



## Kingdom of Cambodia

Nation Religion King

Ministry of Health  
No. 0211 RBS.ORBS

Phnom Penh, 30 March 2011

### Prakas

on

### **Roles and Responsibilities of Control Agent for Pharmaceuticals, Food, Medical equipment, and Cosmetics and Private Medical, Paramedical and Medical Aid Services**

#### **Minster of Health**

- Having seen the Constitution of Cambodia;
- Having seen Royal Decree No. NS/RKT/0908/1055 dated 25 Sep 2008 on the Appointment of the Royal Government of Cambodia;
- Having seen Royal Kram No. NS/RKM/0196/06 dated 24 January 1996 promulgating the Law on the Establishment of Ministry of Health;
- Having seen Royal Kram No. NS/RKM/0696/02 dated 17 June 1996 promulgating the Law on the Management of Pharmaceuticals;
- Having seen Royal Kram No. NS/RKM/0600/09 dated 21 June 2000 promulgating the Law on on the Management of Quality and Safety of Products and Services;
- Having seen Royal Kram No. NS/RKM/1100/10 dated 03 November 2000 promulgating the Law on the Management of Private Medical, Paramedical, and Medical Aide Profession
- Having seen Royal Kram No. NS/RKM/1207/037 dated 28 December 2007 promulgating the Law on on the Amendment of the Law on the Management of Pharmaceuticals;
- Having seen Sub-decree No. 67 ANKr.BK dated 22 October 1997 on the Organization and Functioning of Ministry of Health;

- Having seen Sub-decree No. 94 ANKr.BK dated 11 September 2002 on Procedures and Conditions Authorizing Foreign Medic, Paramedic, and Medical Aide to Practice Private Profession in the Kingdom of Cambodia;
- Having seen Sub-decree No. 133 ANKr.BK dated 28 November 2005 on the Marketing of Products for Infant and Young Child Feeding;
- Having seen Sub-decree No. 122 ANKr.BK dated 28 August 2008 on the Management of Cosmetics;
- Having seen Joint Ministerial Prakas No. 061 SRNB date 16 August 2007 on the Implementation of the Sub-decree on the Marketing of Products for Infant and Young Child Feeding;
- Having seen Joint Ministerial Prakas No. 868 ORTh.BrK dated 22 October 2010 on the Implementation and Coordination of Food Safety System from Farm to Table;
- Having seen Prakas No. 0053 RBS/ORBS dated 06 February 2009 of the Ministry of Health on Conditions in the Marketing of Medicines and Preventive and Curative Products; and
- In pursuant to the necessary requirements of the Ministry of Health;

## **Hereby Decides**

### **Article 1**

Control Agent for Pharmaceuticals, Food, Medical Equipment, Cosmetics, and Private Medical, Paramedical and Medical Aids Services is obliged to inspect all activities related to production, imports and exports, commercial marketing of modern medicines, traditional medicines, supplementary medicines or products, medical equipment, reagent, cosmetics, hygiene and food safety, products for infant and young child feeding, and medical, paramedical, and medical aide services, to ensure the protection of public health and the protection of lives for all citizens in the Kingdom of Cambodia.

### **Article 2**

Roles and Responsibilities of Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics

#### **A. Scope:**

Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics shall be divided into:

1. Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics at central level with the inspection role nationwide.
2. Control Agents for Pharmaceuticals, Medical Equipment and Cosmetics at municipal-provincial levels with the inspection role within their respective territories.

#### **B. Roles and Responsibilities :**

Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics is obliged to inspect and monitor the implementation of Law on the Management of Pharmaceuticals and all regulations related to production, exports and imports, commercial marketing of modern medicines, traditional medicines, supplementary medicines and products, medical equipment, reagent, cosmetics at:

- Modern pharmaceutical manufacturing and packaging establishments, traditional medicine manufacturing establishment and manufacturing establishment for medical equipment;
- Imports and exports establishments for traditional medicines, medical equipment, and cosmetics at both municipal and provincial branches;
- Pharmacies, Depots;
- Traditional medicines stores and cosmetic stores;

- Representative offices of foreign medicine manufacturing factories; and
- Beauty care centers in municipalities and provinces;

**C. Procedures of Inspection:**

In the course of inspection, control agent for Pharmaceuticals, Medical Equipment and Cosmetics shall:

- Possess statement of mission issued by director of respective agency, and
- Wear Control Agent's uniform.

