Unofficial Translation
by JICA HRD

KINGDOM OF CAMBODIA
Nation Religion King

(Logo)
Ministry of Health
No. 0014 អបស/ឱអបស

Phnom Penh Capital, January 13, 2009

PRAKAS
On
the Modification to *Prakas* No. 155 អបស/ឱអបស
Dated March 21, 2000 of the Ministry of Health
On the Formalities and Conditions for Opening or Closure or Relocation of a Pharmaceutical Selling Establishment

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The Minister of Health

Pursuant to

- The Constitution of the Kingdom of Cambodia;
- Royal Decree No. NS/RD/0908/1055, dated September 25, 2008, on the Appointment of the Royal Government of the Kingdom of Cambodia;
- Royal *Kram* NS/RK/0196/06, dated January 24, 1996, promulgating the Law on the Establishment of the Ministry of Health;
- Royal *Kram* CS/RK/0696/02, dated June 17, 1996, promulgating the Law on Pharmaceutical Management ;
- Royal *Kram* NS/RK/1207/037, dated December 28, 2007, promulgating the Law on the Amendment to the Law on Pharmaceutical Management;
- Subdecree No. 67 S.E., dated October 22, 1997, on the Organization and Functioning of the Ministry of Health;
- *Prakas* No. 155 អបស/ឱអបស, dated March 21, 2000, of the Ministry of Health on the Formalities and Conditions for Requesting to Open, Close or Relocate a Pharmaceutical Selling Establishment;
- Necessity of the Ministry of Health;

Hereby decides:

Article 1: The substance of *Prakas* No. 155 អបស/ឱអបស, dated March 21, 2000 of the Ministry of Health has been modified as follows:

Article 2: Pharmaceutical selling establishments are classified into three types:
- Pharmacy managed by pharmacists;
- Sub-pharmacy "A" managed by secondary pharmacists;
- Sub-pharmacy "B" managed by retired health officials with their technical specification as the state's nurse or midwife.

Article 3: The opening, closure, relocation and change of the responsible person of the pharmacy and sub-pharmacy are possible only with authorization from the Ministry of Health.

Article 4: A pharmacy or sub-pharmacy with authorization to open in accordance with the substance of *Prakas* No. 115 សនបឱ, dated February 25, 1991, *Prakas* No. 937 សនបឱ, dated September 6, 1996

and *Prakas* No. 155 អប សរ/ជអប សរ, dated March 21, 2000, still has the right to operate a business.
In case of requesting relocation or change of the responsible person, the above pharmacy or sub-pharmacy shall comply with new conditions of the *prakas* herewith.

Article 5: The number of pharmacies shall be determined according to the number of people in the commune/quarter in proportion to the number of at least 2,000 people per pharmacy.
The Ministry of Health will declare the division of the number of pharmacies in each commune/quarter on an annual basis.

Article 6: The location of pharmacies and sub-pharmacies shall be determined as per the following conditions:
- A pharmacy can be located anywhere in the Kingdom of Cambodia;
- Sub-pharmacy "A" can be located in any commune/quarter where the number of pharmacies is not sufficient as per the proportion determined in Article 5;
- Sub-pharmacy "B" can be located in any commune/quarter where there are fewer sub-pharmacies "A" than the proportion determined in Article 5.

Article 7: Pharmacists of both sexes are entitled to apply to open a pharmacy or sub-pharmacy only if they have the following attributes:
- Have Khmer nationality;
- Hold a degree accredited by the Ministry of Health;
- Are not convicted of any felony listed in the criminal record;
- Are sufficiently healthy to perform work.

Article 8: The necessary application papers for the opening of a pharmacy or sub-pharmacy include:
A. Application for opening a pharmacy or sub-pharmacy with a 1,000-riel stamp, "sample available";
B. Pharmacist or Secondary Pharmacist Diploma accredited by the Ministry of Health;
C. Biographical data of the person concerned, "sample available";
D. Health certificate issued by the Ministry of Health or Provincial-City Health Department;
E. Criminal records with their validity not exceeding three months;
F. Drawing of location with approval remarks from the commune/quarter;
G. Five 4 × 6 cm photos of the person concerned;

The person concerned shall complete the above necessary documents in two copies and submit them to the Provincial-City Department of Health;

Article 9: In case the number of applicants for pharmacy or sub-pharmacy opening are above the number of determined locations, the Ministry of Health will give priority to the person concerned who submits his/her application first and has sufficient necessary papers as set forth in Article 8.

