Cabinet Resolution No. (9) of 2020
Concerning the Executive Regulations of Federal Law No. (9) of 2017 Concerning Veterinary Products

The Cabinet:

- Having reviewed:
- The Constitution;
- Federal Law No. (1) of 1972, on the Competences of Ministries and Powers of Ministers, as amended;
- Federal Law No. (9) of 2017, on Veterinary Products; and
- Based on the Proposal submitted by the Minister of Climate Change and Environment, and approved by the Cabinet,

Hereby resolves as follows:

Article (1)
Definitions

The definitions set out in Federal Law No. (9) of 2017, referred to hereinabove, shall apply to this Resolution. In addition, the following words and expressions shall have the meanings assigned thereto respectively, unless the context requires otherwise:

Registration Certificate	:	An official document issued by the Ministry to certify registration of Veterinary Products and their companies and factories.
Technical Director	:	Every person who holds a certificate of not less than the Bachelor's Degree in Pharmacology or Veterinary Medicine, has experience in pharmaceutical manufacturing, and is licensed in the State.

OTC Veterinary Products	:	Veterinary Products that are dispensed with no need for a prescription.
POM Veterinary Products	:	Veterinary Products that are dispensed only based on a prescription.
Good Manufacturing Practices (GMP)	:	Manufacturing practices that, if duly applied, would guarantee that the product conforms to quality requirements.
Good Storage Practices of Veterinary Products (GSP)	:	Part of quality assurance that ensures that the quality of Veterinary Products is preserved during the storage thereof.
Good Distribution Practices of Veterinary Products (GDP)	:	Part of quality assurance related to maintaining the quality of Veterinary Products by monitoring the activities performed during the distribution.

Article (2)

License

1. Veterinary products companies and factories operating in the State shall obtain a license from the Ministry before initiating the production of Veterinary Products, in accordance with the following conditions and controls:
   a. Obtain the necessary licenses from the Competent Authority.
   b. Satisfy the GMPs to be issued by a resolution of the Minister.
   c. Assign the supervision of veterinary product companies and factories to a Technical Director.
   d. Obtain an environmental permit/license from the competent local authority.
   e. Provide a list of the factory's departments, including production lines.
   f. All means of biosafety, security and safety shall be available at the factory;
   g. Satisfy the Good Storage Practices of Veterinary Products (GSP) to be issued by a resolution of the Minister; and

h. Satisfy the Good Distribution Practices of Veterinary Products (GDP) to be issued by a resolution of the Minister.

2. Veterinary products warehouses in the State shall obtain a license from the Ministry according to the following conditions and controls:
   a. Obtain the necessary license from the Competent Authority;
   b. Satisfy the health and technical requirements of veterinary facilities; and
   c. A veterinarian licensed by the Ministry shall be available.
3. The Ministry shall approve or reject the applications for licensing Veterinary Product companies, not later than (30) thirty days. In case of rejection, its shall indicate the reasons underlying such rejection.
4. The license term of veterinary product companies, factories and warehouses shall be one year. Such a term may be renewed subject to satisfying all the conditions and controls set out in the provisions of this Article.

Article (3)

Veterinary Product Registration Conditions and Controls

1. Veterinary Products shall be registered with the Ministry according to the following technical and health conditions:
   a. Every pharmaceutical concentration or form of a Veterinary Product shall constitute a standalone registration file;
   b. The Veterinary Product required to be registered shall first be merchandised in the country of origin for a period of not less than one year before its registration under the same formulation. Non-merchandised Veterinary Products may, however, be registered if proved to be safe and effective.
   c. If the Veterinary Product submitted for registration is a veterinary vaccine, it shall be a prerequisite for its registration that the relevant disease be prevalent in the State or for the purpose of prevention of an endemic disease in adjacent States.

2. The Veterinary Product registration application file shall be examined according to the following controls:
    a. Assessment of the Veterinary Product's effectiveness;
    b. Assessment of the Veterinary Product's safety within the scope of the intended use;
    c. Assessment of the Veterinary Product's quality;
    d. Provide samples of the Veterinary Product, as decided by the Ministry;
    e. Provide an adequate quantity of the reference active ingredient(s) and other necessary testing supplies; and
    f. The Veterinary Product shall successfully pass the lab analysis throughout the registration phases. If it fails to successfully pass such analysis for three consecutive times, it shall not be registered.
3. Veterinary Products shall be classified as follows:
    a. POM Veterinary Products; and
    b. OTC Veterinary Products.
4. The Ministry may postpone or reject the registration of any Veterinary Product and indicate the rejection reasons.