**Article 3**

**Division of responsibilities of Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics at central level:**

**A. Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics at central level shall have the following responsibilities:**

1. Inspects and monitors the implementation of the Law on the Management of Pharmaceuticals and other regulations of MOH at manufacturers of pharmaceuticals, traditional medicines, psychotropic and addictive drugs, medical equipment and cosmetics, in the Kingdom of Cambodia every one year by using evaluation checklists. Urgent inspection shall be conducted only in compulsory case with permission from MOH;
2. Inspects and monitors the implementation of the Law on the Management of Pharmaceuticals and other regulations of MOH at imports and exports establishments of medicines and cosmetics, imports and exports branch offices of medicines and cosmetics, pharmacies, depots, traditional medicines stores, cosmetic stores and centers by using evaluation checklist. Urgent inspection shall be conducted only in compulsory case with permission from MOH;
3. Monitors distribution of pharmaceuticals and other medical products at markets. Sale or distribution of medicines and these concerned products shall be suspended in case of suspicion. Reports on these suspicious medicines or sample products shall be made for the examination of their quality, and then submitted to the ministry for their decision;
4. Inspects and monitors the implementation of the decentralization and the deconcentration of the ministry by municipal-provincial health departments every trimester by using evaluation checklist;

5. Participates in investigation and elimination of counterfeit medicines within the Kingdom of Cambodia;
6. Inspects and monitors the commercial marketing of modern medicines, traditional medicines, supplementary products, all kinds of traditional wine, medical and dental equipment, reagents for medical laboratories, pharmacy, dentistry and cosmetics, and preventive or curative medicines, and beauty care centers on televisions, radios, newspapers and magazines, journals of medicine, pharmacy, dentistry and by any other means, which does not comply with the permission or without permission from MOH;
7. Monitors and evaluates the procedures in relation to opening, closing, relocation of pharmacies, substitution of responsible pharmacists, and renews the licenses for pharmaceuticals manufacturers, pharmaceuticals exports and imports establishments, cosmetic exports and imports establishments, pharmaceuticals imports and exports branch offices, cosmetics imports and exports branch offices, representative offices of foreign medicine manufacturers, cosmetic stores, and beauty care centers by using evaluation checklist;
8. When undertaking the inspection at business locations as embodied in article 2, Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics is entitled to to temporarily seize counterfeit medicines, medicines which are banned by MOH, medicines without license, expiry medical equipment, reagents, cosmetics, raw materials, compositional materials, and other suspicious exhibits. The Control Agent shall report the cases, through the Secretariat, to Chief of Inter-ministerial Committee for Elimination of Counterfeit Drugs and Illegal Health Services for Poverty Reduction for decision; and
9. Examines all complaints of counterfeit medicines, banned medicines, medicines without license, expiry medical equipment, reagents, cosmetics, raw materials, compositional materials and other suspicious exhibits, and reports the cases to MOH for decision.

**B. Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics at municipal-provincial level:**

1. Monitors the implementation of the Law on Pharmaceuticals and other regulations of MOH that pharmacies and depots, traditional medicine stores, and beauty care centers in the capital city and all provinces shall follow. The inspection shall be carried out at one of the aforementioned places at least every trimester by using evaluation checklist;

