

## Veterinary Products Law In Arab Gulf Cooperation Council Countries

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## Veterinary Products Law in Arab Gulf Cooperation Council Countries

### Article (1)

The terms and expressions defined below have the indicated meaning in front of each definition unless the context reflects other meaning.

**Supreme Council:** Supreme Council of Cooperation Council for the Arabian Gulf Countries.

**Country:** One of the member country in Cooperation Council for the Arabian Gulf Countries.

**Regulation:** Implementing regulation of veterinary products law in the Cooperation Council for the Arabian Gulf Countries.

**Competent Body:** Ministry or concerned body of regulating and monitoring companies and veterinary products factories, its products, and issuance of the necessary licensing.

**Veterinary Products:** A substance or combination of substances used to treat or prevent animal disease, diagnose pathological conditions, reappearance, healing, or change the physiological functions of an animal.

**Veterinary Products Company:** The facility which owns one or more veterinary products companies or has the right of manufacturing and/or marketing the licensed veterinary product.

**Veterinary Medicines Factory:** Establishment in which veterinary products are being manufactured according to current Good Manufacturing Practices (cGMP) of pharmaceutical manufacturing that approved by the competent body.

**Veterinary Products Warehouse:** The place which is specified and licensed by the competent body to import, storage, distribute of wholesale veterinary products.

**Registration Applicant:** Company's representative person or party to register its veterinary products.

**Registration Committee:** it is the committee that analyse and evaluate files of veterinary products registration, its companies, factories, and the provide recommendations regarding its registration, refusal, or revocation.

### Article (2)

Importing, marketing, or handling any veterinary product is not allowed unless it is registered by the competent body in the country.

### Article (3)

The competent body is responsible for the following tasks:

1. Registration of companies and veterinary products factories according to this Law (System) and its regulation.
2. Registration of veterinary products according to this Law and its regulation.
3. Examination of the technical reports from the organizations or international authorities on veterinary products and its companies and doing what is necessary.

4. Monitoring the veterinary products before and after marketing, receiving the reporters from hospitals or veterinary clinics about the quality and safety of veterinary products, and doing what is necessary.
5. A list of the veterinary products which are prohibited to be used in different kinds of animals.
6. Pricing of the veterinary products.
7. Licensing of factories and warehouses of local veterinary products.
8. Permission to clear (Allowing releasing of) imported veterinary products.

#### **Article (4)**

Companies and local veterinary products factories shall have the licensing by competent body according to the requirements and conditions that the implementing regulation specified in this Law (System).

#### **Article (5)**

The veterinary products companies shall register its factories (Its production lines) by the competent body according to conditions and regulations of this Law (System) and its implementing regulation.

#### **Article (6)**

It is not permitted for local veterinary products to begin the production of veterinary products of commercial use unless after being registered by the competent body.

### **Article (7)**

The veterinary products local factory will only be used for manufacturing veterinary products. An approval from the competent authority must be obtained if there are any plans to use the factory for other purposes.

### **Article (8)**

Factories of veterinary products shall be obligated to apply current Good Manufacturing Practices (cGMP) of pharmaceutical manufacturing (cGMP).

### **Article (9)**

If the product registration application is approved, the applicant is obligated to obtain a veterinary product warehouse license because the registration certificate cannot be issued before having a warehouse license.

### **Article (10)**

The competent authority based on the registration committee recommendation can revoke the company registration or the veterinary products factories according to the specified cases by the implementing regulation of this Law (System).

### **Article (11)**

The companies of veterinary products and its registered factories in the country and the veterinary products warehouses represented shall obligate by providing its registered veterinary products.

### **Article (12)**

The competent authority in the country according to conditions and regulations that specified by this Law and its implementing regulation shall register the veterinary products.

### **Article (13)**

All veterinary products shall be subjected to pricing according to principals and regulations, which are specified by the implementing regulation of this Law (System).

### **Article (14)**

The registered certificate of the company or factory will not be issued before registering its first veterinary product.

### **Article (15)**

The competent authority may:

1. Approve the importing of unregistered veterinary products when necessary.

2. Re-exporting the imported veterinary products.

#### **Article (16)**

Local veterinary products may, after the permission of the competent authority, manufacture unregistered veterinary products for exporting purposes.

#### **Article (17)**

It is not allowed to import, handle, or market any registered veterinary product if it has been modified or changed without prior approval by the competent authority.

#### **Article (18)**

Importing of unregistered veterinary product for researches purposes is permissible after the approval of the competent authority, in accordance with the conditions and regulations that determined by the regulation.

#### **Article (19)**

Importing of unregistered veterinary product samples is forbidden.

#### **Article (20)**

The registrar of the veterinary product shall inform the competent authority about the following:

1. Warnings regarding the product issued by the company, factory, organizations, or international regulatory authorities.
2. If the product registration is revoked, suspended, or its trading is banned or its manufacturing is being recalled or terminated in the country of origin or any country in which the product registration took place.

#### **Article (21)**

The good storage and distributing principals of veterinary products must be obligated.

