

Drug Act, B.E. 2510 (1967)

Translation

BHUMIBOL ADULYADEJ, REX.

Given on the 15th day of October B.E. 2510

Being the 22nd year of the present Reign.

His Majesty Bhumibol Adulyadej has been graciously pleased to proclaim that;

Whereas it is expedient to revise the law on the sale of drugs;

Be it, therefore, enacted by the King, by and with the advice and consent of the Constituent Assembly in the capacity of the National Assembly, as follows:

Section 1

This Act is called the "Drug Act, B.E. 2510 (1967)"

Section 2

This Act shall come into force after the expiration of sixty days from the date of its publication in the Government Gazette.

Section 3

The following shall be repealed:

- (1) the Sale of Drug Act, B.E. 2493;
- (2) the Sale of Drug Act, (No.2), B.E. 2498;
- (3) the Sale of Drug Act, (No.3), B.E. 2499;
- (4) the Sale of Drug Act, (No.4), B.E. 2500;
- (5) the Sale of Drug Act, (No.5), B.E. 2505;

Section 4

In this Act;

- (1) Substances recognized by pharmacopoeias notified by the Minister.
- (2) Substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness.
- (3) Substances which are pharma chemicals or semi-processed pharma chemicals.
- (4) Substances intended to affect the health, structure or function of the human or animal body.

Substances under (1) (2) or (4) shall not include:

- (a) Those intended for use in agriculture or industry as notified by the Minister,
- (b) Those intended for use as food for human, operating goods, medical apparatus, cosmetics or device for use in the practice of medicine and a component thereof,
- (c) Those intended for use in science laboratory for research, analysis or verification of disease which is not directly done to human body.

"Modern drug" means a drug intended for use in the practice of modern medicine or the cure of an animal disease;

"Traditional drug" means a drug intended for use in the practice of the traditional medicine or the cure of an animal disease which appears in a pharmacopoeia of traditional drug notified by the Minister, or a drug notified by the Minister as a traditional drug, or a drug of which formula has been registered as that of a traditional drug;

"Dangerous drug" means a modern or traditional drug notified by the Minister as a dangerous drug;

"Specially-controlled drug" means a modern or traditional drug notified by the Minister as a specific-controlled drug;

"External drug" means modern or traditional drug intended for use externally.

"Specific place drug" means modern or traditional drug intended for use in specific places for ears, eyes, nose, mouth, anus, and vagina or gutter urine.

"Household medicine" means a modern or traditional drug notified by the Minister as a household medicine;

"Ready-packed drug" means a modern drug manufactured in a pharmaceutical form, which is packed in a closed or sealed container or packed and which has all the label in accorded, with this Act;

"Herbal drug" means a drug derived from a plant, animal or mineral which has not yet been compounded, dispensed or denatured;

"Practice of modern medicine" means the practice of medicine by dependence on the knowledge acquired through learning on a scientific basis;

"Practice of traditional medicine" means the practice of medicine by dependence on the knowledge acquired from a textbook or through learning which is not on a scientific basis;

"Cure of animal disease" means any action performed directly on an animal body for the purpose of examination or treatment and includes the prevention of disease, elimination of disease, plastic surgery, castration or artificial insemination;

"Produce" means manufacture, dispense, prepare or denature and includes change of drug form or apportion as ready-packed drug;

"Active ingredient" means material which is an important component in the drug and has the power to treat, relief, care or prevents disease, or illness to human or animal.

"Strength of active ingredients" means

- (1) The concentration of the drugs which has a quantity of active ingredients stated as weight per weight, weight per volume or quantity of active ingredients per dosage.
- (2) The effect of healing of the drug that has been tested in laboratory in suitable way or has passed adequate controlled usage.

"Sell" includes dispense of, distribute, issue or barter, for commercial purpose, and possess for sale;

"Label" includes any picture, design or statement displayed on the container or package of sale;

"Accompanying literature" include paper or any other material that the meaning is shown through a picture, figure, sign or any text concerning the drug that is kept or included with the containers or packaging of the drug.

"Drug formula" means formulas of components regardless of form and shall included drug in a processed form ready for use for humans and animals.

"Modern medical practitioner" means a practitioner of modern medicine in the branch of medicine, dentistry, pharmacy, midwifery or nursing under the law on the control of practice of medicine;

"Traditional medical practitioner" means a practitioner of traditional medicine in the branch of medicine or pharmacy under the law on the control of the practice of medicine;

"First-class pharmacist" means a first-class practitioner of traditional medicine in the branch of modern pharmacy;

"Second-class pharmacist" means a second-class practitioner in the branch of modern pharmacy;

"First-class veterinary practitioner" means a first-class veterinary practitioner under the law on the control of the cure of animal diseases;

"Second-class veterinary practitioner" means a second-class veterinary practitioner under the law on the control the cure of animal diseases;

"Licensing authority" means:

- (1) The Secretary-General of the Food and Drug Administration or the person entrusted by him for licensing the production of a drug or the importation or order of a drug in to the Kingdom;
- (2) The Secretary-General of the Food and Drug Administration or the person entrusted by him for the sale of a drug in Changwat Phra Nakhon;
- (3) The Changwat Governor, for the sale of a drug within his territorial Jurisdiction, except Changwat Phra Nakhon;

"Committee" means the Drug Committee under this Act;

"Official" means a person appointed by the Minister to implement this Act;

"Minister" means the Minister having charge and control of execution of this Act.

Section 5

The Minister of Public Health shall have charge and control of the execution of this Act, and the power to appoint official, to issue Ministerial Regulations prescribing fees not exceeding the rates hereto attached, granting exemptions from fees and prescribing other acts for the purpose of carrying out this Act.

Such Ministerial Regulations shall come into force upon their publication in the Government Gazette

CHAPTER I Drug Board

Section 6

There shall be a Board called the "Drug Board" consisting of the Permanent Secretary of the Ministry of Public Health as Chairman, Director-General of Department of Medical Services, Director-General of Department of Communicable Disease Control, Director-General of Department of Medical Sciences, Director-General of Department of Health, Secretary-General of the Food and Drug Board, a representative from the Ministry of Defence, are representative from the Ministry of Agriculture and Cooperatives, two representatives from the Ministry of University Affairs appointed from the Office of the Council of State, Director of the Medical Registration Division of the Office of the Permanent Secretary for Public Health, as members ex officio, and not less than five but not more than nine qualified members appointed by the Minister of which at least two must be practitioner of traditional medicine.

Deputy Secretaries-General of the Food and Drug Administrative shall be member and secretary of the Board, and the Director of Drug Control Division of the office of Food and Drug Board shall be member and assistant secretary.

Section 7

A qualified member shall hold office for a term of two years.

An outgoing member may be re-appointed.

Section 8

Apart from vacation office under Section 7, a qualified member vacated his office upon:

- (1) death;

- (2) resignation;
- (3) being retired by the Minister;
- (4) being a bankrupt;
- (5) being an incompetent or quasi – incompetent person;
- (6) being imprisoned by a final judgment of the Court to a term of imprisonment, except for an offence committed through negligence or petty offence;
- (7) Suspension or revocation of his licence to practise medicine.

When a qualified member vacates his office before the expiration of his term, the Minister shall appoint another person to replace him, and such person shall remain in office for the unexpired term of office of the member he replaces.

Section 9

At a meeting of the Committee not less than one – third of the total number of its member must be present to constitute a quorum. If the Chairman is not present at the meeting, the members present shall elect one from among themselves to be presiding chairman.

