

Federal Law No. (9) of 2017

On 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, on the Competences of Ministries and Powers of Ministers, as amended;
- Federal Law No. (6) of 1979, on 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, on the Practice of Veterinary Medicine Profession;
- Federal Law No. (16) of 2007, Concerning Animal Welfare, as amended;
- Federal Law No. (2) of 2015, on the Commercial Companies;
- Federal Law No. (19) of 2016, on Combating Commercial Fraud; and

In light of the proposal of Minister of Climate Change and Environment, as approved by the UAE Cabinet and the Federal National Council and endorsed by the Federal Supreme Council,

Hereby enact the following Law:

Article (1)

Definitions

Upon applying the provisions hereof, the following words and expressions shall have the meanings ascribed to each of them respectively, unless the context requires otherwise:

- State** : The United Arab of Emirates.
- Ministry** : The Ministry of Climate Change and Environment.
- Minister** : The Minister of Climate Change and Environment.
- Competent Authority** : The relevant local authority in each Emirate.
- Veterinary Product** : A substance, combination of substances or an element of a substance composing treatment for, prevention or diagnosis of medical cases, or otherwise curing or changing physiological functions in animals.
- Veterinary Products Company** : The entity which owns a veterinary products factory, or having 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 authorized representative or entity in charge of getting the company or Veterinary Products registered.
- Registration Committee** : The committee on Registration of Veterinary Products Companies.

Article (2)

License

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

Article (3)

Registration of Companies and Factories

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

Article (4)

Registration Conditions and Controls

Veterinary Products shall be registered with the Ministry according to conditions and controls stipulated by the Executive Regulations hereof.

Article (5)

Registration Certificate

The Ministry shall award 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 conditions and controls stipulated by the Executive Regulations hereof.

Article (6)

Functions of the Ministry

The Ministry shall take over 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. Studying 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 after being marketed, receiving reports from veterinary hospitals or clinics on their quality and safety, as well as taking the necessary actions thereon.
6. Creating and publishing lists of Veterinary Products which use are prohibited for different types of animals.
7. Pricing Veterinary Products according to standards defined by the Executive Regulations hereof.
8. Any other relevant functions on which a Cabinet Resolution is issued.

Article (7)

Functions of the Competent Authority

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

Article (8)

Commencement of Production

The Veterinary Products Factory, which is licensed in the State, may only commence the production after being registered with the Ministry.

Article (9)

Abiding by License Purpose

The Veterinary Products Factory may not be used for an purpose other than the one for which the Factory is licensed, without obtaining the approval of the Ministry.

Article (10)

Good Manufacturing Practice

The Veterinary Products Factory shall apply the standards of good manufacturing practice to the Veterinary Products, as stipulated in the Executive Regulations.

Article (11)

Registration Prerequisite

The Registration Applicant shall be holder of a warehouse license for wholesale trading in veterinary products.

Article (12)

Deregistration

The registration of Veterinary Products Companies and their factories shall be removed under a resolution from the Ministry in the following cases:

1. Falsification of, or manipulation in the documents furnished by them.
2. Final closure of the company or prohibited use of all products thereof.
3. Manipulation in the content of the Veterinary Product, in violation of its registration decision.
4. Violating the registration conditions.
5. Any other cases defined by the Executive Regulations.

Article (13)

Provision of Veterinary Products

The Ministry may obligate the registered Veterinary Products Companies and Factories as well as the Warehouses affiliated thereto 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 otherwise trading in Veterinary Products before registering the same with the Ministry.
2. Importing, marketing or otherwise trading in any registered Veterinary Product if any change or modification is introduced thereto, without the approval of the Ministry.

3. Importing samples of any Veterinary Product for the purpose of researches or marketing, without the approval of the Ministry.

Article (15)

Importation of Unprohibited Veterinary Products

By way of exception from the provisions of in Clause (1) of the previous Article, the Minister may allow the importation of the unprohibited Veterinary Products before the registration, as stipulated by the Executive Regulations hereof.

Article (16)

Manufacture of Unregistered Veterinary Products

Unregistered and unprohibited Veterinary Products may be manufactured for the purpose of exportation, in accordance with conditions and controls defined by the Executive Regulations hereof.

Article (17)

Obligations of Companies, Factories and Warehouses

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

1. Changes introduced to the Veterinary Product or manufacturer.
2. Warnings issued by the company on the safety and effectiveness of the Veterinary Product.
3. If the manufacturing of the Veterinary Product is ceased, suspended or ceased to be traded in the country of origin.

