Unofficial Translation*

DRUGS ACT,
B.E. 2510 (1967)**

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 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 "Drugs Act, B.E. 2510"

Section 2. This Act shall come into force after the expiration of sixty days from the date of its publication in the Government Gazette.[1]

Section 3. The following shall be repealed:

(1) the Sale of Drugs Act, B.E. 2493;

(2) the Sale of Drugs Act, (No.2), B.E. 2498;

(3) the Sale of Drugs Act, (No.3), B.E. 2499;

(4) the Sale of Drugs Act, (No.4), B.E. 2500;

(5) the Sale of Drugs Act, (No.5), B.E. 2505;

Section 4.[2] In this Act;

"drugs" means:

(1) substances recognized by pharmacopoeias notified by the Minister;

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* Translated by Ms. Siriphan Ponrob under contract for the Office of the council of State of Thailand's Law for ASEAN project. –Initial version –pending review and approval by the Office of the Council of State.

** As amended up to the Drugs Act (No. 5) B.E. 2530 (1987).

[1] Published in the Government Gazette, Vol. 84, Part 101, Special Issued, dated 20th October B.E. 2510 (1967).

[2] Section 4 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(2) substances intended for use in the diagnosis, treatment, relief, cure or prevention of human or animal disease or illness;

(3) substances which are pharmaceutical chemicals or semi-processed pharmaceutical 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, sport device, medical apparatus, cosmetics or device for use in the practice of healing arts or 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 healing arts or the cure of an animal disease;

"traditional drug" means a drug intended for use in the practice of the traditional healing arts 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 specially controlled drug;

"external use drug"[3] means modern or traditional drug intended for applying to the outside of the body but shall not include a site-specific drug;

"site-specific drug"[4] means modern or traditional drug intended for applying specifically to ears, eyes, nose, mouth, anus, vagina or gutter urine.

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

[3] The definition of "external use drug" in Section 4 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[4] The definition of "site-specific drug" in Section 4 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

"ready-packed drug"[5] means a modern or traditional drug manufactured in a pharmaceutical from, which is packed in a closed or sealed container or packed and which has all the labels in accordance with this Act;

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

"pharmaceutical chemical" means a pure organic or inorganic substance intended for use in making, adding as additives, preparing or compounding drugs;

"semi-processed pharmaceutical chemical" means an organic or inorganic substance, whether pure or compound, ready for use as a component in producing drugs;

"practice of medicine" means the practice of medicine under the law on medical profession;

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

"practice of traditional arts of healing" means the practice of healing arts by dependence on the knowledge acquired from a textbook or through learning over generations 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 prevention or elimination of disease;

"produce" [6] means to manufacture, mix, prepare or denature and includes change of drug form or apportion as ready-packed drug with or without labels;

"active ingredient" means a material which is an important component in the drug and has the power to treat, relief, care or prevent 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; or

(2) the effect of healing of the drug that has been tested in laboratory in suitable way or has passed adequate controlled usage;

"sell" [7] means to retail, wholesale, dispense of, distribute, dispose as gift or barter for commercial purpose, and shall include possession for sale;

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[5] The definition of "ready-packed drug" in Section 4 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[6] The definition of "produce" in Section 4 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

"wholesale" [8] means to sell directly to a sale licensee, wholesale licensee, ministry, sub-ministry, department, the Thai Red Cross Society, the Government Pharmaceutical Organization, licensee to operate medical facilities, medical practitioner, nursing practitioner, midwifery practitioner, nursing and midwifery practitioner, practitioner of modern arts of healing or veterinary practitioner;

"import station" [9] means any port or place within the Kingdom notified by the Minister upon publication in the Government Gazette as a checkpoint of drugs imported or ordered into the Kingdom;

"label" includes any picture, design, mark or statement displayed on the container or package of drugs;

"accompanying literature" includes paper or any other material that the meaning is shown through a picture, figure, sign or any statement concerning drugs that is inserted or included with the containers or packages of the drugs;

"drug formula" means a formula of drug components regardless of form and shall include a drug in a processed pharmaceutical form ready for use for humans and animals;

"medical practitioner" means a medical practitioner under the law on medical profession;

"practitioner of modern arts of healing" means a practitioner of modern arts of healing in the branch of dentistry, pharmacy, midwifery or nursing under the law on control of practices of healing arts;

"practitioner of traditional arts of healing" means a practitioner of traditional arts of healing in the branch of medicine or pharmacy under the law on control of practices of healing arts;

"first class pharmacist" means a first class practitioner of modern arts of healing in the branch of pharmacy;

"second class pharmacist" means a second class practitioner of modern arts of healing in the branch of pharmacy;

"first class veterinary practitioner" means a licensed first class veterinary practitioner under the law on veterinary profession; [10]

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[7] The definition of "sell" in Section 4 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[8] The definition of "wholesale" in Section 4 was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[9] The definition of "import station" in Section 4 was added by the Drugs Act (No. 5), B.E. 2530 (1987).

"second class veterinary practitioner" means a licensed second class veterinary practitioner under the law on veterinary profession;[11]

"licensee" means a licensee under this Act; in case of a juristic person, includes a manager or a representative of the juristic person who operates the business;

"licensing authority" means:

(1) the Secretary-General of the Food and Drug Administration or the person entrusted by him or her for licensing the production of drugs or the importation or order of drugs into the Kingdom;

(2) the Secretary-General of the Food and Drug Administration or the person entrusted by him or her for the sale of drugs in Bangkok;

(3) the *Changwat* Governor, for the sale of drugs within his territorial Jurisdiction, except Bangkok;

"Committee" means the Drug Committee under this Act;

"competent official" means a person appointed by the Minister for the execution of 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 competent officials, issue Ministerial Regulations prescribing fees not exceeding the rates attached to this Act, granting fee exemptions and determine other operations for the execution of this Act.

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

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[10] The term "first-class practitioner of animal treatment" under the law on the control of treatment animals was replaced by "first-class veterinary practitioner" by virtue of section 5 of the Veterinary Profession Act, B.E. 2545 (2002).

[11] The term "second-class practitioner of animal treatment" under the law on the control of treatment animals was replaced by "second-class veterinary practitioner" by virtue of section 5 of the Veterinary Profession Act, B.E. 2545 (2002).

CHAPTER I
Drug Committee

Section 6.[12] There shall be a Committee called the "Drug Committee" consisting of the Permanent Secretary of the Ministry of Public Health as Chairperson, 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 Administration, a representative from the Ministry of Defence, a representative from the Ministry of Agriculture and Cooperatives, two representatives from the Sub-Ministry of University Affairs appointed from Deans of Faculties of Pharmacy, a representative 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 practitioners of traditional arts of healing.