A final decision of the meeting shall be by majority of votes.

Each member shall have one vote. In case of an equality of votes, the presiding chairman shall have a casting vote.

Section 10

The Committee shall have the duty to submit recommendations and opinions in the following matters:

- (1) the licensing of the production or sale of a drug, or importation or order of a drug into the Kingdom, and the registration of a drug formula;
- (2) the suspension, revocation of a licence or revocation of a drug formula registration;
- (3) the establishment of the rule, procedures and conditions concerning the production or sale of a drug. importation or order of a drug into the Kingdom, importation of a drug as sample for examination, and the inspection of the place of production or sale of a drug, importation or order into the Kingdom and of storage of a drug;
- (4) the exercise of the power by the Minister under Section 76 or Section 77;
- (5) other matters as entrusted by the Minister

Section 11

The Committee shall have the power to appoint subcommittees consider, study or analyze the matters within the authority of the Committee and Section 9 shall apply mutatis mutandis to meetings of the subcommittees.

CHAPTER II

Application for and issue of a Licence concerning Modern Drugs

Section 12

No person shall produce or sell a modern drug or import or order a modern drug in to the Kingdom, unless he has obtained a licence from the licensing authority.

The application for and grant of a licence shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 13

The provision of Section 12 shall not apply to:

- (1) The production of drugs by Ministries, public bodies and departments which have a duty to prevent or treat disease, and by the Thai Red Cross and pharmaceutical organization,
- (2) The production of drugs in accordance with the prescription of a practitioners in the vacationers medicine or practitioners in the art of healing for a particular patient or in accordance with the prescription of a veterinary for a particular animal,
- (3) The sale of herbal drugs which are not dangerous drugs, the sale of common household dregs, the sale of drugs, the sale of drugs by practitioners in the art of healing in the field of dentistry to their care of the sale of drugs by veterinaries to their treatment or prevention of animal disease or the sale of drugs by ministries, public bodies and departments which have a duty to prevent or treat disease and by the Thai Red Cross and pharmaceutical organization,
- (4) The personal bringing into the Kingdom of drugs required for personal use for thirty drugs,
- (5) The importation by ministries, public bodies and departments which have a duty to prevent or treat disease, and by the Thai Red Cross and pharmaceutical organization.

Section 14

The licensing authority may issue a licence to produce or sell modern drugs, or to import or order modern drugs into the Kingdom, when it appears that the applicant:

- (1) Is the owner of the business and has sufficient property or status to be able to establish and operate the business.
- (2) Is not less than twenty years of age,
- (3) Is resident in Thailand,
- (4) Has not been sentenced by the Court's final judgment or a legitimate order to a jail term for an offence that requires guilty intentions as a component or in an offence against laws on narcotics, laws on substances having effects on the mind or nerve laws on the sale of drugs or this Act unless the offender has been released for not less than two years prior to the date of application for the licence,
- (5) Is not mentally defective or declared incompetent or quasi-incompetent,
- (6) Does not have any sickness as specified in the Government Gazette promulgated by the Minister,
- (7) Has premises to produce, sell, import or store drugs and equipment for use in the production, sale or storage of drugs and the control or maintenance of the quality of drugs of the character and quantity prescribed in Ministerial Regulations,
- (8) Uses a trade name which is not a repetition of or similar to the trade name used by a licensee whose licence is suspended or has been revoked for less than a full year,
- (9) Have persons to act in accordance with Section 38, Section 39, Section 40, Section 41, Section 42, Section 43, or Section 44 as the case may be.

Person with duty to perform in accordance with (9) must remain at the place of production, place of sale or place of sale or place of importation of drugs into the Kingdom and at that place only.

In the event the applicant is a juristic person, the manager or agent of juristic person who conduct its affairs qualified under (2) and (3) and does not have prohibited characteristics as specified in (4) (5) or (6)

Section 15

The categories of licences for modern drugs are as follows:

- (1) a licence to produce modern drugs;
- (2) a licence to sell modern drugs;
- (3) a licence for modern drug wholesale
- (4) a licence to sell only ready-packed modern drugs which are not dangerous or specially-controlled drugs;
- (5) a licence to sell only ready-packed modern drugs for veterinary use;
- (6) a licence to import or order drugs into the Kingdom;

A licensee under (1) or (6) shall be also deemed to be licensee under (2) in respect of the drugs which he produces, imports or orders into the Kingdom, as the case may be.

A licensee under (3) shall be also deemed to be licensed under (3) (4) and (5)

A licensee under (3) shall be also deemed to be licensed under (4) and (5) for wholesale only

Section 16

A licensee issued under Section 15 shall also cover the employees or agents of the licensee.

An act of an employee or agent of the licensee covered under paragraph One shall be also deemed to be the act of the licensee unless the licensee can prove that it was impossible for him to have knowledge or control of such act.

Section 17

Licences issued under Section 15 shall remain valid until the 31st December of the year of issued a licensee who wished to renew his licence shall, before its expiration, file an application for renewal. When the application has been filed, the business may be continued until the Licensor gives and order refusing to renew the licence.

Applications for renewal and renewal of licences shall be in accordance with the rules, procedures and conditions prescribed in Ministerial Regulations.

A Licensee whose licence has expired not more than one month may file an application for exemption stating the reason for extension of the licence but the application for exemption is not a reason for offences committed prior to the application for extension of licence.

An application for renewal of licence after one month from the date the licence has expired is not permitted.

Section 18

Where the licensing authority does not issue not grant the renewal of a licence, the applicant has a right to appeal in writing to the Minister within thirty days from the date of the receipt of the notice from the licensing authority informing that the licence will not be issued or renewal granted.

The decision of the Minister shall be final.

Where the licensing authority refuses to renew a licence to produce modern drugs pending the decision of the appeal by the Minister under paragraph two, the Minister has, at the request of the power to permit a temporary operation of the business.

CHAPTER III

Duties of a Licensee concerning Modern Drugs

Section 19

Licenses are prohibited from:

- (1) Producing or selling modern drugs in premises other than those prescribed in the licence with the exception of wholesale sales
- (2) Producing or selling drugs which do not correspond to the category of license.
- (3) Selling modern drugs which are dangerous or specially-controlled drugs to the licensee under Section 15 (4)

Section 20

Persons licensed to produce modern drugs must have at least two first class pharmacists with the duty to act as provided in Section 38 and provide at least one pharmacist on duty for the duration of business hours.

Section 21

Persons licensed to sell modern package drugs must have a first or second class pharmacist with the duty to act as provided in Section 39 or Section 40 on duty for the duration of business hours.

Section 22

Persons licensed to sell modern package drugs other than dangerous or specially controlled drugs must have a first or second class pharmacist or practitioners in the vocation medicine or first class practitioners in the modern art of healing in the fields of dentistry, midwifery or nursing with the duty to act as provided in Section 41 on duty for the duration of business hours.

Section 23

Persons licensed to sell modern packaged drugs for veterinary use must have a first or second class pharmacist, first or second class pharmacist, first or second class veterinary with the duty to act as provided in Section 42 or Section 43 or duty for the duration of business hours.

Section 24

Persons licensed to produce modern drugs must have a first class pharmacist with the duty to act as provided in Section 44 on duty at the premises to import drugs or store drugs for the duration of business hours.