Article 10: The ministry will provide answers about the request for opening, relocation and change of the responsible person of the pharmacy and sub-pharmacy to the person concerned within no more than 30 days following the date of receipt of sufficient and correct necessary papers.

Article 11: A pharmacist or secondary pharmacist shall be entitled to submit an application to open only one pharmacy or sub-pharmacy and may not work in other medical professions.

Article 12: Following receipt of the decision from the Ministry of Health to open a pharmacy or sub-pharmacy, the person concerned shall open its doors to serve the public within three months at the latest. After the above period, should the center not be in operation, the decision shall be automatically considered null and void at the discretion of the Provincial-City Department of Health. If an appropriate reason is provided, the above specified period may be extended for only another three months as per the request of the person concerned.

Article 13: The Ministry of Health has the right to revoke the decision on the opening, relocation or change of responsible person of a pharmacy and sub-pharmacy if it is found that:

A. The address of the location is contrary to the decision on the opening or relocation;
B. The necessary papers are forged;
C. Or the person concerned does not arrange his/her pharmacy or sub-pharmacy in accordance with the determined conditions;
D. Or the person concerned has been convicted of any criminal offense; or
E. The pharmacy or sub-pharmacy is not in operation within three or six months as stipulated in Article 12.

Article 14: Relocation of pharmacy or sub-pharmacy from one place to another is possible only if that relocation is in the same district, the responsible person is not changed and [it] has been in operation to serve the public for more than six months.

Article 15: Necessary application papers for relocation include:

A. Application for relocation with a 1,000-riel stamp, "sample available";
B. Decision on the opening of pharmacy-sub-pharmacy;

C. Drawing of new location with approval remarks from the commune/quarter;
D. Three 4 × 6 cm photos of the person concerned;
D. Three 4 × 6 cm photos of the person concerned;

The person concerned shall complete the above necessary application papers in two copies and submit them to the Ministry of Health, Department of Medicines, Foodstuffs, Medical Equipment and Cosmetic Products, through the Provincial-City Health Department.

Article 16: The change of responsible person of pharmacy or sub-pharmacy from one person to another shall be authorized only if the new responsible person has sufficient qualifications in compliance with the conditions set forth in Article 2 without relocation and it has been in operation to serve the public for more than six months with written approval between the replaced person and the substitute.

Article 17: The necessary application papers for the change of responsible person shall include:

A. Application with 1,000-riels stamp;
B. Agreement between the replaced person and the substitute;
C. Decision on the opening of the pharmacy or sub-pharmacy;
D. Pharmacist or Secondary Pharmacist Degree accredited by the Ministry of Health of the replaced person;
E. Biographical data of the substitute;
F. Health certificate of the substitute issued by the Ministry of Health or Provincial-City Health Department;
G. Criminal record of the substitute with a validity not exceeding three months;
H. Five 4 × 6 cm photos of the substitute concerned;

The person concerned shall complete the above necessary application papers in two copies and submit them to the Ministry of Health, Department of Medicines, Foodstuffs, Medical Equipment and Cosmetic Products, through the Provincial-City Health Department.

Article 18: Sub-pharmacy "A" managed by a secondary pharmacist can submit the application for a change of pharmacy type if that secondary pharmacist becomes a senior pharmacist without any relocation or change of the responsible person and has been in operation to serve the public for more than six months.

Article 19: The necessary application papers for change of pharmacy type include:

A. An application for change of pharmacy with a 1,000-riel stamp;
B. A decision on the opening of sub-pharmacy, "original copy";
C. A pharmacist diploma accredited by the Ministry of Health;

The person concerned shall complete the above necessary application papers in two copies and submit them to the Ministry of Health, Department of Medicines, Foodstuffs, Medical Equipment and Cosmetic Products, through the Provincial-City Health Department.

Article 20: Pharmacy or sub-pharmacy organization:

A pharmacy or sub-pharmacy shall be separated from a residential place, and both its interior and exterior shall be clean and properly organized as per the following stipulations:

A. There shall be an operation surface area of at least 20m² for pharmacies and 16m² for sub-pharmacies;
B. There shall be a pharmacy or sub-pharmacy signboard with a white background and blue letters, and with a minimum size of 0.6 × 3.8 meters;
C. Advertisements in all forms on pharmacy or sub-pharmacy signboards shall be prohibited;
D. There shall be sufficient clean white glass cabinets for displaying medicines, medical equipment...;
E. There shall be a counter for a cashier and medicine courier;
F. There shall be special medicine cabinet(s) for storing addictive drugs and psychotropics;
G. There shall be a refrigerator to store medicines that are required to be held at a limited temperature;
H. There shall be a set of scales for weighing;
I. The warehouse for storing medicines, if any, shall comply with the technical pharmaceutical specifications;
J. The medicine mixing room, if any, shall be prepared in compliance with the technical pharmaceutical specifications;
K. There shall be tables for pharmacists to work at.