The Deputy Secretary-General of the Food and Drug Administration shall be member and secretary, and the Director of Drug Control Division of the office of Food and Drug Administration shall be member and assistant secretary.

Section 7. A qualified member shall hold office for a term of two years.

A qualified member who vacates office may be re-appointed.

Section 8. In addition to vacating office at the expiration of term, a qualified member vacates office upon:

(1) death;

(2) resignation;

(3) being dismissed 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) being under suspension or revocation of the licence to practice healing arts.

[12] Section 6 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

In the case where a qualified member vacates office before the expiration of term, the Minister may appoint another person to replace such member and the appointed person shall remain in office for the remaining term of the replaced member.

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 Chairperson is not present at the meeting, the members present shall elect one from among themselves to preside over the meeting.

The decision of the meeting shall be by majority of votes.

Each member shall have one vote. In case of an equality of votes, the Chairperson of the meeting shall have an additional vote as 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 drugs, or importation or order of drugs into the Kingdom, and the registration of drug formulas;

(2) the suspension, revocation of a licence or revocation of register of drug formulas;

(3) the prescription of the rules, procedures and conditions concerning the production or sale of drugs, importation or order of drugs into the Kingdom, importation of drugs as sample for examination, and the inspection of the premises of production or sale of drugs, importation or order into the Kingdom and storage of drugs;

(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 sub-committees in order to consider, study or analyze the matters within the authority of the Committee; and section 9 shall apply *mutatis mutandis* to meetings of the sub-committees.

CHAPETER II
Application and issuance of Licences 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 or she 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. [13] The provision of section 12 shall not apply to:

(1) production of drugs by ministries, sub-ministries and departments which have a duty to prevent or treat disease, and by the Thai Red Cross Society and the Government Pharmaceutical Organization,

(2) production of drugs in accordance with the prescription of a practitioners of medicine or practitioners of the healing arts for a particular patient or in accordance with the prescription of a veterinary practitioner for a particular animal,

(3) sale of herbal drugs which are not dangerous drugs, sale of common household drugs, sale of drugs by practitioners of medicine or practitioners of the healing arts in the field of dentistry to their patients, sale of drugs by veterinary practitioners to their treatment or prevention of animal disease, or sale of drugs by ministries, sub-ministries and departments which have a duty to prevent or treat disease and by the Thai Red Cross Society and the Government Pharmaceutical Organization,

(4) personal bringing into the Kingdom of drugs in the amount as necessary for personal use for thirty days,

(5) importation by ministries, sub-ministries and departments which have a duty to prevent or treat disease, and by the Thai Red Cross Society and the Government Pharmaceutical Organization.

The exempted person under (1) and (5) must apply to the rules, procedures and conditions prescribed in the Ministerial Regulation. [14]

Section 14. [15] 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) has residence in Thailand;

(4) has not been sentenced by final judgment of the Court or a legitimate order to imprisonment for an offense that requires guilty intentions as a component or in an offense against the law on narcotics, law on psychotropic substances, law 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;

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[13] Section 13 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[14] Section 13 paragraph two was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[15] Section 14 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(5) not insane, incompetent or quasi-incompetent;

(6) is not affected with a disease notified 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 characteristics and quantities prescribed in the 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 revoked for less than one year;

(9) [16] has 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.

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

In the case where the applicant is a juristic person, the manager or the representative of juristic person who operates business must have the qualifications under (2) and (3) and does not have prohibited characteristics as specified in (4) (5) or (6).

Section 15. [17] 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 (3) in respect of the drugs which he or she produces, imports or orders into the Kingdom, as the case may be.

A licensee under (2) 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 such act is beyond his or her knowledge or control.

Section 17. [18] A licence issued under section 15 shall remain valid until the 31st December of the year of issued. A licensee who wishes to renew the licence shall, before its expiration, file an application for renewal. When the application has been filed,

[16] Section 15 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[17] Section 14 (9) was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[18] Section 17 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

the business may be continued until the licensing authority gives an order refusing to renew the licence.

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

A licensee whose licence has expired not more than one month may file an application for dispensation stating the reason for extension of the licence but the application for dispensation is not a reason to excuse from liability for offences committed prior to the application for extension of licence which deemed to operate business without 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 or 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 not be 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 appellant, the power to permit a temporary operation of the business.

CHAPTER III
Duties of Licensees concerning Modern Drugs

Section 19. A licensee 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. [19] A licensee 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.

In case of necessity to control production of modern drugs, the licensing authority may specify that a licensee must have more first class pharmacists with the duty to act as provided in section 38 than that specified in paragraph one in accordance with the rules prescribed in the Ministerial Regulation. [20]

Section 21. [21] A licensee to sell modern 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 21 *bis*. [22] A licensee to wholesale modern drugs must have a first or second class pharmacist with the duty to act as provided in section 40 *bis* on duty for the duration of business hours.

Section 22. [23] A licensee to sell modern package drugs other than dangerous or specially controlled drugs must have a first or second class pharmacist or practitioners of medicine or first class practitioners of modern arts 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.

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[19] Section 20 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[20] Section 20 paragraph two was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[21] Section 21 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[22] Section 21 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[23] Section 22 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 23. [24] A licensee to sell modern ready-packed drugs for veterinary use must have a first or second class pharmacist, first or second class veterinary practitioners with the duty to act as provided in section 42 or section 43 or duty for the duration of business hours.

Section 24. [25] A licensee to import or order modern drugs into the Kingdom 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. [26] A licensee to produce modern drugs shall:

(1) arrange for a sign, in an open 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 sigh to show that it is a place for the production of drugs;

(b) a sigh to show first name, last name and qualification of a person on duty and the office time;

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(2) arrange for an analysis of the raw material and drugs produced before dispatching them from the premises of production together with the evidence showing the particulars of each analysis to be kept for not less than five years;

(3) provide labels corresponding to the formulas registered affixed to containers and packages for drugs produced of which the details show:

(a) the name of the drug;

(b) the numbers or codes of the drug formula registration;

(c) the quantity of the drug contained;

(d) the name and quantity or strength of the important active ingredients of the drug;

(e) the numbers or letters indicating the lot and analysis;

(f) the name of the producer and the province where the premises of production is located;

(g) the date of production;

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[24] Section 23 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[25] Section 24 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[26] Section 25 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

(h) the words “dangerous drug”, “specially controlled drug”, “external use drug”, “site-specific drug”, as the case may be, in clearly visible red letters where the drug is a dangerous or specially controlled or external use or site-specific drug;

(i) the words “common household drug” where the drug is a common household drug;

(j) the words stating “veterinary drug” where the drug is for veterinary use;

(k) the words “expiry date” and the expiry date where 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 statement 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 where it is a drug notified by the Minister under section 76 (9). If the label also includes the accompanying literature, the warning may be shown at any part of the label or accompanying literature;

(6) prepare a list of raw materials used in the production of the drugs, a list of drugs produced and sold, and keep samples of the drugs produced, in accordance with the Ministerial Regulation;

(7) do as otherwise provided in the Ministerial Regulation.

