Unofficial Translation
by JICA HRD

KINGDOM OF CAMBODIA
Nation Religion King

Ministry of Health
No. 364 សនឱ

PRAKAS
ON
THE IMPLEMENTATION OF VISAS FOR AND REGISTRATION OF MEDICINES

The Minister of Health

Pursuant to:

The Constitution of the Kingdom of Cambodia;

Royal Decree of His Majesty Preah Bat Samdech Norodom Sihanouk Varman, King of the Kingdom of Cambodia, dated November 1, 1993, on the Establishment of the Royal Government of Cambodia;

Subdecree No. 44 S.E., dated August 10, 1994, of the Royal Government of Cambodia on Visas for and Registration of Medicines;

Hereby decides

Article 1: The creation of visas for and registration of medicines aims to control the production, import, export and trading of medicines in the Kingdom of Cambodia in order to ensure the quality of medicines and the production rights of manufacturers.

Article 2: Visas for and registration of medicines, which are of equal importance, are authorizations for trading on the market (*Autorisation de mise sur le marché*) for medicines for which visas have been acquired and registration of medicines from the Ministry of Health.

Article 3: Visas for and registration of medicines are valid for five years from the date of issuance of the visas for and registration of medicines. Three months before expiration, the person concerned shall complete papers to apply for the renewal of the visas for and registration of medicines to the Ministry of Health in accordance with the conditions defined in article 6 or 7.

Article 4: Medicines shall be appropriately packaged according to the defined conditions:

- On the outer box or bottle shall appear the name of the medicine, its international name, level – excipients – quality of treatment (indication), contraindication (*contre indication*), dosage and usage … label (vignette), stating value of AMM, expiry date … etc.;
- There shall be a description of the medicines inside (*Notice ou prospectus*);
- On the strip or bottle or tube of the medicine, there shall be additional specifications of the lot number and expiry date;

- For a medicine comprising a poisonous substance, there shall be a special label and note: "sale with prescription".

Article 5: Poisonous substance (*substance véneneuse*) refers to a substance that can cause serious or secondary danger or addiction or damage to the nervous system.

Article 6: Medicines manufactured locally can be displayed for sale only if there are approval visas from the Ministry of Health. To apply for medicine visas, one shall complete the following documents:
- Application for medicine visa (sample available)
- Summary characteristics of the medicine (*Resumé des caractéristiques du produit)*
- Pharmaceutical document (*Document pharmaceulique*)
- Summary pharmacology document (*Document pharmacologique en resumé*)
- Summary toxicology document (*Document toxicologique en resumé*)
- Summary clinic document (*Document clinique*)
- Ten samples of medicine (*Echantillon medical*)
- Receipt of visa fees at 100 US dollars for each set of documents.

Article 7: Medicines imported from abroad can be displayed for sale only if there is approval of registration from the Ministry of Health. To apply for registration of medicine, the following documents shall be completed:
- Application for registration of medicine (sample available)
- Certificate of the manufacturing capacity and ability of the manufacturing country in accordance with the conditions determined by the World Health Organization (*Certificat B.P.F.*)
- Certificate of authorization for trading on the market of the manufacturing country (*Certificat A.M.M.*)
- Certificate of authorization for trading on the market of other countries (if any)
- Summary characteristics of the medicine (*Resumé des caractéristiques du produit)*
- Pharmaceutical document (*Document pharmaceulique*)
- Summary pharmacology document (*Document pharmacologique en resumé*)
- Summary toxicology document (*Document toxicologique en resumé*)
- Summary clinic document (*Document clinique*)
- Ten samples of medicine
- Receipt of registration fee payment (100 US dollars) for each set of documents.

Article 8: Medicine made of one or more active ingredients, which is officinal (*Officinales*) stated in the pharmacopeia (*Pharmacopée*) of France, England, Japan, America, Europe may be exempted from completion of documents of the medicine's pharmacology, and clinic toxicology.

Article 9: The request for registration of traditional medicines imported from abroad shall be subject to completion of the following documents:
- Application for registration of medicine, sample available
- Certificate of authorization for trading on the market of the manufacturing country (*Certificat A.M.M.*)
- Summary characteristics of the medicine (*Resumé des caractéristiques du produit*)
- Pharmaceutical document
- Clinic document
- Ten samples of medicine
- Receipt of registration fees (100 US dollars) for each set of documents.

Article 10: A request for visas for traditional medicines produced locally shall be subject to completion of the following documents:
- Application for medicine visas (sample available)
- Summary characteristics of the medicine (*Resumé des caractéristiques du produit*)
- Pharmaceutical document
- Clinic document
- Ten medicine samples
- Receipt of visa fees (50 US dollars) for each set of documents.

Article 11: Technical documents shall be written in Khmer, French or English.

Article 12: If necessary, the person concerned shall provide additional documents or reagents required for analysis as per the request of the national laboratory.

Article 13: The medicines for medical and pharmaceutical research study (not for sale) can be exempted from the request for registration of medicine.

Article 14: Medicines of different dosage (*Dosage*), galenical forms (*Forme galenique*) or different manufacturers shall have different visas, registrations of medicines.

Article 15: In case there is any modification, whether [great or] small, to the excipients or presentation, the person concerned shall request prior authorization from the Ministry of Health before s/he can put [the medicine] on sale, by paying a fee of 50 dollars per set of documents for such modification.

Article 16: The Ministry of Health has the right to reject the application for visas for or registrations of medicines for those medicines which:

- The Ministry of Health has found to be of little or no importance for preventing or treating any disease, or to be potentially harmful to the health of users;
- The manufacturing country has issued a ban for use in the manufacturing country;
- Have inaccurate or fraudulent technical documents (*Inexact ou frauduleux*).

In case of rejection, the fees for visas for and registrations of medicines will not be reimbursed to the person concerned.

Article 17: The Ministry of Health is entitled to postpone or revoke visas for and registrations of medicines for those medicines which:
- Are harmful to the health of users;
- Are subject to quality-related accusation from the local or overseas competent ministry;
- Are banned by the manufacturing country for use;
- Have inaccurate or fraudulent sample documents.

Article 18: Medicines which are displayed on sale without visas for and registrations of medicines or improperly as per the exhibits shall be classified into ones secretly produced or illegally imported, and the offender shall be punished according to the laws in force.

Article 19: The Inspectorate-General of the Ministry of Health and the Department of Medicines and Supply shall give instructions, monitor and inspect the implementation of this *prakas* as per their respective duties.

Article 20: This *prakas* shall take legal effect from the date of signature onwards.

Phnom Penh Capital, October 26, 1994
Minister of Health
(Signature and stamp)

Dr. CHHEA THAING

CC:
- Cabinet of the National Assembly
- Cabinet of the First Prime Minister
- Cabinet of the Second Prime Minister
- Ministry of Justice
- Ministry of Economy and Finance
- Ministry of Commerce
- Ministry of Information
- Cabinet of the Ministry of Health
- Inspectorate–General of the Ministry of Health
- Capital–Provincial–City Department of Health
- Department of Medicines and Supply
- Pharmaceutical Factory
- Pharmaceutical Import–Export Company
- Pharmacies, sub-pharmacies, traditional medicine dispensaries
- Records