Article (4)

Registration Certificate

The Ministry shall issue a registration certificate for veterinary products companies and factories and for the veterinary product itself. The term of such a certificate shall be five (5) years, renewable for similar terms, subject to satisfying all the technical requirements for registering Veterinary Product companies and factories and fulfilling the conditions and controls set forth in Article (3) above in respect of the registration of veterinary products.

Article (5)

Veterinary Product Pricing

1. A Veterinary Product shall be priced based on the following pricing criteria:
   a. Factory price in the country of origin;
   b. Wholesale prince in the country or origin;
   c. Product consumer price in the country of origin and in countries where the product is merchandised;
   d. CIF price proposed by the company to the State in the currency of the country of origin;
   e. CIF price to all countries where the Veterinary Product is merchandised at the time of being submitted for registration in the State;
   f. Significance of the treatment Veterinary Product; and
   g. Prices of similar Veterinary Products registered in the State.
2. Sale price of the imported Veterinary Product shall be set according to the criteria referred to in Clause (1) above, taking into account the lowest price quoted.
3. Sale price of locally-manufactured Veterinary Product shall be set according to the criteria cited in Paragraphs (e, f and g) of Clause (1) above, taking into account the lowest price quoted.
4. The company, or its agent, shall notify the Ministry when the CIF price of any of its Veterinary Products registered in the State becomes different from the CIF price due to increase or decrease.
5. Veterinary Products shall be repriced every (5) five years of the registration date thereof after being presented to the registration committee.
6. The Ministry shall review Veterinary Product's prices where necessary.

Article (6)

Good Manufacturing Practices (GMP)

Local Veterinary Product factories shall apply the below-mentioned GMP of pharmaceutical manufacturing throughout the manufacturing process, so as to ensure the safety and quality of Veterinary Products, as well as any other controls issued under a resolution of the Minister in coordination with the Competent Authority.

a. Technical staff;
b. Facilities and production sites;
c. Machinery and equipment used in the production;
d. Raw materials and packaging and filling materials;
e. Production and manufacturing process;
f. Packaging and labelling control;
g. Storage and marketing;
h. Laboratory control; and
i. Documentation.

Article (7)

Deregistration of Veterinary Product Companies and Factories

Veterinary Product companies and their factories shall be deregistered by a resolution of the Ministry in the following cases:

1. If the documents submitted are counterfeited or manipulated.
2. If the company is permanently closed down or if its entire products are prohibited from being used.
3. If the Veterinary Product's content is manipulated in violation of its registration resolution.
4. If the registration conditions are violated.
5. Failure to comply with the conditions based on which the Registration Certificate has been granted.
6. If unregistered or prohibited products are marketed or advertised.

7. If Veterinary Product companies or factories continue to circulate a Veterinary Product despite the deregistration thereof.

Article (8)

Importation of Non-Prohibited and Unregistered Veterinary Products

1. The Minister may permit the importation of non-prohibited Veterinary Products before they are registered in the following cases:
    a. The Veterinary Product required to be imported shall belong to life-saving or extremely important Veterinary Products or other Veterinary Products which have no registered alternative or are unavailable in the local market; or
    b. The importation shall take place for the benefit of veterinary hospitals, clinics, farms or livestock projects in the State.
2. The Minister may permit the importation of unregistered and non-prohibited Veterinary Products for the purpose of scientific research or organizing medical veterinary exhibitions.

Article (9)

Manufacturing of Unregistered Veterinary Products

The Ministry may grant the local Veterinary Product factory an approval to manufacture unregistered and non-prohibited Veterinary Products for the purpose of exportation, in accordance with the following conditions and controls:

1. Acceptable justifications for manufacturing the Veterinary Product shall be furnished;
2. A guarantee shall be furnished indicating that the Veterinary Product shall not be marketed in the State;
3. A certificate of origin shall be obtained for the Veterinary Product from the competent federal authority in the State for exportation purpose only.

Article (10)

Veterinary Product Advertising

1. No Veterinary Product may be advertised in mass media without prior approval of the Ministry, in accordance with the following conditions and controls:
   a. The advertisement's content shall be submitted to the Ministry according to the requirements approved by the same;
   b. The advertisement's content may not contradict the leaflet and the Summary of Product Characteristics (SPC);
   c. The advertisement may not contain misleading information;
   d. The advertisement may not contain any phrase prejudicial to other Veterinary Products;
   e. The advertisement's target category shall be identified; and
   f. For POM Veterinary Products, the approval shall be limited to advertising in scientific magazines, conferences and forums.
2. Any person, for whom or in whose name the advertising approval is issued shall cease to make the same in any of the following cases:
   a. If new developments occur indicating that the Veterinary Product is risky or ineffective; or
   b. The Ministry suspends the advertisement and announces the underlying reasons.

