veterinary medical use.
    f. Any other Veterinary Medical Products for which a resolution is issued by the Cabinet.
2. Pharmaceutical Establishments licensed to operate in the field of Veterinary Medical Products in the State in accordance with the applicable legislation, including those located in the free zones:
    a. Veterinary medical warehouses and storage facilities.
    b. Factories of Veterinary Medical Products and contract Veterinary Medical Products manufacturing organizations (CMO) for.
    c. Contract research and development organizations (CRDO).
    d. Veterinary non-clinical and clinical research entities.

e. Pharmaceutical laboratories.
f. Bioequivalence Centers.
g. Pharmaceutical consultancy offices.
h. Veterinary pharmacies.
i. Veterinary biobanks.
j. Marketing offices.
k. Any other Veterinary Pharmaceutical Establishments for which a resolution is issued by the Cabinet.

Article (3)

Approved Pharmacopoeias

The provisions stipulated in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that supersedes it, shall apply with respect to the reference and approved pharmacopoeias, which include Veterinary Medical Products.

Article (4)

Classification of Veterinary Medical Products

The Establishment shall classify the Veterinary Medical Products intended to be imported, manufactured locally, or circulated within the State. The classification shall be based on the nature, composition, use, and potential risk level of the product to animal, human, and environmental health, in accordance with the standards and controls issued by a decision of the Board of Directors.

Article (5)

List of Veterinary Vaccines

A list of veterinary vaccines shall be prepared by agreement between the Ministry and the Establishment, and the Establishment shall, by virtue of this list, issue marketing authorizations for any type of veterinary vaccine.

Article (6)

Exclusive Marketing Authorization

1. The Establishment may grant exclusive marketing authorization for a Veterinary Medical Product to specific entities according to the activities they conduct within the State, in the cases, for the periods, and under the controls and conditions issued by a decision of the Board of Directors.
2. It is prohibited to manufacture, import, distribute, possess, sell, or use the Veterinary Medical Product concerned with exclusive marketing in the State unless exclusive marketing authorization has been obtained from the Establishment.
3. The Establishment shall issue the exclusive marketing authorization for veterinary vaccines in accordance with the list referred to in Article (5) of this Decree by Law.

Article (7)

Marketing Authorization

1. Without prejudice to the applicable legislation, it is prohibited to import, export, distribute, possess, display, sell, re-market, or manufacture any Veterinary Medical Product in the State for the purpose of circulation therein, unless marketing authorization, of any type, has been obtained from the Establishment.
2. As an exception to Clause (1) of this Article, all categories of Veterinary Medical Products that are compounded in a veterinary pharmacy licensed to practice compounding pharmacy activities are exempted from the requirement of obtaining marketing authorization, in accordance with the controls and conditions specified by a resolution of the Board of Directors.
3. The Establishment shall issue the marketing authorization for veterinary vaccines in accordance with the list referred to in Article (5) of this Decree by Law.
4. By a resolution of the Cabinet, based on the Chairman's proposal, any Veterinary Medical Products may be exempted from the requirement of obtaining marketing authorization for their circulation in the State.

Article (8)

Conditions and Controls for Granting Marketing Authorization

1. The marketing authorization for a Veterinary Medical Product shall be issued by the Establishment in accordance with the following conditions and controls:
   a. The applicant shall be a veterinary pharmaceutical establishment licensed as a marketing office, a manufacturer of Veterinary Medical Products, or a veterinary medical warehouse designated by the marketing authorization holder.
   b. The applicant shall implement a quality assurance system, a traceability system for the Veterinary Medical Product, a veterinary pharmacovigilance system, and a post-marketing surveillance (PMS).
   c. The Veterinary Medical Product shall have obtained marketing authorizations from reference authorities, or fulfill the research information that proves its efficacy, safety of use, and conformity to the approved quality specifications, including the results of clinical evaluation or bioequivalence and post-marketing results.
   d. Submission of a certificate of analysis for the Veterinary Medical Products or a quality certificate for their batches that proves their quality or safety from a laboratory licensed or approved by the Establishment.
   e. The applicant shall have the right to market it in accordance with the rules established for intellectual property rights and trademarks. If the Veterinary Medical Product is a generic, the applicant shall ensure compliance with the applicable legislation regarding the protection of intellectual property and trademarks and submit evidence of the use of innovator products' information and data.
   f. Submission of a valid Good Manufacturing Practice (GMP) certificate from the Establishment and/or from the concerned regulatory authority in the country of origin and/or any of the reference authorities approved by the Establishment.
   g. All information and data related to the Veterinary Medical Product and its method of use shall be available on the inner and outer labels and in the printed or electronic leaflet of the Veterinary Medical Product, and the product shall comply with the labeling guidelines issued by the Establishment.

h. Any other conditions or controls specified by the Executive Regulations of this Decree by Law.

2. The Establishment may request any other data to ensure the safety and efficacy of the product, assess its environmental impact, or to ensure the safety of its use for food-producing animals to ensure the safety of consumption of their derivatives.
3. Without prejudice to the provisions of international agreements to which the State is a party, and the provisions of intellectual property legislation in force in this regard, the Establishment may grant marketing authorization for a generic product based on its bioequivalence and qualitative equivalence with a Veterinary Medical Product for which the legal protection has expired and for which a marketing authorization was previously issued.
4. The Executive Regulations of this Decree by Law shall specify the other conditions, requirements, and controls for granting marketing authorization, classified according to the type of Veterinary Medical Product and whether it is a generic, innovator, pioneer, or an orphan product.

Article (9)

Validity Period of Marketing Authorization and Renewal

1. The marketing authorization shall be valid for (5) five years and may be renewed for similar periods in accordance with the conditions and controls specified by the Executive Regulations of this Decree by Law.
2. An application for renewal of the marketing authorization shall be submitted within (90) ninety days prior to the expiry date of the marketing authorization.
3. The marketing authorization holder may not continue the activity authorized under the marketing authorization issued for the specific Veterinary Medical Product after the expiry date of the marketing authorization and until its renewal, unless the Establishment deems otherwise. The Establishment may permit the marketing authorization holder to continue the activities related to some Veterinary Medical Products if necessity, and for a period determined by the Establishment, in accordance with the conditions it decides in this regard.

4. The Establishment may grant a marketing authorization for a period shorter than the period referred to in Clause (1) of this Article, in accordance with the controls specified by the Executive Regulations of this Decree by Law.

Article (10)

Conditional Marketing Authorization

1. Without prejudice to the legislation in force regarding intellectual property, the Establishment may issue a conditional marketing authorization for the following Veterinary Medical Products:
   a. Orphan Veterinary Medical Products that have been approved internationally by some reference authorities on a temporary basis.
   b. Veterinary Medical Products for the treatment of life-threatening and serious diseases, where their use provides significant therapeutic benefit, and for which no alternative or equivalent Veterinary Medical Product authorized in the State is available.
   c. Veterinary Medical Products not available in the State for which no equivalent alternative is available.
   d. Any other products specified by the Executive Regulations of this Decree by Law.
2. The Establishment shall issue the conditional marketing authorization for veterinary vaccines in accordance with the list referred to in Article (5) of this Decree by Law.

Article (11)

Conditions and Controls for Granting Conditional Marketing Authorization

1. The conditional marketing authorization for a Veterinary Medical Product shall be issued by the Establishment in accordance with the following conditions:
   a. Fulfilling the conditions referred to in paragraphs (a, b, d, g) of Clause (1) of Article (8) of this Decree by Law.
   b. Evaluating of the Veterinary Medical Product's compliance with the marketing authorizations issued by reference authorities, or providing complete information and data on the justifications for the Veterinary Medical Product's receipt of conditional

marketing authorization from the country of origin or one of the reference authorities for evaluation.

c. Submitting a pledge confirming that an application for the marketing authorization referred to in Articles (7) and (8) of this Decree by Law will be submitted immediately upon the end of the reasons and justifications that necessitated requesting conditional marketing authorization, in the event the marketing authorization holder wishes to continue circulating the Veterinary Medical Product after the end of these reasons and justifications.

d. Any other conditions specified by the Executive Regulations of this Decree by Law.

2. The conditional marketing authorization for the Veterinary Medical Product is issued in accordance with the following controls:

a. Use of Veterinary Medical Products that have obtained conditional marketing authorization on specific animals or animal species without the need for conducting clinical trials.

b. Marketing of Veterinary Medical Products that have been granted conditional marketing authorization to address the temporary shortage of an equivalent licensed Veterinary Medical Product in the State, provided that the Veterinary Medical Product is licensed in another country with similar monitoring of Veterinary Medical Products, and there is no identical, licensed, and available Veterinary Medical Product in the State.

c. Any other controls specified by the Executive Regulations of this Decree by Law.

Article (12)

Validity Period of Conditional Marketing Authorization and Renewal

1. The conditional marketing authorization shall be valid for a period of one year and may be renewed for similar periods if the reasons and justifications for requesting the conditional marketing authorization continue.
2. The application for renewal of the conditional marketing authorization shall be submitted within (90) ninety days prior to the expiry date of the conditional marketing authorization,

and the renewal shall be carried out in accordance with the same conditions and controls specified for its initial issuance.

