



**Kingdom of Cambodia**  
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**Ministry of Health**

Ref.: 275អ.ប.ស/ឱ.អ.ប.ស

Phnom Penh, October 12, 1998

**Minister of Health**

**To**

- Presidents of Pharmaceutical Establishments
- Presidents of Medicine Import and Export Establishments

**Subject:** Visa and registration of traditional medicines produced locally and imported abroad

**References:-** Sub-decree No. 44 អនក្រឹត្យ, dated August 10, 1994, on the Visa-Registration of Medicines

-Prakas No. 364 ស្របច្បាប់, dated October 26, 1994, on the Implementation of Medicine Visa-Registration

With regard to the above subject and references, I would like to inform you that all kinds of produced or imported traditional medicines cannot be sold in the Kingdom of Cambodia unless the medicines have been visaed or registered and approved by the Ministry of Health.

Applications for medicine visa-registration are on sale at the Department of Medicine, Food, Medical Equipment and Cosmetics, located at house number 4, Ung Pokun street (former street 109), Mittapheap quarter, 7 Makara district, Phnom Penh.

Telephone: 855 023 880247

Fax: 855 023 880247

E-mail: [moh-cpn@forum.org.kh](mailto:moh-cpn@forum.org.kh)

Department of Medicine, Food, Medical Equipment and Cosmetics shall receive the applications from the date of this signature.

Please accept the assurances of my high esteem.

((Signed and stamped))

**Dr. CHHEA THANG**

<b>Procedures for Visaing Traditional Medicines</b>
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All types of locally-manufactured traditional medicines cannot be sold in the country unless the medicines have been visaed and approved by the Ministry of Health.

All documents for visa shall be written in Khmer, English, or French.

Applications for visa are:

1. Administrative Documents:

- 1.1 Proposal (sample is available)
- 1.2 Summary of medicine characteristic (sample is available)
- 1.3 Permit to open establishments for production of traditional medicines or buildings for sale of traditional medicines

2. Medicine Documents:

2.1 Components shall be clearly described.

- In case other components are used, there shall be a clear description of their names, quantity, and functions.

2.2 Description of each component:

- 2.2.1 Names of plants, animals, and rock (original names, Latin names, and family names) (attached herewith photos or paintings)
- 2.2.2 Sources: nature, planting, raising (indicate insecticide if it is used in planting)
- 2.2.3 Methods and time of harvest
- 2.2.4 Processing methodology
- 2.2.5 How to preserve
- 2.2.6 Indicate insecticide or fungicide (if it is used in preservation)
- 2.2.7 Indicate functions and physical forms of plants, animals, or rock used in medicine production  
Please indicate names, chemical structures, and physical-chemical forms of active substances and other substances within each component (if any).

2.3 Production Methods:

The outline of production lines shall describe each stage from start to finish.

2.4 Quality Control Methods of Finished Products:

- Physical-chemical analysis
- Analysis of poisonous metal – arsenic, lead, mercury
- Analysis of microbe

2.5 Stability Study of Finished Products:

- Manufactured and expiry date

3. Clinical Documents:

Past documentation about experimental treatment of the ill with the indication of:

- Methodology of experimental treatment
- Positive and negative results
- Conclusion

4. Sample Medicines: 10 units
5. Visa Fees: USD50

<b>Procedures for Registration of Traditional Medicines</b>
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All types of overseas-imported traditional medicines cannot be sold in the country unless the medicines have been registered and approved by the Ministry of Health. All documents for registration shall be written in Khmer, English, or French.

I. Traditional medicines made of plants, animals, or rock which have been or not have been processed in a simple method:

Applications for registration are:

1. Administrative Documents:

- 1.1 Proposal (sample is available)
- 1.2 Export permit of an original country or exporting country
- 1.3 Certificate of sanitary plants issued by a competent institution of the exporting country

2. Medicine Documents:

There shall be a clear description of:

- 2.1 Names of plants, animals, and rock (original names, Latin names, and family names) (attached herewith photos or paintings)
- 2.2 Sources: nature, planting, raising (indicating insecticide if it is used in planting)
- 2.3 Methods and time of harvest
- 2.4 Indicate functions and physical forms of plants, animals, or rock used in medicine production
- 2.5 Processing methodology
- 2.6 How to preserve
- 2.7 Indicate insecticide or fungicide (if it is used in preservation)
- 2.8 Harvest and expiration date

3. Sample Medicines: 10 units according to exporting shapes

4. Registration Fees: USD100

II. All kinds of traditional medicines made of one or several types of substances and traditional medicines made of various componential substances:

1. Administrative Documents:

- 1.1 Proposal (sample is available)
- 1.2 Sale permit (original) issued by a competent institution of a production country  
In case the permit is a copy, it shall be certified by a competent authority.
- 1.3 Certificate of good technical condition implementation of production (original) issued by a competent institution of a production country  
In case the certificate is a copy, it shall be certified by a competent authority.
- 1.4 Summary of medicine characteristic (sample is available)

2. Medicine Documents:

- 2.1 Components shall be clearly described.
  - In case other components are used, there shall be a clear description of their names, quantity, and functions.
- 2.2 Description of each component:
  - 2.2.1 Names of plants, animals, and rock (original names, Latin names, and family names) (attached herewith photos or paintings)
  - 2.2.2 Sources: nature, planting, raising (indicating insecticide if it is used in planting)
  - 2.2.3 Methods and time of harvest
  - 2.2.4 Processing methodology
  - 2.2.5 How to preserve
  - 2.2.6 Indicate insecticide or fungicide (if it is used in preservation)
  - 2.2.7 Indicate functions and physical forms of plants, animals, or rock used in medicine production. Please indicate names, chemical structures, and physical-chemical forms of active substances and other substances within each component (if any).
- 2.3 Production Methods:

The outline of production lines shall describe each stage from start to finish.
- 2.4 Quality Control Methods of Finished Products:
  - Physical-chemical analysis
  - Analysis of the identity of active substances and componential substances
  - Analysis of poisonous metal – arsenic, lead, mercury
  - Analysis of microbe
- 2.5 Stability Study of Finished Products:
  - 2.5.1 Study methodology
    - Duration
    - Level of temperature and wetness during the study
    - Number of dozens (three dozens) indicating manufactured and expiry date
    - Parameters set in the study
  - 2.5.2 Result table
  - 2.5.3 Conclusion
3. Clinical Documents:

Past documentation about experimental treatment of the ill with the indication of:

  - Methodology of experimental treatment
  - Positive and negative results
  - Conclusion
4. Sample Medicines: 10 units
5. Registration Fees: USD100

Phnom Penh, October 12, 1998

Minister  
(Signed and stamped)

Dr. CHHEA THANG