Article (11)

Veterinary Products Importation Rules

1. Veterinary Products shall be imported through Veterinary Product warehouses licensed by the Ministry.
2. Veterinary Product warehouses shall be prohibited from importing any Veterinary Product unless it has been registered with the Ministry.

Article (12)

Veterinary Product Storage Rules

Veterinary Products shall be stored according to the manufacturer's instructions; provided that the storage place shall be designed and fitted out in a way that maintains good storage conditions and ensures the quality of Veterinary Products, in accordance with the following:

1. The place shall be dry and non-exposed to direct sunlight;
2. Veterinary Products shall not be directly placed on the ground;
3. Storage places shall be enough to store different substances with spaces between the materials stored, and shall be furnished with all measures and means that minimize potential risks; and
4. Separate records shall be kept to continuously record temperatures and humidity in the storage places.

Article (13)

Veterinary Product Circulation Rules

Subject to the provisions of Articles (8) and (9) above, Veterinary Product companies, factories and warehouses shall be prohibited from:

1. Merchandising or circulating any Veterinary Product prohibited or unregistered in the State; and
2. Selling a Veterinary Product to any unlicensed entity, pursuant to the legislation in force in the State.

Article (14)

Veterinary Product Transport Rules

1. Veterinary Product transport conditions shall be commensurate with the environment, ambient atmospheric conditions and storage conditions identified in the label, through engaging means of transport that ensure safe transport of Veterinary Products during the transportation.

2. Separate records shall be kept to continuously record temperatures and humidity in the means of transport.
3. Subject to the provisions set out in Item (1) above, the technical procedures and requirements approved by the Competent Authority shall be observed when Veterinary Products are transported.

Article (15)

Veterinary Products Sale and Circulation Rules

1. A veterinary prescription may only be dispensed or changed by a competent veterinarian licensed according to the legislation in force in the State.
2. Veterinary antibiotics may not be dispensed without a prescription.
3. Antibiotics may not be used for preventative purposes, immunity enhancement or growth stimulation.
4. All veterinary facilities shall keep records and documents of selling and dispensing Veterinary Products for a period of one year from the issuance date thereof.

Article (16)

Disposal of Veterinary Products

1. Veterinary Products shall be disposed of in the following cases:
    a. If the circulation of the Veterinary Product is suspended or put on hold, or if the Veterinary Product is deregistered;
    b. Recall or withdrawal of the Veterinary Product decided to be destroyed;
    c. If it is established that the Veterinary Product is adulterated, damaged or expired;
    d. If the Veterinary Product violates the registration specifications; and
    e. If the Veterinary Product is stored under inappropriate storage conditions.

2. Veterinary Products shall be disposed of by a specialized company duly licensed by the Competent Authority or by the manufacturer if it has the safe technical means necessary to carry out the same.
3. Subject to the provisions of Items (1) and (2) above, the technical procedures and requirements approved by the Competent Authority shall be complied with when Veterinary Products are disposed of.
4. The Ministry may require the Veterinary Product companies, factories and warehouses to re-export Veterinary Products intended to be disposed to the initial exporting entity.
5. Veterinary Product companies, factories and warehouses shall bear the cost of Veterinary Product disposal or re-export.

Article (17)

Grievances

A grievance may be filed against any decision issued by the Ministry in implementation of the provisions of this Resolution, within (30) thirty days of the date of knowledge, with a committee to be formed by a resolution of the Minister for such purpose. The Committee shall decide on the grievance within (15) fifteen days of the date of being filed thereto. The decision issued on the grievance shall be final.

Article (18)

Executive Resolutions

The Minister shall issue the resolutions necessary for executing the provisions of this Resolution.

Article (19)

Repeals

Any provision contradicting or repugnant to the provisions of this Resolution shall hereby be repealed.

Article (20)

Publication and Entry into Force

This Resolution shall be published in the Official Gazette, and shall enter into force as of the day following the date of its publication.

Mohammed bin Rashid Al Maktoum

Prime Minister

Issued by us

Dated: 8th Jumada Al Thani, 1441 AH,

Corresponding to: 2nd February 2020 AD