3. The applicant for the conditional marketing authorization may not continue to practice the activity mentioned in the conditional marketing authorization after its expiry date.
4. The Establishment may grant a conditional marketing authorization for a period shorter than the period referred to in Clause (1) of this Article, in accordance with the controls specified in the Executive Regulations of this Decree by Law.
5. If the marketing authorization holder wishes to continue circulating the Veterinary Medical Product after the expiry of the conditional marketing authorization and the cessation of the reasons and justifications for its submission, they shall apply for the marketing authorization referred to in Articles (7) and (8) of this Decree by Law.

Article (13)

Emergency Use Authorization

Without prejudice to the legislation in force regarding intellectual property and as an exception to the conditions and controls of marketing authorization, the Establishment may issue an emergency use authorization for certain Veterinary Medical Products needed by the State in the event of a public health emergency, epidemic, or pandemic, which is declared in accordance with the legislation in force in this regard. The Establishment shall, in agreement with the Ministry, establish a mechanism to ensure the expedited issuance of emergency use authorization for veterinary vaccines.

Article (14)

Conditions and Controls for Emergency Use Authorization

1. The emergency use authorization for the Veterinary Medical Product is issued in accordance with the following conditions:
    a. There is evidence proving the efficacy of the Veterinary Medical Product in diagnosing, treating, or preventing the diseases related to the public health emergency, epidemic, or pandemic.
    b. The known and potential benefits of the Veterinary Medical Product outweigh its risks.

c. The unavailability of sufficient, approved, and available alternatives to the Veterinary Medical Product for diagnosing, treating, or preventing diseases related to the public health emergency, epidemic, or pandemic.
d. Availability of data from clinical research or clinical trials or any other reference sources that prove the safety and efficacy of the Veterinary Medical Product.
e. Existence of a plan submitted by the marketing authorization holder to monitor the use of the Veterinary Medical Product and manage any risks associated with its use.
f. Any other conditions specified by the Executive Regulations of this Decree by Law.

2. In the event the State or part of its territory is exposed to a public health emergency, epidemic, or pandemic, which is declared in accordance with the legislation in force in this regard, the Establishment may grant emergency use authorization and an import permit for the generic product before the expiry of the legal protection period of the reference innovator product.

Article (15)

Validity and Extension of Emergency Use Authorization

1. The emergency use authorization for the Veterinary Medical Product shall be valid for the duration of the public health emergency, epidemic, or pandemic declared by the State, and until an announcement is made stating the end of the public health emergency, epidemic, or pandemic, unless another period is determined by the Establishment.
2. The Establishment may review the issued emergency use authorization and consider its revocation based on new evidence or changes in the public health emergency or related to the epidemic or pandemic.
3. The Establishment may extend the validity of the issued emergency use authorization for periods determined thereby if the public health emergency continues, and the Veterinary Medical Product continues to meet the necessary standards.
4. The entity that submitted the application for emergency use authorization may not continue the activity mentioned in the emergency use authorization after its expiry date.
5. If the marketing authorization holder wishes to continue circulating the Veterinary Medical Product after the expiry of the emergency use authorization and the cessation of

the reasons and justifications for its submission, they shall apply for the marketing authorization referred to in Articles (7) and (8) of this Decree by Law.

Article (16)

Fast-Track Marketing Authorization

1. The Establishment shall establish a fast track with simplified procedures that are aligned with quality, safety, and efficacy requirements and international agreements to grant marketing authorizations for innovator Veterinary Medical Products of therapeutic or preventive importance.
2. The Executive Regulations of this Decree by Law shall specify the Veterinary Medical Products permitted to be included in the fast track provided for in Clause (1) of this Article, and the conditions, controls, and requirements for submitting an application for marketing authorization within this track.

Article (17)

Resubmission of Application for Marketing Authorization and Conditional Marketing Authorization

The marketing authorization or conditional marketing authorization issued by the Establishment shall be deemed invalid, and the marketing authorization holder may not use it. They shall resubmit a new application for a marketing authorization or conditional marketing authorization for the same Veterinary Medical Product in any of the following cases:

1. Substantial changes in the composition or formulation of the Veterinary Medical Product.
2. Substantial changes in the dosage form or its concentration.
3. Changes in the classification of the type of Veterinary Medical Product or its route of administration, which were not included in the current marketing authorization or conditional marketing authorization.
4. Substantial changes in the manufacturing and production process that may affect the quality, safety, or efficacy of the Veterinary Medical Product.

5. Existence of substantial changes in the design of the veterinary medical device.
6. Voluntary withdrawal of the Veterinary Medical Product from the market for subsequent reintroduction with significant changes.
7. The results of veterinary pharmacovigilance operations require the withdrawal of the Veterinary Medical Product or its re-evaluation and the implementation of substantial changes thereto.
8. Any other cases specified by the Executive Regulations of this Decree by Law.

Article (18)

Approval of Minor Changes to the Veterinary Medical Product

The marketing authorization holder shall submit an application to the Establishment to apply minor changes to the Veterinary Medical Product, without the need to submit a new application for marketing authorization of any of its types as referred to in Articles (7) and (8) of this Decree by Law, in any of the following cases:

1. Any changes in the composition of inactive substances in the Veterinary Medical Product.
2. Any new uses of the Veterinary Medical Product, whether as new indications for use or its suitability for a new animal species.
3. Any change in the packaging form of the Veterinary Medical Product or its inner leaflet.
4. Changes related to the manufacturing site of the Veterinary Medical Product or to the marketing authorization holder or minor changes in the manufacturing method.
5. Any other cases specified by the Executive Regulations of this Decree by Law.

Article (19)

Revocation of Marketing Authorization of All Types, or Revocation of Emergency Use Authorization, and Transfer of Ownership

1. The Establishment may issue a decision to revoke the marketing authorization of any of its types or revoke the emergency use authorization for a Veterinary Medical Product in the State, in the following cases:

a. The locally manufactured Veterinary Medical Product has not been placed on the market within (2) two years from the date of being granted the marketing authorization without an acceptable excuse from the Establishment.
b. The imported Veterinary Medical Product has not been placed on the market within one year from the date of being granted the marketing authorization without an acceptable excuse from the Establishment.
c. Unavailability of the Veterinary Medical Product in the market for (2) two consecutive years after its placement on the market without an acceptable excuse from the Establishment.
d. The Veterinary Medical Product that obtained an emergency use authorization or conditional marketing authorization has not been placed on the market without an acceptable excuse from the Establishment.
e. If it is proven that the marketing authorization of any of its types or the emergency use authorization was obtained based on incorrect documents or documents that were forged or tampered with.
f. If a decision is issued to ban the manufacture, distribution, or circulation of the Veterinary Medical Product in the State or in the country of origin or any of the reference authorities accredited by the Establishment.
g. If repeated non-application of the principles of Good Manufacturing Practice (GMP) by the manufacturer of Veterinary Medical Products or the Veterinary Medical Products Contract Manufacturing Organization is proven.
h. If the lack of safety and security of the Veterinary Medical Product or repeated non-conformity with quality standards is proven upon conducting laboratory tests.
i. If a decision is issued to ban the activity of the Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization.
j. Any other cases specified by the Executive Regulations of this Decree by Law.

2. With the approval of the Establishment, the ownership of the marketing authorization or conditional marketing authorization for a Veterinary Medical Product may be transferred to other parties in accordance with the conditions and cases specified by the Executive Regulations of this Decree by Law.

Article (20)

Intellectual Property Protection

Without prejudice to the legislation in force regarding intellectual property, the documents and data related to the innovator Veterinary Medical Product and the Veterinary Medical Product with at least one new active ingredient, whether developed in the State or imported, shall be subject to a protection period. The Executive Regulations of this Decree by Law shall specify the period, mechanism, and system related to regulatory protection.

Article (21)

Scientific Fraud

Veterinary Pharmaceutical Establishments licensed to manufacture, market, or distribute a Veterinary Medical Product or to provide veterinary pharmaceutical consultancy shall refrain from any falsification, manipulation, theft, or scientific plagiarism of published studies and research, which affects the legal rights established for the owners of these studies and research.

Article (22)

Pricing of the Veterinary Medical Product

For a Veterinary Medical Product to be circulated in the State, it is required to affix the specified price label for this product on the package, in accordance with the general rules issued by a resolution of the Board of Directors, which specify the categories subject to pricing by the Establishment and its pricing mechanism.

Article (23)

Obligations of the Marketing Authorization Holder

The marketing authorization holder or their representative for the purpose of marketing Veterinary Medical Products shall be committed to the following:

1. Appoint one or more qualified persons residing in the State, in accordance with the controls specified by the Executive Regulations of this Decree by Law.

2. Comply with the provisions and controls stipulated in Article (24) of this Decree by Law.
3. Monitor the movement of the Veterinary Medical Product in the distribution channels.
4. Provide the required capabilities and systems to follow up on the requirements for obtaining marketing authorization of any of its types or the emergency use authorization for the Veterinary Medical Product.
5. Monitor the performance of the licensed Veterinary Medical Product after its marketing, and receive reports from Veterinary Pharmaceutical Establishments and Veterinary Establishments regarding the effectiveness, safety, and quality of the Veterinary Medical Product.
6. Comply with the guidelines and standards issued by the Establishment regarding veterinary pharmacovigilance, including notifying the Establishment of warnings issued by the marketing office, the manufacturer of Veterinary Medical Products, the contract manufacturing organization for Veterinary Medical Products, or international organizations or bodies regarding the Veterinary Medical Product that has obtained marketing authorization of any of its types or emergency use authorization, or if the marketing authorization issued for the Veterinary Medical Product is revoked, suspended, withdrawn, or its manufacturing is stopped in the country of origin or any other country that has issued a marketing authorization therefor.
7. Follow up on the procedures for withdrawing the Veterinary Medical Product.
8. Follow up on matters of patent protection and manufacturing rights for the product.
9. Notify the Establishment of warnings issued regarding the safety and efficacy of the Veterinary Medical Product.
10. Notify the Establishment of the cessation of manufacturing, suspension, or cessation of circulation of the Veterinary Medical Product in the country of origin.