Section 25

Persons licensed to produce modern drugs shall:

- (1) arrange for a sign, in the public place in front of the premises for producing drugs accordance with the category of the license which can be easily seen from outside the building as follows:
 - (a) a sign show that it is a place for the production drugs;
 - (b) a sign show first name, last name and qualification of the one who have the duty and the office time,

Substances used in making the sign, appearance, colour, size of the sign, size of letters and the text on the sign shall be in accordance with Ministerial Regulations..

- (2) arrange for an analysis of the raw material and drugs produced before despatching them from the place of production, the evidence showing the particulars of each analysis to be kept for not less than five years.
- (3) provide labels corresponding to the formula registered affixed to containers and packing for drugs produced shall always be fully labelled to show:
 - (a) the name of the drug;

- (b) numbers or codes of the drug contained;
 - (c) the quantity of the drug contained;
 - (d) the name and quantity or strength of the important active ingredients of the drug;
 - (e) numbers or letters indicating the lot and analysis;
 - (f) the name of the producer and the province where the place of production is located;
 - (g) date of production;
 - (h) the words "dangerous drug" "specially controlled drug" " external drug" " specific place drug" as the case may be in clearly visible red letters where the drug is a dangerous or specially controlled or external or specific place drug;
 - (i) the words "common household drug" if the drug is a common household use;
 - (j) the expiry date if the drug has been notified by the Minister under Section 76 (7) or (8)
- (4) use labels and accompanying literature corresponding to the formula registered and the text on the label and accompanying literature must be easy to read. If the accompanying literature is in a foreign language, it shall also be in Thai.
 - (5) provide a warning as to the use of the drug in the label and accompanying literature in the even, it is a drug notified by the Minister under Section 76 (9).
 - (6) prepare a list of raw materials used in the production of the drugs, a list of drugs produced, sold and keep samples of the drugs produced, in accordance with Ministerial Regulations.
 - (7) do as otherwise provided in Ministerial Regulations.

In the event that the drug produced cannot show the text in (3) (a) to (k) on the container, at least it must show the text in (3) (a) (d) and (k).

In the event that the drug is produced for export outside the Kingdom, the text in the label and accompanying literature must have the name Thailand, any other text which the producer wishes to have exemption must receive permission from the licenser.

In the event the licensee to produce modern drugs wishes to change the label concerning the expiry date in (3) (k) must file an application according to the rules, procedures and conditions prescribed in Ministerial Regulations.

Section 26

Persons licensed to sell modern drugs shall:

- (1) arrange for a sign, in the public place in front of the premises for selling drugs accordance with the category of the licence which can be easily seen from outside the building as follows:
 - (a) a sign show that it is a place for the selling drugs;
 - (b) a sign show first name, last name and qualification of the person who has the duty and the business hours;

Substances is made for a sign, appearance, colour, size of a sign, size of letters and the text shown on the sign shall be in accordance to the Ministerial Regulations.

- (2) keep veterinary drugs in a place separate from other drugs
- (3) keep each of the following separately:
 - (a) dangerous drugs;
 - (b) specially controlled drugs;

- (c) other drugs;
- (4) keep a separate place for compounding drugs in accordance with prescriptions of partitions in the vocation medicine or practitioners in the modern art of healing or veterinaries and for the storage of drugs for such purpose.
- (5) provide that the containers and packing for drugs shall always be fully labelled as prescribed in Section 25 (3),
- (6) prepare a list of drugs bought or sold as specified in Ministerial Regulations.
- (7) do as otherwise in Ministerial Regulations.

The provisions of paragraph one shall apply mutatis mutandis to licensees who have been licensed under Section 15 (3) and (4).

Section 27

Persons licensed to import modern drugs shall:

- (1) arrange for a sign, in the public place in front of the premises for importing drugs in accordance with the category of the licence which can be easily seen from outside the building as follows:
 - (a) a sign to show that it is a place for the importing drugs,
 - (b) a sign show first name, last name and qualification of the one who have the duty and the office time,

Substances used in making the sign appearance, colour, size of the sign, size of letter and the text shown in the sign shall be as prescribed in Ministerial Regulations.

- (2) provide a certificate from the producer giving the particulars of an analysis of the drug imported to be kept for not less than five years. If the certificate from the producer is in a foreign language, it shall also be in Thai, and the drug containers will always be fully labelled as prescribed at least in Section 25 (3), (a) (c) (d) (f) (h) and (k) with the exception of the text in (F) requires the name of city or country that the drug was produced instead of the name of the province.
- (3) Before the drugs can be sold, the labels on the containers or packing must have all the characteristics and text as specified in Section 25 (3) with the exception of the text in (f) requires the name of city or country that the drug was produced instead of the name of the province.

In the event that the drug brought or ordered into the Kingdom does not have the text required in Section in Section 25 (3) (a) to (k) on the container, at least it must show the text in Section 25 (3) (a) (c) (e) and (k).

- (4) use labels and accompanying literature corresponding to the formula registered and text in labels and accompanying literature must easily see. If the accompanying literature is in a foreign language, it shall also be in Thai.
- (5) prepare a list of drugs brought or ordered into the Kingdom, for sale or storage of sample drugs brought or ordered into the Kingdom. This shall be done in according with Ministerial Regulations,
- (6) do as otherwise provided in Ministerial Regulations.

Section 29

Licensees shall display their licences of pharmacists, practitioners in the vocation medicine, first class practitioners in the modern art of the healing in the fields of dentistry, midwifery or nursing or veterinaries in a conspicuous place at the place of production, sale or importation, as the case may be.

Section 30

No licensee shall move the place to produce or sell drugs to import or order drugs into the Kingdom, or to store drugs, except by permission of the licensing authority.

The application for and the grant of a permission shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 31

No licensee shall produce modern drugs at the place to produce drugs while the pharmacist is not present therein to perform the duties.

Section 32

No licensee shall a dangerous or a specially-controlled drug while the pharmacist or the veterinary practitioner is not present to perform the duties.

Section 33

When a licensee desires to change the person who performs the duties under Section 38, Section 39, Section 40, Section 41, Section 42, Section 43, or Section 44, he shall notify the licensing authority of the same in writing, and the change may be made when permission is granted by the licensing authority.

In the case where a licensee has no person to perform the duties mentioned in paragraph one, he shall notify the licensing authority of the same in writing within seven days from the date he has no such person.

Section 33 bis

In the event that the person with duty to perform at the place production, sale or importation of drugs into the Kingdom is not able to perform the duty temporarily, not more than 60 days the licensee must provide a person with the same qualifications as the person with day, to perform the duty instead the licensee must submit a prior written notification to the licensor and it shall be deemed that the person performing the duty instead is the person with duty under Section 38, Section 39, Section 40, Section 41, Section 42, Section 43 or Section 44 as the case may be.

The written notification under paragraph one shall be as prescribed in the Commissions regulations.

Section 34

A person, having the duties under Section 38, Section 39, Section 40, Section 41, Section 42, Section 43, or Section 44, who no longer desires to perform the duties, must notify the licensing authority of the same in writing within seven days from the date of the termination of his duties.

Section 35

Any licensee who ceases to operate the licensed business under this Act shall notify the licensing authority of the same in writing within fifteen days from the date of ceasing thereof, and the licence shall be deemed to expire from the date of the cessation of the business as notified.

Section 36

A licensee who notifies of the cessation of the business any sell his remaining drugs to another licensee or a person deemed appropriate by the licensing authority within ninety days from the date of the cessation of the business except where the licensing authority allows an extension for the said period.

