

Federal Law No. (9) of 2017 Regarding Veterinary Products

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

Having reviewed:

- The Constitution;
- Federal Law No. (1) of 1972, Regarding the Competences of Ministries and Powers of Ministers, as amended;
- Federal Law No. (6) of 1979, Regarding the Veterinary Quarantine, as amended;
- Federal Law No. (3) of 1987, Promulgating the Penal Code, as amended;
- Federal Law No. (35) of 1992, Promulgating the Criminal Procedures Law, as amended;
- Federal Law No. (10) of 2002, Regarding the Practice of Veterinary Profession;
- Federal Law No. (16) of 2007, Regarding Animal Welfare, as amended;
- Federal Law No. (2) of 2015, Regarding the Commercial Companies;
- Federal Law No. (19) of 2016, Regarding Combating Commercial Fraud; and
- Upon the proposal of Minister of Climate Change and Environment, and the approval of the Cabinet and the Federal National Council and ratification by the Federal Supreme Council.

Hereby promulgate the following Law:

Article (1)

Definitions

For the purpose of applying the provisions of this Law, the following words and expressions shall have the meanings assigned to each of them unless the context otherwise requires:

State	: The United Arab of Emirates.
Establishment	: Emirates Drug Establishment.
Chairman	: Chairman of the Establishment.
Competent Authority	: The relevant local authority in each Emirate.

- Veterinary Product** : A substance, combination of substances or a material input of a substance prepared for the treatment, prevention, or diagnosis of medical conditions, or for the restoration or modification of physiological functions in animals.
- Veterinary Products Company** : The entity which owns a veterinary products factory, or has the right to manufacture or market the Veterinary Product.
- Veterinary Products Factory** : The facility in which Veterinary Products are manufactured.
- Veterinary Products Warehouse** : The place allocated and licensed to import, store or distribute Veterinary Products on wholesale basis.
- Registration Applicant** : The company's official representative or authorized entity responsible for registering the company or veterinary products.
- Registration Committee** : The committee responsible for the Registration of Veterinary Products Companies.

Article (2)

License

Veterinary Products Companies, Factories and Warehouses operating in the State shall obtain a license from the Establishment, in accordance with conditions and controls stipulated by the Executive Regulations of this Law.

Article (3)

Registration of Companies and Factories

Subject to the provisions of Article (7), the Veterinary Products Companies, and factories operating outside the State shall, before commencing any activity in the State, be registered with the Establishment.

Article (4)

Registration Conditions and Controls

Veterinary Products shall be registered with the Establishment according to conditions and controls stipulated by the Executive Regulations of this Law.

Article (5)

Registration Certificate

The Establishment shall issue a Registration Certificate to the Veterinary Products Companies and Factories and also to the Veterinary Product. The term of such certificate shall be five years and may be renewed for similar terms, in accordance with the conditions and controls stipulated by the Executive Regulations of this Law.

Article (6)

Functions of the Establishment

The Establishment shall undertake the following functions and powers:

1. Licensing the Veterinary Products Companies, Factories and Warehouses in the State.
2. Registering the Veterinary Products Companies and Factories operating outside the State, before commencing their activities in the State.
3. Registering Veterinary Products.
4. Reviewing the technical reports received from international organizations or bodies, on Veterinary Products and their companies, as well as taking the necessary actions thereon.
5. Monitoring the Veterinary Products post marketing, receiving reports from veterinary hospitals or clinics on their quality and safety, as well as taking the necessary actions thereon.
6. Establishing and publishing lists of Veterinary Products prohibited for use in various animal species.
7. Pricing Veterinary Products according to principles specified by the Executive Regulations of this Law.

8. Any other relevant functions as may be assigned by virtue of a resolution issued by the Cabinet.

Article (7)

Functions of the Competent Authority

Without prejudice to Clause (1) of Article (6) herein, the Competent Authority shall carry out all other procedures related to local licensing.

Article (8)

Commencement of Production

A licensed veterinary products factory in the State may not commence production unless it has been registered with the Establishment.

Article (9)

Abiding by License Purpose

The Veterinary Products Factory may not be used for any purpose other than the one for which the Factory is licensed, except with the approval of the Establishment.

Article (10)

Good Manufacturing Practice

The Veterinary Products Factory shall comply with the principles of good manufacturing practice for the Veterinary Products, as stipulated in the Executive Regulations.

Article (11)

Registration Condition

The Registration Applicant shall hold a warehouse license for wholesale trading in veterinary products.