In the case where the drugs produced cannot show all statements in (3) on the container, the licensee to produce drugs may be exempted to show any or all the statements in (3) (c) (d) (e) (f) (g) (i) and (j) upon prior permission of the licensing authority.

In the case where the drug is produced for export outside the Kingdom, the statements in the label and accompanying literature must have the country name of Thailand. Any other statements which the producer wishes to have exemption must receive permission from the licensing authority.

In the case where the licensee to produce modern drugs wishes to change the label concerning the expiry date in (3) (k), he or she must file an application according to the rules, procedures and conditions prescribed in the Ministerial Regulation.

Section 26.[27] A licensee to sell modern drugs shall:

[27] Section 26 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(1) arrange for a sign, in an open place in front of the premises for selling 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 selling drugs;

(b) a sign to show first name, last name and qualification of the person on duty and the business hours;

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(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 practitioners of medicine or practitioners of modern arts of healing or veterinary practitioners and for the storage of drugs for such purpose.

(5) provide that the containers and packages for drugs shall always be fully labeled as prescribed in section 25 (3);

(6) prepare a list of drugs purchased or sold as specified in the Ministerial Regulation;

(7) do as otherwise specified in the Ministerial Regulation.

The provisions of paragraph one shall apply *mutatis mutandis* to licensees who have been licensed under section 15 (4) and (5).

Section 26 *bis*.[28] A licensee to wholesale modern drugs shall comply *mutatis mutandis* with section 26 paragraph one except for the preparation of separate place for compounding drugs under section 26 (4).

Section 27.[29] A licensee to import modern drugs shall:

(1) arrange for a sign, in an open 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;

[28] Section 26 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[29] Section 27 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

(b) a sign to show first name, last name and qualification of the person on duty and the office time;

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(2) provide a certificate from the producer giving the particulars of an analysis of the drugs 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 shall always be fully labeled as prescribed in section 25 (3) with the exception of the statement 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, provide the labels on the containers or packages which must have all the characteristics and statements as specified in section 25 (3) with the exception of the statement in (f) requires the name of city or country that the drug was produced instead of the name of the province and also specify the name of the importer of or person who orders the drugs as well as the premises of importation or ordering thereof;

(4) use labels and accompanying literature corresponding to the formula registered and statement in labels and accompanying literature must be easily seen. 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 where it is a drug notified by the Minister under section 76 (9). If the warning is in a foreign language, it shall also be in Thai. In case the label also includes the accompanying literature, the warning may be shown at any part of the label or accompanying literature;

(6) prepare a list of drugs imported or ordered into the Kingdom and those for sale, and to storage of sample drugs imported or ordered into the Kingdom, as prescribed in the Ministerial Regulation;

(7) do as otherwise provided in the Ministerial Regulation.

In the case where the drugs imported or ordered into the Kingdom under (2) or (3) contained in such small containers that it cannot show all statements under section 25 (3) thereon, the licensee to import or order drugs may be exempted to show any or all the statements under section 25 (3) (c) (d) (e) (f) (g) (i) and (j) upon prior permission of the licensing authority.

Section 27 *bis*.[30] A modern drug imported or ordered into the Kingdom must undergo an inspection by a competent official at the import checkpoint.

The inspection of the competent official shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

Section 28. In the case where a licence is lost or substantially damaged, the licensee shall notify the licensing authority of the same and shall file an application for a substitute within fifteen days as from the date of acknowledgement of the loss or damage.

An application for and issuance of a substitute licence shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

Section 29.[31] A licensee shall display his or her own licence and that of a pharmacist, practitioner of medicine, first class practitioner of modern arts of the healing in the fields of dentistry, midwifery or nursing or veterinary practitioners in an open and conspicuous place at the premises of production, sale, or importation or ordering, 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 sell 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 wishes 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 or she shall notify the licensing authority of the same in writing, and the change may be made when the permission is granted by the licensing authority.[32]

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

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[30] Section 27 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[31] Section 29 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[32] Section 33 paragraph one was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

Section 33 *bis.*[33] In the case where the person with duty to perform at the place production, sale, or importation or ordering of drugs into the Kingdom is not able to perform the duty temporarily of not more than sixty days, the licensee must provide a person with the same qualifications to perform the duty instead of that person. In this regard, the licensee must submit a prior written notification to the licensing authority and it shall be deemed that the substitute person 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 Rules of the Committee.

Section 34.[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 wishes 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 cessation, and the licence shall be deemed to expire on the date of the cessation of such business.

Section 36. A licensee who notifies of the cessation of the business may sell his or her 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 such period.

Section 37. If a licensee dies and a person who is qualified to be a licensee under this Act gives notice of his or her intention 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 or her intention shall be deemed a licensee under this Act from the date of the death of the licensee.

CHAPTER IV
Duties of Pharmacists, First Class Practitioners of Modern Arts of Healing in the Branch of Medicine, Dentistry, Midwifery of Nursing, or Veterinary Practitioners[35]

[33] Section 33 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[34] Section 34 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[35] Title of chapter IV was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 38.[36] A first class pharmacist under section 20 shall be on duty at the premises of production during the duration of business hours and shall have following duties:

(1) to exercise control to ensure that the production of drugs conforms to the formulas registered under section 79;

(2) to exercise control to ensure that drug labels and accompanying literature are as section 25 (3) (4) and (5);

(3) to exercise control to ensure that drug labels and labeling of drug containers or packages is correct as this Act;

(4) to exercise control over the sale of drugs to ensure compliance with section 39;

(5) to exercise control the preparation of the list of drugs and the keeping of sample drugs under section 25 (6);

(6) to do as otherwise provided in the Ministerial Regulation.

Section 39. A first class pharmacist under section 21 shall be on duty at the premises of sale of modern drugs during the duration of business hours and shall have the following duties:

(1) to exercise control over the separation of drugs under section 26 (2) and (3);

(2) to exercise control over the labeling in accordance with section 26 (5);

(3) to exercise control over the sale of drugs to ensure compliance with this Act;

(4) to compound drugs at the place provide by the licensee in accordance with section 26 (4);

(5) to provide labels on containers or packages of drugs compounded to the prescriptions of practitioners of medicine, practitioners of modern arts of healing or veterinary practitioners in accordance with the rules , procedures and conditions prescribed in the Ministerial Regulation.