Section 37

If a licensee dies and a person who is qualified to be a licensee under this Act gives notice of his desire to the licensing authority within thirty days from the date of the death of the licensee, to continue the operation of the licensed business of the deceased, such person may continue to operate the business until the licence expires. In such case, the person giving notice of his desire shall be deemed a licensee under this Act from the date of the death of the licensee.

CHAPTER IV

Duties of a Pharmacist, a First-Class Modern Medical Practitioner in the Branch of Medicine, Dentistry, Midwifery of Nursing, or a Veterinary Practitioner

Section 38

First class pharmacists under Section 20 on duty at the place of production for the whole duration of business hours and have following duties:

- (1) Exercise control to insure that the production of drugs conforms to the formulae registered under Section 79,
- (2) Exercise control to insure that drug labels and accompanying as Section 25 (3) (4) and (5),
- (3) Exercise control to insure that drug labels and labelling of drug containers or packing is correct as this Act.
- (4) Exercise control over the sale of drugs to insure compliance with Section 39,
- (5) Exercise control the list of drugs and keeping sample drugs under Section 25 (6),
- (6) Do as otherwise provided in Ministerial Regulations.

Section 39

First class pharmacists under Section 21 on duty at the place of sale of modern drugs during the duration of business hours and shall have the following duties:

- (1) Exercise control over the separation of drugs under Section 26 (2) and (3),
- (2) Exercise control over labelling in accordance with Section 26 (5),
- (3) Exercise control over the sale of drugs to insure compliance with this Act.
- (4) Compound drugs at the place provide by the licensee in accordance with Section 26 (4),
- (5) Label containers or packaging for drugs compounded to the prescriptions of practitioners in the vocation medicine, practitioners in the modern art of healing or veterinaries in accordance with the rules, procedures and conditions prescribed in Ministerial Regulations.
- (6) Exercise control over the delivery of dangerous or specially controlled drugs or drugs prescribed by practitioners in the vocation medicine, practitioners in the modern art of healing or veterinaries,
- (7) Exercise control the list of drugs under Section 26 (6),
- (8) Do as otherwise provided in Ministerial Regulation".

Section 40

A second-class pharmacists under Section 21 shall act in accordance with Section 39 in the same way as a first-class pharmacist except that he may not dispense, sell and deliver a specially controlled drug.

Section 41

First or second class pharmacists practitioners in the vocation medicine, first class practitioners in the modern art of healing in the field of dentistry, midwifery or nursing under Section 22 on duty at the place of sale of modern drugs, only packaged drugs that is not dangerous drugs or specially controlled drugs during the duration of business hours and shall have the following duties;

- (1) exercise control over labelling in accordance with Section 26 (5),
- (2) exercise control to insure that packaged drugs are not broken and sold in any from but that produced by the producer,

- (3) exercise control in preparing the list of drugs under Section 26 (6),
- (4) do as otherwise provided in Ministerial Regulations.

Section 42

First class pharmacists or first class veterinary as under Section 23 on duty at the place of sale of modern drugs, only packaged drugs for animals during the duration of business hours and shall have the following duties:

- (1) exercise control over the separation of drugs under Section 26 (3),
- (2) exercise control over labelling in accordance with Section 26 (5),
- (3) exercise control in insure that package drugs for veterinary use are not broken and sold in any form but that produced by the producer,
- (4) exercise control over the delivery of packaged dangerous or specially controlled drugs for veterinary use,
- (5) exercise control the lost of drugs as Section 26 (6),
- (6) do as otherwise provided in Ministerial Regulations.

Section 43

A second-class pharmacist or a second-class veterinary practitioner under Section 23 shall act in accordance with Section 42 in the same way as a first-class pharmacist or a first-class veterinary use which is a specially-controlled drug.

Section 44

First class pharmacists under Section 24 on duty at the place of importation of drugs into the country or place of storage during the duration of business hours and shall have the following duties:

- (1) exercise control over the importation of drugs to insure conformity to the formula registered under Section 79,
- (2) exercise control over labelling in accordance with Section 27 (2) and (3),
- (3) exercise control with procedures connected with the licence of the producer showing the details of the analysis of drugs under Section 27 (2) and accompanying documents under Section 27 (4),
- (4) exercise control over the sale of drugs to insure compliance with Section 39,
- (5) exercise control the list of drugs and keeping sample drugs as Section 27 (5),
- (6) exercise control over the importation of drugs,
- (7) exercise control over the storage of the imported drugs at the storage place,
- (8) do as otherwise provided in Ministerial Regulations.

Section 45

Pharmacists, practitioners in the vocation medicine, first class practitioners in the modern art of healing in the fields of dentistry, midwifery or nursing, veterinaries shall be prohibited from doing any act in a place for the production, sale or importation of drugs without being named as the persons having the duty to act in such place.

CHAPTER V

Application for and issue of a Licence Concerning Traditional Drugs

Section 46

No person shall produce or sell a traditional drug, or import or order a traditional drug into the Kingdom, unless he has obtained a licence from the licensing authority.

The application for and the grant of a licence shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 47

The provisions of Section 46 shall not apply to:

- (1) the production of a drug by a Ministry, sub-Ministerial Department in its function of the prevention or treatment of a disease, the Thai Red Cross Society and the Government Pharmaceutical Organization,
- (2) the preparation of a traditional drug by a traditional medical practitioner in accordance with the pharmacopoeia notified by the Minister under Section 76 (1) only for his own patients or for resale;
- (3) the sale of a herbal drug which is not a dangerous drugs or the sale of a household medicine;
- (4) the importation of a drug with the person into the Kingdom not exceeding the amount required for his personal use for thirty days, and the importation or order of a drug into the Kingdom by a Ministry, sub-Ministry, Department in its function of the prevention or treatment of a disease, the Thai Red Cross Society and the Government Pharmaceutical Organization.

Section 48

The licensor may issue a licence to produce, sell or import traditional drugs when it appears that the applicant:

- (1) is the owner of the business and has sufficient property or status to be able to establish and operate the business,
- (2) is not less than twenty full, years of age,
- (3) is resident in Thailand,
- (4) has not been sentenced by the court 's or a legitimate order to a jail term for an offence that requires guilty intentions as a component or in an offence against laws on narcotics, laws on substance having effect on the mind or never, laws on the sale or drugs or this Act unless the offender has been released for not less two years prior to the date of application for the licence,
- (5) is not mentally defective, or declared incompetent or quasi-incompetent,
- (6) is not afflicted as notified by the Minister in Government Gazette,
- (7) has the clean and hygienic premises to produce, sell, import or store drugs,
- (8) use a trade which is not a repetition of or similar to the trade name used by a licensee whose licence is suspended or has been revoked for less than a full year,
- (9) have persons to act in accordance with Section 68, Section 69 or Section 70.

Person who has the duty to comply with (9) must be permanently person either at a place of producing the medicine, or place of import or export the medicine only.

In the event the applicant is a juristic person, the managers or agents of juristic person conducting the business must have characteristics as prescribed in (2) and (5) and do not have prohibited characteristics as prescribed in (4) (5) or (6).

Section 49

The categories of licences for traditional drugs are as follows:

- (1) a licence to produce traditional drugs;
- (2) a licence to sell traditional drugs;
- (3) a licence to import or order traditional drugs into the kingdom.

A licensee under (1) or (3) shall be also deemed to be licensed under (2) in respect of the drug which he produces, or imports or orders into the Kingdom, as the case may be.

