Federal Law No. 9

Issued on 11/06/2017 Corresponding to 16 Ramadan 1438 H

ON VETERINARY PRODUCTS

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

After perusal of the Constitution,

Federal Law no. (1) of 1972 on the Competencies of Ministries and Powers of the Ministers, and its amendments;

Federal Law no. (6) of 1979 on the veterinary quarantine, and its amendments;

Federal Law no. (3) of 1987 promulgating the Penal Code, and its amendments;

Federal Law no. (35) of 1992 promulgating the Criminal Procedure Law, and its amendments;

Federal Law no. (10) of 2002 on the practice of the Veterinary Medicine Profession;

Federal Law no. (16) of 2007 on animal protection, and its amendments;

Federal Law no. (2) of 2015 on the Commercial Companies;

Federal Law no. (19) of 2016 on Combating Commercial Fraud;

And according to the suggestion of the Minister of Climate Change and Environment, the approval of the Cabinet and the Federal National Council and the ratification of the Federal Supreme Council,

Issued the following Law:

Article 1 - Definitions

In the implementation of the provisions of this Law, the following words and expressions shall have the meanings stated beside them unless the context requires otherwise:

State: The United Arab Emirates.

Ministry: Ministry of Climate Change and Environment.

Minister: Minister of Climate Change and Environment.

Competent Authority: Local authority concerned in every Emirate.

Veterinary Product: Substance, combination of substances or ingredient of a substance prepared for treatment, prevention or diagnosis of medical conditions, repair or alteration of the animals' physiological functions.

Products Company: Owner of the veterinary plant or holder of the right of manufacture or marketing of Veterinary Products.

Veterinary Products Plant: Entity in which the Veterinary Products are manufactured.

Veterinary Products Warehouse: Place specified and licensed for the import, storage or whole distribution of Veterinary Products.

Registration Applicant: Official representative or entity approved by the company for the registration of the latter or of Veterinary Products.

Registration Committee: Registration Committee of the Veterinary Products Companies.

Article 2- Licence

The Veterinary Products companies, plants and warehouses at the State shall obtain a licence from the Ministry according to the conditions and rules determined by the Implementing Regulation of this Law.

Article 3- Registration of Companies and Plants

Taking Article (7) into consideration, the Veterinary Products companies and warehouses operating outside the State shall register at the Ministry before commencing any activity inside the State.

Article 4- Registration Conditions and Rules

Veterinary Products shall be registered at the Ministry according to the conditions and rules determined by the Implementing Regulation of this Law.

Article 5- Certificate of Registration

The Ministry shall grant a certificate of registration to the Veterinary Products companies and warehouses and to the Veterinary Products, of a period of five years, renewable for similar periods according to the conditions and rules determined by the Implementing Regulation of this Law.

Article 6- Tasks of the Ministry

The Ministry shall:

1- License the Veterinary Products' companies, plants and warehouses inside the State.

2- Register the Veterinary Products' companies and plants operating outside the State before commencing their activities inside the State.

3- Register the Veterinary Product.

4- Study the technical reports submitted by the international organisations or authorities on the Veterinary Products and their companies and take necessary action in their regard.

5- Monitor the Veterinary Products after their marketing, receive reports from veterinary hospitals or clinics on the quality and safety thereof, and take necessary action in their regard.

6- Prepare and publish lists of the Veterinary Products prohibited to be used on various animal species.

7- Carry out the pricing of the Veterinary Products according to the principles determined by the Implementing Regulation of this Law.

8- Any other relevant tasks for which a decision is issued by the Cabinet.

Article 7- Tasks of the Competent Authority

Without prejudice to Clause (1) of Article (6) of this Law, the Competent Authority shall proceed with all other procedures related to the licensing locally.

Article 8- Commencement of Production

The Veterinary Products Plant licensed at the State shall not commence production until after registration at the Ministry.

Article 9- Adherence to the Purpose of the Licence

The Veterinary Products Plant shall not be used for any purpose other than that for which it was licensed after obtaining the consent of the Ministry.

Article 10- Good Manufacturing

The Veterinary Products Plant shall comply with the principles of good manuacturing of Veterinary Products, as determined by the Implementing Regulation.

Article 11- Registration Condition

The Registration Applicant shall hold a warehouse licence in order to carry out whole trading of Veterinary Products.