(6) to exercise control over the delivery of dangerous or specially controlled drugs or drugs prescribed by practitioners of medicine, practitioners of modern arts of healing or veterinary practitioners;

(7) to exercise control the preparation of the list of drugs under section 26 (6);

(8) to do as otherwise provided in the Ministerial Regulation.

[36] Section 38 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 40. A second class pharmacist under section 21 shall act in accordance with section 39 in the same way as a first class pharmacist except that he or she may not dispense, sell and deliver a specially controlled drug.

Section 40 *bis.*[37] A first class pharmacist under section 21 *bis* shall be on duty at the premises of wholesale of modern drugs during the duration of business hours and shall have the following duties:

(1) to exercise control over the separation of drugs under section 26 (2) and (3);

(2) to exercise control over the labeling in accordance with section 26 (5);

(3) to exercise control the preparation of the list of drugs under section 26 (6);

(4) to exercise control over the wholesale of modern drugs;

(5) to do as otherwise provided in the Ministerial Regulation.

Section 41.[38] A first or second class pharmacist, practitioner of medicine, first class practitioner of modern arts of healing in the branch of dentistry, midwifery or nursing under section 22 shall be on duty at the premises of sale of modern drugs, only for ready-packed drugs that is not dangerous drugs or specially controlled drugs during the duration of business hours and shall have the following duties;

(1) to exercise control over the labeling in accordance with section 26 (5);

(2) to exercise control to ensure that ready-packed drugs are not repacked and sold in a different way from that produced by the producer;

(3) to exercise control the preparation of the list of drugs under section 26 (6);

(4) to do as otherwise provided in the Ministerial Regulation.

Section 42.[39] A first class pharmacist or first class veterinary practitioner under section 23 shall be on duty at the premises of sale of modern drugs, only for ready-packed drugs for veterinary use during the duration of business hours and shall have the following duties:

(1) to exercise control over the separation of drugs under section 26 (3);

(2) to exercise control over the labeling in accordance with section 26 (5);

(3) to exercise control to ensure that ready-packed drugs for veterinary use are not repacked and sold in a different way from that produced by the producer;

(4) to exercise control over the delivery of packaged dangerous or specially controlled drugs for veterinary use;

(5) to exercise control the preparation of the list of drugs under section 26 (6);

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[37] Section 40 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[38] Section 41 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[39] Section 42 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

(6) to do as otherwise provided in the Ministerial Regulation.

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 practitioner except those relevant to the control of delivery of a specially controlled drug for veterinary use.

Section 44.[40] A first class pharmacist under section 24 shall be on duty at the premises of importation or ordering of drugs into the Kingdom or storage of drugs during the duration of business hours and shall have the following duties:

(1) to exercise control over the importation or ordering of drugs to ensure conformity to the formula registered under section 79;

(2) to exercise control over the labeling in accordance with section 27 (2) (3) and (5);

(3) to exercise control with procedures connected with the certificate of the producer showing the details of the analysis of drugs under section 27 (2) and accompanying literature under section 27 (4);

(4) to exercise control over the sale of drugs to ensure compliance with section 39;

(5) the preparation of the list of drugs and the keeping of sample drugs under section 25 (6);

(6) to exercise control over the importation of drugs;

(7) to exercise control over the storage of the imported drugs at the storage place;

(8) to do as otherwise provided in the Ministerial Regulation.

Section 45.[41] A pharmacist, practitioner of medicine, first class practitioner of modern arts of healing in the branch of dentistry, midwifery or nursing, veterinary practitioner shall be prohibited from doing any act in a place for the production, sale or importation or ordering of drugs without being named as the persons having the duty to act in such place.

CHAPTER V
Application for and Issuance of Licences
Concerning Traditional Drugs

[40] Section 44 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[41] Section 45 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 46. No person shall produce or sell a traditional drug, or import or order a traditional drug into the Kingdom, unless he or she 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-ministry, 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 practitioner of traditional arts of healing in accordance with the pharmacopoeia notified by the Minister under section 76 (1) only for his or her own patients or for resale;

(2 *bis*)[42] the sale of a traditional drug by a licensee to sell a modern drug, a licensee to wholesale a modern drug and a licensee to sell a modern drug only for a ready-packed drug which is not dangerous drugs or specially controlled drugs;

(3) the sale of a herbal drug which is not a dangerous drugs or the sale of a common household drug;

(4) the importation of a drug with the person into the Kingdom not exceeding the amount required for his or her 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.[43] The licensing authority may issue a licence to produce, sell or import or order traditional drugs when it appears that the applicant:

(1) is the owner of the business and has sufficient assets or financial status to be able to establish and operate the business;

(2) is not less than twenty years of age;

(3) has residence in Thailand;

(4) has not been sentenced by a final judgment of the court or a legitimate order to imprisonment for an offense that requires guilty intentions as a component or in an offense against the law on narcotics, law on psychotropic substances, law 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;

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[42] Section 47 (2 *bis*) was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[43] Section 48 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(5) not insane, incompetent or quasi-incompetent;

(6) is not affected with a disease notified by the Minister;

(7) has the clean and hygienic premises to produce, sell, import or order, or store drugs;

(8) use a trade name which is not a repetition of or similar to the trade name used by a licensee whose licensce is suspended or revoked for less than one year;

(9) has persons to act in accordance with section 68, section 69 or section 70.

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

In the case where the applicant is a juristic person, the manager or the representative of juristic person who operates business must have the qualifications under (2) and (3) and does not have prohibited characteristics as specified 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 such act is beyond his or her knowledge or control.

Section 51.[44] A licence issued under section 49 shall remain valid until the 31st December of the year of issuance. A licensee who wishes to renew the licence shall, before its expiration, file an application for renewal. When the application has been filed, the business may be continued until the licensing authority gives an order refusing to renew the licence.

An application for renewal and permission shall be in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulation.

[44] Section 51 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

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 to excuse from liability for offenses 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 Licensees concerning Traditional Drugs

Section 53.[45] 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.[46] A licensee to produce traditional drugs must have a practitioner of traditional arts of healing to perform the duty under section 68 on duty during the duration of business hours.

A licensee under paragraph one who produces more than fifty formulas shall have a practitioner of traditional arts to perform the duty under section 68 in such number as prescribed in the Ministerial Regulation.

Section 54 *bis.*[47] A licensee to produce traditional drugs who produces traditional drugs by process of tablet pressing or coating or by other similar means and use pharmaceutical chemicals or semi- processed pharmaceutical chemicals in such process as

[45] Section 53 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[46] Section 51 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[47] Section 54 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

well as mixing preservatives in traditional drugs shall comply with the rules and procedures prescribed in the Ministerial Regulation.