Section 50

A licence issued under Section 49 shall also cover the employees or agents of the licensee.

An act of an employee or agent of the licensee covered under paragraph one shall be also deemed to be the act of the licensee unless the licensee can prove that it was impossible for him to have knowledge or control of such act.

Section 51

Licences issued under Section 49 shall remain valid until the 31st December of the year of issue. A licensee who wishes to renew his licence shall, before its expiration, file an application for renewal. When the application has been filed, the business may be continued until the licensor gives an order refusing to renew the licence.

Applications for renewal and permission shall be in accordance with the rules, procedures and conditions prescribed in Ministerial Regulations.

A licensee whose licence has expired not more than one month may file an application for exemption stating the reason for the extension of the licence but the application for exemption is not a reason for offences committed prior to the application for extension of licence which is deemed to be conducting business with an expired licence.

An application for renewal of licence after one month from the date the licence has expired is not permitted."

Section 52

Where the licensing authority does not issue, or grant the renewal of, a licence, the applicant has a right to appeal in writing to the Minister within thirty days from the date of receipt of notices from the licensing authority that the licence will not be issued or renewed.

The decision of the Minister shall be final.

Where the licensing authority refuses to renew a licence to produce traditional drugs pending the decision of the appeal by the Minister under paragraph two, the Minister has, at the request of the appellant, the power to permit a temporary operation of the business.

CHAPTER VI

Duties of a Licensee concerning Traditional Drugs

Section 53

No licensee shall produce sell traditional drugs outside the place prescribed in the licence, except in case of a direct wholesale to a licensee to sell traditional drugs.

Section 54

Persons licensed to produce traditional drugs must have traditional medical practitioner with the duty to act as provided in Section 68 on duty during the duration of business hours.

The person applying for licence under clause one which produces more than fifty formulas shall have a traditional medical practitioner as the person performing the duty under Section 68 on duty during the duration of the business hours.

Section 55

Persons licensed to sell traditional drugs must have a traditional medical practitioner with the duty to act as provided in Section 69 on duty during the whole duration of business hours.

Section 56

Persons licensed to import traditional drugs must have a traditional medical practitioner with the duty to act as provided in Section 70 on duty at the place of import of traditional drugs or the storage of drugs during the duration of business hours.

Section 57

Persons licensed to produce traditional drugs shall:

- (1) arrange for a sign, in the public place in front of the premises for producing drugs accordance with the category of license which can be easily seen from outside the building as follows:

- a. sign show that it is a place for the production drugs,
- b. sign show first name, last name and qualification of the one who have a duty and the office time.

Substances is made for a sign, appearance, colour, size of a sign, size of literal and the text show on the sign shall be in accordance with Ministerial Regulations.

- (2) provide labels corresponding to the formula registered be affixed to the containers and packing for drugs produced shall always be fully labelled to show:

- a. the name of the drug;
- b. numbers or codes of the certificate of formula registration;
- c. the quantity of the drug contained;
- d. numbers or letters indication the lot;
- e. the name of the producer and the province where the place of production is located;
- f. date of production;
- g. the words "traditional drug" must have provided easily seen;
- h. the words "external drug" or "Specific place drug" as the case may be in clearly visible red letters where the drug is an external or specific place drug
- i. the word "common household drug" if the drug is a common household drug;
- j. the word "for veterinary use" in the event the drug is for veterinary use;

- (3) use labels and accompanying literature corresponding to the formula registered and the text on the labels and accompanying literature must be easy to read. If the accompanying literature is in a foreign language, it shall also be in Thai;

- (4) prepare a list of drugs produced or sold as prescribed in Ministerial Regulations.

- (5) do as otherwise provided in Ministerial Regulations.

In the event that the drug is produced cannot show the text in (2) (a) to (j) on the container, at least it must show the text in (2) (a), (c) or (d).

In the event that the drug is produced for export outside the Kingdom, the text in the label and accompanying literature must have the name Thailand any other text which the producer wishes to have exemption must receive permission from the licensor and the text in (2) (g),(h) and (I) shall not be applied.

Section 58

Persons licensed to sell traditional drugs shall

- (1) arrange for a sign in the public place in front of the premises for selling, drugs accordance with the category of license which can be easily seen from outside the building as follows:

- a. a sign show that it is a place for the selling drugs;

- b. a sign show first name, last name and qualification of the one who have the duty and the office hours,

Substances is made for a sign, appearance, colour size of a sign size of literal and the text shown and the sign shall be in accordance to the Ministerial Regulations.

- (2) provide that the containers and packing for drugs shall always be fully labelled as prescribed in Section 57 (2).
- (3) do as otherwise provided in Ministerial Regulations.

Section 59

Persons licensed to import traditional drugs shall:

- (1) arrange for a sign in the public place in front of the promises for importing drugs accordance with the category of license which can be easily seen from outside the building as follows:
 - a. a sign show that it is a place for the importing drugs:
 - b. a sign show first name, last name and qualification of the one who have the duty and the office hours,

Substances is made for a sign, appearance, colour, size of sign, size of literal and the text shown on the sign shall be in accordance to the Ministerial Regulations.

- (2) the drug containers will always be fully labelled of the drug imported as prescribed at least in Section 57 (2) (a) (c) (f) and (g) with the exception of the text in (e) requires the name of city or country that the drug was produced instead of the name of the province.
- (3) before the drugs can be sold, the labels on the containers or packages must have all the characteristics and text as specified in Section 57 (2) with the exception of the text in (f) requires the name of city or country that the drug was produced instead of the name of the province. In the even that the drug brought or ordered into the Kingdom does not have the text required in Section 57 (2) (a) to (j) on the container, at least it must show the text in Section 57 (2) (a) (c) and (d).
- (4) use labels and accompanying literature corresponding to the formula registered and text labels and accompanying literature must easily seen. If the accompanying literature is in a foreign language, it shall also be in Thai,
- (5) prepare a list of drugs brought or ordered into the Kingdom, for sale or storage of sample drugs brought or ordered into the Kingdom. This shall be done in accordance with Ministerial Regulations,
- (6) do as otherwise provided in Ministerial Regulations”

Section 60

In case of loss or destruction in the essential part of a licence, the licensee shall notify the licensing authority of the same and file an application for a licence substitute within fifteen days from the date of knowledge of such loss or destruction.

The application for and the issue of a licence substitute shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 61

A licensee shall display his licence and that of the traditional medical practitioner in a conspicuous place at the place to product or sell drugs, or to import or order drugs into the Kingdom, s the case may be.

Section 62

No licensee shall move the place to produce or sell drugs to import or order drugs into the Kingdom or to store drugs except by permission of the licensing authority.

The application for and the grant of a permission shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 63

When a licensee desires to change the person who performs the duties under Section 68, Section 69 or Section 70, he shall notify the licensing authority of the same in writing, and the change may be made when permission is granted by the licensing authority.

In the case where a licensee has no person to perform the duties mentioned in paragraph one, he shall notify the licensing authority of the same in writing within seven days from the date he has no such person.

Section 63 bis

In the event that the person with duty to perform at the place of production sale or importation of drugs into the Kingdom is not able to perform the duty temporarily not more than 60 days, the licensee must provide a person with the same qualification as the person with duty, to perform the duty instead, the licensee must submit a prior written notification to the licensor and if shall be deemed that the person performing the duty instead is the person with duty under Section 68, Section 69 or Section 70 as the case may be.

