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LAW ON THE MANAGEMENT OF PHARMACEUTICALS

This law was adopted by the National Assembly on May 9, 1996
during its 6th Session of its first legislature.

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 on or many kinds of substances which are primarily made from chemicals, bio-products, microbes, plants combined in order to:

- use in the prevention or treatment of human or animal diseases,
- use in the medical or pharmaceutical research or diagnosis,
- change or support the functioning of the organs.

ARTICLE 3:
Shall be also considered as pharmaceuticals:

1. scrum and vaccines,
2. blood or blood products,
3. traditional medicines,
4. products which are composed of poisonous substances which are included in a list to be determined by Sub-Decree.

ARTICLE 4:
Pharmacists who may have the right to engage in the production, import, export and trade of pharmaceuticals are those who have fulfilled the following qualifications:

- have Khmer nationality,
- have a Pharmaceutical Diploma recognized by the Ministry of Health,
- have never been found guilty for any criminal offence,
- have sufficiently good health to accomplish the job.

Production, import, export and trading of the traditional medicines shall be determined by Sub-Decree.

CHAPTER II: MANAGEMENT OF POISONOUS SUBSTANCES FOR HEALTH

ARTICLE 5:

Poisonous substances refer to those pharmaceutical 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: PRODUCTION, TRADE, IMPORT AND EXPORT OF PHARMACEUTICALS

ARTICLE 7:
Technical procedures and conditions for the production and the functioning of the pharmaceutical manufacturing establishments shall be determined by Sub-Decree.

A Prakas (Proclamation) of the Ministry of Health shall determine:

- the formalities and conditions to apply for authorization to open, close or change of location of pharmacies, pharmaceutical manufacturing establishments, or companies involved in importing and exporting pharmaceuticals,
- the formalities and conditions for application for a visa on the pharmaceutical log-book,
- the formalities and technical conditions for the management and preservation of pharmaceuticals,
- the formalities and conditions for advertising of pharmaceuticals, and
- procedures for the production, import, export and trade of pharmaceuticals.

The determination of the number of pharmacies for each commune/sangkat shall be determined by the Ministry of Health based on the number of citizens in each respective commune or sangkat.

ARTICLE 8:
1. Authorization from the Ministry of Health shall be required for:
    - the opening, closing or changing of location of pharmacies, companies involved in importing and exporting pharmaceuticals or pharmaceutical manufacturing establishments.
    - businesses involved in importing and exporting pharmaceuticals,
    - importation, exportation and storage of pharmaceuticals and raw materials for the production of pharmaceuticals,
    - advertisement of pharmaceuticals.

2. The production, import, export and trade of pharmaceuticals for veterinarians 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 the event of an absence of the pharmacist, there must be a replacement who shall possess appropriate qualifications as determined by the Ministry of Heath.

CHAPTER IV: AUTHORITY TO SUPERVISE

ARTICLE 9:
Oversight and control of pharmaceutical activities shall be the competence of the Ministry of Health.

Oversight and control of pharmaceutical for veterinarians shall be the competence of the Ministry of Agriculture, Fishery and Forestry.

CHAPTER V: PENALTIES

ARTICLE 10:
Shall be penalized to a fine from 1,000,000 (one million) to 10,000,000 (ten million) riels and to a suspension of (activity) production or import, export or trade of pharmaceuticals for a period from one (1) month to three (3) months, or to either one of the above two punishment terms, exclusive of punishment for other offenses, for any person who:

1. advertised pharmaceuticals without authorization from the Ministry of Health.

2. who violated procedures and conditions for the production, import, export and trade of pharmaceuticals.

3. opened or changed locations of pharmacies, conducted businesses involved in importing and exporting pharmaceuticals or manufactured pharmaceuticals without proper authorization from the Ministry of Health.

4. produced, imported, exported or stored pharmaceuticals or pharmaceutical raw materials without proper authorization from the Ministry of Health.

5. sold pharmaceuticals without approval or keeping a log-book or sold those pharmaceuticals which are prohibited by the Ministry of Health.

   For repeated offenses, the offender shall be penalized twice the fine and be suspended from activities of production, import, export or may be subjected to either one of the two punishments.

Pharmaceuticals, raw materials, equipment and other materials which are conected to the offenses as stated in the sub-para. (4) and (5) shall be confiscated as State's property or be destroyed.

The Ministry of Health shall have the rights to immediately suspend temporarily the offending advertisement of pharmaceuticals, production, import-export and business of pharmaceuticals and shall prepare a judicial case to be forwarded to the court.

ARTICLE 11:
Shall be subjected to a fine of from 1,000,000 (One Million) to 5,000,000 (Five Million) riels or to punishment to imprisonment from six (6) days to one (1) month or, to both of these two punishments, for any person who obstructed the competent agents as stated in article 9 above, to prevent them from accomplishing their inspection duties.

ARTICLE 12:
Shall be subjected to a fine from 20,000,000 (twenty million) to 50,000,000 (fifty million) riels or to punishment to imprisonment from (5) years to ten (10) years or, to both of the punishments, for any person who deliberately engaged in producing, importing, exporting or trading of pharmaceutical containing addictive substances without authorization, counterfeit pharmaceuticals, pharmaceuticals of damaged quality or expired pharmaceuticals which affected the health or lives of consumers.

ARTICLE 13:
Shall also be punished with the same terms as set forth in articles 10, 11 and 12, for any civil servant who acts as accomplice or who commits an abuse of his/her own duties during the implementation of articles 10, 11 and 12.

CHAPTER VI : TRANSITIONAL PROVISION

ARTICLE 14:
From the date this law enters into effect until the year 2005, the Ministry of Health shall have the right to issue Prakas (Proclamations) authorizing those retired health officials who have capacity to open pharmacies in the Khums (communes) or sankats (districts) which do not yet have proper pharmacies as specified in articles 4 and 7 of this law.

CHAPTER VII: FINAL PROVISION

ARTICLE 15:
All provisions contrary to this law shall be hereby repeated.

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during its 6th Session of its first legislature.

The Acting President of the National Assembly