Article 12- Cancellation of Registration

The registration of the Veterinary Products companies and plants shall be cancelled by a decision of the Ministry in the following cases:

1- Forgery or manipulation of the submitted documents.

2- Permanent closure of the company or prohibition of use of all its products.

3- Manipulation of the contents of the Veterinary Product in violation of its registration decision.

4- Violation of the registration conditions.

5- Any other cases determined by the Implementing Regulation.

Article 13- Provision of Veterinary Products

The Ministry may compel the registered Veterinary Products companies and plants and the warehouses representing the same, to provide their registered Veterinary Products in case of absence of alternatives.

Article 14- Prohibited Acts

The following shall be prohibited:

1- Import, marketing or trading of Veterinary Products before their registration at the Ministry.

2- Import, marketing or trading of any registered Veterinary Product in case of any change or amendment made thereto without the consent of the Ministry.

3- Import of samples of any Veterinary Product for the purpose of research or marketing without the consent of the Ministry.

Article 15- Import of Non-Prohibited Veterinary Products

As an exception to Clause (1) of the previous Article, the Minister may permit the import of non-prohibited Veterinary Products prior to registration, as determined by the Implementing Regulation of this Law.

Article 16- Manufacturing of Non-Registered Veterinary Products

Non-registered and non-prohibited Veterinary Products may be manufactured only for the purpose of export according to the conditions and rules determined by the Implementing Regulation of this Law.

Article 17- Obligations of the Companies, Plants and Warehouses

The Veterinary Products companies, plants and warehouses shall notify the Ministry of the following:

1- Changes occurring to the Veterinary Product or the producing company.

2- Warnings issued by the company concerning the safety and effectiveness of the Veterinary Product.

3- If the manufacturing or trading of the Veterinary Product is discontinued or suspended in the country of origin.

4- Repeated complaints received by them concerning their Veterinary Products.

Article 18- Advertising of the Veterinary Product

The Veterinary Product shall not be advertised in the media except with the consent of the Ministry, according to the conditions and rules determined by the Implementing Regulation of this Law.

Article 19- Registration Committee of Veterinary Products and their Companies

1- A Committee shall be established at the Ministry under the name (Registration Committee of Veterinary Products and their Companies). A decision shall be issued by the Minister on the formation and work system thereof as well as the mechanism of grievance against the decisions issued by it.

2- The Committee referred to in Clause (1) of this Article shall:

a- Register the Veterinary Products companies and plants.

b- Register the Veterinary Products.

c- Ensure that the Veterinary Products Plants apply the principles of good practice of pharmaceutical manufacturing upon registration.

d- Any other relevant competencies assigned by the Minister.

Article 20- Obligations of the Ministry

The Ministry shall prohibit the import, discontinue the distribution, prohibit the trading, withdraw or retrieve the Veterinary Product or suspend or cancel the registration thereof in the following cases:

1- Making changes or amendments thereto without the consent of the Ministry.

2- Reports are submitted by the Ministry on its toxicity or any serious side effects thereof.

3- Reports are submitted by the Ministry on the presence of a defect in the quality or effectiveness thereof.

4- Suspension of the use thereof upon the recommendation of relevant international regulatory organisations or authorities.

5- Deletion of its registration or suspension of its production at the country of origin.

6- Invalidity of the information related thereto submitted in the registration file.

7- Failure of the company or its agent to submit a registration renewal application of the Veterinary Product before a period of at least (180) days from the date of expiry of the certificate of registration.

8- Any other cases determined by the Implementing Regulation of this Law.

Article 21- Rules of the Veterinary Products

The Implementing Regulation shall determine the rules related to the import, manufacturing, storage, trading, transport, sale and disbursement of Veterinary Products.

Article 22- Disposal of Veterinary Products

The Veterinary Products companies, plants and warehouses shall, upon disposal of the destroyed or expired Veterinary Products, carry out such disposal in a way that respects public safety conditions and does not lead to the pollution of environment according to the legislation in force.

The Implementing Regulation shall determine the mechanisms, rules and cases of disposal of Veterinary Products.

Article 23- Penalties

Shall be punished by imprisonment and a fine not less than (10,000) ten thousand AED and not exceeding (500,000) five hundred thousand AED or by any of these penalties, whoever:

1- Sells, offers, acquires, manufactures or composes a fraudulent, spoiled, expired, contraindicated or imitated Veterinary Product.