Article (24)

Appointment of a Veterinary Pharmaceutical Establishment

1. The marketing authorization holder shall appoint one or more Veterinary Pharmaceutical Establishments licensed by the Establishment to import and distribute Veterinary Medical

Products into the State as an importer of the Veterinary Medical Product that has obtained a marketing right, in accordance with the following controls:

a. The marketing authorization holder shall notify the Establishment of the designation of one primary veterinary pharmaceutical establishment from among the appointed pharmaceutical establishments by the marketing authorization holder to undertake all the licensing activities for the product, veterinary pharmacovigilance activities, and full life cycle management of the Veterinary Medical Product completely.
b. A single application shall be submitted by the veterinary pharmaceutical establishment specified in paragraph (a) of this clause to obtain a marketing authorization of any of its types for each Veterinary Medical Product, regardless of the number of designated Veterinary Pharmaceutical Establishments.
c. All designated Pharmaceutical Establishments are obligated to import Veterinary Medical Products within one year from the date of issuance of the authorization.

2. The local marketing authorization holder for locally manufactured Veterinary Medical Products is obligated to appoint one or more licensed Pharmaceutical Establishments in the State to store and distribute the Veterinary Medical Product that has obtained a marketing right, either by establishing dedicated facilities for that purpose at the local factory licensed by the Establishment or by appointing one or more Pharmaceutical Establishments to perform these tasks.
3. The Executive Regulations of this Decree by Law shall specify any controls or conditions related to this Article.
4. The Cabinet may, based on the Chairman's proposal and in accordance with the controls specified thereby, exempt the marketing authorization holder from applying the provision of this Article.

Article (25)

Obligations of the Appointee by the Marketing Authorization Holder

The qualified person appointed by the marketing authorization holder is obligated to the following:

1. Provide pharmaceutical or scientific information about the marketed Veterinary Medical Product and ensure its accuracy and conformity with the information approved by the Establishment.
2. Inform the Establishment of any change or update in the manufacturing methods, composition, source of active ingredients, form, packaging, inspection methods, or of any new use, modification, update, addition, or deletion of the uses of the Veterinary Medical Product specified in the marketing authorization of any of its types, or in the emergency use authorization.
3. Comply with the guidelines and standards issued by the Establishment regarding veterinary pharmacovigilance.
4. Follow up on post-marketing reports of the Veterinary Medical Product, and reports on its efficacy, safety of use, and quality during its circulation in the State.

Article (26)

Liability of the Qualified Person and the Marketing Authorization Holder

The qualified person shall be jointly liable with the marketing authorization holder, for any violations of the provisions of this Decree by Law, particularly with respect to maintaining all records and documentation related to the activity of circulating the Veterinary Medical Product.

Article (27)

Non-Clinical and Clinical Research on Veterinary Medical Products

1. It is prohibited to conduct non-clinical research on the target animal. The Executive Regulations of this Decree by Law shall specify the conditions, controls, and procedures for non-clinical research.
2. It is prohibited to conduct any clinical trials for Veterinary Medical Products before conducting non-clinical research on such products to ensure the safety and efficacy of the intended medical intervention on the target animals of the clinical studies.
3. The conditions, controls, and procedures for clinical research on Veterinary Medical Products shall be issued by a resolution of the Cabinet.

Article (28)

Approved or Licensed Laboratory

A laboratory study, a certificate of analysis of a Veterinary Medical Product, or a quality certificate for a batch or batches of a Veterinary Medical Product shall not be accepted as a document authorizing its quality, stability, or safety, unless it has been conducted and approved by an approved or licensed laboratory by the Establishment, and in accordance with the good practice standards prepared or adopted by the Establishment for good laboratory practice.

Article (29)

Conditions for Manufacturing a Veterinary Medical Product

1. No Veterinary Medical Product intended for marketing in the State may be manufactured unless a marketing authorization of any of its types or an emergency use authorization has been obtained from the Establishment, provided that it is manufactured in a factory licensed in the State.
2. No Veterinary Medical Product intended for export may be manufactured in the State unless a permit has been obtained from the Establishment, and in accordance with the controls and conditions specified by the Executive Regulations of this Decree by Law.

Article (30)

Good Practice

The Board of Directors shall issue a decision specifying the rules, guidelines, and standards of good practice that are aligned with internationally recognized guiding principles and standards, to ensure the quality, efficiency, and safety of Veterinary Medical Products as well as the operational standards of Veterinary Pharmaceutical Establishments. The decision shall also specify the mechanism for issuing good practice certificates according to the activity and category of the establishment.

Article (31)

Transfer and Lending of Manufacturing Materials

1. Without prejudice to the approvals that may be required from the Competent Authority, it is not permitted to loan or transfer solvents, preservatives, and excipients between Veterinary Medical Products Manufacturing Facilities or Contract Manufacturing Organizations and other licensed factories in the State except with the approval of the Establishment, in a manner that does not prejudice the specifications, safety, security, and quality of the Veterinary Medical Product intended to be manufactured.
2. The Executive Regulations of this Decree by Law shall specify the cases, conditions, and controls for obtaining the approval referred to in Clause (1) of this Article.

Article (32)

Enhancing Investment in the Veterinary Medical Industries Sector

The Cabinet shall issue a resolution, based on the proposal of the Chairman and after coordination with the Ministry, the Competent Authority, and any other concerned authority, establishing a system of incentives and benefits to attract investment and support innovation and development in the veterinary medical industries sector.

Article (33)

Approval or Permit for Import, Export, or Re-export of a Veterinary Consignment

1. It is not permitted to import, export, or re-export any Veterinary Consignment except after the issuance of an approval or permit from the Establishment in accordance with the decisions issued thereby.
2. The cases exempted from Clause (1) of this Article shall be specified by a resolution of the Cabinet based on the proposal of the Chairman after coordination with the Ministry, the Competent Authority, and any other concerned authority, and in accordance with the controls and conditions contained in the resolution.

Article (34)

Conditions for Issuing an Import, Export, or Re-export Approval or Permit

1. An approval or permit to import, export, or re-export any Veterinary Consignment shall be issued by the Establishment in accordance with the following conditions:
   a. The existence of a valid marketing authorization of any type, an emergency use authorization, or a manufacturing permit issued by the Establishment for the Veterinary Medical Product within the Veterinary Consignment intended for import, export, or re-export. Products exempted from obtaining marketing authorization in accordance with the provisions of Article (7) of this Decree by Law shall be excluded from this condition.
   b. The applicant shall be a marketing office, a Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization, or a Veterinary Medical Warehouse licensed to practice the specified activity in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.
   c. Any other conditions specified by the Executive Regulations of this Decree by Law.
2. The Executive Regulations of this Decree by Law shall specify the cases in which Veterinary Medical Products may be imported, exported, or re-exported within Veterinary Consignments before the issuance of marketing authorization of any type or emergency use authorization.
3. The Establishment may verify the fulfillment of the conditions referred to in Clause (1) of this Article and may also verify the shipping conditions by inspecting the Veterinary Consignments.
4. The Establishment may restrict or prohibit the import, export, or re-export of certain Veterinary Medical Products or Veterinary Consignments if their use poses a risk to human or animal health, or if circumstances indicate that they may be intended for illegal purposes.
5. A decision issued by the Board of Directors shall establish a list of Veterinary Medical Products whose import, export, or re-export is restricted or prohibited, including Veterinary Medical Products prohibited for use in different animal species.

6. Without prejudice to the legislation in force regarding controlled and semi-controlled, and narcotic, and psychotropic substances and products, the Board of Directors shall issue a decision regulating the procedures related to Veterinary Medical Products consignments that are in temporary transit through the State's ports or are transiting through the State without entering its territory.

Article (35)

Revocation of Import, Export, or Re-export Approval or Permit and Transfer of its Ownership

1. The Establishment shall issue a decision revoking the approval or permit it has issued for the import, export, or re-export of a Veterinary Consignment in any of the following cases:
   a. If it is proven that the approval or permit was obtained from the Establishment based on forged documents or incorrect information.
   b. If any data is received proving that the Veterinary Medical Products within the veterinary consignment intended for import, export, or re-export are unsafe.
   c. The existence of any reasons that necessitate the revocation or resubmission of the marketing authorization of any type or the emergency use authorization issued for the veterinary medical product.
   d. The withdrawal or suspension of the marketing authorization of any type or the emergency use authorization issued for the Veterinary Medical Product within the Veterinary Consignment in the country of origin, or if the country of origin revokes the international export permit.
   e. Any other cases specified by the Executive Regulations of this Decree by Law.
2. The ownership of the import, export, or re-export approval or permit issued by the Establishment may not be transferred to another party. If such transfer occurs, the approval or permit shall be revoked, and a new application for an import, export, or re-export approval or permit shall be submitted.

