

**KINGDOM OF CAMBODIA  
NATION - RELIGION - KING**

**3**

**Ministry of Agriculture, Forestry and Fisheries**

**3**

No. 384 ProrKor.KorSorKor

**PRAKAS  
ON  
PROCEDURES FOR MANAGING VETERINARY MEDICINES AND  
BIOLOGICAL MATERIALS IN TRADE AND MIXING**

**3**

**THE MINISTER OF AGRICULTURE, FORESTRY AND FISHERIES**

- Having seen the Constitution of the Kingdom of Cambodia.
- Having seen Royal Decree No. NorSor / RorKorTor / 0918 / 925 dated 6 September 2018 on Appointment of the Royal Government of Cambodia.
- Having seen Royal Decree No. NorSor / RorKorTor / 0320 / 421 dated 30 March 2020 on Appointment of and Change to the Members of the Royal Government of Cambodia.
- Having seen Royal Kram No. NorSor / RorKorTor / 0618 / 012 dated 28 June 2018 promulgating the Law on Organization and Functioning of the Council of Ministers.
- Having seen Royal Kram No. NorSor / RorKorMor / 0196 / 13 dated 24 January 1996 promulgating the Law on Establishment of the Ministry of Agriculture, Forestry and Fisheries.
- Having seen Royal Kram No. NorSor / RorKorTor / 0116 / 003 dated 28 January 2016 promulgating the Law on Animal Health and Production.
- Having seen Sub-Decree No. 17 OrNorKror.BorKor dated 07 April 2000 on Organization and Functioning of the Ministry of Agriculture, Forestry and Fisheries.
- Having seen Sub-Decree No. 105 ANKr.BK dated Aug 22, 2005 on Assignment of Additional Tasks to the Ministry of Agriculture, Forestry and Fisheries and the establishment of the Department of Internal Audit, Department of Planning and Statistics, Department of International Cooperation and Center for Agriculture Information and Documents under the Ministry of Agriculture, Forestry and Fisheries.
- Having seen Sub-Decree No. 188 OrNorKror.BorKor dated 14 November 2008 on Transformation of the General Directorate of the Ministry to the General Secretariat, Upgrading of the Forestry Administration and Fisheries Administration to the level of General Directorate, Upgrading of the Department of Agronomy and Soil Improvements to the General Directorate of Agriculture, and Transformation of the General Directorate of

Rubber Plantation to the General Directorate of Rubbers under supervision of the Ministry of Agriculture, Forestry and Fisheries.

- Having seen Sub-Decree No. 224 OrNorKror.BorKor dated 28 October 2016 on Upgrading Department of Animal Production and Health to General Directorate of Animal Health and Production.
- Having seen Sub-Decree No. 81 OrNorKror.BorKor dated 21 June 2019 on Amendment to Article 2, Article 25, Article 26 and Article 35 of the Sub-Decree No. 188 OrNorKror.KorBor dated 14 November 2008 and to a new Article 27 of the Sub-Decree No. 118 OrNorKror.KorBor dated 26 July 2017.
- Having Seen the Joint Prakas No. 1013 SorHorVor.BrorKor dated 28 December 2012- the Ministry of Agriculture, Forestry and Fisheries and the Ministry of Economy and Finance on Provision of Public Services.
- Having Seen the Prakas No. 208 ProrKor.KorSorKor dated 25 April 2018 on Procedure and Standard Requirements for Registration of Veterinary Medicines.
- Having seen Prakas No. 414 ProrKor.KorSorKor dated 01 October 2019 on Procedure to Issue Permit and Technical Standards for Importation, Exportation, Transit, Manufacturing, Mixing, Repackaging, Stockpiling, Supplying-Distribution, Wholesale-Retail and Transportation of Veterinary Medicines.
- Referring to the need by the Ministry of Agriculture, Forestry and Fisheries.

## **HEREBY DECIDES**

### **CHAPTER 1**

#### **GENERAL PROVISIONS**

##### **Article 1**

This Prakas aims to define the procedures for the management of all types of veterinary medicines and biological materials, active ingredients and compounds in trade, manufacturing, and mixing to ensure their quality, efficacy and safety in order to protect animal health and wellbeing, human health, consumer interests, and to contribute to environmental protection.

##### **Article 2**

The Prakas shall apply to all activities related to management of all types of veterinary medicines and biological materials, active substances and compounds in trade, manufacturing and mixing in the Kingdom of Cambodia.

