



KRAM

We,

NS/RPhM/1207/037

His Majesty Prince Norodom Sihanouk,
The King of the Kingdom of Cambodia,

having seen the Constitution of the Kingdom of Cambodia;

- having seen Kret No. NS/RKT/0704/124 dated July 15, 2004 on the appointment of the Royal Government of Cambodia;
- having seen Kram No. 02/NS/94 dated July 20, 1994 on the organization and functioning of the Council of Ministers;
- having seen Kram No. 0196-06 dated January 24, 1996 on the establishment of the Ministry of Health;
- having seen Kram No. ChS/RKM/0696/02 dated June 17, 1996 on the management of Pharmaceutical.
- Upon the proposition of the Prime Minister Hun Sen and the Minister of Health;

Promulgate;

The law on the amendment of law on management of Pharmaceuticals, adopted by the National Assembly of the Kingdom of Cambodia on November 8, 2007, during the 7th session of the third legislature, and entirely approved by the Senate of its form and legal concepts on December 6, 2007 during the 4th senate plenary meeting of the second legislature, the text of which appears as below:

Royal Kingdom of Cambodia

Nation Religion King

ព្រះរាជាណាចក្រកម្ពុជា

Law

on the

Amendment of Law on Management of Pharmaceutical

Article 1:

Article 2, 4, 8, 9, 10, 12 and 13 of the Law on Management of Pharmaceutical which have been promulgated by Kram No. ChS/RKM/0696/02 dated on June 17, 1996 shall be amended as below:

Article 2- New:

1. A pharmaceutical is one or many kinds of substances which are primarily from chemicals, bio-products, microbes, plants combined in order to use in the prevention or treatment of human or animal diseases, or to use in the medical or pharmaceutical research or diagnosis, or change or support the functioning of the organs.
2. A counterfeit pharmaceutical is a medication which may contain inactive ingredients or inappropriate quantities of active ingredients, or may not contain enough active ingredients as mentioned on the label, or has the packaging, design, identification similar to or the same as the original products or may be produced or packaged without licensing from the Ministry of Health.

Article 4-New:

Both genders of Cambodian nationality or foreigner may have right to run a pharmaceutical manufacturing establishment, or importing/exporting establishment and trade of pharmaceutical in Cambodia.

All activities pertaining to technical production, storage, distribution and wholesale shall be under control and responsibility of technical pharmacist who 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,
- hold a membership of Cambodian pharmacist council.

As regards to the production, import, export and trading of the traditional medicines, shall be determined by Sub-Decree.

All the details shall be determined by Prakas of the Ministry of Health.

Article 8-New:

- 1- Authorization from the Ministry of Health is required for:
 - the opening, closing or relocation of pharmaceutical manufacturing establishment, pharmaceutical import companies, pharmaceutical import and distribution companies, pharmaceutical export companies, pharmaceutical wholesale companies, pharmacies and pharmaceutical depots,
 - the importation of addictive drug, drug affected nervous systems, raw materials and ingredients containing addictive substance which have been specified in the addictive drug control law.
 - the importation of pharmaceutical, raw materials, packaging materials, and pharmaceutical manufacturing machine,
 - the advertisement of pharmaceutical,
- 2- The importation, distribution, sale display of pharmaceutical and all kinds of cosmetic products in Cambodia shall have registered number from the Cambodia's Ministry of Health.
- 3- The productions, import, export and trade of pharmaceutical for the veterinary, shall be determined by a joint Prakas of the Ministry of Health and the Ministry of Agriculture, Fishery and Forestry.
- 4- In each pharmaceutical manufacturing establishment, import-export company, pharmaceutical wholesale company, pharmacies, there must be the presence of a pharmacist. In case when in the absence of the pharmacist, there must be a substitution that shall have appropriate qualification, in accordance with what determined by the Ministry of Health.

Article 9-New:

- 1- The instruction and control on what are concerning with the activities of pharmaceutical, shall be the competence of the Ministry of Health, who shall appoint Health agents to have formal and informal monitoring at the pharmaceutical manufacturing establishment, pharmaceutical import companies, pharmaceutical import and distribution companies, pharmaceutical export companies, pharmaceutical wholesale companies, pharmacies and pharmaceutical depots, cosmetics sale companies, and transportation means.

Should any necessary arises, the Ministry of Health bears right to ask for intervention from concerned Ministry or agents.