2. When undertaking the inspection of medical vans, pharmacies, depots, traditional medicine stores, cosmetic stores, and beauty care centers, the Control Agent for Pharmaceuticals, Medical Equipment and Cosmetics is entitled to temporarily seize counterfeit medicines, medicines which are banned by MOH, medicines without license, expiry medicines, suspicious medicines, and undeclared cosmetics. The Control Agent shall report the cases, through the Secretariat, to Chief of Municipal-Provincial Commission for Elimination of Counterfeit Drugs and Illegal Health Services for decision;
3. Monitors the commercial marketing of modern medicines, traditional medicines, supplementary medicines or products, all kind of traditional wine, medical and dental equipment, reagent equipment for medical laboratories, pharmacy, dentistry and cosmetics, preventive and curative medicines, and beauty care centers on televisions, radios, newspapers and magazines, journals of medicine, pharmacy and dentistry and by any other means, which does not comply with the permission or without permission from MOH;
4. Monitors and evaluates the procedures of opening, closing, relocation, substitution of person in charge, and renews licenses of pharmacies, depots, traditional medicine stores, as stipulated in Prakas 0014 ABS/MABS dated 13 January 2009 on the procedures and conditions for opening, closing or relocation of pharmacy. However, for exports and imports branch offices of pharmaceuticals and cosmetics as well as for provincial beauty care centers, inspection shall be undertaken through provincial health departments by using the checklist. The result of the evaluation shall be submitted to Department of Pharmaceuticals, Food, Medical Equipment, Cosmetics, MOH;
5. Monitors and takes appropriate action to eliminate unauthorized pharmaceuticals;
6. Shall send reports of activities of Control Agent for Pharmaceuticals, Food, Medical Equipment, and Cosmetics to Department of Pharmaceuticals, Food, Medical Equipment, Cosmetics, MOH every trimester.

#### **Article 4**

#### **Roles and Responsibilities of Control Agent for Food**

##### **A. Scope:**

1. Control Agent for Hygiene and Food Safety at central level has an inspection scope on hygiene and food safety nationwide; and

2. Control Agent for Hygiene and Food Safety at municipal-provincial level has an inspection scope on hygiene and food safety within their respective territories.

**B. Roles and Responsibilities:**

Control Agent for Hygiene and Food Safety are responsible for advising, inspecting, and monitoring the implementation of regulations related to hygiene, food safety, content, logo and imitative cases of products for infant and young child feeding or other similar products at:

- Restaurants, Food Stalls, Markets, Public Places, Food Product Stores and Distribution Chains;
- Pharmacies, depots, or health care or education systems, both direct and indirect, for mothers and pregnant women, including nursery and day care centers.

**C. Procedures of Inspection:**

In every inspection, the Control agent for Hygiene and Food Safety shall:

- Possess mission statement issued by respective agency; and
- Wear Control Agent's uniform.

**Article 5**

**Division of Responsibilities of Control Agent for Food Safety and Hygiene at central, and municipal-provincial levels:**

**A. Responsibilities of Control Agent for Food Safety and Hygiene at central level:**

1. Inspects and monitors the implementation of regulations related to food hygiene and safety, content, logo and imitative case of products for infant and young child feeding or other similar products every trimester by using evaluation checklist. Urgent inspection shall occur only in compulsory case with permission from MOH;
2. Monitors the distribution flow of food products and, in case of suspicion, report the case to MOH for decision;
3. Inspects and monitors the implementation of the decentralization and the deconcentration of the ministry at municipal-provincial health departments four times per year by using evaluation checklist;
4. Collaborate with concerned ministries in monitoring hygiene at various food manufacturers;

5. Participate with concerned ministries to control illegal food, products for infant and young child feeding or other similar products nationwide;
6. Monitor the commercial marketing of products for infant and young child feeding and other similar products on radios, television, newspapers and magazines, journals of medicine, pharmacy, dentistry, workshops and by other means to sell products for infant and young child feeding at markets, public places or pharmacies, depots or other health care systems;
7. Stops all the marketing of products for infant and young child feeding and other similar products which are contrary to the MOH's permission or Sub Decree 133 ANKr, BK;
8. Examines all complaints from consumers of products for infant and young child feeding and other similar products nationwide;
9. When undertaking inspection at business locations as embodied in article 4, Control Agent for Food Safety and Hygiene is entitled to temporarily seize counterfeit products for infant and young child feeding and other similar products, which are suspicious of bad quality or expiry, and contain food additives prohibited by MOH or relevant ministries. The Control Agent shall report the case to MOH.
10. In the case restaurants and food stalls do not comply with hygiene and safety guidelines issued by MOH or cause health or life-threatening impacts on citizens, the Control Agent shall report to MOH and concerned ministries for decision.