4. If frequent complaints are received by the company on its Veterinary Products.

Article (18)

Advertising Veterinary Product

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

Article (19)

Committee on Registration of Veterinary Products and Their Companies

1. A committee called the (Committee on Registration of Veterinary Products and Their Companies) shall be formed at the Ministry. The formation of such Committee, its working system and the mechanism of challenging the decisions issued thereby shall be governed by a resolution from the Minister.
2. The Committee referred to in Clause (1) of this Article shall have the competent over the following:
 - a. Registering Veterinary Products Companies and Factories.
 - b. Registering Veterinary Products.
 - c. Ensuring that Veterinary Products Factories apply the standards of good practice pharmaceutical manufacture upon registration.
 - d. Any other relevant competences assigned to same by the Minister.

Article (20)

Obligations of the Ministry

The Ministry shall prohibit importing, suspend, distributing, preventing the trading, withdrawing or retrieve the Veterinary Product, or otherwise suspending or deregistering the product in the following cases:

1. Changes or modifications are made to the product without the consent of the Ministry.
2. In case the Ministry has reports on the toxicity of the product or the emergence of serious side effects of same.
3. In case the Ministry has reports demonstrating that the quality or effectiveness of the product is defective.
4. Suspension of its use based on a recommendation from the relevant international supervisory organizations or bodies.
5. Deregistration or suspension of its production from the country of origin.
6. Invalidity 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 expiry date of the registration certificate.
8. Any other cases defined by the Executive Regulations hereof.

Article (21)

Rules on Veterinary Products

The Executive Regulations shall set out the rules of importing, manufacturing, storing, trading in, transporting, selling and disbursing 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 observes the requirements of general safety and does not cause environment pollution, in accordance with legislations in force.

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 penalized with 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, as follows:

1. Sold, offered for sale, possessed, manufactured or formulated a fiddled, corrupted or expired Veterinary Product, or otherwise inconsistent with the product information or proven to be a fake product.
2. Brought to the State, transported or stored an unregistered, fiddled, corrupted, expired or fake Veterinary Product, or otherwise embarked on bringing any of same.
3. Brought to the State packages or wrappers of a certain Veterinary Product, with intent to commit fraud or counterfeiting.
4. Manufactured, printed, possessed, sold or offered packages or wrappers of a certain Veterinary Product, with intent to commit fraud or counterfeiting.
5. Manufactured, imported, marketed or traded in any Veterinary Product that is not

registered with the Ministry.

6. Introduced any change or modification to a registered Veterinary Product, without the consent of the Ministry.

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

Article (24)

Whoever imported, traded in or marketed any registered Veterinary Product to which a change or modification is introduced, without the consent of the Ministry, shall be penalized with 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 imported samples of any Veterinary Product for the purpose of research and marketing, without the consent of the Ministry, shall be penalized with 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 used a Veterinary Products Factory for any purpose other than the purpose of manufacturing Veterinary Products, without the consent of the Ministry, shall be penalized with 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 penalized with 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. Furnished invalid information related to the Veterinary Product, or abstained from submitting the information required by the Ministry.
2. Used invalid information to promote the Veterinary Product, whether labeled on the product or by advertising same.
3. Advertised Veterinary Products on the Media, without the consent of the Ministry.

Article (28)

No Prejudice to Severer Penalty

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

Article (29)

Conciliation

1. A criminal action on the offences set forth in Article (27) shall only be instituted by a written request by the Ministry or the Competent Authority.
2. Conciliation 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 in which it will determine the conciliation controls, as well as the consideration of conciliation for each offence referred to in this Article.

Article (30)

Administrative Penalties

The Ministry, or the Competent Authority, may impose any of the following administrative penalties in case of violating any provisions hereof 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. Final closure of the Veterinary Product Company, Factory or Warehouse.

Article (31)

Law Enforcement

Employees, who are designated by a resolution of the Minister of Justice, in agreement with the Minister or the chairman of the Competent Authority, shall have the capacity as law enforcement officers for defecting the acts committed in violation of the provisions hereof, as well as the regulations and resolutions issued in implementation hereof.

Article (32)

Adjustment of Status

Veterinary Products Companies, Factories and Warehouses, existing as of the effective date hereof, shall be required to adjust their statuses pursuant to the provisions hereof, within six months from the effective date hereof. Such deadline may be extended for a similar period under a resolution from the Cabinet.

Article (33)

Determination of Fees

The Cabinet shall issue a resolution determining the prescribed fees, pursuant to the provisions hereof.

Article (34)

The Executive Regulations

The Cabinet shall promulgate the Executive Regulations hereof, within six months from the effective date of the Law.

Article (35)

Repeal

Each provision violating or contradicting with the provisions hereof shall be repealed.

Article (36)

Publication & Entry into Force

This Law shall be published in the Official Gazette, and it shall come into effect on the day following 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