



Kingdom of Cambodia
Nation Religion King
.....

Royal Kram No.
Dated: June 17, 1996

Royal Kram
On
Management of the Pharmaceuticals
We,

Preahbath Samdech Preah Norodom Sihanouk Varaman

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Preah Chau Krong Kampuchea Thipdey

- Having seen the Constitution of the Kingdom of Cambodia;
- Having seen Royal Kret dated September 24, 1993 on the appointment of the First Prime Minister and the Second Prime Minister of the Royal Government of Cambodia
- Having seen Royal Kret dated November 1, 1993 on the appointment of the Royal Government of Cambodia;
- Having seen Royal Kram No. SN02/94 dated July 20, 1994 on the organizing and functioning of the Council of Ministers;
- Having seen Royal Kret No. SN-RKT-1094-83 dated October 24, 1994 on the modification of the compositions of the Royal Government of Cambodia;
- Having seen Royal Kret No. SN-RKT-1094-90 dated October 31, 1994 on the modification of the compositions of the Royal Government of Cambodia;
- Having seen Royal Kram No. SN-RKT-0196-06 dated January 24, 1996 on the creation of the Ministry of Health;
- Upon the proposition of the two Prime Ministers and the Minister of Health;

Promulgate

The law on the Management of Pharmaceuticals adopted by the National Assembly of the Kingdom of Cambodia on May 9, 1996, during the 6th plenary session of the 1st legislature, with the following texts:

CHAPTER I

GENERAL PROVISIONS

Article 1:

The objective of this law is to govern all pharmaceuticals in the Kingdom of Cambodia.

Article 2:

A pharmaceutical is one or many kinds of substances which are primarily from chemicals, bio-products, microbes, plants combined in order to:

- use for prevention or treatment of human or animal diseases,
- use for medical or pharmaceutical researches or diagnosis,
- change or support the functioning of the organs,

Article 3:

Shall be also considered as pharmaceuticals:

- 1- serum or vaccines,
- 2- blood or blood products,
- 3- traditional medicines,
- 4- products that are composed of poisonous substances, which are stipulated in the Sub-Decree,

Article 4:

Only pharmacist(s) who has the following qualification as stated below may have rights to manufacture pharmaceuticals, import and export of pharmaceuticals and conduct a pharmaceutical business:

- Cambodian (Khmer) nationality,
- Hold a pharmaceutical Diploma accredited by the Ministry of Health,
- Have never been convicted of any criminal offence,
- Have good health to carry out the job,

With regard to the manufacture of traditional medicines, import and export of pharmaceuticals and conduct of business of traditional medicines, shall be determined by Sub-decree.

CHAPTER II MANAGEMENT OF POISONOUS SUBSTANCES IN HEALTH SECTOR

Article 5:

Poisonous substances refer to those pharmaceuticals or substances or compounds of substances or plants that may cause danger to health or lead to the addiction of humans or animals.

These poisonous substances shall be determined by Sub-decree.

Article 6:

The formalities and conditions for the production, import, export and trade of poisonous substances shall be determined by Sub-decree.

**CHAPTER III
MANUFACTURING, TRADE, IMPORT
AND EXPORT OF PHARMACEUTICALS**

Article 7:

Technical procedures and conditions for manufacturing and functioning of the pharmaceutical manufacturing establishments shall be determined by Sub-decree.

A Prakas of the Ministry of Health shall determine of:

- the formality and conditions to apply for authorization to start up or close or change location of the pharmacies, pharmaceutical manufacturing establishments or companies for importing and exporting of pharmaceuticals,
- the formality and conditions to apply for a visa and registration of pharmaceuticals,
- the formality and technical conditions for the management, and preservation of pharmaceuticals,
- the formality and conditions for advertising of pharmaceutical products, and
- procedures for manufacturing, import and export of pharmaceutical and pharmaceutical business.