Section 55.[48] A licensee to sell traditional drugs must have a practitioner of traditional arts of healing to perform the duty under section 69 on duty during the duration of business hours.

Section 56.[49] A licensee to import or order traditional drugs into the Kingdom must have a practitioner of traditional arts of healing to perform the duty under section 70 on duty at the place of import or order of traditional drugs or the storage of drugs during the duration of business hours.

Section 57.[50] A licensee to produce traditional drugs shall:

(1) arrange for a sign, in an open 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) a sign to show that it is a place for the production drugs;

(b) a sign to show first name, last name and qualification of a person who have a duty and the office time.

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(2) provide labels corresponding to the formula registered be affixed to the containers and packages for drugs produced of which the details show:

(a) the name of the drug;

(b) the numbers or codes of the certificate of formula registration;

(c) the quantity of the drug contained;

(d) the numbers or letters indication the lot;

(e) the name of the producer and the province where the premises of production is located;

(f) date of production;

(g) the words “traditional drug” which must have provided easily seen;

(h) the words “external use drug” or “site-specific drug” as the case may be in clearly visible red letters where the drug is an external use or site-specific drug;

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[48] Section 55 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[49] Section 51 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[50] Section 51 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(i) the word "common household drug" where the drug is a common household drug;

(j) the word "veterinary drug" where the drug is for veterinary use;

(3) use labels and accompanying literature corresponding to the formula registered and the statement on the labels and accompanying literature must be easily seen. 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 the Ministerial Regulation;

(5) do as otherwise provided in the Ministerial Regulation.

In the case where the size of a container is so small that it cannot show all statements in (2) thereon, the licensee to produce traditional drugs may be exempted to show any or all the statements in (2) (c) (d) (e) (g) (h) (i) and (j) upon prior permission of the licensing authority.[51]

In the case where the drug is produced for export outside the Kingdom, the statements in the label and accompanying literature must have the country name of Thailand. Any other statements which the producer wishes to have exemption must receive permission from the licensing authority and the provisions in (2) (g) (h) (i) shall not apply hereto.

Section 58.[52] A licensee to sell traditional drugs shall:

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

(a) a sign to show that it is a place for the selling drugs;

(b) a sign to show first name, last name and qualification of a person who have the duty and the office hours;

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(2) provide that the containers and packages for drugs shall always be fully labeled as prescribed in Section 57 (2);

(3) do as otherwise prescribed in the Ministerial Regulations.

Section 59. [53] A licensee to import traditional drugs shall:

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[51] Section 57 paragraph two was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[52] Section 58 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[53] Section 59 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

(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 to show that it is a place for the importing drugs;

(b) a sign to show first name, last name and qualification of the one who have the duty and the office hours,

Objects used in making the signs, appearances, colours, sizes of the signs, and sizes of letters and the statements on the signs shall be in accordance with the Ministerial Regulation;

(2) the drug containers will always be fully labeled of the drug imported as prescribed at least in section 57(2) with the exception of the statement 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 statements as specified in section 57(2) with the exception of the statement in (f) requires the name of city or country that the drug was produced instead of the name of the province, and also specify the name of the importer of or person who orders the drugs as well as the premises of importation or ordering thereof;

(4) use labels and accompanying literature corresponding to the formula registered and the statements in the labels and accompanying literature must be easily seen. If the accompanying literature is in a foreign language, it shall also be in Thai;

(5) prepare a list of drugs imported or ordered into the Kingdom and those for sale, and to storage of sample drugs imported or ordered into the Kingdom, as prescribed in the Ministerial Regulation;

(6) do as otherwise provided in the Ministerial Regulation.

In the case where the drugs imported into the Kingdom under (2) or to be sold under (3) contained in such small containers that it cannot show all statements under section 57 (2) thereon, the licensee to import or order traditional drugs may be exempted to show any or all the statements under section 57 (2) (c) (d) (e) (g) (h) (i) and (j) upon prior permission of the licensing authority.

Section 59 *bis*. [54] A traditional drug imported or ordered into the Kingdom must undergo an inspection by a competent official at the import checkpoint.

The inspection of the competent official shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

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[54] Section 59 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

Section 60. In the case where a licence is lost or substantially damaged, the licensee notify the licensing authority of the same and shall file an application for a substitute within fifteen days as from the date of acknowledgement of the loss or damage.

An application for and issuance of a substitute licence shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

Section 61. A licensee shall display his or her own licence and that of a practitioner of traditional arts of healing in a conspicuous place at the premises to product or sell drugs, or to import or order drugs into the Kingdom, as 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 wishes to change a person who performs the duties under section 68, section 69 or section 70, he or she shall notify the licensing authority of the same in writing, and the change may be made when the 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 or she shall notify the licensing authority of the same in writing within seven days from the date he or she has no such person.

Section 63 *bis*.[55] In the case where the person with duty to perform at the premises of production, sale, or importation or ordering of drugs into the Kingdom is not able to perform the duty temporarily not more than sixty days, the licensee must provide a person with the same qualification to perform the duty instead of that person. In this regard, the licensee must submit a prior written notification to the licensing authority and it shall be deemed that the substitute person 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 Rules of the Committee.

Section 64. A person having the duties under section 68, section 69, or section 70 who no longer wishes to perform the duties, shall notify the licensing authority of the same in writing within seven days from the date of the termination of his duties.

[55] Section 63 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

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.

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 except where the licensing authority allows an extension for such period.

Section 67. If a licensee dies and a person who is qualified to be a licensee under this act gives notice of his or her intention 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 or her intention shall be deemed a licensee under this act form the date of the death of the licensee.

CHAPTER VII
Duties of Practitioners of Traditional Arts of Healing

Section 68.[56] A practitioner of traditional arts of healing under section 54 shall be on duty at the premises of production during the duration of business hours and shall have the following duties:

(1) to exercise control to ensure that the production of drugs conforms to the formulas registered under section 79;

(2) to exercise control to ensure that drugs labels and accompanying literature are as section 57 (2) and (3);

(3) to exercise control to ensure that repacking in portion and labeling of drug containers or packages is correct as provisions of this Act,

(4) to exercise control over the sale of drugs to ensure compliance with section 69;

(5) to exercise control over the preparation of a list of drugs under section 57(4);

(6) to do as otherwise provided in the Ministerial Regulation.

Section 69.[57] A practitioner of traditional arts of healing under section 55 shall be on duty at the premises of sale of drugs during the duration of business hours and shall have the following duties:

(1) to exercise control over labeling in accordance with section 58 (2);

(2) to exercise control over the sale of drugs to ensure compliance with this Act;

[56] Section 68 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[57] Section 69 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(3) to do as otherwise provided in the Ministerial Regulation.