Article 21: A pharmacy or sub-pharmacy can display the following types of goods for sale:

A. Medicines for the health sector;
B. Personal hygiene products, cosmetic products, quality dietary products for preventing or curing diseases;
C. Medical and dental materials and equipment;
D. Reagent materials for medical and pharmaceutical laboratories.

Article 22: A pharmacy and sub-pharmacy shall have the right to:

A. Wholesale and retail sale of the products as stipulated in Article 21 to state's and private health service units, sub-pharmacies and customers for personal use;
B. Administer some medicines according to prescriptions and pharmaceutical rules;
C. Order the purchase of pharmaceutical products only from pharmaceutical establishments or pharmaceutical import-export establishments.

Article 23: A sub-pharmacy shall have the following rights:

A. Retail sale of products as stipulated in Article 21 as per the register of the Ministry of Health to customers for personal disease treatment;
B. Order the purchase of pharmaceutical products only from pharmacies.

Article 24: Business formalities

A. The responsible person (pharmacists, secondary pharmacist or retired health official) shall be present at the pharmacy or sub-pharmacy to manage activities in his/her pharmaceutical selling establishment;
B. The seller shall wear a white medical shirt and wear a name tag;
C. The seller shall be able to read, write and explain prescriptions and describe pharmaceutical slips;
D. The pharmaceutical names (addictive drugs and psychotropics) provided to customers shall be registered in the prescription records;
E. At the time of providing medicines according to prescription, [s/he] shall clearly check the name and signature of the medical practitioner, names of medicines, and the amount, dosage and usage. In case of finding that the prescription is not correct or beyond the [allowed] dose or is contrary to the medical rules, [s/he] shall request the customer to ask the medical doctor to reissue the prescription and shall not take the risk of selling [the medicines];
F. The prescription by which medicines have already been provided shall be stamped by the pharmacy or sub-pharmacy and have the date of selling medicines, in particular additive drugs and psychotropics.

Article 25: It is prohibited to:

A. Display medicines from illegal sources for sale;
B. Display medicines with no label (*vignette*) for sale;
C. Display for sale the medicines banned by the Ministry of Health;
D. Display expired medicines for sale;
E. Display products not determined in Article 21 for sale;
F. Operate other businesses in the pharmaceutical selling establishment.

Article 26: Should the responsible person (pharmacist or secondary pharmacist or retired health official) be absent for less than one year, that pharmacy or sub-pharmacy shall have a substitute responsible person with qualifications such as:

- Senior pharmacist or pharmacy student of year 5 for pharmacy;
- Secondary pharmacist for sub-pharmacy "A";

- Retired health official with the proper technical level for a sub-pharmacy "B";
- The above substitution shall be effective only with authorization from the Ministry of Health.

Article 27: The period for substitution shall not exceed one year, but in case proper grounds are provided or the responsible person is dead, the said substitution period can be extended for a further year. As for sub-pharmacy "B", in case of the death of the responsible person, the operation shall become invalid.

Article 28: The substance of *Prakas* No. 155 អប្ស/ឱអប្ស, dated March 21, 2000, of the Ministry of Health and any provisions contrary to the *prakas* herewith shall be abrogated.

Article 29: The General Department of Technical Health, the General Inspectorate of the Ministry of Health, the Department of Medicines, Foodstuffs, Medical Equipment and Cosmetic Products and the Department of Health of Phnom Penh Capital and provinces-cities shall be obliged to effectively implement the *prakas* herewith according to their respective duties.

Article 30: The *prakas* herewith shall take effect from the date of signature onwards.

(Signature and stamp)

MAM BUNHENG

CC:
- General Secretariat of the National Assembly
- Office of the Council of Ministers
  Ministry of Justice
- Ministry of National Assembly-Senate Relations and Inspection
- Phnom Penh City and Provincial-City Halls
  "for information and cooperation"
- Ministry of Information "for dissemination"
- General Inspectorate of the Ministry of Health
- General Department of Technical Health
- Secretariat of Provincial-City Committees and Commissions
  for the Elimination of Counterfeit Medicines and Illegal Health Services
- Department of Medicines, Foodstuffs, Medical Equipment and Cosmetic Products
- Phnom Penh Capital and Provincial-City Departments of Health
- Relevant pharmaceutical selling establishments
  "for information"
- Records
- Archives *(Initials)*