### **CHAPTER 2**

#### **PROCEDURES FOR MANAGEMENT OF VETERINARY MEDICINE AND BIOLOGICAL MATERIALS IN TRADE, MANUFACTURING AND MIXING**

##### **SECTION 1**

**IMPORTATION, EXPORTATION, TRANSIT, MANUFACTURING, MIXING, REPACKAGING,  
STOCKPILING, SUPPLYING-DISTRIBUTION, WHOLESALE-RETAIL, AND TRANSPORTATION**

**Article 3**

A natural person or legal entity intending to import, export, transit, manufacture, concoct, repackage, stockpile, supply-distribute, wholesale-retail, and transport veterinary medicines and biological materials, active substances, and compounds shall comply with Prakas No. 414 ProrKor.KorSorKor dated 01 October 2019 on Procedures for Issuance of Permits and Technical Standards for Importation, Exportation, Transit, Manufacturing, Mixing, Repackaging, Stockpiling, Supplying-Distribution, Wholesale-Retail and Transportation of Veterinary Medicines.

**SECTION 2**

**PUBLICATION AND ADVERTISEMENT**

**Article 4**

A natural person or legal entity intending to publish or advertise any type of veterinary medicines and biological materials, active substances, and compounds shall apply for approval prior to publicizing and advertising that type of veterinary medicines and biological materials, active substances, and compounds in compliance with the provisions and procedures of the Law on Animal Health and Production.

Articles to be published and disseminated, audio-visual materials, presentations, technical instructions to be shared in seminars, technical materials for field demonstration, or other materials for advertising veterinary medicine and biological materials, active substances, and compounds shall have prior approval from the General Directorate of Animal Health and Production, of the Ministry of Agriculture, Forestry and Fisheries.

**Article 5**

A natural person or legal entity shall submit an application to the General Directorate of Animal Health and Production, of the Ministry of Agriculture, Forestry and Fisheries, for permission to publish or advertise veterinary medicines and biological materials, active substances, and compounds at least thirty (30) days before the date of publication or advertisement.

The application for the permission to publish or advertise veterinary medicine and biological materials, active substances, and compounds shall be submitted with the applicant's annual dissemination program-plan indicating the dates and venues for such dissemination, advertisement, seminars, or field demonstration, along with the text or technical instructions to be used in the events for the General Directorate of Animal Health and Protection to review, study or to make any necessary corrections in accordance with the technical requirements and relevant provisions in effect.

**Article 6**

Articles publishing about or advertising veterinary medicines and biological materials, active substances, and compounds shall:

1. Contain technical information in accordance with the guidelines provided by the General Directorate of Animal Health and Production

2. Be in conformity with the information or data provided in the attached labels or technical documents of the veterinary medicine and biological materials, active substances, and compounds; and as stated during registration.
3. Provide, at minimal, a description as follows:
  - The identity of the veterinary medicines and biological material, active substances, and compound including trade name, common name, trademark, and relevant physical characteristics;
  - The identity of the company holding the registration certificate, the registration number, the country, and the company of origin responsible for the manufacturing, mixing, importation, exportation, supplying/ distribution, or repackaging;
  - The how-to of using the product subject to advertisement;
  - The quality, efficacy and safety of the veterinary medicine and biological material, active substances, and compound; and
  - An instruction on the package in Khmer telling consumers to read the label before using

#### **Article 7**

After obtaining an approval for the articles publishing about and advertising the veterinary medicines and biological materials, active substances, and compounds; the natural person or legal entity shall have the right to advertise in the media, and to carry out dissemination or advertising programs of the veterinary medicine and biological materials, active substances and compounds in his/her respective capital or province by notifying the Municipal/Provincial Department of Agriculture, Forestry and Fisheries for cooperation.

### **SECTION 3**

#### **THE COMPLETION OF VOCATIONAL EDUCATION**

#### **Article 8**

The supplier-distributor or wholesaler-retailer of veterinary medicines and biological materials, active substances, and compounds shall hold a certificate of completion of vocational education as a prerequisite in order to apply for a permit to supply-distribute or to wholesale-retail.

The supplier-distributor of veterinary medicine and biological materials, active substances, and compounds must submit an application for vocational education in order to be eligible to conduct his/her operations to the General Directorate of Animal Health and Production

The wholesaler-retailer of veterinary medicines and biological materials, active substances, and compounds shall submit an application for vocational education in order to be eligible to conduct his/her operation to the Office of Animal Health and Production, of his/ her respective Municipal/Provincial Department of Agriculture, Forestry and Fisheries,.

The Office of Animal Health and Production, of the Municipal/Provincial Department of Agriculture, Forestry and Fisheries, shall submit a request to the General Directorate of Animal Health and Animal Production to collaborate in carrying out vocational education and issuing certificates of completion of vocational education.

## **Article 9**

General Directorate of Animal Health and Production and the Office of Animal Health and Production, of the Municipal/Provincial Department of Agriculture, Forestry and Fisheries, shall have the duty to organize vocational education and to provide services to deliver vocational education on trading veterinary medicine and biological materials, active ingredients, and compounds in its respective jurisdiction.