**B. Responsibilities of Control Agent for Food Safety and Hygiene at municipal-provincial level:**

1. Inspects and monitors the implementation of regulations of MoH related to hygiene and food safety at municipal-provincial level every trimester by using evaluation checklist;
2. Monitor locations requesting the issuance of certificate of food hygiene. However, for food product manufacturers at municipal-provincial level, the inspection shall be done by municipal-provincial health departments by using the evaluation checklist, following which the report shall be sent to Department of Pharmaceuticals, Food, Medical Equipment and Cosmetics, MoH;
3. When undertaking inspection at places as embodied in article 4, the Control Agent for Food Safety and Hygiene at municipal-provincial level shall collaborate closely with those involved to achieve a smooth inspection process;



4. Monitor the commercial marketing of products for infant and young child feeding and other similar products on televisions, radios, newspapers and magazines, journals of medicine, pharmacy, dentistry, workshops and by other means, without the permission from MoH; and
5. All reports from Control Agent for Food Safety and Hygiene at municipal-provincial level shall be submitted to Department of Pharmaceuticals, Food, Medical Equipment and Cosmetics, MoH in every trimester.

## **Article 6**

### **Roles and Responsibilities of Control Agent for Private Medical, Paramedical, and Medical Aide Services:**

#### **A. Scope:**

Control Agent for private medical, paramedical and medical aid practices shall be divided into:

1. Control Agent for Private Medical, Paramedical, and Medical Aide Services at central level with inspection role nationwide; and
2. Control Agent for Private Medical, Paramedical, and Medical Aide Services at municipal-provincial level with inspection role within their respective authority.

#### **B. Roles and Responsibilities:**

Control Agent for Private Medical, Paramedical, and Medical Aide Services are responsible for advising, inspecting and monitoring of the implementation of laws, Sub Decrees, Prakas, Circulars and other announcements on professional practices of private medical, paramedical, and medical aide services at:

- Obstetrics and Gynecology Cabinets,
- Nursing Cabinets,
- Physical Therapy Cabinets,
- Medical Cabinets,
- Dental Cabinets,
- Ophthalmology Cabinets,
- ENT Cabinets,

- Dermatology Cabinets,
- Psychiatric Cabinets,
- Private hospitals,
- Polyclinics,
- Clinics,
- Pediatrics Clinics,
- Obstetrics and Gynecology Clinics,
- Medical Laboratories,
- Dental Clinics,
- Cosmetic Centres,
- Ophthalmology Clinics,
- ENT Clinics,
- Dermatology Clinics,
- Psychiatric Clinics,
- Referral offices for transferring patients, and
- Private medical, paramedical, and medical aide services in necessary cases,

**C. Procedures of Inspection:**

For every inspection, the Control Agent for private medical, paramedical, and medical aide services shall:

- Possess statement of mission issued by director of respective agent; and
- Wear the Control Agent's uniforms.

**Article 7**

**Division of responsibilities of Control Agent for private medical, paramedical, and medical aide services at central and municipal-provincial levels:**

**A. Control Agent for Private Medical, Paramedical, and Medical Aide Services at central level has the following responsibilities:**

1. Inspects and monitors the implementation of laws, Sub Decrees, Prakas, Circulars and other announcements of MoH on private medical, paramedical and medical aide services

and beauty care centers at private hospitals, polyclinics, clinics, Pediatrics Clinics, Obstetrics and gynecology Clinics, Medical Laboratories, Dental Clinics, cosmetic centers, Ophthalmology Clinics, ENT clinics, Dermatology Clinics, Psychiatric Clinics, referral offices for transferring patients, and other private medical, paramedical and medical aide services as necessary in all provinces and capital;

