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**Law No. (19) of 2014 approving the Law (statute) of the Veterinary Products in the Cooperation Council for the Arab States**

We, Hamad bin Isa Al Khalifa, King of the Kingdom of Bahrain.

Having reviewed the Constitution,

And the Penal Code promulgated by Legislative Decree No. (15) of 1976, as amended;

And Legislative Decree No. (18) of 1997 regarding the Organization of the Pharmacy Profession and Pharmaceutical Centres, and Law No. (8) of 2002 approving the Veterinary Quarantine Regulation in the Cooperation Council for the Arab States;

And the Law (statute) of the Veterinary Products in the Cooperation Council for the Arab States, issued with binding adoption by decision of the Supreme Council of the Council of Arab States at its thirty-second session held in Riyadh, Kingdom of Saudi Arabia, on Monday and Tuesday, 24-25 Muharram 1433 A.H., corresponding to 19-20 December 2011;

The Council of Representatives and the Shura Council have approved the following law, which we have ratified and enacted:

**Article One**

The Law (statute) of the Veterinary Products in the Cooperation Council for the Arab States, issued with binding adoption by decision of the Supreme Council of the Council of Arab States at its thirty-second session held in Riyadh, Kingdom of Saudi Arabia, on Monday and Tuesday, 24-25 Muharram 1433 A.H., corresponding to 19-20 December 2011, attached to this Law, has been approved.

**Article Two**

In application of the provisions of the attached Law (statute), the expression "Competent Authority" refers to the department concerned with Animal Wealth farming and veterinary products within the Ministry responsible for Animal Wealth affairs, and the expression "Competent Minister" refers to the Minister concerned with Animal Wealth affairs.

**Article Three**

The categories of fees payable for services and licences provided in accordance with the provisions of the attached Law (statute) and its Implementing Regulation are determined by Decision of the Minister responsible for Animal Wealth after approval by the Council of Ministers.

**Fourth Article**

The party concerned may submit a grievance against decisions taken pursuant to the provisions of this Law (statute) and its implementing regulation to the competent Minister within thirty days from the date of their announcement or publication, and the grievance shall be decided within thirty days from the date of its submission. If the complaint is rejected, the rejection shall be substantiated and deemed to have been adopted. A period of thirty days from the date of its submission without a reply shall constitute an implicit rejection of the grievance, and the party concerned shall have the right to appeal against the decision to reject the grievance within a period of thirty days from the date on which he was informed of the rejection or considered it to have been rejected.

An appeal against any of the aforementioned decisions may only be admitted directly before the competent court if it has been the subject of an appeal.

**Fifth Article**

Without prejudice to any more severe penalty provided for in the Penal Code or any other Law, anyone who commits any of the acts stipulated in Article (27) of the attached Law (statute) shall be punished by a term of imprisonment not exceeding three months and a fine not less than five thousand dinars, but not more than fifty thousand dinars, or by one of these two penalties.

In the event of a conviction, the court may order the destruction of the materials and confiscate the machines used to commit the offence for the benefit of the department responsible for animal welfare and veterinary products.

It may also order the cancellation of the licence of the factory or warehouse in which the offence was committed, or its closure until the offence is rectified, in accordance with the procedures specified by the implementing regulation of this Law.

The penalty shall be doubled to its minimum and maximum limits if the offence is repeated within a period of one year from the date of expiry of the penalty or its limitation period.

d- The aforementioned administration has the right to suspend the licence of the factory or warehouse or to close it and to seize the materials and machines used until the violation is judged.

**Article Six**

The Minister in charge of animal welfare shall take the necessary decisions to apply the provisions of this Law and, until such decisions are taken, the regulations and decisions currently in force shall continue to be applied as long as they are not contrary to the provisions of this Law.

**Article Seven**

The Prime Minister and the ministers– each within his jurisdiction- shall implement this Law, and it shall come into force from the day following the date of its publication in the Official Gazette.

King of Kingdom of Bahrain

Hamad Bin Isa Al Khalifa

Promulgated in Riffa Palace:

On: 5 Ramadan 1435 A.H.