The written notification under paragraph one, shall be as prescribed in the Commission regulations.

Section 64

A person, having the duties under Section 68, Section 69, or Section 70 who no longer desires to perform the duties, shall notify the licensing authority of the same in writing seven days from the date of the termination of his duties.

Section 65

Any licensee who ceases to operate the licensed business under this act shall notify the licensing authority of the same in writing within fifteen days from the date of cessation thereof, and the licence shall be deemed to expire from the date of the cessation of the business as notified.

Section 66

A licensee who notifies of the cessation of the business may continue to sell his remaining drugs to another licensee or to a person deemed appropriate by the licensing authority within ninety days from the date of the cessation of the business concept where the licensing authority allows an extension for the said period.

Section 67

If a licensee dies and a person who is qualified to be a licensee under this act gives notice of his desire to the licensing authority within thirty days from the date of the death of the licensee to continue operating the licensed business of the deceased, such person may continue to operate the business until the licence expires. In such case the person giving notice of his desire shall be deemed a licensee under this act from the date of the death of the licensee.

CHAPTER VII

Duties of a Traditional Medical Practitioner

Section 68

Traditional medical practitioner under Section 54 on duty at the place of production during the duration of business hours and shall have the following duties,

- (1) exercise control insure that the production of drugs conforms to the formulae registered under Section 79,

- (2) exercise control to insure that drugs labels and accompanying as Section 57 (2) and (3),
- (3) exercise control to insure that packing and labelling of drug containers or packings is correct as this act,
- (4) exercise control over the dale of drugs to insure compliance with Section 69,
- (5) exercise control over the list of drugs under Section 57 (4),
- (6) do as otherwise provided in Ministerial Regulations.

Section 69

Traditional medical practitioner under Section 55 on duty of the place of sale of drugs during the duration of business hours and shall have the following duties.

- (1) exercise control over labelling in accordance with Section 58 (2),
- (2) exercise control over the sale of drugs to insure compliance with this act,
- (3) do as otherwise provided in Ministerial Regulations.

Section 70

Traditional medical practitioner under Section 56 on duty at the place of importation or place of storage during the duration of business hours and shall have the following duties.

- (1) exercise control over the importation of drugs to insure conformity to the formulae registered under Section 79,
- (2) exercise control over labelling in accordance with Section 59 (2),
- (3) exercise control to insure that accompanying as Section 59 (4),
- (4) exercise control over the sale of drugs to insure compliance with Section 69,
- (1) exercise control the list of drugs under Section 59 (5),
- (6) exercise control the importation of drugs,
- (7) exercise control over the storage of drugs imported at the place of storage,
- (8) do as otherwise provided in Ministerial Regulations.

Section 71

Traditional medical practitioner shall be prohibited from doing any act in a place for the production sale or importation of drug without being named as the persons having the duty to act in such place.

CHAPTER VIII

Fake Drugs, Sub-Standard Drugs, Deteriorated Drugs

Section 72

It shall be prohibited to produce, sell or import the following drugs:

- (1) Fake drugs,
- (2) Sub-standard drugs,
- (3) Deteriorated drugs,
- (4) Drugs which has not been registered,
- (5) Drugs whose formula registration has been cancelled for the licensee to produce drugs and licensee to import drugs into the Kingdom or drugs which the drug formula registry has been withdrawn for more than 6 months for the licensee to sell drugs.

- (6) Drugs whose formula registration has been ordered cancelled by the Minister.

The text in (4) shall not be applied the Ministries and Departments with duty to prevent or cure disease the Thai Red Cross or the Pharmaceutical Department.

Section 73

The following drugs or substances are fake drugs:

- (1) a drug or substance which is wholly or partly an imitation of a genuine drug;
- (2) a drug which shows the name of another drug, or an expiry date which is false;
- (3) a drug which shows a name or mark of a producer, or the location of the produce the drug, which is false;
- (4) Drugs which falsely show that they are in accordance with a formula which has been registered;
- (5) Drugs produced with active substances which quantity or strength lower than the minimum or higher than the maximum standards prescribed in the registered formula under Section 79 by more than twenty percent.

Section 74

The following are sub-standard drugs:

- (1) Drugs produced with active substances which quantity or strength are lower than be minimum or higher than the maximum standards prescribed in the registered formula to a degree less than the stated in Section 73 (5),
- (2) Drugs produced so that their purity or other characteristics which are important to their quality differ from the standards prescribed in the registered formula under Section 79 or drug formulas which the Minister has ordered the drug formula registry under Section 86 bis,

Section 75

The following drugs are deteriorated drugs:

- (1) a drug the expiry date of which as shown on the label has been reached;
- (2) a drug which has so denatured as to have the characteristics of a fake drug under Section 73 (5) or a drug differing from the standard under Section 74.

CHAPTER IX

Notices concerning Drugs

Section 76

The Minister is empowered to give notice in the Government Gazette listing:

- (1) Pharmacopoeias;
- (2) Substances which are drugs;
- (3) Dangerous drugs;
- (4) Specially controlled drugs;
- (5) Common household drugs;
- (6) Traditional drugs;
- (7) Drugs whose expiry date must be given on the label;
- (8) Duration of usage of some drugs;
- (9) Drugs for the use of which a warning must be given in the accompanying literature and the text of such warnings.

In the event that the Minister has fixed the duration of usage of any drug under (8) if any licensee can prove or that with evidence that the duration of usage might be longer than that fixed by the Minister, the Minister with the approval of the Committee may lengthen the duration of usage for that drug for the licensee who was able to prove or text as a particular case by giving notification in the Government Gazette.

Section 77

The Minister shall have the power to publish in the Government Gazette specifying a disease or the symptoms thereof, which a drug is prohibited from being advertised as capable of curing, mitigating, treating or preventing.

Section 77 bis

For the purpose of safeguarding the welfare of the people, the Minister with the recommendation of the Commission has the power to fix the number of place of sale of drug in a particular area by giving notification in the Government Gazette.

Section 78

A notification of the Minister under this Chapter shall be made upon the recommendation of the Committee.

CHAPTER X

Registration of a Drug Formula

Section 79

Any person licensed to produce or import drugs who wished to produce or import drugs whose modern drugs or traditional drugs or traditional drugs is required first to apply to the competent officer for registration of the formula. Upon receipt of certificate of formula registration, the Drug may be produced or imported.

Section 79 bis

Section 79 shall not be applied to:

- (1) drugs that is pharmaceutical chemicals or semi-processed pharmaceutical chemicals that is not packaged drugs,
- (2) Herbal drugs,
- (3) Sample drugs that have received permission to produce, import into the Kingdom for application to register drugs formula in accordance with the rules regulations and conditions prescribed in Ministerial regulations.

Section 80

The application for registration of a drug formula under Section 79 shall Give the following particulars:

- (1) the name of the drug;
- (2) the name and quantity of the ingredients of the drug;
- (3) the drug contents;
- (4) the analytical method of the standard of a modern drug in the case where the analytical method employed is not in the pharmacopoeia notified by the Minister;
- (5) the label;
- (6) the accompanying leaflets;
- (7) other particulars as prescribed in the Ministerial Regulation.

Section 81

An amendment of particulars in the registration of a drug formula may be made upon the permission of the official.

Section 82

An application for a drug formula registration or an amendment of the particulars thereof, and the issue of certificate of a drug formula registration or an amendment of the particulars thereof shall be in accordance with the rules, procedures and conditions as prescribed in the Ministerial Regulation.