Article (12)

Revocation of Registration

The registration of Veterinary Products Companies and their factories shall be revoked pursuant to the Establishment's decision in the following cases:

1. Falsification, or manipulation of, the submitted documents.
2. Permanent closure of the company or prohibition on the use of all products thereof.
3. Manipulation of the content of the Veterinary Product, in violation of its registration decision.
4. Violation of the registration conditions.
5. Any other cases specified by the Executive Regulations.

Article (13)

Provision of Veterinary Products

The Establishment may obligate the registered Veterinary Products Companies and Factories as well as their representative Warehouses to provide their registered Veterinary Products in case the alternative product is not available.

Article (14)

Prohibited Acts

The following acts are prohibited:

1. Importing, marketing or circulating Veterinary Products before their registration with the Establishment.
2. Importing, marketing or circulating any registered Veterinary Product if any change or modification is introduced thereto, without the approval of the Establishment.
3. Importing samples of any Veterinary Product for the purpose of research or marketing, without the approval of the Establishment.

Article (15)

Importation of Non-Prohibited Veterinary Products

Notwithstanding Clause (1) of the preceding Article, the Chairman may allow the importation of the non-prohibited Veterinary Products before the registration, as stipulated by the Executive Regulations of this Law.

Article (16)

Manufacture of Unregistered Veterinary Products

Unregistered and non-prohibited Veterinary Products may be manufactured for the purpose of exportation, in accordance with conditions and controls specified by the Executive Regulations of this Law.

Article (17)

Obligations of Companies, Factories and Warehouses

The Veterinary Products Companies, Factories and Warehouses shall notify the Establishment of the following:

1. Changes introduced to the Veterinary Product or manufacturing company.
2. Warnings issued by the company regarding the safety and efficacy of the Veterinary Product.
3. If the manufacture of the Veterinary Product has been discontinued, suspended or ceased to be traded in the country of origin.
4. Frequent complaints received concerning their Veterinary Products.

Article (18)

Advertising of Veterinary Products

The Veterinary Product may only be advertised in the Media after the approval of the Establishment is obtained, in accordance with the conditions and controls defined by the Executive Regulations of this Law.

Article (19)

Committee for the Registration of Veterinary Products and Their Companies

1. A committee called the (Committee for the Registration of Veterinary Products and Their Companies) shall be formed within the Establishment. The formation of such Committee, its rules of procedure and the grievance mechanism against the decisions issued thereby shall be governed by a decision issued by the Chairman.
2. The Committee referred to in Clause (1) of this Article shall be competent to perform the following:
 - a. Registering Veterinary Products Companies and Factories.
 - b. Registering Veterinary Products.
 - c. Ensuring that Veterinary Products Factories comply with the standards of Good Manufacturing Practice (GMP) upon registration.
 - d. Any other relevant competences assigned to same by the Chairman.

Article (20)

Obligations of the Establishment

The Establishment shall prohibit the import, suspend the distribution, prevent the circulation, withdraw or recall the Veterinary Product, or suspend or deregister the product in the following cases:

1. Changes or modifications are made to the product without the approval of the Establishment.
2. In case the Establishment receives reports indicating the toxicity of the product or the occurrence of serious side effects of same.
3. In case the Establishment receives reports indicating that the quality or effectiveness of the product is defective.
4. Suspension of its use based on a recommendation from the relevant international regulatory organizations or bodies.
5. Revocation of the product registration or suspension of its production in the country of origin.
6. Inaccuracy of information, submitted in the registration file, related to the product.

7. In case the company or its agent fails to submit an application for Veterinary Product registration renewal, at least (180) days prior to the expiration of the registration certificate.
8. Any other cases defined by the Executive Regulations of this Law.

Article (21)

Special Rules on Veterinary Products

The Executive Regulations shall set out the rules for importing, manufacturing, storing, circulating, transporting, selling and dispensing of Veterinary Products.

Article (22)

Disposal of Veterinary Products

Veterinary Products Companies, Factories and Warehouses shall dispose of Veterinary Products, which are destroyed or expired, in a manner that complies with the requirements of general safety and does not cause environmental pollution, in accordance with the applicable legislation.

The Executive Regulations define the methods, controls and cases of disposing of Veterinary Products.