#### **Article (22)**

Advertising of veterinary products is prohibited without a prior approval by the competent authority according to the conditions and regulations specified by the implementing regulation of this Law (System).

#### **Article (23)**

The competent authority shall be responsible of forming committees that are concerned of registration the companies and factories (Production lines) of veterinary products, to ensure of applying good manufacturing practices of pharmaceutical manufacturing during registration process. The implementing regulation of this Law (System) shall specify the regulation of committee's procedures, how it works, its tasks, and any regulatory regulations.

#### **Article (24)**

the following procedures must be carried out If the competent authority finds any defects in the veterinary product that might affect its safety, efficiency, or it has been modified or changed without the competent authority approval, or if it violates a provision of this Law:

1. Banning its importing.
2. Suspend its trading.
3. Suspension its registration.
4. Revocation its registration.
5. Recalling.
6. Withdrawing.

This must be done in accordance to specified cases by the regulation of this Law (System).

#### **Article (25)**

The competent body shall issue a decree to determine the due fees in accordance with this Law (System) and its implementing regulation.

#### **Article (26)**

The validity duration of registration certificate for companies, factories of veterinary products and its products, local factories and veterinary products warehouses is 5 years, and it can be renewed for the same period in accordance to the requirements and conditions that the implementing regulation specifies.

### Article (27)

Any person Who commits following violations will be considered as a violator of this Law:

1. Deceived or counterfeiting in veterinary product – or the intentions to do such act.
2. Sold, obtained, manufactured, or combine a veterinary product that is counterfeited, decomposed, expired, or in contrary to the product data.
3. Introduced, transferred, or stored unregistered veterinary product that is counterfeited, decomposed, expired, or trying to bringing in such products into the country.
4. Using incorrect information on the veterinary product or its advertisement for promoting purposes.
5. Bringing in or tried to bring bottles or packages of certain veterinary product for the counterfeiting purposes.
6. Manufactured, printed, obtained, sold, or displayed bottles or packages of certain veterinary product for counterfeiting purposes.
7. Import, export, re-export, manufacture, market, sold, stored, or display the veterinary product to his favour or for others favour by violating the provisions of this Law or its regulations.
8. Provided wrong information regarding the veterinary product, or prevented of providing information that is required by the competent authority.
9. Lack of obligation to the decisions which issued by the competent authority in implementation of this Law and its regulation.
10. Selling of promoting the veterinary products without a license.

## Article (28)

In case of any violation regarding this Law provisions and its regulation, the seized veterinary products shall be dealt with as follows:

### 1: Registered Products

1. Seizing of them and their related documents if necessary.
2. Taking samples to be tested when necessary.
3. Destroying counterfeited, decomposed, expired, or violated products.

### 2: Destroying unregistered products.

## Article (29)

The competent authority is responsible of forming a committee or more to supervise on violated veterinary products destroying process. The cost of destroying procedure will be on violator expense.

## Article (30)

Everyone who violates any of this Law) or its regulation shall be penalized with one or more of the following penalties:

1. Fine of no more than 5,000,000 SAR or its equivalent cost in the currency of the other country.
2. Closure of the factory or the warehouse until solving the violation.

3. Revoke of the factory or warehouse licensing.

4. Jail for no more than 5 years.

If the violations repeated by the violator, the penalties may be multiplied (doubled).

### **Article (31)**

If the competent authority has sized violation in a facility that licensed by another authority, it can ask the authority which issued the license to revoke it.

### **Article (32)**

1: The competent authority shall be responsible to carry out the punishments (penalties) which are mentioned in Article (30) of this Law except jailing penalty. This must be carried out in accordance to regulations and procedures stated in this Law and its implementing regulation.

2: If the competent authority believes that such violation requires jail penalty or associates with a criminal act, the issue shall be referred to the concerned authority in the country to be investigated to do the legal (Regulatory) procedures and to refer this issue to the competent court. The authority has the right to close the factory or warehouse until the sentence is issued.

3: The competent authority shall issue a table that contains a classification of the specified penalties and violations t – except jail penalty-.

### **Article (33)**

Anyone who is negatively affected by the decisions that are taken according to the provisions of this Law (System) may notify complaint to the competent authority in accordance to the applicable complaints regulations in every country.

### **Article (34)**

The competent authority may inspect on the veterinary products and seize the provisions in order to ensure the implementation of the provisions of this Law and its implementing regulation by official employees who have the authority of carrying judicial seizure in accordance to the applicable Laws in every country.

### **Article (35)**

The employees who have authority of carrying judicial seizure may enter the places which their activates are included in the provisions of this Law and its implementing regulation, in order to ensure the implementation of its provisions and to seize the violated cases.

### **Article (36)**

Agricultural Cooperation Committee has the right in interpretation, suggestion, and modification of this Law.

### **Article (37)**

Agricultural Cooperation Committee shall adopt the implementing regulation of this Law compulsorily.

### **Article (38)**

This Law is mandatory, and it comes into force after 180 days of its authorization by the Supreme Council.