Section 83

The competent officer shall be prohibited from registering a drug formula when the committee is of opinion that:

- (1) the drug is included in Section 72 (1) or (6);
- (2) the application for registration of the drug formula is not in conformity with Section 80 and Section 82;
- (3) the properties ascribed to the drug whose formula is to be registered are incredible or the drug may be unsafe for use;
- (4) the name used for the drug is boastful, impolite or may be misleading;
- (5) drugs using the name not compatible to the good culture of Thailand or in a way that might destroy the value of the Thai language;

The order refusing to register the drug formula by competent officials shall be final.

Section 84

The provisions of Section 83 shall apply mutatis mutandis to the amendment of particulars in the registration of drug formula.

Section 85

The licensee to produce drugs or licensee to import drugs into the Kingdom must submit an annual report concerning the production or importation of drugs that the formula has been registered each formula in the form prescribed in Ministerial Regulations within the 31st March of the following year.

Any drug that the formula has been registered but not produced or not imported into the Kingdom for two consecutive years, the drug formula shall be withdrawn.

Section 86

If, after registration of formula, it appears that the drug does not have the properties as registered or may be unsafe for use or is a drug included in Section 72 (1) or the drug has changed into a material intended for use as food or as cosmetics will permission and has received permit to sell the food under controlled or has received a certificate of registration of cosmetics as prescribed in the law concerning cosmetics, the Minister, with advice of the committee, is empowered to order the cancellation of such drug formula registration. Cancellation shall be by notification in the Government Gazette.

Order of the Minister shall be final

Section 86 bis

For the purpose of safeguarding the welfare of the drugs users, the Minister with the advice of the Committee is empowered to order a change in the Registration of drug formula as deemed appropriate or necessary.

Section 87

In case of loss or destruction in the essential part of a certificate of drug formula registration, the licensee shall notify the official of the same and file an application for a

certificate substitute within fifteen days from the date of knowledge of such loss or destruction.

The application for and the issue of a certificate of a drug formula registration shall be in accordance with the rules, procedures and conditions as prescribed in the Ministerial Regulation.

CHAPTER XI

Advertisement

Section 88

An advertisement for the sale of a drug shall:

- (1) not be boastful of its therapeutic properties or of its ingredients as being miraculously or completely capable of curing, mitigating, treating or preventing a disease or illness, nor shall any other wording of similar meaning be used;
- (2) not falsely or exaggeratedly show its therapeutic properties;
- (3) not cause to be understood that it has a substance as its chief or component ingredient, which in fact it has not or does have but less than the quantity as caused to be understood;
- (4) not cause to be understood that it is an abortifacient or a strong emmenagogue;
- (5) not cause to be understood that it is an aphrodisiac or a birth control drug;
- (6) not show the therapeutic properties of a dangerous or a specially-controlled drug;
- (7) contain no certification or laudation of its therapeutic properties by any other person;
- (8) not show its therapeutic properties as being capable of curing, mitigating, treating or preventing disease or symptom thereof as notified by the Minister under Section 77.

The provisions of (5) and (6) do not apply to the statement on the label or accompanying leaflet of a drug, and those of (1), (4), (5), (6), (7) and (8) do not apply to an advertisement directed to a medical practitioner or a veterinary practitioner.

Section 88 bis

The advertisement to sell drugs through radio amplifier, television slides or motion picture or through printed matter must:

- (1) receive permission for the text, sound or picture used in the advertisement from the licensor;
- (2) follow the conditions set by the licensor.

Section 89

No sale of drugs shall be advertised impolitely, or by means of singing and dancing, or by showing the distress or suffering of a patient.

Section 90

No sale of drugs shall be advertised by means of a gift or lottery drawing.

Section 90 bis

The Secretary of the food and Drugs Administration is empowered to issue written orders to cease any advertisement deemed to be contrary to this act.

CHAPTER XII

Officials

Section 91

In the performance of their duties, competent officers are empowered to:

- (1) enter upon the premises for the production, sale, importation or storage of drugs during working hours to inspect compliance with this act;
- (2) take reasonable quantities of drugs as samples for testing or analysis;
- (3) in the event there is reason to suspect the committee of an offence under this act may can enter any premises in the interests of prosecution, size or attach drugs and tools and equipment concerned with such offence including drug containers or packings and documents concerning such drug;
- (4) announce the results of test and analysis of the quality of the drugs text under (2) to the public with the consent of the Committee in the interest of protecting the safety of the drug users;
- (5) In the event that the competent officials learn that any drug is not safe or might be harmful to drug users the competent officials are empowered to call for the storage or order the licensee to produce drugs or the licensee to import drugs into the Kingdom recall their drugs within a period fixed by the competent officials and is empowered to destroy the drugs in accordance with the rules, procedures as prescribed in Ministerial Regulations.

In the performance of their duties under paragraph one, competent officers shall be given reasonable facilities by licensees and all persons concerned with the production sale or importation of drugs on the said premises.

Section 92

In the execution of his duty, the official must show his identity card at the request of the persons concerned.

The identity card of an official shall be in the form prescribed in the Ministerial Regulation.

Section 93

The drug as well as the drug container or package and document seized under Section 91, the owner of which is not apparatus, or for which the public prosecutor has give a final non-prosecution order, or which the court has not adjudged confiscated, and which is not claimed by its owner or possessor within ninety days from the date of its seizure or the date of knowledge of the final order of non-prosecution or the date of the court's final judgment, as the case may be, shall become the property of the Ministry of Public Health.

If the article seized is perishable or if the delay would risk damage or incur storage costs in excess of the market price of the drug, the official may arrange to sell such drug as well as the drug container job package and document at public auction before the prescribed time. The net proceeds there from shall be held in its stead.

Section 94

In the execution of this act, the official shall be an official under the Penal Code.

CHAPTER XIII

Suspension and Revocation of a Licence

Section 95

When it appears to the licensing authority that any licensee has not complied with this act or the Ministerial Regulation issued under this Act, the licensing authority, with the advice of

the Board, has the power to order the suspension of the licence for a period of not more than one hundred and twenty days each time; or where a licensee is prosecuted for an offence under this act, the same may order the suspension of the licence pending the final judgment of the court.

A licensee whose licence has been suspended must cease the production or sale of drugs, or the importation or order of drugs into the Kingdom, as the case may be; during such suspension, he may not apply for any other licence under this act.

Section 96

When it appears to the licensing authority that a licensee lacks the qualifications under Section 14 or Section 48, the licensing authority with the advice of the Committee has the power to order the revocation of the licence.

A licensee whose licence has been revoked must cease the production or sale of drugs, or the importation or order of drugs into the Kingdom, as the case may be, and may not apply for any licence under this act until a period of two years from the date of the revocation has elapsed. It shall be at the discretion of the licensing authority whether or not to issue another licence.

Section 97

The order of suspension or revocation of a licence shall be notified in writing to the licensee, and where the person whose licence has been suspended or revoked is not found or refuses to accept the said order, it shall be posted in a conspicuous place at the place to produce or sell drugs, or import or order drugs into the Kingdom, and the licensee shall be deemed to have knowledge thereof from the date of its posting.

The orders of suspension and revocation of a licence may also be published in a newspaper or by other additional means.

Section 98

The licensing authority with the advice of the Committee has the power to order the withdrawal of the suspension of a licence before the expiration of the time limit when satisfied that the licensee whose licence has been suspended has complied with this act or the Ministerial Regulation issued under this act.