Article (36)

Personal Use of Veterinary Medical Products

1. It is not permitted to bring, possess, or carry a Veterinary Medical Product by any person upon entering the State for personal use, nor to bring a Veterinary Medical Product through shipping companies, unless the Veterinary Medical Product is unavailable in the State and has no equivalent alternatives. This is subject to obtaining the Establishment's approval in accordance with the controls and procedures specified by the Executive Regulations of this Decree by Law.
2. It is not permitted to possess or carry a Veterinary Medical Product by any person upon leaving the State for personal use, nor to send a Veterinary Medical Product through shipping companies, except after obtaining the Establishment's approval in accordance with the controls and procedures specified by the Executive Regulations of this Decree by Law.

Article (37)

Provision of Veterinary Medical Products

1. None of the following categories may refrain from providing a Veterinary Medical Product that has a marketing authorization of any type, an emergency use authorization, or an exemption thereof, in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof, without a legitimate justification or with the intent to monopolize. The Establishment may take appropriate measures to compel them to provide the Veterinary Medical Products:
   a. The marketing authorization holder.
   b. The qualified person appointed by the marketing authorization holder.
   c. The licensed Veterinary Pharmaceutical Establishment designated by the marketing authorization holder for the import and marketing of Veterinary Medical Products.
2. The categories referred to in Clause (1) of this Article shall maintain a sufficient stock of the Veterinary Medical Product in the State, to ensure its availability for use within the State in accordance with the standards and requirements specified by a decision of the Board of Directors.

3. The categories referred to in Clause (1) of this Article shall notify the Establishment of any potential or actual shortage in the stock of Veterinary Medical Products, in accordance with the mechanism established by the Establishment in coordination with the Ministry and the Competent Authority.

Article (38)

Veterinary Medical Product Information

1. No Veterinary Medical Product may be circulated or marketed unless the information and data recorded on the product's inner and outer label and in its printed or electronic leaflet are consistent with the information and data contained in its marketing authorization of any type or emergency use authorization, or are identical to the approved details in the country of origin if the product is exempt from obtaining a marketing authorization. The Establishment shall specify the data that shall be registered on the inner and outer label and in the information leaflet for the Veterinary Medical Product.
2. Both Arabic and English languages shall be used, at a minimum, on the inner and outer label and in the printed and electronic leaflet of the Veterinary Medical Product. If this is not feasible, the Establishment may approve the use of the English language at a minimum.

Article (39)

Circulation of Veterinary Medical Products Requiring a Prescription

Non-veterinary Pharmaceutical Establishments are prohibited from importing, marketing, selling, displaying, storing for the purpose of circulation, or circulating any Veterinary Medical Product that requires a prescription for dispensing.

Article (40)

Circulation of Veterinary Medical Products Without a Prescription

The Board of Directors shall issue a decision specifying the types of non-Veterinary Pharmaceutical Establishments permitted to market, sell, display, store, or circulate Veterinary

Medical Products that may be dispensed without a prescription, a list of these products, and the procedures, controls, and conditions regulating their sale, display, storage, and circulation.

Article (41)

Prescribing and Selling Veterinary Medical Products

1. The prescription and sale of Veterinary Medical Products shall be subject to the following controls:
   a. A veterinary prescription may not be dispensed or altered except by a specialized and licensed veterinarian in accordance with the legislation in force in the State.
   b. Veterinarians may not prescribe a Veterinary Medical Product for new uses or for species not indicated as target species in the inner leaflet.
   c. Veterinary antibiotics may not be dispensed without a prescription.
   d. Antibiotics may not be used for prophylactic purposes, to enhance immunity, or to stimulate growth.
   e. All Veterinary Establishments shall maintain records and documents related to the sale and dispensing of Veterinary Medical Products for a period of one year from their date of issuance.
   f. Any other controls specified by the Executive Regulations of this Decree by Law.
2. A veterinarian may prescribe therapeutic alternatives in cases where a Veterinary Medical Product with a marketing authorization of any type or an emergency use authorization is unavailable, in accordance with the controls specified by the Executive Regulations of this Decree by Law.
3. The Executive Regulations of this Decree by Law shall specify the specifications of a veterinary prescription.

Article (42)

Prohibition of Circulation and Sale

1. The circulation of adulterated, defective, expired, grey market Veterinary Medical Product, or products prohibited from circulation under the legislation in force in the State is prohibited.

2. The sale of free promotional samples of Veterinary Medical Products is prohibited. The phrase "Free medical sample not for sale" shall be written clearly and indelibly on the outer and inner labels in both Arabic and English.

Article (43)

National Policy for the Strategic Stockpile of Veterinary Medical Products

The Establishment shall issue the National Policy for the Strategic Stockpile of Veterinary Medical Products after its approval by the Cabinet. The Establishment shall be responsible for its management and monitoring its implementation at the federal and local levels in coordination with the National Emergency Crisis and Disasters Management Authority and other concerned authorities at the federal and local levels.

Article (44)

Promotion of and Advertising for the Veterinary Medical Product

1. It is prohibited to advertise, publicize, or promote Veterinary Medical Products by any means, whether visual, written, or audio, or on social media, except after obtaining the approval of the Establishment.
2. It is prohibited to advertise, publicize, or promote restricted materials, or controlled, semi-controlled, hazardous, or toxic substances and products.
3. The Establishment may prohibit the advertising, publicity, or promotion of certain Veterinary Medical Products in accordance with the controls specified by the Executive Regulations of this Decree by Law.

Article (45)

Conditions for Issuing Approval for Advertising a Veterinary Medical Product

Approval for advertising, publicizing, or promoting Veterinary Medical Products shall be issued by the Establishment in accordance with the following conditions:

1. The existence of a valid marketing authorization of any type or an emergency use authorization issued by the Establishment for the Veterinary Medical Product to be advertised. Products exempted from obtaining marketing authorization in accordance with the provisions of Article (7) of this Decree by Law are exempted from this condition.
2. The applicant shall be a licensed Veterinary Pharmaceutical Establishment in the State.
3. The advertising material shall be truthful, non-misleading, and supported by evidence that reflects the approved information and uses of the Veterinary Medical Product.
4. The advertising material shall clearly disclose any risks or side effects associated with the Veterinary Medical Product.
5. Any other conditions specified by the Executive Regulations of this Decree by Law.

Article (46)

Validity Period of the Approval for Advertising a Veterinary Medical Product

The approval for advertising, publicizing, or promoting the Veterinary Medical Product issued by the Establishment shall be valid for the period specified by the applicant, provided that this period does not exceed one year.

Article (47)

Revocation of the Approval for Advertising a Veterinary Medical Product and Transfer of its Ownership

1. The Establishment may issue a decision to revoke its approval for advertising, publicizing, or promoting the Veterinary Medical Product during its validity period and take measures to withdraw the advertisement from all media in which it was published, whether visual, written, or audio, or on social media, in coordination with the concerned authorities, in any of the following cases:
   a. If it is proven that the approval was obtained from the Establishment as a result of submitting forged documents or incorrect or misleading information.
   b. Non-compliance of the advertising materials submitted to the Establishment with the published advertisement.

c. If any new data emerges after the publication of the advertisement proving the lack of safety of the advertised Veterinary Medical Product.
d. Failure to meet any of the conditions for issuing the approval for advertising the Veterinary Medical Product as stipulated in Article (45) of this Decree by Law, after the advertisement has been published.
e. Revocation or suspension of the marketing authorization of any type or the emergency use authorization issued for the advertised Veterinary Medical Product.
f. Any other cases specified by the Executive Regulations of this Decree by Law.

2. The ownership of the approval for advertising the Veterinary Medical Product issued by the Establishment may not be transferred to another party. In the event of a transfer, the advertising approval shall be revoked, and a new application for approval for advertising the Veterinary Medical Product shall be submitted.

Article (48)

Safe Disposal of Veterinary Medical Products

1. The safe disposal of Veterinary Medical Products shall be carried out through a specialized company authorized by the Competent Authority, or through the Veterinary Pharmaceutical Establishment that manufactures them, provided it has the appropriate safe technical means to do so.
2. The safe disposal of Veterinary Medical Products shall be carried out in accordance with mechanisms and controls that meet public safety requirements and prevent environmental pollution, in accordance with the legislation in force in this regard, in the following cases:
   a. Cessation of circulation, suspension, or deregistration of a Veterinary Medical Product for which destruction has been decided.
   b. Recall or withdrawal of a Veterinary Medical Product for which destruction has been decided.
   c. Proof of fraud, adulteration, or expiry of the Veterinary Medical Product.
   d. The Veterinary Medical Product's non-compliance with the specifications of its Marketing Authorization, of any type, or its Emergency Use Authorization.

e. Storage of the Veterinary Medical Product under unsuitable storage conditions, after confirming that it is no longer fit for use.
f. Any other case specified by a resolution of the Board of Directors.

3. With due regard to the provisions of Clauses (1) and (2) of this Article, the procedures and technical requirements approved by the Competent Authority for the safe disposal of Veterinary Medicinal Products must be adhered to.
4. The Establishment may require marketing offices, Veterinary Medical Products manufacturing facilities or Contract Manufacturing Organizations, or Veterinary Medical Warehouses to re-export imported Veterinary Medical Products intended for safe disposal to the entity from which they were received, in coordination with the Competent Authority.
5. The Veterinary Pharmaceutical Establishments referred to in Clause (4) of this Article shall bear the costs of the safe disposal or re-export process for the Veterinary Medicinal Products intended for disposal.