Article (23)

Penalties

Whoever commits any of the below violations shall be punished by imprisonment and/or a fine not less than (AED 10,000) ten thousand dirhams and not more than (AED 500,000) five hundred thousand dirhams:

1. Selling, offering for sale, possessing, manufacturing or formulating a counterfeit, adulterated or expired Veterinary Product, or otherwise non-compliant with the product information or forged.
2. Importing into the State, transporting or storing an unregistered, counterfeit, adulterated, expired or forged Veterinary Product, or otherwise attempting to import any of same.

3. Importing into the State packages or labeling of a certain Veterinary Product, with intent to commit fraud or forgery.
4. Manufacturing, printing, possessing, selling or offering packages or containers of a certain Veterinary Product, with intent to commit fraud or forgery.
5. Manufacturing, importing, marketing or circulating any Veterinary Product that is not registered with the Establishment.
6. Introducing any change or modification to a registered Veterinary Product, without the approval of the Establishment.

In all cases, the court shall order that the seized substances, subject of the violation, be confiscated.

Article (24)

Whoever imports, circulates or markets any registered Veterinary Product that has been modified or altered, without the approval of the Establishment, shall be punished by imprisonment and/or a fine of not less than (AED 50,000) fifty thousand dirhams and not more than (AED 500,000) five hundred thousand dirhams.

Article (25)

Whoever imports samples of any Veterinary Product for the purpose of research or marketing, without the approval of the Establishment, shall be punished by imprisonment and/or a fine of not less than (AED 20,000) twenty thousand dirhams and not more than (AED 100,000) one hundred thousand dirhams.

Article (26)

Whoever uses a Veterinary Products Factory for any purpose other than the manufacture of Veterinary Products, without the approval of the Establishment, shall be punished by imprisonment and/or a fine of not less than (AED 50,000) fifty thousand dirhams and not more than (AED 500,000) five hundred thousand dirhams.

Article (27)

Whoever commits any of the below violations shall be punished by a fine of not less than (AED 10,000) ten thousand dirhams and not more than (AED 200,000) two hundred thousand dirhams, as follows:

1. Furnishing false information related to the Veterinary Product or abstaining from furnishing the information required by the Establishment.
2. Using false information to promote the Veterinary Product, whether labeled on the product or in its advertisement.
3. Advertising Veterinary Products in the Media, without the approval of the Establishment.

Article (28)

Without Prejudice to Harsher Penalty

The application of penalties set forth in this Law shall not prejudice any harsher penalty provided in any other law.

Article (29)

Reconciliation

1. A criminal action on the offences set forth in Article (27) may only be initiated upon a written request from the Establishment or the Competent Authority.
2. Reconciliation may take effect for the offences set forth in Article (27), before referring the action to the competent court, subject to the payment of an amount not exceeding (AED 150,000) one hundred and fifty thousand dirhams for each offence.
3. The Cabinet shall issue a resolution specifying the reconciliation controls and the financial amount for reconciliation for each offence referred to in this Article.

Article (30)

Administrative Penalties

The Establishment, or the Competent Authority, may impose any of the following administrative penalties in case of violating any provisions of this Law or the Executive Regulations thereof:

1. Warning.
2. Closure of the Veterinary Product Company, Factory or Warehouse for a period of no more than six months.
3. Permanent closure of the Veterinary Product Company, Factory or Warehouse.

Article (31)

Judicial Enforcement

Employees, who are designated by a resolution of the Minister of Justice, in agreement with the Chairman or the Head of the Competent Authority, shall have the capacity as judicial enforcement officers for determining the acts committed in violation of the provisions of this Law, as well as the regulations and resolutions issued in implementation thereof.

Article (32)

Regularization

Veterinary Products Companies, Factories and Warehouses, existing from the date this Law enters into force, shall be required to regularize their statuses pursuant to the provisions thereof, within six months from its effective date. Such period may be extended for an equivalent duration under a resolution from the Cabinet.

Article (33)

Determination of Fees

The Cabinet shall issue a resolution determining the fees prescribed in accordance with the provisions of this Law.

Article (34)

The Executive Regulations

The Cabinet shall promulgate the Executive Regulations of this Law, within six months from the date it enters into force.

Article (35)

Repeal

Each provision that contradicts or conflicts with the provisions of this Law shall be repealed.

Article (36)

Publication and Entry into Force

This Law shall be published in the Official Gazette, and shall enter into force from the date of its publication.

Khalifa bin Zayed Al Nahyan

President of the United Arab of Emirates

Issued by us at the presidential place in Abu Dhabi,

Dated: 16 th Ramadan 1438 AH

Corresponding to: 11 th June 2017