Section 99

The licensee whose licence has been suspended or revoked has a right to appeal to the Minister within thirty days from the date of knowledge of the order. The minister has the power to dismiss the appeal or to amend the order of the licensing authority in a way favourable to the appellant.

The decisions of the Minister shall be final.

The appeal under paragraph one does not stay the enforcement of the order of suspension or revocation of the licence.

Section 100

A person whose licence has been revoked may sell his remaining drugs to another licensee or to a person deemed appropriate by the licensing authority within a period of sixty days from the date of knowledge of the order of the revocation of the licence or the decision of the Minister, except where the licensing authority allows an extension for the said period.

Section 101

Any person who violates Section 12 shall be liable to imprisonment for a term not exceeding five years and to a fine not exceeding the thousand Baht.

Section 102

Any licensee who violates Section 19 or Section 30 shall be liable to a fine from two thousand to five thousand Baht.

Section 103

Any licensee who does not comply with Section 20, Section 21, Section 22, Section 23 and Section 24 shall be liable to imprisonment not exceeding three months or a fine not exceeding five thousand Baht or both and shall be liable to a fine of five hundred Baht per day until the licensee has performed correctly to the law.

Section 104

Any licensee who produces, sells, or imports drugs after his licence has expired without having applied for renewal of the licence shall be liable to a fine one hundred Baht per day for each day the licence has expired”.

Section 105

Any licensee who fails to comply with Section 25, Section 26 or Section 27 shall be liable to a fine from two thousand to ten thousand Baht.

Section 106

Any licensee who fails to comply with Section 28, Section 29, Section 33, Section 35, Section 60, Section 61, Section 63, Section 81 or Section 87 shall be liable to a fine not exceeding one thousand Baht.

Section 107

Any person who violates Section 31 or Section 32 shall be liable to a fine from one thousand to five thousand Baht.

Section 107 bis

Any licensee not giving notification to providing a replacement to perform duty as prescribed in Section 33 bis shall be liable to fine of not more than five hundred Baht.

Section 108

Any person who is charged with the duties and fails to comply with Section 34 or Section 64 shall be liable to a fine not exceeding five hundred Baht.

Section 109

Any person who is charged with the duties and fails to comply with Section 38, Section 39, Section 40, Section 41, Section 42, Section 43, or Section 44 shall be liable to a fine from one thousand to five thousand Baht.

Section 110

Any person who violates Section 45 shall be liable to a fine from one thousand to five thousand Baht.

Section 111

Any person who violates Section 46 shall be liable to imprisonment for a term not exceeding three years and to a fine not exceeding five thousand Baht.

Section 112

Any licensee who violates Section 53 or Section 62 shall be liable to fine from one thousand to three thousand Baht.

Section 113

Any licensee who does not comply with Section 54, Section 55 or Section 56 shall be liable to imprisonment not exceeding one month or a fine not exceeding two thousand Baht or both and shall be liable to a fine of one hundred Baht per day until the licensee has performed correctly to the law.

Section 114

Any licensee who fails to comply with Section 57, Section 58 or Section 59 shall be liable to a fine from one thousand to five thousand Baht.

Section 114 bis

Any licensee not giving notification to providing a replacement to perform duty as prescribed in Section 63 bis shall be liable to a fine of not more than five hundred Baht.

Section 115

Any traditional medical practitioner who fails to comply with Section 68, Section 69 or Section 70 shall be liable to a fine from five hundred to two thousand Baht.

Section 116

Any traditional medical practitioner who violates Section 71 shall be liable to a fine from five hundred to two thousand Baht.

Section 117

Any person producing a fake drug in violation of Section 72 (1) shall be liable to imprisonment for a term three years to life and to a fine from ten thousand to fifty thousand Baht.

Section 118

Any person who, in violation of Section 72 (2) or (5), produces a drug differing from the standard or a drug the formula registration of which the Minister has ordered revoked, shall be liable to imprisonment for a term from two to five years and to a fine from four thousand to twenty thousand Baht.

Section 119

Any person who, in violation of Section 72 (1), sells a fake drug or imports or orders a fake drug into the Kingdom, shall be liable to imprisonment for a term from one to twenty years and to a fine from two thousand to ten thousand Baht.

If the person acting under paragraph one acted without knowledge that the drug was fake, he shall be liable to a fine from one thousand to five thousand Baht.

Section 120

Any person who, in violation of Section 72 (2) or (5), sells or imports or orders into the Kingdom, a drug differing from the standard or a drug the formula registration of which the Minister has ordered revoked, shall be liable to imprisonment for a term from six months to three years and to a fine from one thousand to five thousand Baht.

If the person acting under paragraph one acted without knowledge that the drug differed from the standard or that its formula registration had been ordered revoked by the Minister, he shall be liable to a fine not exceeding five thousand Baht.

Section 121

Any person who, in violation of Section 72 (3), sells or imports or orders into the kingdom a deteriorated drug, shall be liable to imprisonment for a term not exceeding on year or to a fine not exceeding three thousand Baht, or to both.

If the person acting under paragraph one acted without knowledge that the drug had deteriorated, he shall be liable to a fine not exceeding three thousand Baht.

Section 122

Any person who, in violation of Section 72 (4), produces, sells, or imports or orders into the Kingdom a drug without a formula registration, shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding five thousand Baht, or to both.

Section 123

Any licensee who fails to comply with Section 79 shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding five thousand Baht, or to both.

Section 123 bis

Any licensee not performing as prescribed in Section 83 paragraph one shall be liable to a fine from one thousand Baht to five thousand Baht and shall be liable to a fine of one hundred Baht per day until the licensee has performed correctly.

Section 123 ter

Any licensee submitting a false annual report concerning the production or importation of drugs into the Kingdom as prescribed in Section 85 paragraph one shall be liable to imprisonment not exceeding three months or a fine not exceeding five thousand Baht or both.

Section 124

Whoever advertises the sale of drugs violation of Section 88, Section 88 bis, Section 89 and Section 90 shall be liable to imprisonment not exceeding six months or a fine not exceeding ten thousand Baht or both.

Section 124 bis

Whoever violates the order suspending the advertisement for sale of drugs by the Secretary of the Food and Drug Administration as prescribed in Section 90 bis shall be liable to imprisonment not exceeding three months or a fine not exceeding five thousand Baht or both and shall be liable to fine of five hundred Baht per day until the order has been followed.

Section 125

Whoever, failing to give facility, obstructs a competent officer in the performance of his duties or not obeying the order of competent officials under Section 91 shall be liable to imprisonment not exceeding one month or a fine not exceeding one thousand Baht or both.

Section 125 bis

Any licensee who produces drugs, sell drugs or import drugs into the Kingdom while the licence to produce sell or import drugs into the Kingdom as the case may be, is suspended as prescribed in Section 95 shall be liable to imprisonment not exceeding five years and a fine of not exceeding ten thousand Baht.

Section 126

When a penalty is imposed under Section 101, Section 111, Section 117, Section 118, Section 119, Section 120, Section 121, or Section 122, the drug, the instrument and the accessory appliance used in the production of the drug, as well as the drug container or package relating to the offence of the case shall be confiscated by the Ministry of Public Health in order to be destroyed or dealt with as it deems appropriate.

Section 126 bis

All the offence in this act which the penalty is a fine only, the Secretary of the Food and Drugs Administration or a person the Secretary of the Food and Drug Administration authorized is empowered to, set the fine.

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