Article (49)

Controlled and Semi-Controlled Substances and Products, and Veterinary Chemical Precursors

The same provisions set forth in Federal Decree by Law No. (30) of 2021 Regarding the Control of Narcotic Drugs and Psychotropic Substances, and in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, and any other laws that may supersede them, shall apply to the controlled and semi-controlled substances and products, and chemical precursors related to Veterinary Medical Products.

Article (50)

Circulation of Prohibited and Restricted Substances

1. The circulation of Prohibited and Restricted Substances shall be subject to the following controls:

a. The manufacturing, import, export, or re-export of Prohibited Substances, as specified by a decision of the Board of Directors, is prohibited.
b. The circulation of Restricted Substances is permitted for their use in specific areas, while their use in other areas is prohibited. A decision shall be issued by the Board of Directors specifying such substances and their areas of use.
c. By a decision of the Board of Directors, an exception may be granted for the use of any Restricted Substances outside the specified areas, for therapeutic or scientific research purposes, based on a request from the Emirates Racing Authority, the Competent Authority, the research entity, licensed Veterinary Pharmaceutical Establishments, or licensed Veterinary Establishments.
d. An exception may be granted for the import, manufacturing, or circulation of any of the Prohibited Substances, and their use for therapeutic or scientific research purposes, based on a request from the Emirates Racing Authority, the Competent Authority, the research entity, licensed Veterinary Pharmaceutical Establishments, or licensed Veterinary Establishments. A decision of the Board of Directors shall determine the cases in which this exception may be granted, as well as its conditions and procedures.

2. The regulation of the circulation of Prohibited and Restricted Substances in the field of horse and equestrian racing shall be subject to the provisions set forth in Federal Law No. (7) of 2015 Regarding the Combating of Substances Prohibited in Horse Racing and Equestrian Sports, and any amendments thereto.

Article (51)

National System for Tracking and Tracing Veterinary Medical Products

1. The tracking and tracing of Veterinary Medical Products from the manufacturer to the end-user shall be carried out within the national system for the circulation, tracking, and tracing of medical products, established and regulated in accordance with the provisions set forth in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that may supersedes it.

2. The provisions set forth in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that may supersedes it, related to the national system for the circulation, tracking, and tracing of medical products, shall apply to veterinary medical products. The Establishment shall make the system available for use and reporting to the following additional categories in the State:
   a. The Ministry.
   b. The Competent Authority.
   c. The Emirates Racing Authority.
   d. The Veterinary Pharmaceutical Establishment.
   e. The Veterinary Establishment.
   f. Any other concerned entity.

Article (52)

Database of Veterinary Medical Products

All data and information related to Veterinary Medical Products, their technical specifications, and all approvals issued in respect thereof, as referred to in this Decree by Law, shall be kept in the Medical Products database established and regulated in accordance with the provisions set forth in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that may supersedes it. The same procedures, mechanisms, and obligations stipulated in the said database shall apply thereto.

Article (53)

Database of Veterinary Pharmaceutical Establishments

All data and information related to Veterinary Pharmaceutical Establishments shall be kept in the Pharmaceutical Establishments and biobanks database established and regulated in accordance with the provisions set forth in Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other

law that may supersedes it. The same procedures, mechanisms, and obligations stipulated in the said database shall apply thereto.

Article (54)

Veterinary Pharmacovigilance

1. The Board of Directors shall issue a decision specifying the controls, conditions, and practices of Veterinary Pharmacovigilance that must be adhered to by the Marketing Authorization holder and licensed Veterinary Pharmaceutical Establishments.
2. Without prejudice to the legislation in force in this regard, the Establishment shall be responsible for raising awareness among practitioners of the veterinary profession, Veterinary Pharmaceutical Establishments, and members of the public about safety information related to Veterinary Medical Products and all matters related to licensing decisions, revocation, and the results of post-marketing surveillance.
3. The Veterinary Pharmaceutical Establishment, the Veterinary Establishment, the Ministry, the Competent Authority, the Emirates Racing Authority, and any other concerned entity, its employees, and practitioners of veterinary professions shall report the following to the Establishment:
    a. Any serious Side Effects, serious Adverse Events, or serious Adverse Reactions, whether expected or unexpected, for the Veterinary Medical Product during its use or from local and international Veterinary Clinical Research conducted thereon, as soon as known, and not exceeding (5) five days from the date of awareness. The reporting can be in the form of initial reports, provided that follow-up reports are submitted within a maximum of (15) fifteen days from the date of reporting, including a reassessment of the case and completion of the data.
    b. Any non-serious Side Effects, Adverse Events, or Adverse Reactions for the Veterinary Medical Product during its use or from local and international Veterinary Clinical Research conducted thereon, within (90) ninety days of receiving the related reports, provided that the reporting is in the form of completed reports.

c. Any complaint or report of a recall of a batch of the veterinary medical product or the entire veterinary medical product, within or outside the State, within a period not exceeding (15) fifteen days from the date of awareness of the complaint or report.

d. Any suspicion of fraud, adulteration, or misrepresentation in the Veterinary Medical Product or suspicion of illicit trade of Veterinary Medical Products by third parties, immediately from the date of awareness.

e. Any defects in the quality of the Veterinary Medical Product within (15) fifteen days of receiving the reports related thereto.

4. Members of the public may report directly to the Establishment or report to the Veterinary Pharmaceutical Establishment, the Veterinary Establishment, the Ministry, or the Competent Authority, any of the cases mentioned in Clause (3) of this Article, immediately from the date of awareness.
5. The Establishment shall establish and manage the national electronic system for receiving and documenting reports of the cases referred to in Clause (3) of this Article, and the related data and information received from the categories specified in Clauses (3) and (4) of this Article. The Establishment shall be committed to raising awareness among these categories regarding the reporting mechanism and the use of the system.
6. The Establishment shall determine the mechanism for documenting reports in the system referred to in Clause (5) of this Article, which may be received through the system referred to in Article (51) of this Decree by Law, or verbally or in writing outside the system, by the categories specified in Clauses (3) and (4) of this Article.
7. The Establishment shall investigate the reports received for the cases referred to in Clause (3) of this Article, and verify their accuracy and precision in coordination with Veterinary Establishments or Veterinary Pharmaceutical Establishments. In this regard, it may conduct announced and unannounced inspection operations, take samples, and request the necessary information and documents. Based on the results of the investigation, the Establishment shall suspend or withdraw the concerned Veterinary Medical Product or take any other necessary measures or actions to prevent the recurrence of such report.

Article (55)

Prohibition of Import, Suspension of Distribution, Ban on Circulation, or the Suspension or Withdrawal of a Veterinary Medical Product

1. The Establishment may prohibit the import, suspend the distribution, ban the circulation, suspend, recall, or withdraw a Veterinary Medical Product, or revoke its Marketing Authorization of any type or its Emergency Use Authorization, if it is necessary to verify information indicating its lack of quality, safety, or efficacy. The Establishment must issue a decision to withdraw the Veterinary Medical Product completely or Batches of it within (30) thirty days from the date of suspension, in any of the following cases:
   a. If it is established that the Veterinary Medical Product is adulterated or does not conform to the quality, safety of use, or efficacy specifications approved by the Establishment.
   b. If it is established that the Veterinary Medical Product is toxic or harmful under the conditions of use recommended by the manufacturing or marketing company.
   c. If an unexpected and serious Side Effect or Adverse Reaction to the Veterinary Medical Product occurs after its use under the conditions of use recommended by the manufacturing or marketing company.
   d. If the Marketing Authorization of any type or the Emergency Use Authorization for the Veterinary Medical Product is revoked, or its validity period has expired without a renewal application being submitted.
   e. If it is established that the Marketing Authorization of any type or the Emergency Use Authorization for the Veterinary Medical Product was granted based on incorrect documents or data, or on unauthorized uses.
   f. If the Marketing Authorization issued for it in the country of origin has been revoked or its production has been suspended there.
   g. If the use of the Veterinary Medical Product has been suspended based on a recommendation from relevant international regulatory organizations or authorities, or if studies and technical reports from international organizations or authorities on Veterinary Medical Products and their establishments indicate the need for such action.

h. If any changes or modifications are made to the Veterinary Medical Product without obtaining the necessary approval in accordance with the provisions of Articles (17) and (18) of this Decree by Law.

2. The Establishment shall verify the validity of the cases referred to in Clause (1) of this Article by checking their accuracy and precision with the relevant Veterinary Establishments or Veterinary Pharmaceutical Establishments. It may conduct announced or unannounced inspection operations, take samples, and request the necessary information and documents.
3. In all cases, the Establishment, the Ministry, the Competent Authority, the Emirates Racing Authority, and any other concerned entity must coordinate regarding any measures taken in accordance with this Article. The Ministry also has the right to suspend the Veterinary Medical Product in the Veterinary Establishments licensed thereby, with the obligation to inform the Establishment.

Article (56)

Certificate of Free Sale and Certificate of a Pharmaceutical Product for Veterinary Medical Products

The Establishment shall issue a Certificate of Free Sale or a Certificate of a Pharmaceutical Product for Veterinary Medical Products, provided that the applicant is the Marketing Authorization holder for the Veterinary Medical Products or their representative. The Executive Regulations of this Decree by Law shall determine the conditions and controls for the issuance of the two Certificates by the Establishment, and their validity period, according to the nature and use of the veterinary medical product.