### **SECTION 4**

#### **RECOGNITION OF TECHNICAL STAFF**

## **Article 10**

Technical staff on duty at an establishment that imports, exports, manufactures, concocts, repackages veterinary medicines and biological materials, active substances, and compounds shall meet the appropriate qualifications in order to be recognized by the General Directorate of Animal Health and Production as follows:

1. Holding a certificate of veterinary medicine or any other certificate equivalent to a bachelor's degree or higher, recognized by the Ministry of Agriculture, Forestry and Fisheries.
2. Holding a certificate of completion of vocational education issued by the General Directorate of Animal Health and Production.

In case of termination or change of technical staff, an establishment that imports, exports, manufactures, concocts, repackages veterinary medicines and biological materials, active substances, and compounds shall report to the General Directorate of Animal Health and Production in order to request for recognition of new technical staff on duty at an establishment.

### **SECTION 5**

#### **OVERALL RULES AND OBLIGATIONS OF PERMIT HOLDER**

## **Article 11**

A natural person or legal entity holding a permit or certificate for operations related to veterinary medicines, biological materials, active substances, and compounds shall fulfill the obligations as follows:

- Display all permits or certificates for relevant operations in his/her establishment or place of business.
- Report to or notify competent entities in charge of animal health and production in his/her respective area about accidents or negative effects of the veterinary medicines and biological materials, active substances, and compounds.
- Declare the types and volumes of veterinary medicines and biological materials, active substances, and compounds in business, trade, manufacturing or mixing, and record in its logbook of all its relevant operations.
- Maintain hygienic conditions in and around his/ her place of production and business.
- Exercise regular training on safety rules for all relevant operations, and equip all staff on duty with safety protection equipment.

- Identify and apply technical standards for use and maintenance of tools used with veterinary medicines and biological materials, active ingredients, and compounds; and safety protection equipment.
- Regularly implement health check-ups and health care programs for staff directly handling veterinary medicines and biological products, active substances, and compounds.
- In case of non-compliance with the standard requirements, the specified technical standards, or having risks affecting animal, human and environmental health the natural person or legal entity holding a permit or certificate shall recall the veterinary medicines and biological materials, active substances, and compounds to prevent the potential hazards, and bear all associated costs.
- Fulfill other obligations as provided for in the provisions and procedures of the Law on Animal Health and Production, and other regulations in force.

### **Article 12**

A company with operations relating to importation, exportation, manufacturing, mixing, repackaging, stockpiling or supplying-distribution of veterinary medicines and biological materials, active substances, and compounds in the Kingdom of Cambodia is required to display at its establishments the relevant permits and certificates, and maintain registration certificate of the veterinary medicines and biological materials, active substances, and compounds.

The wholesaler-retailer of veterinary medicines and biological materials, active substances, and compounds in a capital/province shall put on display in his/ her showroom the permit and relevant certificates, and shall maintain the registration certificates of the veterinary medicines and biological products, active substances and compound, indicating their registration numbers.

## **SECTION 6 LOGBOOK**

### **Article 13**

Establishments with operations relating to veterinary medicines and biological materials, active substances, and compounds shall keep a logbook to record all operations in accordance with the guidelines on the deployment and implementation of logbook for all operations in relation to veterinary medicines and animal feed. by Ministry of Agriculture, Forestry and Fisheries as determined by General Directorate of Animal Health and Production.

## **CHAPTER 3**

### **OBLIGATION TO PAY PUBLICSERVICE FEES**

### **Article 14**

A natural person or legal entity requesting for vocational education, recognition of technical staff on duty at an enterprise, and publication and advertisement of veterinary medicines and biological materials, active substances, and compounds shall be required to pay public service fees to the National Budget in accordance with the Joint Prakas by the Minister of Economy and Finance and Minister of Agriculture, Forestry and Fisheries on the Provision of Public Services.

**CHAPTER 4**  
**FINAL PROVISIONS**

**Article 15**

All provisions that contradict this Prakas shall be considered null and void.

**Article 16**

Secretary General, Inspector General, Director General of Animal Health and Production, Director of Agricultural Legal Affairs Department, Heads of all entities under Ministry of Agriculture, Forestry and Fisheries, and all provincial Directors of Departments of Agriculture, Forestry and Fisheries shall be responsible for enforcing this Prakas in accordance with their respective duties from the date it is signed hereunder.

Done in Phnom Penh, 02 October 2020

**Minister,**  
**Ministry of Agriculture, Forestry and Fisheries**

**Recipients:**

**Veng Sakhon**

- Office of the Council of Ministers
- All relevant ministries and agencies
- Cabinet of Samdech Techo Prime Minister
- Cabinet of Deputies Prime Minister
- Capital / provincial administrations
- As in article 16
- Royal gazette
- File and archive

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