- 2- Health Agents shall have the qualification as Police Justice Officer. Procedures in obtaining the qualification as the Police Justice Officer of Health agents shall be

determined by joint Prakas of the Ministry of Health and the Ministry of Justice. Roles and responsibilities of health agents who have obtained the qualification as Police Justice Officer shall be determined by Prakas of the Ministry of Justice.

- 3- For what are concerning to the instruction and control on the kinds of pharmaceutical for the veterinary, shall be the competence of the Ministry of Agriculture, Fishery and Forestry.

Article 10-New:

- 1- Shall be penalized to a fine from 1,000,000 (one million) to 5,000,000 (five million) riels for any person who:
 - Advertised pharmaceutical and cosmetic products through radio, television, magazine, newspaper, brochure, and workshop or by other means without authorization from the Ministry of Health.
 - who violated the procedure and conditions for the management and preservation of pharmaceutical.
 - Opened, closed, or changed locations of the pharmacies, pharmaceutical depots, and establishments of cosmetic sales without authorization from the Ministry of Health.
- 2- Shall be penalized to a fine from 5,000,000 (five million) to 10,000,000 (ten million) riels for any person who:
 - Opened, closed, or relocated of pharmaceutical wholesale establishment, import and distribution pharmaceutical companies, import-export of pharmaceutical companies without authorization from the Ministry of Health.
 - violated the procedure and conditions of trading, import-export of pharmaceutical.
 - imported or exported or produced of pharmaceutical without authorization from the Ministry of Health.
 - Distributed, sale display or sold of pharmaceutical products and cosmetics without visa or registration from the Ministry of Health.
 - sold pharmaceutical of damaged quality and expired date.
- 3- Shall be penalized to a fine from 10,000,000 (ten million) to 2,000,000 (twenty million) riels for any person who:
 - Opened, closed, or changed locations of pharmaceutical manufacturing establishment without authorization from the Ministry of Health.
 - violated the technical procedure and conditions of pharmaceutical production.
 - imported the raw materials, half-finished products, packaging materials, pharmaceutical manufacturing machine without authorization from the Ministry of Health.
 - Produced pharmaceutical of which its quality does not meet the standard for proposing a visa.
 - Stored the raw materials, packaging materials, pharmaceutical manufacturing machine, pharmaceutical products outside of their business or manufacturing establishment without authorization from the Ministry of Health.

- 4- Should any of the offenses above causes serious damage to public health, human or animal's life, the Ministry of Health shall suspend immediately the activities of production, import, export and trade of pharmaceutical, and prepare a file to be forwarded to the courts to impose the punishment in accordance to the law.
- 5- All of the offences which is penalized to a fine from 1,000,000 (one million) to 10,000,000 (ten million) riels, the Ministry of Health bears right to impose interim penalty.
In case the offender does not pay interim penalty, the Ministry of Health shall prepare the file to be forwarded to the courts.

Article 11-New:

Shall be subjected to penalize to imprison from 1 to 6 months or penalize to a fine from 2,000,000 (two million) to 10,000,000 (ten million) Riels or both of the punishment for any person who obstructed the implementation of this law.

Article 12-New:

- 1- Shall be the subject to penalize to imprison from 5 to 10 years and penalize to a fine from 20,000,000 (two million) to 10,000,000 (ten million) Riels, for any person who:
 - Deliberately engaged in producing, importing, storing of addictive drug, or any drug affected nervous systems, raw materials and ingredients containing addictive substance which have been specified in the Addictive Drug control Law or Prakas of the Ministry without any authorization.
 - Distributing, sale display or sold of any addictive drug or drug affected nervous system which are not medically beneficial or prohibited by the Ministry of Health.
 - Producing, importing, distributing, sale display or sale of counterfeit pharmaceutical.
- 2- Should any of the offenses above causes serious damage to public health, human or animal's life, the Ministry of Health shall immediately suspend activities of producing, importing, exporting and trading and prepare a file to be forwarded to the court in order to impose the punishment in accordance to the law.

Article 13-New:

Shall be penalized in administrative penalty for civil servant who is complicity or who commits an abuse of his/her own duties during the implementation of the articles 10-new, 11-new, and 12-new. In serious case, shall prepare the file to be forwarded to the court.

Royal Palace, Phnom Penh, December 28, 2007

Signature: **Norodom Sihanouk**

Having submitted to the King for signature,
Prime Minister
Signature :**Hun Sen**

Having submitted for Samdech Hun Sen
Prime Minister of the Kingdom of Cambodia
Minister for Health

Signature: **NuthSokhom**

No. 17 Ch.L.
Phnom Penh, January 3, 2008
Vice Secretary General of the Royal Government
KhutChinken