Article (57)

Licensing of a Veterinary Pharmacy

1. No person may open a Veterinary Pharmacy unless they have obtained a license from the Ministry and fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Veterinary Pharmacy, the following is required:

a. An undertaking that its management shall be entrusted, in a professional capacity, to a licensed veterinarian, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard.
b. Fulfillment of the technical and health conditions and other conditions specified by the Executive Regulations of this Decree by Law.

3. If the Veterinary Pharmacy, licensed in accordance with the provisions of this Article, wishes to add the activity of a compounding Veterinary Pharmacy, it must obtain a valid Good Compounding Practice certificate from the Establishment, and fulfill any other technical and health conditions for practicing the compounding Veterinary Pharmacy activity as specified by the Executive Regulations of this Decree by Law.
4. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in Veterinary Pharmacies activities or to allow full foreign ownership, while specifying the percentage of nationals' participation on the Boards of Directors of companies established within its competence. The license to open a Veterinary Pharmacy shall be issued according to the commercial license issued by that authority.
5. Veterinary Pharmacies operating in free zones are exempted from the percentage referred to in Clause (4) of this Article, as are any other Veterinary pharmacies specified by a resolution of the Cabinet.
6. A Veterinary Pharmacy may provide its services electronically in accordance with a system issued by a resolution of the Minister or their delegate.

Article (58)

Licensing of Veterinary Medical Warehouses Storage Facilities

1. No person may open a Veterinary Medical Warehouse or Storage Facility unless they have obtained a license to do so from the Establishment and fulfilled the necessary approvals from the Competent Authority.

2. To obtain a license to open a veterinary medical store or warehouse, the following is required:
    a. An undertaking that its management will be entrusted, in a professional capacity, to a licensed veterinarian or a pharmacist, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard. If the activity of the medical warehouse or storage facility is limited to veterinary medical devices, its management may be entrusted to a licensed medical equipment engineer, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard.
    b. Obtaining a valid Good Storage and Distribution Practice certificate from the Establishment.
    c. Fulfillment of the technical and health conditions and other conditions specified by the Executive Regulations of this Decree by Law.
3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in the activity of Veterinary Medical Warehouses or Storage Facilities, or to allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of companies established within its competence. The license to open a Veterinary Medical Warehouse or Storage Facility shall be issued according to the commercial license issued by that authority.
4. Veterinary Medical Warehouses or Storage Facilities operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Veterinary Medical Warehouses or Storage Facility specified by a resolution of the Cabinet.
5. A Veterinary Medical Warehouse or Storage Facility may provide its services electronically in accordance with a system issued by a resolution of the Chairman or their delegate.
6. Without prejudice to the required approvals from the local competent authorities, with the approval of the Establishment, medical warehouses and storage facilities licensed under Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy

Profession, and Pharmaceutical Establishments, or any other law that may supersedes it, may be authorized to add activities of import, export, storage, and sale of Veterinary Medical Products, in accordance with the controls and conditions specified by the Executive Regulations of this Decree by Law.

Article (59)

Licensing of Veterinary Medical Products Manufacturing Facilities and Contract Manufacturing Organizations

1. No person may open a Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization unless they have obtained a license from the Establishment and fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization, the following is required:
   a. An undertaking that its management will be entrusted, in a professional capacity, to a licensed veterinarian or a pharmacist, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard.
   b. Obtaining a valid Good Manufacturing Practice certificate from the Establishment.
   c. The license applicant or their legal representative must be the owner of the Manufacturing Facility and legally responsible for complying with the legislation and instructions issued by the Establishment regarding the Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization.
   d. Fulfillment of the technical and health conditions and other conditions specified by the Executive Regulations of this Decree by Law.
3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in the activity of Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organizations, or to allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of companies established within its

competence. The license to open the factory for Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization shall be issued according to the commercial license issued by that authority.

4. Veterinary Medical Products Manufacturing Facilities and Contract Manufacturing Organizations operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Veterinary Medical Products Manufacturing Facilities and Contract Manufacturing Organizations specified by a resolution of the Cabinet.
5. The Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization shall not be used for any purpose other than that for which it was licensed to manufacture, except with the approval of the Establishment. The Executive Regulations of this Decree by Law shall specify the controls and conditions for granting such approval.

Article (60)

Licensing of Marketing Offices

1. No person may open a Marketing Office unless they have obtained a license to do so from the Establishment and fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Marketing Office, the following is required:
    a. Submission of proof that the applicant for the Marketing Office license represents the Marketing Authorization holder for the Veterinary Medical Product to be marketed in the State.
    b. An undertaking that its management will be entrusted, in a professional cap to a licensed veterinarian or a pharmacist, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard, or a licensed medical equipment engineer, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard, according to the nature of the Veterinary Medical Products marketed by the Office.
    c. Fulfillment of the technical and health conditions and other conditions specified by the Executive Regulations of this Decree by Law.

3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company the activity of Marketing Offices, or allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of companies established within its competence. The license to open the Marketing Office shall be issued according to the commercial license issued by that authority.
4. Marketing Offices operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Marketing Offices specified by a resolution of the Cabinet.
5. Marketing Offices may provide their services electronically in accordance with a system issued by a resolution of the Chairman or their delegate.

Article (61)

Licensing of Veterinary Biobanks

1. No person may open a Veterinary Biobank unless they have obtained a license from the Establishment and have fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Veterinary Biobank, the following shall be required:
   a. The presence of a Quality Management System (QMS) compatible with the activities licensed to be conducted.
   b. The presence of a suitable system for tracking biological samples, and a system for reporting, investigating, registering, and communicating information regarding the occurrence of any serious complications or Adverse Reactions that may affect the quality and safety of these samples.
   c. Fulfillment of the technical and health conditions and other requirements specified in the Executive Regulations of this Decree by Law.
3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the

contribution of nationals in the share capital of a company engaged in the activity of Veterinary Biobanks or allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of companies established within its jurisdiction. The license to open the Veterinary Biobank shall be issued in accordance with the commercial license issued by that authority.

4. Veterinary Biobanks operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are any other Veterinary Biobanks specified by a resolution of the Cabinet.
5. The Ministry shall be responsible for licensing units for the collection, preservation, storage, and distribution of biological samples operating in artificial insemination centers.
6. Units for the collection, preservation, storage, and distribution of biological samples operating in artificial insemination centers shall be licensed by the Ministry in accordance with the conditions and controls stipulated in the legislation in force in this regard.

Article (62)

Pharmaceutical Consultancy Office

A pharmaceutical consultancy office licensed in accordance with the provisions of Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that may supersedes it, may provide consultations in the field of Veterinary Medical Products. The provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof shall apply thereto.

Article (63)

Pharmaceutical Laboratories

A Pharmaceutical Laboratory licensed in accordance with the provisions of Federal Decree by Law No. (38) of 2024 Regarding Medical Products, the Pharmacy Profession, and Pharmaceutical Establishments, or any other law that replaces it, may perform various laboratory analyses of veterinary medical products. The provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof shall apply to it.

Article (64)

Licensing of Contract Research and Development Organizations

1. No person may open a Contract Research and Development Organization (CRDO) unless they have obtained a license from the Establishment and fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Contract Research and Development Organization (CRDO), the following shall be required:
   a. An undertaking to entrust its management, in a professional capacity, to a licensed veterinarian or a pharmacist, who shall be dedicated full-time to working therein, in accordance with the legislation in force in this regard.
   b. Obtaining a valid Good Clinical Practice for Veterinary Clinical Research certificate from the Establishment.
   c. Fulfillment of the technical and health conditions and other requirements specified in the Executive Regulations of this Decree by Law.
3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in the activity of Contract Research and Development Organizations (CRDO) or allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of companies established within its jurisdiction. The license to open the Contract Research and Development Organization (CRDO) shall be issued in accordance with the commercial license issued by that authority.
4. Contract Research and Development Organizations (CRDO) operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are other Contract Research and Development Organizations (CRDO) specified by a resolution of the Cabinet.

Article (65)

Licensing of Veterinary Non-Clinical and Clinical Research Entities

1. No person may open a Veterinary Non-Clinical or Clinical Research Entity unless they have obtained a license from the Establishment and fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Veterinary Clinical Research Entity, the following shall be required:
    a. Obtaining a valid Good Clinical Practice certificate from the Establishment.
    b. An undertaking to provide qualified and specialized staff in the field of Veterinary Clinical Research in accordance with the legislation in force in this regard.
    c. An undertaking to comply with the standards and requirements for animal welfare, biosecurity, and the use of animals in clinical research.
    d. Fulfillment of the technical and health conditions for licensing as specified in the Executive Regulations of this Decree by Law.
3. To obtain a license to open a Veterinary Non-Clinical Research Entity, the following shall be required:
    a. An undertaking by the Veterinary Non-Clinical Research Entity to comply with the principles and rules of Good Practice issued or adopted by the Establishment.
    b. An undertaking to provide qualified and specialized staff in the field of Non-Clinical Veterinary Research in accordance with the legislation in force in this regard.
    c. An undertaking to comply with the standards and requirements for animal welfare, biosecurity, and the use of animals in non-clinical experiments.
    d. Fulfillment of the technical and health conditions for licensing as specified in the Executive Regulations of this Decree by Law.
4. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in the activity of Veterinary Non-Clinical and Clinical Research Entities or allow full foreign ownership, while specifying the percentage of nationals' participation in the Boards of Directors of

companies established within its competence. The license to open the Veterinary Non-Clinical and Clinical Research Entity shall be issued in accordance with the commercial license issued by that authority.