Section 70.[58] A practitioner of traditional arts of healing under section 56 shall be on duty at the premises of importation or ordering, or storage of drugs during the duration of business hours and shall have the following duties:

(1) to exercise control over the importation or order of drugs to ensure conformity to the formulas registered under section 79;

(2) to exercise control over labeling in accordance with section 59 (2);

(3) to exercise control to ensure that accompanying literature is as section 59 (4);

(4) to exercise control over the sale of drugs to ensure compliance with section 69;

(5) to exercise control the preparation of a list of drugs under section 59 (5);

(6) to exercise control the importation or order into the Kingdom of drugs;

(7) to exercise control over the storage of drugs imported or ordered into the Kingdom at the place of storage;

(8) to do as otherwise provided in the Ministerial Regulation.

Section 71.[59] A practitioner of traditional arts of healing shall be prohibited from doing any act in a place for the production sale or importation or ordering of drugs into the Kingdom without being named as the persons having the duty to act in such place.

[58] Section 69 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[59] Section 69 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

CHAPTER VIII
Fake Drugs, Sub-Standard Drugs, Deteriorated Drugs

Section 72. No person shall 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 the formula registration of which has been cancelled for the licensee to produce drugs and licensee to import or order drugs into the Kingdom or drugs of which the drug formula registry has been withdrawn for more than six months for the licensee to sell drugs;

(6) drugs the formula registration of which has been ordered cancelled by the Minister.

The provision in (4) shall not apply to ministries, sub-ministries and departments with duty to prevent or cure disease, the Thai Red Cross Society and the Government Pharmaceutical Organization.

Section 73. The following drugs or substances are fake drugs:

(1) drugs or substances which are wholly or partly an imitation of genuine drugs;

(2) drugs which show the name of another drug, or an expiry date which is false;

(3) drugs which show a name or mark of a producer, or the location of the produce the drug, which is false;

(4)[60] drugs which falsely show that they are in accordance with a formula which has been registered;

(5)[61] 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.[62] The following are sub-standard drugs:

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[60] Section 73 (4) was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[61] Section 73 (5) was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[62] Section 74 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

(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 that 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 amendment in drug formula registration under section 86 *bis*.

Section 75. The following drugs are deteriorated drugs:

(1) drugs the expiry date of which as shown on the label has been reached;

(2) drugs which have so denatured as to have the characteristics of fake drugs under section 73 (5) or sub-standard drugs under section 74.

Section 75 *bis*[63] No person shall sell mixing ready-packed drugs to the buyer by mixing any medications for one use as polypharmacy for treatment, relief, cure or prevention of a disease or a symptom of any disease.

CHAPTER IX
Notifications concerning Drugs

Section 76.[64] The Minister shall have power to notify 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 expiry date of which 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 statement of such warnings.

In the case where 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

[63] Section 75 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[64] Section 76 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

extend the duration of usage for that drug for the licensee who was able to prove or test 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 treating, mitigating, curing or preventing.

Section 77 *bis.*[65] For the purpose of safeguarding the welfare of the people, the Minister with the recommendation of the Committee shall have the power to fix the number of place of sale of drugs in a particular area by giving notification in the Government Gazette.

Section 77 *ter.* [66] For the purpose of controlling drugs imported or ordered into the Kingdom, the Minister shall have the power to specify an import checkpoint 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 Drug Formulas

Section 79.[67] A licensee to produce or import or order drugs, who wishes to produce, or import or order into the Kingdom of modern drugs or traditional drugs, is required first to apply to the competent official for registration of the formulas thereof. Upon receipt of certificate of formulas registration, the drugs may be produced, or imported or ordered.

Section 79 *bis*.[68] The provisions of section 79 shall not apply to:

(1) drugs that is pharmaceutical chemicals or semi-processed pharmaceutical chemicals that is not ready-packed drugs;

(2) herbal drugs;

(3) sample drugs that have received permission to produce, import or order into the Kingdom for application to register drugs formulas in accordance with the rules, procedure and conditions prescribed in the Ministerial regulation;

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[65] Section 77 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[66] Section 77 *ter* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[67] Section 79 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[68] Section 79 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

(4)[69] drugs that have received permission to import or order into the Kingdom in accordance with the rules, procedure and conditions prescribed by the Minister with the approval of the Committee in the Government Gazette.

Section 80. The application for registration of a drug formula under section 79 shall detail 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 literature;

(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 competent official.

Section 82. An application for a drug formula registration or an amendment thereof, and the issuance 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.[70] The competent official shall be prohibited from registering a drug formula when the committee is of opinion that:

(1) the drug is that specified in section 72 (1) or (6);

(2) the application for registration of the drug formula is not in accordance with section 80 and section 82;

(3) the properties ascribed to the drug the formula of which is to be registered are incredible or the drug may be unsafe for use;

(4) the name used for the drug is exaggerated, impolite or may be misleading;

(5) the name used for the drug is 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 the competent official shall be final.

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[69] Section 79 *bis* (4) was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[70] Section 79 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 84. The provisions of section 83 shall apply *mutatis mutandis* to the amendment of particulars in the registration of drug formula.

Section 85.[71] A licensee to produce drugs or licensee to import or order drugs into the Kingdom must submit an annual report concerning the production or importation or order of drugs that the formula has been registered each formula in the form prescribed in the Ministerial Regulation within the 31st March of the following year.

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

Section 86.[72] 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 fake drug under section 72(1) or the drug has changed into a material intended for use as food or as cosmetics with permission to produce for sale of the specially controlled food or has received a certificate of registration of cosmetics under the relevant laws, the Minister shall, with the recommendation of the Committee, have power to order the cancellation of such drug formula registration. The cancellation shall be by notification in the Government Gazette.

The order of the Minister shall be final.

Section 86 *bis*.[73] For the purpose of safeguarding the welfare of the drugs users, the Minister shall, with the recommendation of the Committee, have power to order an amendment in the Registration of drug formula as deemed appropriate or necessary.

Section 87. In the case where a certificate of drug formula registration is lost or substantially damaged, the licensee shall notify the competent official of the same and file an application for a certificate substitute within fifteen days from the date of acknowledgement of such loss or damage.

An application for and the issuance 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:

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[71] Section 85 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[72] Section 86 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[73] Section 86 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

(1) not be exaggerated of its therapeutic properties or of its ingredients as being miraculously or completely capable of treating, mitigating, curing 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 mislead 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 mislead that it is an abortifacient or a strong emmenagogue;

(5) not mislead 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 treating, mitigating, curing or preventing disease or symptom thereof as notified by the Minister under section 77.