2- Enters to the State, transports or stores a non-registered, fraudulent, spoiled, expired or imitated Veterinary Product or attempts any of the same.

3- Enters to the State packages or covers of a certain Veterinary Product with the intent of fraud or imitation.

4- Makes, prints, acquires, sells or offers packages or covers of a certain Veterinary Product with the intent of fraud or imitation.

5- Manufactures, imports, markets or trades any Veterinary Product not registered at the Ministry.

6- Makes any change or amendment to a registered Veterinary Product without obtaining the consent of the Ministry.

In all cases, the Court shall rule the confiscation of the seized substances subject of the violation.

Article 24

Shall be punished by imprisonment and a fine not less than (50,000) fifty thousand AED and not exceeding (500,000) five hundred thousand AED or by any of these penalties, whoever imports, trades or markets any registered Veterinary Product to which a change or amendment is made without obtaining the consent of the Ministry.

Article 25

Shall be punished by imprisonment and a fine not less than (20,000) twenty thousand AED and not exceeding (100,000) one hundred thousand AED or by any of these penalties, wheover imports samples of any Veterinary Product for the purpose of research or marketing without obtaining the consent of the Ministry.

Article 26

Shall be punished by imprisonment and a fine not less than (50,000) fifty thousand AED and not exceeding (500,000) five hundred thousand AED or by any

of these penalties, whoever uses the Veterinary Products Plant for any purpose other than the manufacturing of Veterinary Products without obtaining the consent of the Ministry.

Article 27

Shall be punished by a fine not less than (10,000) ten thousand AED and not exceeding (200,000) two hundred thousand AED, whoever:

1- Provides incorrect information related to the Veterinary Product or refrains from providing information requested by the Ministry.

2- Uses incorrect information for the promotion of a Veterinary Product whether on the product or in the advertising thereof.

3- Advertises the Veterinary Products in the media without obtaining the consent of the Ministry.

Article 28- No Prejudice to any more Severe Penalty

The imposition of the penalties set forth in this Law shall not prejudice any other more severe penalty stipulated in another Law.

Article 29- Reconciliation

1- The criminal action shall not be set in motion for the crimes set forth in Article (27) without a written request from the Ministry or the Competent Authority.

2- Reconciliation may be made for the crimes set forth in Article (27) before referring the case to the competent Court against an amount not exceeding (150,000) one hundred and fifty thousand AED per each crime.

3- The Cabinet shall issue a decision stating the rules of reconciliation and the financial amount for the reconciliation of each of the crimes set forth in this Article.

Article 30- Administrative Sanctions

The Ministry or the Competent Authority may impose any of the following administrative sanctions in case of violation of any provision of this Law or its Implementing Regulation: 1-Warning.

2- Closure of the Veterinary Products Company, plant or warehouse for a period not exceeding six months.

3- Permanent closure of the Veterinary Products Company, plant or warehouse.

Article 31- Judicial Officers

The employees specified by a decision from the Minister of Justice, under agreement with the Minister or head of the Competent Authority, shall have the capacity of judicial officers in the proof of acts occurred in violation to the provisions of this Law, its Regulation and decisions issued pursuant thereto.

Article 32- Adjustment of the Situation

The Veterinary Products companies, plants and warehouses existing at the time of entry into effect of this Law shall adjust their situation according to the provisions of this Law within six months from the date of its entry into force. The period may be extended for a similar period by a decision from the Cabinet.

Article 33-Determination of Fees

The Cabinet shall issue a decision to determine the fees as per the provisions hereof.

Article 34- Implementing Regulation

The Cabinet shall issue the Implementing Regulation of this Law within six months from the date of its entry into effect.

Article 35- Abrogation

Any provision violating or contradicting the provisions of this Law shall be abrogated.

Article 36- Publication and Entry into Effect of the Law

This Law shall be published in the Official Gazette and shall enter into effect on the day following the date of publication thereof.

Issued by Us at the Presidential Place in Abu Dhabi:

On: 11 June 2017 Corresponding to: 16 Ramadan 1438 H Khalifa bin Zayed Al Nahyan President of the United Arab Emirates State

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