5. Veterinary Non-Clinical and Clinical Research Entities operating in free zones are exempted from the percentage referred to in Clause (4) of this Article, as are other Veterinary Non-Clinical and Clinical Research Entities specified by a resolution of the Cabinet.
6. If a Veterinary Non-Clinical and Clinical Research Entity wishes to import Veterinary Medical Products, it must obtain approval from the Establishment in accordance with the provisions of this Decree by Law, provided that the purpose of the import is for the performance of the activity it is licensed to conduct and not for commercial or circulation purposes.
7. A resolution shall be issued by the Chairman on the Good Clinical Practice standards for Veterinary Clinical Research, including standards and requirements for animal welfare and the use of animals in clinical experiments, in coordination with the Ministry and the Competent Authority.

Article (66)

Licensing of Bioequivalence Centers

1. No person may open a Bioequivalence Center unless they have obtained a license from the Establishment and have fulfilled the necessary approvals from the Competent Authority.
2. To obtain a license to open a Bioequivalence Center, the following shall be required:
   a. An undertaking to provide qualified and specialized staff in the field of Bioequivalence research and studies in accordance with the legislation in force in this regard.
   b. Obtaining a valid Good Clinical Practice for Veterinary Research and/or Good Laboratory Practice certificate from the Establishment.
   c. Fulfillment of the technical and health conditions and other requirements specified in the Executive Regulations of this Decree by Law.

3. Subject to the provisions of the Commercial Companies Law, or any resolutions issued by the Cabinet in this regard, the local authority concerned with company affairs in the relevant Emirate shall have the authority to determine a specific percentage for the contribution of nationals in the share capital of a company engaged in the activity of Bioequivalence Centers or to allow full foreign ownership, while determining the percentage of nationals' participation in the Boards of Directors of companies established within its competence. The license to open the Bioequivalence Center shall be issued in accordance with the commercial license issued by that authority.
4. Bioequivalence centers operating in free zones are exempted from the percentage referred to in Clause (3) of this Article, as are other Bioequivalence Centers specified by a resolution of the Cabinet.

Article (67)

Validity and Renewal of Veterinary Pharmaceutical Establishment Licenses

1. A license to open a Veterinary Pharmaceutical Establishment shall be valid for a period of not less than one year, renewable. The license holder must commit to practicing only the activity for which the license is granted.
2. A license renewal application shall be submitted within (60) sixty days prior to the expiry validity period.
3. Failure to submit a license renewal application within (90) ninety days from the date of its expiry shall result in its automatic revocation.
4. The licensee may not continue to carry out the licensed activity from the date of expiry of the license until its renewal, except for a valid excuse accepted by the Establishment.

Article (68)

Prohibitions

1. Veterinary Pharmaceutical Establishments are prohibited from the following:
   a. Engaging in any activity for which they are not licensed.
   b. Trading in adulterated or unfit-for-use Veterinary Medical Products.
   c. Forging or tampering with documents submitted to obtain a license.

d. Tampering with the content of a Veterinary Medical Product in violation of its Marketing Authorization or Emergency Use Authorization.
e. Continuing the circulation of a Veterinary Medical Product for which the Marketing Authorization, of any type, or Emergency Use Authorization has been revoked.
f. Dealing with other unlicensed Veterinary Pharmaceutical Establishments.
g. Any other prohibitions stipulated in the Executive Regulations of this Decree by Law, according to the type of veterinary pharmaceutical establishment.

2. The owner of the Veterinary Pharmaceutical Establishment shall be liable for violating of the provisions of this Article, whenever it is established that they were aware of the violation and that their breach of any of their imposed obligations caused its occurrence.
3. The Executive Regulations of this Decree by Law shall set out the procedures for suspending and revoking the licenses of Veterinary Pharmaceutical Establishments.

Article (69)

Transfer of Veterinary Pharmaceutical Establishments or Assignment of Ownership

1. Subject to the legislation in force in the State, a Veterinary Pharmaceutical Establishment may not be transferred from one location to another, nor may any change be made to the plan under which its license was issued, without the approval of the Establishment or the Ministry, and after obtaining the necessary approvals from the Competent Authority, each within its competence. The Executive Regulations of this Decree by Law shall specify the conditions and controls for the transfer of Veterinary Pharmaceutical Establishments.
2. Without prejudice to the legislation in force in the State, with the approval of the Establishment or the Ministry, and after obtaining the necessary approvals from the Competent Authority, each within its competence, the ownership of a Veterinary Pharmaceutical Establishment may be assigned to others in accordance with the conditions and controls specified in the Executive Regulations of this Decree by Law.

Article (70)

Precautionary Closure

1. The Establishment or the Ministry, each within its competence, shall issue an immediate decision to close a Veterinary Pharmaceutical Establishment as a precautionary measure in coordination with the Competent Authority if its continued operation poses a risk to public health or as a result of committing violations that warrant precautionary closure as specified by the Executive Regulations of this Decree by Law.
2. In all cases, the matter must be referred to the committee specified in Article (74) of this Decree by Law within (7) seven working days from the date of the precautionary closure to consider and decide on the alleged violations and determine the penalty to be imposed on the Veterinary Pharmaceutical Establishment, within a period not exceeding (10) ten working days from the date of referring the matter thereto.

Article (71)

Supervision and Inspection

1. The Establishment or the Ministry, each within its competence, shall conduct inspection and supervision of the compliance of Veterinary Pharmaceutical Establishments with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof, including the conditions of the issued licenses, approvals, and permits. For this purpose, it may carry out inspections, take samples, and request the necessary information and documents.
2. The Competent Authority shall conduct inspection and supervision of the compliance of Veterinary Pharmaceutical Establishments with the local legislation in force in this regard and shall impose the relevant administrative sanctions.
3. Subject to the legislation in force in the State regarding customs and port security, the Establishment shall conduct supervision and inspection of Veterinary Medical Product consignments at ports and entry points throughout the State, including free zones, and shall issue the necessary release authorization for imported Veterinary Medical Product consignments if they meet the comply with conditions stipulated in Article (34) of this Decree by Law.

4. The Establishment shall cooperate with the Ministry or the Competent Authority to conduct joint supervision of the compliance of licensed Veterinary Pharmaceutical Establishments and to verify the availability of sufficient stock of Veterinary Medical Products therein. It may form working teams to conduct joint supervision.

Article (72)

Administrative Sanctions

1. The Establishment or the Ministry, each within its competence, may impose any of the following administrative sanctions in the event of a violation of any provision of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof by Veterinary Pharmaceutical Establishments:
   a. A written warning.
   b. A written notice.
   c. A fine of not less than (AED 1,000) one thousand dirhams and not exceeding (AED 1,000,000) one million dirhams.
   d. Temporary suspension of the license for a period not exceeding (6) six months.
   e. Revocation of the license.
2. The Establishment or the Ministry, each within its competence, in the event of detecting any violation of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof, shall take the following measures regarding the seized Veterinary Medical Products:
   a. Seize the Veterinary Medical Products that have obtained Marketing Authorization, of any kind, or Emergency Use Authorization, and the related documents, when necessary.
   b. Take samples of the Veterinary Medical Products that have obtained Marketing Authorization, of any kind, or Emergency Use Authorization for analysis if necessary.
   c. Take the necessary measures for the safe disposal of Veterinary Medical Products that have obtained Marketing Authorization, of any kind, Emergency Use Authorization, or are exempt therefrom, and which are deemed adulterated, degraded, expired, or non-compliant, in observance of the provisions of Article (48) of this Decree by Law.

d. Take the necessary measures for the safe disposal of Veterinary Medical Products that have not obtained Marketing Authorization, of any kind, or Emergency Use Authorization, in observance of the provisions of Article (48) of this Decree by Law.

3. If the Establishment or the Ministry, each within its competence, detects a violation at a location licensed by another authority, it may request that authority to revoke its license.

Article (73)

Sanctions Register

A register shall be established at the Establishment or the Ministry, each within its competence, in which violations and sanctions imposed on licensees shall be recorded in accordance with the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.

Article (74)

Supervisory Committee

A committee for the supervision of veterinary practices related to the provisions of this Law, its Executive Regulations and Resolutions shall be established within the Establishment or the Ministry, as the case may be. It shall be competent to examine violations of the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof by the establishments licensed thereby, and to take the necessary measures regarding these violations and impose the administrative sanctions provided for in this Decree by Law.

Article (75)

Grievance against an Administrative Sanction

1. Anyone against whom a decision of an administrative sanction has been issued in implementation of the provisions of this Decree by Law may file a grievance before the Grievance Committee formed at the Establishment by a decision of the Chairman, or at the Ministry by a decision of the Minister, each within its competence, within (15) fifteen days from the date the grievant is notified of the decision.

2. The Grievance Committee shall decide on the grievance within (30) thirty days from the date of its submission. Failure to respond to the grievance within this period shall be considered a rejection.
3. The decision issued by the Grievance Committee shall be final.
4. The administrative sanction decision referred to in Clause (1) of this Article shall not be enforced against the Veterinary Pharmaceutical Establishment before the expiry of the period prescribed for submitting a grievance or the period prescribed for its consideration, as the case may be.

Article (76)

Non-prejudice to Criminal or Civil Liability

Administrative accountability in accordance with the provisions of this Decree by Law shall not prejudice criminal or civil liability, where applicable.