The provisions of (5) and (6) shall not apply to the statement on the label or accompanying literature of a drug, and those specified in (1), (4), (5), (6), (7) and (8) shall not apply to an advertisement directed to a practitioner of arts of healing, practitioner of medicine or a veterinary practitioner.[74]

Section 88 *bis.*[75] The advertisement to sell drugs through radio, amplifier, television, motion picture or film, or through printed matter must:

(1) receive permission for the statement, sound or picture used in the advertisement from the licensing authority; and

(2) comply with the conditions specified by the licensing authority.

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*.[76] The Secretary-General of the food and Drugs Administration shall have power to issue written orders to cease any advertisement deemed to be contrary to this act.

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[74] Section 88 paragraph two was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[75] Section 88 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[76] Section 90 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

CHAPTER XII
Competent Officials

Section 91.[77] In the performance of duties, a competent official shall have the following powers:

(1) to enter into the premises of production, sale, importation or ordering, or storage of drugs during working hours to inspect for the compliance with this act;

(2) to take reasonable quantities of drugs as samples for testing or analysis;

(3) in the case where there is a cause for suspicion that an offence under this Act has been committed, may enter any premises to inspect drugs and may size or attach drugs and tools and equipment concerned with such offence including drug containers or packages and documents concerning such drugs;

(4) to announce the results of test and analysis of the quality of the drugs texted 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 case where it appears to the competent official that any drug is not safe or might be harmful to drug users, the competent official shall have power to call that drug or to order the licensee to produce drugs, the licensee to sell drugs or the licensee to import or order drugs into the Kingdom recall their drugs within a period fixed by the competent official and shall have power to destroy the drugs in accordance with the rules, procedures as prescribed in the Ministerial Regulation.

In the performance of the duties of the competent official under paragraph one, the licensee and all persons concerned with the production, sale, or importation or order of drugs shall provide reasonable facilities to the competent official on the said premises.

Section 92. In the performance of duties, the competent official shall produce an identity card at the request of the persons concerned.

The identity card of the competent 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 appeared, or for which the public prosecutor has give a final non-prosecution order, or to which the court has not adjudged confiscation, and which is not claimed by its owner or possessor within ninety days from the

[77] Section 91 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

date of its seizure or the date of acknowledgement of the final order of non-prosecution or the date of the final judgment of the court, as the case may be, shall become the property of the Ministry of Public Health.

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

Section 94. In the execution of this act, the competent official shall be the official under the Penal Code.

CHAPTER XIII
Suspension and Revocation of Licences

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 shall, with the recommendation of the Committee, have 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 shall, with the recommendation of the Committee, have 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 an open and conspicuous place at the premises to produce or sell drugs, or import or order drugs into the Kingdom, and the licensee shall be deemed to have acknowledged 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 shall, with the recommendation of the Committee, have 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 acknowledgement of the

order. The Minister shall have the power to dismiss the appeal or to amend the order of the licensing authority in a way favorable 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 acknowledgement of the order of the revocation of the licence or the decision of the Minister, except where the licensing authority allows an extension for such period.

CHAPTER XIV
Penalties

Section 101. Any person who violates section 12 shall be liable to imprisonment for a term of not exceeding five years and to a fine not exceeding ten thousand baht.

Section 102.[78] Any licensee who violates section 19 or section 30 shall be liable to a fine from two thousand to five thousand baht.

Section 103.[79] Any licensee who fails to comply with section 20, section 21, section 22, section 23 and section 24 shall be liable to imprisonment of not exceeding three months or to a fine not exceeding five thousand baht or to both and to additional fine at a daily rate of five hundred baht until due compliance with legal requirements.

Section 104.[80] Any licensee who produces or sells drugs, or imports or orders drugs into the Kingdom after his licence has expired without having applied for renewal of the licence shall be liable to a fine at a daily rate of one hundred baht for each day the licence has expired.

Section 105.[81] 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 105 *bis*.[82] Any person who to comply with section 27 *bis* or section 59 *bis* shall be liable to a fine from two thousand to ten thousand baht.

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[78] Section 102 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[79] Section 103 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[80] Section 104 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[81] Section 105 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

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*.[83] Any licensee who fails to give notification to providing a substitute person to perform duty as prescribed in section 33 *bis* shall be liable to fine not exceeding 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.[84] 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.[85] 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 of not exceeding three years and to a fine not exceeding five thousand baht.

Section 112.[86] Any licensee who violates section 53 or section 62 shall be liable to a fine from one thousand to three thousand baht.

Section 113.[87] Any licensee who fails to comply with section 54, section 55 or section 56 shall be liable to imprisonment of not exceeding one month or to a fine not exceeding two thousand baht or to both and to additional fine at a daily rate of one hundred baht until due compliance with legal requirements.

Section 113 *bis*.[88] Any licensee who fails to comply with section 54 *bis* shall be liable to a fine not exceeding five thousand baht.

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.

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[82] Section 105 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[83] Section 107 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[84] Section 109 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[85] Section 110 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[86] Section 112 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[87] Section 113 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[88] Section 113 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

Section 114 *bis.*[89] Any licensee who fails to give notification to providing a substitute person to perform duty as prescribed in section 63 *bis* shall be liable to a fine of not exceeding five hundred baht.

Section 115. Any practitioner of traditional arts of healing 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.[90] Any practitioner of traditional arts of healing who violates section 71 shall be liable to a fine from five hundred to two thousand and five hundred baht.

Section 117. Any person who, in violation of section 72(1), produces a fake drug shall be liable to imprisonment for a term from three years to life and to a fine from ten thousand to fifty thousand baht.

In production of a fake drug as prescribed in section 73 (2) (3) or (4) which is in violation of section 72 (1), if the producer can prove that such fake drug is not harmful to the drug users, he or she shall be liable to imprisonment for a term of not exceeding five years and to a fine not exceeding twenty thousand baht.[91]

Section 118.[92] Any person who, in violation of section 72 (2) or (6), produces a sub-standard drug or a drug the formula registration of which the Minister has ordered revoked, shall be liable to imprisonment for a term form two to five years and to a fine from four thousand to twenty thousand baht.

Any person who, in violation of section 72 (5), produces a drug the formula registration of which is revoked, shall be liable to imprisonment of not exceeding two years and to a fine not exceeding 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 who commits an act under paragraph one has committed it without knowledge that the drug was fake, he or she shall be liable to a fine from one thousand to five thousand baht.

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[89] Section 114 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[90] Section 116 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[91] Section 117 paragraph two was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[92] Section 118 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

Section 120.[93] Any person who, in violation of section 72(2) or (6), sells or imports of orders into the Kingdom, a sub-standard drug or a drug the formula registration of which the Minister has ordered revoked, shall be liable to imprisonment for a term of not exceeding three years and to a fine not exceeding five thousand baht.

