# (National Coat-of-Arms) KINGDOM OF CAMBODIA Nation Religion King

Royal Government of Cambodia No. 23 S.E.

#### **SUBDECREE**

On

### Production, Import - Export and Trade of Traditional Medicines for the Health Sector

#### The Royal Government

#### Pursuant to:

- The Constitution of the Kingdom of Cambodia;
- Royal Decree, dated September 24, 1993, on the Appointment of the First Prime Minister and the Second Prime Minister;
- Royal Decree, dated November 1, 1993, on the Appointment of the Royal Government of Cambodia;
- Royal *Kram* No. 02/NS/94, dated July 20, 1994, on the Organization and Functioning of the Council of Ministers;
- Royal Decree No. CS/RD/1094/83, dated October 24, 1994, on the Adjustment to the Components of the Royal Government of the Kingdom of Cambodia;
- Royal *Kram* No. NS/RK/0196/03, dated January 24, 1996, on the Establishment of the Ministry of Health;
- Royal *Kram* No. CS/RK/0196/02, dated June 17, 1996, on Pharmaceutical Management;
- Royal Decree No. CS/RD/0897/147, dated August 7, 1997, on the Adjustment to the Components of the Royal Government of the Kingdom of Cambodia;
- Subdecree No. 67 S.E., dated October 22, 1997, on the Organization and Functioning of the Ministry of Health;
- Request from the Minister of Health;
- Approval from the Council of Ministers during a session held on March 12, 1998;

Hereby decides:

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Chapter 1
General Provisions

- **Article 1:** This subdecree aims to control the production, import and export and trading of traditional medicines in the Kingdom of Cambodia.
- **Article 2:** Traditional medicines are nutrients used to prevent or cure human and animal diseases, including:
  - Plant or animal or mineral that is unprocessed or processed in accordance with an ordinary method;
  - A product that is mixed or produced by a single or several types of nutrients with uncertain chemical structure and is originated from plant, animal or mineral.
- **Article 3:** Production, import and export and trade of traditional medicines can be conducted provided that there is authorization from the Ministry of Health.

#### Chapter 2

#### Right to Trade in Traditional Medicine

- **Article 4:** A pharmacist being entitled to produce, import and export traditional medicines shall have the following qualifications:
  - Having Khmer nationality;
  - Holding a pharmacist diploma acknowledged by the Ministry of Health;
  - Having never been convicted of any criminal offense;
  - Being sufficiently healthy to perform the work.
- **Article 5:** A practitioner of traditional medicines who is entitled to trade in traditional medicines shall have the following qualifications:
  - Having Khmer nationality;
  - Having knowledge of mixing traditional medicines of plants, animals or minerals as well as examining and curing ordinary diseases according to traditional medical practice with a certificate of practitioner of traditional medicines acknowledged by the Ministry of Health;
  - Having never been convicted of any criminal offense;

- Being sufficiently healthy to perform the work.

- **Article 6:** The Ministry of Health may authorize foreign pharmacists and practitioners of traditional medicines to practice traditional medicine profession in the Kingdom of Cambodia should it see the necessity in society.
- **Article 7:** Traditional medicines that can be produced and imported exported shall have permits or registrations approved by the Ministry of Health.
- **Article 8:** The Ministry of Health determines, by a *prakas*, the following:
  - The formalities and conditions for requesting to open, or to relocate or transfer funds of the production establishment, import export establishment and the building where the traditional medicines are sold;
  - The formalities and conditions for requesting permits for and registration of traditional medicines;
  - The formalities and technical conditions for managing and taking care of traditional medicines;
  - The formalities and conditions for the promotion of traditional medicines;
  - The formalities for the production, import export and trading of traditional medicines.

#### **Article 9:** There shall be an authorization from the Ministry of Health for:

- The opening, relocation and change of responsible person of a production establishment, import export establishment and the building where the traditional medicines are sold;
- The production, import export and storage of traditional medicines and raw materials for the production of traditional medicines;
- Promotion of traditional medicines.

### Chapter 3 Production of Traditional Medicines

- **Article 10:** Production of traditional medicine in the industrial form shall be carried out within a pharmaceutical establishment with proper organization in accordance with the technical conditions defined by a *prakas* from the Ministry of Health.
- **Article 11:** Production of traditional medicines shall be under the inspection and responsibility of one or more pharmacists according to the scale of production.

# Chapter 4 Import – Export of Traditional Medicines

- **Article 12:** The import export of traditional medicines shall be carried out via a pharmaceutical establishment with proper organization in accordance with the requirements of the Ministry of Health.
- **Article 13:** Traditional medicines requested for importation shall be selected in the list of traditional medicines already registered with the Ministry of Health.

Imported traditional medicines shall have the demonstrative form and be of good quality in proper accordance with the sample medicines being deposited.

# Chapter 5 Trading in Traditional Medicines

- **Article 14:** Display for sale, and sale and storage of traditional medicines shall be carried out within the building selling traditional medicines with proper organization in accordance with requirements of the Ministry of Health.
- **Article 15:** The building selling traditional medicines shall have the presence of a practitioner of traditional medicines to control the activities in his/her building.

In case there is no responsible practitioner of traditional medicines, there shall be another substitute traditional medicine practitioner with the authorization of the Ministry of Health.

#### **Article 16:** It is prohibited to:

- 1- Sell counterfeit and poor quality traditional medicines;
- 2- Sell traditional medicines mixed with modern medicines;
- 3- Sell dangerous traditional medicines on the list prohibited by the Ministry of Health;
- 4- Conduct other businesses in the building selling traditional medicines.

### **Chapter 6 Final Provisions**

**Article 17:** Any provisions contrary to the said subdecree shall be abrogated.

**Article 18:** The Co-Ministers of the Council of Ministers; the Minister of Health and relevant ministries/institutions shall undertake to implement this subdecree from the date of signature onwards.

	Phnom Penh Capital, April 28, 1998	
	First Prime	Second Prime
To have informed: His Excellency the First Prime Minister Samdech the Second Prime Minister	<b>Minister</b> (Signature and stamp)	<b>Minister</b> (Signature and stamp)
Minister of Health	ING HUOT	HUN SEN

Dr. CHHEA THAING

(Signature)

#### <u>CC</u>:

- Cabinet of the King
- General Secretariat of the National Assembly
- Cabinet of His Excellency the First Prime Minister
- Cabinet of Samdech the Second Prime Minister
- As stipulated in Article 18
- Records Archives