Criminal Penalties

Article (77)

Whoever commits any of the following acts shall be punished by imprisonment and a fine of not less than (AED 10,000) ten thousand dirhams and not exceeding (AED 500,000) five hundred thousand dirhams, or by either of these two penalties:

1. Circulated, sold, offered, possessed, manufactured, or compounded a Veterinary Medical Product that is adulterated, degraded, expired, or counterfeited non-compliant with the product information.
2. Imported into the State, transferred, or stored a Veterinary Medical Product that has not obtained a Marketing Authorization, of any kind, or an Emergency Use Authorization, or is not exempt therefrom, or is adulterated, degraded, expired, or counterfeited, or attempted to import any of the same.
3. Imported into the State packages or wrappers for a specific Veterinary Medical Product with the intent to adulterate or counterfeit.
4. Manufactured, printed, possessed, sold, or offered packages or wrappers for a specific Veterinary Medical Product with the intent to adulterate or counterfeit.

Article (78)

Whoever commits any of the following acts shall be punished by imprisonment and a fine of not less than (AED 50,000) fifty thousand dirhams and not exceeding (AED 500,000) five hundred thousand dirhams, or by either of these two penalties:

1. Imported, exported, or re-exported any Veterinary Medical Product without obtaining an approval or a permit from the Establishment.
2. Imported, circulated, or marketed any Veterinary Medical Product that has obtained Marketing Authorization, of any kind, Emergency Use Authorization, or an exemption therefrom, and introduced any change or modification thereto without obtaining the approval of the Establishment.
3. Used a Veterinary Medical Products Manufacturing Facility or Contract Manufacturing Organization for any purpose other than the manufacturing of Veterinary Medical Products without obtaining the approval of the Establishment.

Article (79)

Whoever imports samples of any Veterinary Medical Product for research or marketing purposes without obtaining an approval or a permit from the Establishment shall be punished by imprisonment and a fine of not less than (AED 20,000) twenty thousand dirhams and not exceeding (AED 100,000) one hundred thousand dirhams, or by either of these two penalties. In all cases, the court shall order the confiscation of the seized materials subject of the violation.

Article (80)

Whoever commits any of the following acts shall be punished by imprisonment and a fine of not less than (AED 50,000) fifty thousand dirhams and not exceeding (AED 200,000) two hundred thousand dirhams, or by either of these two penalties:

1. Practiced an unlicensed activity in a Veterinary Pharmaceutical Establishment or dealt with unlicensed establishments.

2. Practiced the licensed activity after the expiry of the license in violation of the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.
3. Forged or tampered with any documents submitted to obtain the license.

Article (81)

Whoever commits any of the following acts shall be punished by imprisonment and a fine of not less than (AED 100,000) one hundred thousand dirhams and not exceeding (AED 500,000) five hundred thousand dirhams, or by either of these two penalties:

1. Engaged in misrepresentation, fraud, theft, or scientific plagiarism of published studies and research related to the development, manufacture, marketing, or distribution of a Veterinary Medical Product, or the provision of veterinary pharmaceutical consultations, in a manner that affects the legal rights established for the owners of such studies and research.
2. Conducted a non-clinical study of Veterinary Medical Products on target animals.
3. Conducted any clinical trial on Veterinary Medical Products before conducting preliminary non-clinical research of the Veterinary Medical Products to ensure the safety and efficacy of the intended medical intervention on the target animals of the clinical studies.

Article (82)

Whoever commits any of the following acts shall be punished by imprisonment for a period of not less than (6) six months and not exceeding one year, and a fine of not less than (AED 50,000) fifty thousand dirhams and not exceeding (AED 200,000) two hundred thousand dirhams, or by either of these two penalties:

1. The Marketing Authorization holder or their appointed representative, as the case may be, violated the guidelines and standards issued by the Establishment concerning Pharmacovigilance.

2. Refrained to supply a Veterinary Medical Product that has obtained a Marketing Authorization, of any kind, an Emergency Use Authorization, or an exemption therefrom, in an unlawful manner or with the intention of monopolization.
3. Circulated or marketed any Veterinary Medical Product without ensuring that the information and data on the inner or outer label and the paper or electronic leaflet of the product are identical to the information and data contained in its Marketing Authorization, Emergency Use Authorization, or are consistent with the details approved in the country of origin if the product is exempt from obtaining Marketing Authorization.
4. Violated Clause (1) of Article (41) of this Decree by Law.

Article (83)

Whoever commits any of the following acts shall be punished by a fine of not less than (AED 10,000) ten thousand dirhams and not exceeding (AED 200,000) two hundred thousand dirhams:

1. Provided false information regarding the Veterinary Medical Product or refrained from providing information requested by the Establishment.
2. Used false information to promote the Veterinary Medical Product, whether on the product itself or in its advertising.
3. Advertised, promoted, or publicized Veterinary Medical Products by any means, whether visual, written, or audible, or on social media, without obtaining the approval of the Establishment.
4. Violated the pricing approved by the Establishment for Veterinary Medical Products.
5. Manufactured, imported, marketed, or circulated any Veterinary Medical Product that has not obtained a Marketing Authorization, of any kind, an Emergency Use Authorization from the Establishment, or an exemption therefrom.
6. Introduced any change or modification to a Veterinary Medical Product that has obtained a Marketing Authorization, of any kind, an Emergency Use Authorization, or an exemption therefrom, without obtaining the approval of the Establishment.
7. A non-veterinary pharmaceutical establishment imported, marketed, sold, offered, stored, or circulated any Veterinary Medical Product requiring a prescription.

Article (84)

Non-prejudice to a More Severe Penalty

The application of the penalties stipulated in this Decree by Law shall not prejudice any more severe penalty provided for in any other law.

Article (85)

Grievance against Resolutions Issued in Implementation of this Decree by Law

Without prejudice to the text of Article (75) of this Decree by Law, a person against whom a decision is issued pursuant to the other resolutions issued in implementation of the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof, may file a grievance before the Grievance Committee formed for this purpose by a decision of the Chairman or the Minister, each within their competence, within (15) fifteen days from the date of being notified of the decision under grievance. The grievance must be decided upon within (30) thirty days from the date of its submission. Failure to respond to the grievance within this period shall be considered a rejection. The decision issued on the grievance shall be final.

Article (86)

Judicial Enforcement Officers

By a decision of the Minister of Justice in agreement with the Chairman or the Minister, or by a decision of the head of the competent local judicial authority in agreement with the head of the Competent Authority, as the case may be, certain employees of the Establishment, the Ministry, or the Competent Authority, as the case may be, may be granted the capacity of judicial enforcement officers to detect violations that fall within their jurisdiction in conflict with the provisions of this Decree by Law, its Executive Regulations, or the resolutions issued in implementation thereof.

Article (87)

Obtaining Necessary Licenses

Obtaining the licenses stipulated in this Decree by Law shall not exempt from obtaining other licenses required by the laws, regulations, or systems in force in the State, and from obtaining the necessary approvals, permits, or licenses from the local authorities in accordance with the legislation in force in each Emirate.

Article (88)

Mutual Notification

The Establishment, the Ministry, and the Competent Authority shall set a mechanism for mutual notification of data and information related to the implementation of the provisions of this Decree by Law, its Executive Regulations, and the resolutions issued in implementation thereof.

Article (89)

Regularization of Statuses

All persons subject to the provisions of this Decree by Law at the time of its issuance shall regularize their statuses in accordance with its provisions, within a period not exceeding one year from the date of its entry into force, which may be extended by a resolution of the Cabinet.

Article (90)

Fees

The Cabinet shall, upon the proposal of the Minister of Finance, issue the necessary resolutions to determine the fees charged by federal authorities for services related to the implementation of the provisions of this Decree by Law, its Executive Regulations, and the resolutions promulgated in implementation thereof.

Article (91)

Executive Regulations and Implementing Resolutions for this Decree by Law

1. The Cabinet shall, upon the proposal of the Chairman and after coordination with the Ministry, the Competent Authority, and any other concerned authority, promulgate the Executive Regulations for this Decree by Law.
2. The Chairman or the Minister may, each within their respective competences, promulgate any other decisions necessary for the implementation of the provisions of this Decree by Law, including the list of violations and administrative sanctions, in accordance with the provisions of this Decree by Law.

Article (92)

Delegation of Certain Competences

The Cabinet may issue a resolution delegating some of the competences of the Ministry or the Establishment, stipulated in this Decree by Law, to any federal or local government authority, upon the proposal of the Minister or the Chairman, each within their respective competences.

Article (93)

Repeals

1. Federal Law No. (9) of 2017 Regarding Veterinary Products is hereby repealed, and any other provision that contradicts or conflicts with the provisions of this Decree by Law shall also be repealed.
2. The regulations and resolutions related to Veterinary Medical Products issued prior to the entry into force of this Decree by Law shall remain in effect, to the extent that they do not conflict with its provisions, until they are superseded by new ones in accordance with the provisions of this Decree by Law.

Article (94)

Publication and Entry into Force of the Decree by Law

This Decree by Law shall be published in the Official Gazette and shall enter into force as of 1 January 2026.

Mohamed bin Zayed Al Nahyan

President of the United Arab Emirates

Issued by Us at the Presidential Palace - Abu Dhabi:

On: 9 Rabi' Al-Akhir 1447 A.H.

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