Any person who, in violation of section 72 (5), sells or imports or orders into the Kingdom a drug the formula registration of which is revoked, shall be liable to imprisonment of not exceeding one year and to a fine not exceeding ten thousand baht or to both.

If the person who commits an act under paragraph one and paragraph two has committed it without knowledge that the drug was a sub-standard drug or that its formula registration had been revoked by the Minister or that has been canceled, he or she 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 who commits an act under paragraph one has committed it without knowledge that the drug had deteriorated, he or she 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 of not exceeding three years or to a fine not exceeding five thousand baht, or to both.

Section 122 *bis.*[94] Any person who violates section 75 *bis* shall be liable to imprisonment for a term of not exceeding five years or to a fine not exceeding fifty thousand baht, or to both.

Section 123. Any licensee who fails to comply with section 79 shall be liable to imprisonment for a term of not exceeding three years or to a fine not exceeding five thousand baht, or to both.

Section 123 *bis.*[95] Any licensee who fails to comply with in section 83 paragraph one shall be liable to a fine from one thousand baht to five thousand baht and to additional fine at a daily rate of one hundred baht until due compliance with legal requirements.

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[93] Section 120 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[94] Section 113 *bis* was added by the Drugs Act (No. 5), B.E. 2530 (1987).

[95] Section 123 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

Section 123 *ter*.[96] Any licensee who submits a false annual report concerning the production of drugs or importation or order of drugs into the Kingdom as prescribed in section 85 paragraph one shall be liable to imprisonment of not exceeding three months or to a fine not exceeding five thousand baht, or to both.

Section 124.[97] Any person who advertises the sale of drugs in violation of section 88, section 88 *bis*, section 89 and section 90 shall be liable to a fine not exceeding one hundred thousand baht.

Section 124 *bis.*[98] Any person who violates the order suspending the advertisement for sale of drugs by the Secretary-General 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 to both, and to additional fine at a daily rate of five hundred baht until due compliance with the order.

Section 125.[99] Any person, who fails to give facility, obstructs a competent official in the performance of duties or fails to obey the order of the competent official under section 91, shall be liable to imprisonment not exceeding one month or a fine not exceeding one thousand baht, or to both.

Section 125 *bis*.[100] Any licensee who produces drugs, sells drugs or imports or orders drugs into the Kingdom while the licence to produce or sell drugs, or import or order drugs into the Kingdom, as the case may be, is suspended as prescribed in section 95 shall be liable to imprisonment of not exceeding five years and to 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*.[101] All the offences under this Act which are only punishable by a fine shall be settled by the Secretary-General of the Food and Drug Administration or the person entrusted by him or her.

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[96] Section 123 *ter* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[97] Section 124 was amended by the Drugs Act (No. 5), B.E. 2530 (1987).

[98] Section 124 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[99] Section 125 was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[100] Section 125 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

[101] Section 126 *bis* was added by the Drugs Act (No. 3), B.E. 2522 (1979).

In the case where the drug, the drug container or package, and document relating to the offence has been seized, the case may be settled by the Secretary-General of the Food and Drug Administration or the person entrusted by him or her only when the offender has consent that the seized objects shall become the property of the Ministry of Public Health.[102]

Transitory Provisions

Section 127. Any licence to operate drug selling business under the law on sales of drugs prior to the day this Act coming into force shall continue to be valid until the expiration thereof. The licensee who wishes to continue producing or selling drugs, or importing or ordering drugs into the Kingdom already filed an application under this Act shall continue the operation of business according to the existing licence until a new licence is issued or until the refusal notice by the licensing authority is received. If the new licence is issued, the licensee must take all actions to comply with the provisions of this Act within one hundred and twenty days from the date of issuance of the license.

If the licensee to operate drug selling business under paragraph one does not wish to continue his or her business or the application filed under this Act is refused by the licensing authority, he or she may sell his remaining drugs to another licensee or to a person deemed appropriate by the licensing authority within ninety days from the date the existing licence has expired or the date the refusal notice by the licensing authority is received, as the case may be, except where the licensing authority allows an extension for such period.

Section 128. The certificate of formula registration of drug issued under the law on sales of drugs prior to the day this Act coming into force shall be valid as follows:

(1) the certificate of formula registration of drug issued in B.E. 2505 and B.E. 2506 shall be valid until 31st December B.E. 2512;

(2) the certificate of formula registration of drug issued in B.E. 2507 and B.E. 2508 shall be valid until 31st December B.E. 2513;

(3) the certificate of formula registration of drug issued after B.E. 2508 shall be valid until 31st December B.E. 2514;

Section 129. All drugs produced, sold, or imported or ordered into the Kingdom legally under the law on sales of drugs prior to the day this Act coming into force, within three years from the date of coming into force of this Act, shall be exempted from

[102] Section 126 *bis* paragraph two was added by the Drugs Act (No. 5), B.E. 2530 (1987).

the compliance with provisions relating to labels as prescribed in section 25(3), section 26(5), section 27(3), section 57(2), section 58(2) and section 59(2) of this Act.

Countersigned by:
Field Marshal Thanom Kittikachorn
Prime Minister
Certified Correct Translation
(Mr. .....)
Secretary-General of the Council of State

Rates of Fees[103]

A. For Category of Modern Drugs:
(1) Modern drug producing licence 10,000 baht each
(2) Modern drug sale licence 3,000 baht each
(2 bis)[104] Modern drug wholesale licence 3,000 baht each
(3) Modern drug sale licence; only for ready-packed drugs which is not dangerous or specially controlled drugs 2,000 baht each
(4) Modern drug sale licence; only for ready-packed drugs which is veterinary drugs 2,000 baht each
(5) Modern drug import or order licence 20,000 baht each
(6) Testing or Analysing drugs formula of which to be registered 1,000 baht each
(7) Certificate of formula Registration of modern drugs 3,000 baht each
(8) Substitute licence 100 baht each
(9) Substitute certificate 100 baht each

B. For Category of Traditional Drugs:
(1) Traditional drug producing licence 5,000 baht each
(2) Traditional drug sale licence 1,500 baht each
(3) Traditional drug import or order licence 10,000 baht each
(4) Testing or Analysing drugs formula of which to be registered 500 baht each
(5) Certificate of formula Registration of modern drugs 1,500baht each
(6) Substitute licence 100 baht each
(7) Substitute certificate 100 baht each

[103] Rates of fees was amended by the Drugs Act (No. 3), B.E. 2522 (1979).

[104] Rate of fee in (2 *bis*) under A. For Category of Modern Drugs, was added by the Drugs Act (No. 5), B.E. 2530 (1987).

C. Other Applications:

(1) Renewal of the licence

Same rate to each type of licence

(2) Renewal of the certificate

Same rate to each type of certificate