Corresponding to: 3 July 2014

**Law (statute) of the Veterinary Products in the Cooperation Council for the Arab States**

Article (1)

The following terms and expressions shall have the meanings assigned to them below, unless the context requires otherwise.

**Supreme Council:**The Supreme Council of the Gulf Cooperation Council

**State:**One member state in the Gulf Cooperation Council.

**Regulation:**Implementing Regulation for the Law (statute) of the Veterinary Products in the Cooperation Council for the Arab States.

**The Competent Authority:** Ministry or concerned authority 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 authority.

Warehouse for veterinary preparations: Designated place approved by the competent authority to import, store or wholesale veterinary preparations.

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

**Registration Committee:**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 authority in the country.

Article (3)

The competent authority is responsible for the following tasks:

Registration of companies and veterinary products factories according to this Law and its regulation.

Registration of veterinary products according to this Law and its regulation.

Examination of the technical reports from the organizations or international authorities on veterinary products and its companies and doing what is necessary.

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.

A list of the veterinary products which are prohibited to be used in different kinds of animals.

Pricing of the veterinary products.

Licensing of factories and warehouses of local veterinary products.

Permission to clear (Allowing releasing of) imported veterinary products.

Article (4)

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

Article (5)

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

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)

Manufacturers of veterinary preparations must adhere to the principles of Good Pharmaceutical Manufacturing Practice (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 (statute).

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)

Veterinary preparations must be registered with the country's competent authority in accordance with the conditions and controls specified by this law (the Regulation and its implementing regulation).

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 (statute).

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:

Approve the importing of unregistered veterinary products when necessary.

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:

Warnings regarding the product issued by the company, factory, organizations, or international regulatory authorities.

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 (statute).

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 (statute) 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 founds 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:

Banning its importing.

Suspend its trading.

Suspension its registration.

Revocation its registration.

Recalling.

Withdrawing.

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

Article (25)

The competent authority shall issue a decree to determine the due fees in accordance with this Law (statute) 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 any of the following acts shall be deemed to be in breach of the provisions of this Law (statute):

Deceived or counterfeiting in veterinary product - or the intentions to do such act.

Sold, obtained, manufactured, or combine a veterinary product that is counterfeited, decomposed, expired, or in contrary to the product data.

Introduced, transferred, or stored unregistered veterinary product that is counterfeited, decomposed, expired, or trying to bringing in such products into the country.

Using incorrect information on the veterinary product or its advertisement for promoting purposes.

Bringing in or tried to bring bottles or packages of certain veterinary product for the counterfeiting purposes.

Manufactured, printed, obtained, sold, or displayed bottles or packages of certain veterinary product for counterfeiting purposes.

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 regulation.

Provided wrong information regarding the veterinary product, or prevented of providing information that is required by the competent authority.

Lack of obligation to the decisions which issued by the competent authority in implementation of this Law (statute) and its regulation.

Selling of promoting the veterinary products without a license.

Article (28)

In the event of a violation of the provisions of this law (statute) and its regulations, the veterinary preparations seized will be treated as follows:

First: Registered Products

Seizing of them and their related documents if necessary.

Taking samples to be tested when necessary.

Destroying counterfeited, decomposed, expired, or violated products.

**Second:** 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 (20)

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

A fine not exceeding five million Saudi riyals or its equivalent in the country's national currency.

Closure of the factory or the warehouse until solving the violation.

Revoke of the factory or warehouse licensing..

Jail for no more than five years.

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

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)

First: The competent authority shall be responsible to carry out the punishments (penalties) which are mentioned in Article (20) of this Law (statute). Except jailing penalty which shall be carried out in accordance to regulations and procedures stated in this Law(statute) and its implementing regulation.

**Second:** 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.

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

Article (33)

Any person aggrieved by decisions rendered in application of the provisions of this law may lodge a complaint with the competent authority in accordance with the complaint Regulations in force in each country.

Article (34)

The competent authority may inspect on the veterinary products and seize the violations in order to ensure the implementation of the provisions of this Law (statute) 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 Police may enter the places which their activities are included in the provisions of this Law (statute) 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 (statute).

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.