2. Monitors and evaluates the procedures of opening or closing, transforming, relocation, or substitution of the professionals of private hospitals, polyclinics, clinics, Pediatrics Clinics, Obstetrics and gynecology Clinics, Medical Laboratories, Dental Clinics, Cosmetic Centres, Ophthalmology Clinics, ENT clinics, Dermatology Clinics, Psychiatric Clinics and referral offices for transferring patients, and other private medical, paramedical and medical aide services as necessary in all provinces and capital;
3. Enforces the implementation of laws, Prakas, Sub Decrees, Circulars and other announcements of MOH on private medical, paramedical and medical aid practices and other private medical aids as necessary among managers and Control Agent of private services in all provinces and capital;
4. Inspects and monitors the implementation of the decentralization and deconcentration of the MOH by capital and provincial health departments every trimester by using evaluation checklist;
5. Monitors all illegal health service and the violation of regulations at Obstetrics and Gynecology Cabinets, Nursing cabinets, Physical therapy cabinets, Medical Cabinets, Dental Cabinets, private hospitals, polyclinics, clinics, Pediatric clinics, Obstetrics and Gynecology clinics, medical laboratories, Dental clinics, Cosmetic Centres, Ophthalmology clinics, ENT clinics, Dermatology Clinics, Psychiatric Clinics, referral offices for transferring patients in all provinces and capital;
6. Inspects and monitors the commercial marketing of private medical, paramedical and medical aid services on radios, televisions, newspapers, magazines, brochures and by other visual means, which does not comply with the permission or without permission from MOH;
7. The Control Agent bears the right to temporarily suspend private medical, paramedical and medical aid services in the case of health or life-threatening impacts on citizens; and
8. Sends trimester and annual report of statistics of Private medical, Paramedical and Medical Aides Services submitted by all provinces and capital, to MOH.

**B. Responsibilities Control Agent for Private Medical, Paramedical and Medical Aide Services at municipal-provincial level:**

1. Monitors and evaluates the request of opening, closing, relocation, substitution of professionals in charge of polyclinics, clinics, Pediatrics Clinics, Obstetrics and Gynecology Clinics, Medical Laboratories, Dental Clinics, and ophthalmology clinics, ENT Clinics, Dermatology Clinics, Psychiatric Clinics, and submit the result of the inspection to Hospital Department of MoH;
2. Collaborates with Control Agent for Private Medical, Paramedical and Medical Aide Services at central level (Hospital Department);
3. Inspects and monitors the commercial marketing of private medical, paramedical and medical aid services on radios, televisions, newspapers and magazines, brochures and other visual means that does not comply with the permission or without permission from MOH;
4. Monitors and take appropriate action to eliminate illegal health services; and
5. Sends annual and semester reports of activities of Control Agent for Private Medical, Paramedical and Medical Aide Services to MOH (Hospital Department) regularly.

#### **Article 8**

#### **Collaboration between Control Agent for Pharmaceuticals, Medical Equipment, Cosmetics, and Control Agent for Private Health Services**

- Where a private pharmacy or depot is operated or where a pharmacy, depot, traditional medicine store, imports and exports establishment runs a nursing or treatment cabinet, the Control Agent for Pharmaceutical, Medical Equipment, and Cosmetics shall collaborate with Control Agent for Private Health Services in inspecting their operation and take legal action when appropriate.
- Both Control Agents shall jointly inspect health product and equipment stores without permission from MoH.

#### **Article 9**

Any persons who obstruct the inspection conducted by the Control Agent shall be punishable according to the existing law.

#### **Article 10**

Any provisions which are contradictory to those of this Prakas shall be abrogated.

#### **Article 11**

Cabinet of MoH, Technical Directorate of MoH, Inspectorate General of MoH, Department of Drugs, Food Safety, Medical Equipment and Cosmetics, Hospital Department, Municipal-Provincial Health Departments, Control Agent for Pharmaceuticals, Medical Equipment, Cosmetics, Control Agent for Hygiene and Food Safety, and Control Agent for Private Medical, Paramedical, and Medical Aide Services shall implement their respective responsibilities as stipulated in this Prakas in an effective manner.

#### **Article 12**

This Prakas shall be in effect from the date of the signature.

Recipients:

- As stated in Article 11
- Documentation-Archives

[Signature & Seal]

Mam Bunheng

Minister of Health