The determination of the number of pharmacies for each commune/Sangkat shall be decided by the Ministry of Health based on the number of citizens of each respective commune/Sangkat.

Article 8:

1- Shall request for authorization from the Ministry of Health for:

- the opening, closing or changing of location of pharmacies, pharmaceutical import-export companies and pharmaceutical manufacturing establishments,
- the businesses of importing, exporting of pharmaceuticals,
- the importation, exportation and storage of pharmaceuticals and raw materials for manufacturing pharmaceuticals,
- the advertisement of pharmaceuticals.

2- The production, import, export and business of pharmaceuticals for the veterinary shall be determined by a joint Prakas (joint proclamation) of the Ministry of Health and the Ministry of Agriculture, Fishery and Forestry.

3-In each pharmacy, there must be the presence of a pharmacist. In case there is the absence of the pharmacist, there must be a replacement-person with appropriate qualification which determined by the Ministry of Health.

CHAPTER IV SUPERVISORY AUTHORITY

Article 9:

The instruction and control relating to pharmaceutical activities shall be under the competence of the Ministry of Health.

The instruction and control of all types of veterinary medicines shall be under the competence of the Ministry of Agriculture, Fishery and Forestry.

CHAPTER V PENALTIES

Article 10:

Any person who committed any activities as stated below shall be fined from 1,000,000 (one million) Riels to 10,000,000 (ten million) Riels and suspend manufacturing, import, export and pharmaceutical businesses for a period of one (1) month to three (3) months, or either one of the above two punishments, however this punishment does not consider yet other offenses,

1- advertise pharmaceuticals without authorization from the Ministry of Health;

2- violate the procedure and conditions of manufacturing, import, export and pharmaceutical business;

3- the opening, closing or changing of location of pharmacies, pharmaceutical import-export companies and pharmaceutical manufacturing establishments without authorization of the Ministry of Health;

4- produced or imported or exported or stored of pharmaceuticals or raw materials for producing medicines without authorization of the Ministry of Health;

5- sold of pharmaceutical without the visas or registration or sold of pharmaceuticals that are prohibited by the Ministry of Health;

In case of recidivism, the fine shall be double and suspended manufacturing or import, export or business of pharmaceutical or be subjected to either one of the two punishment.

Pharmaceutical, raw materials, equipment and other materials that are relating to the offenses, as stated in point 4 and 5 shall be confiscated as State's property or destroyed.

The Ministry of Health has rights to immediately suspend for temporary of the unauthorized advertisement of pharmaceutical, manufacturing, import-export and business of pharmaceutical and shall file a complaint against them to the courts.

Article 11:

Shall be fined from 1,000,000 (one Million) Riels to 5,000,000 (five million) Riels or imprisoned from six (6) days to one (1) month or punishments of both for any person who obstructed the inspection of competent agents as stated in the Article 9 above;

Article 12:

Shall be fined from 20,000,000 (twenty million) Riels to 50,000,000 (fifty million) Riels or imprisoned from five (5) years to ten (10) years or punishments of both for any person who deliberately engaged in producing, importing, exporting or trading of pharmaceutical containing addictive substances without authorization, counterfeit drugs, pharmaceutical of non-quality or expiry date that affected to the health or lives of the consumers.

Article 13:

Shall also be punished with the same terms as set forth in the Articles 10, 11 and 12 for civil servant who accomplices or abuse his/her duties when s/he implement Articles 10, 11 and 12.

CHAPTER VI TRANSITIONAL PROVISIONS

Article 14:

From the date that this law is entering into effect until the year 2005, the Ministry of Health has the rights to issue a Prakas (proclamations) authorizing those retired health officials who have capacity to open pharmacies in the communes/Sangkats that is inadequate pharmacies as specifying in Articles 4 and 7 of this law.

CHAPTER VII FINAL PROVISIONS

Article 15:

All provisions contrary to this law shall be null and void.

Phnom Penh, May 9, 1996
The acting President of the National Assembly,
Loy Sim Chheang