Herbal Product Act
B.E. 2562 (2019)

His Majesty King Maha Vajiralongkorn Bodindradebayavarangkun

Given on the 26th of April B.E. 2562 (2019)

Being the fourth year of the present reign

His Majesty King Maha Vajiralongkorn Bodindradebayavarangkun is graciously pleased to proclaim that,

Whereas it is expedient to enact a law on herbal products,

This Act contains certain provisions in relation to the restriction of rights and liberty of persons, in respect of which section 26 in conjunction with section 33, section 34, section 37 and section 40 of the Constitution of the Kingdom of Thailand so permit by the virtue of law;

Whereas the rationale and necessity for the restriction of rights and liberty of persons under this Act are to ensure that the production, importation, or sale of herbal products meet standards, through the systems of licensing, product registration, notification, or listing; to ensure that herbal products will be safe and meet international standards; to substitute the importation of modern drugs and dietary supplements from abroad; and to enhance Thailand's competitiveness in international trade. The enactment of this Act is consistent with the conditions prescribed in section 26 of the Constitution of the Kingdom of Thailand.

Be it, therefore, enacted by the King, by and with the advice and consent of the National Legislative Assembly serving as the National Assembly, as follows:

Section 1 This Act is called the "Herbal Product Act, B.E. 2562 (2019)".

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

Section 3 The herbal products that have been implemented under this Act shall be exempted from compliance with the laws on drugs or the laws on food.

Section 4 In this Act,

"herb" means natural products derived from plants, animals, microorganisms or minerals that are used, mixed, compounded or processed into herbal products;

"herbal product" means:

(1) herbal drugs and shall also include Thai traditional drugs, developed herbal drugs, traditional drugs for use in humans under the law on drugs or drugs that are derived from the knowledge of alternative medicine as prescribed and notified by the Minister, upon the recommendation of the Committee, for the treatment, cure and relief of human illnesses or the prevention of diseases;

(2) products made from herbs or products of which active ingredients are herbs or are derived from herbs that are ready for use in humans to improve their health or the function of their body, strengthen the structure or the function of human body or reduce the risk factors of a disease;

(3) substances intended for use as ingredients in the production of herbal products;

(4) other substances prescribed and notified by the Minister upon the recommendation of the Committee as herbal products.

The provisions of (1), (2) or (3) shall not include the followings:

(a) substances intended for use in agriculture, industry or other activities as prescribed and notified by the Minister upon the recommendation of the Committee;

(b) substances classified as modern drugs, traditional drugs for use in animals, foods for humans or animals, sport devices, instruments or devices for health promotion, cosmetics, medical devices, psychotropic substances, narcotics, hazardous

substances, or any other substances as prescribed and notified by the Minister upon the recommendation of the Committee;

"Thai traditional drug" means a drug derived directly from herbs or from the mixing, compounding, or processing of herbs, which are intended for use, based on the Thai Traditional medicine knowledge or the drugs prescribed and notified by the Minister, as Thai traditional drugs.

"developed herbal drug" means a drug derived directly from herbs or from the mixing, compounding or processing of herbs, which is not a Thai traditional drug or drugs that are derived from the knowledge of alternative medicine;

"Thai traditional medicine" means the medical procedures relating to the examination, diagnosis, treatment, cure, or prevention of diseases, or the promotion and rehabilitation of human health, midwifery, traditional Thai massage, and shall also include the preparation or production of Thai traditional drugs, based on the knowledge or treatises that have been passed down and developed from generation to generation.

"active ingredient" means material which is an important component of an herbal product or a substance in an herbal product used for the treatment, cure and relief of human illness or for the prevention of disease, health promotion and body nourishment nutrition or the reduction of risk factors of a disease.

"strength of active ingredient" means:

(1) the concentration of an herbal product which has the quantity of active ingredients stated as weight per weight, weight per volume or quantity of active ingredients per dosage;

(2) the expression of activity or therapeutic effect of an herbal product that has been laboratory tested based on a standard method or a method that has been sufficiently and effectively used.

"formula" means a formula which specifies the components of ingredients which contain herbs, regardless of the form, and shall include an herbal product in a processed pharmaceutical form which is ready for use in humans;

"produce" means to manufacture, mix, compound, or process herbal product and shall also include to change the form, apportion, and to repack from its original container or package for sale;

"import" means to bring or order a product into the Kingdom;

"sell" means to trade, distribute, give away or barter for commercial purpose and shall include to have in possession for sale;

"label" means any statement which is displayed on herbal product containers or packages;

"package insert" means a piece of paper or any material that conveys a meaning through the use of any statement about a product that has been inserted, included or displayed on herbal product containers or packages;

"statement" means any act with the use of letters, images, artificial marks, pictures, motion pictures, light, sound, marks or any other activities to have the general public understand the intended meaning;

"advertise" means any activity, undertaken by any means, to have the public see, hear or acknowledge a statement for commercial purpose, and shall include sales promotion activities;

"sales promotion" means the provision of information, the persuasion or any activity, undertaken by any means, with the intention of increasing herbal product use and activity for commercial purpose;

"herbal product consideration process" means the consideration of applications, verification of documents, evaluation of technical documents, testing and analysis, inspection of places of the production, importation, sale, or storage of herbal products, or inspection for the issuance of licence, certificate of product registration, notification receipt, or listing receipt, and any other consideration on the matter of herbal products.

"medical and healthcare professional" means a medical practitioner, pharmacy practitioner, Thai traditional medicine practitioner, applied Thai traditional medicine practitioner or any other type of medical and healthcare professionals as prescribed and notified by the Minister;

"licensee" means a person who is granted a licence under this Act; in the case where the licensee is a juristic person, it shall also include a representative or a person authorized by the juristic person to act on his or her behalf;

"person on duty" means a person whose name appears on a licence as the person who is licensed to perform the duties under this Ac;

"licensing authority" means:

(1) the Secretary-General of the Food and Drug Administration or a person entrusted by the Secretary-General for the licensing of the production or the importation of herbal products and the issuance of a certificate of product registration, notification receipt, listing receipt and for the licensing of herbal product advertisement;

(2) the Secretary-General of the Food and Drug Administration or a person entrusted by the Secretary-General for the licensing of the sale of herbal products in Bangkok;

(3) a Provincial Governor or a person entrusted by the Governor for the licensing of the sale of herbal products in the province within the Governor's territorial jurisdiction, except Bangkok;

"Policy Committee" means the National Herbal Policy Committee;

"Committee" means the Herbal Product Committee

"competent official" means a person appointed by the Minister for the implementation of this Act;

"Secretary-General" means the Secretary-General of the Food and Drug Administration

"Director-General" means the Director-General of the Department of Thai Traditional and Alternative Medicine

"Minister" means the Minister having charge and control of the 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 officials, issue the Ministerial Regulations prescribing fees not exceeding the rates of fees in the addendum to this Act, grant a reduction or exemption of fees, determine other operations and issue notifications for the execution of this Act.

In issuing the Ministerial Regulations prescribing the rates of fees under paragraph one, the Minister may prescribe different rates of fees, taking into account the categories, types or characteristics of herbal products as well as the sizes and types of the business operations.

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

Section 6 The Minister, upon the recommendation of the Committee, shall have the power to prescribe and issue notifications on the following subjects:

(1) name, category, type or characteristics of herbal products whose production or importation for sale require a licence;

(2) name, category, type or characteristics of herbal products whose production or importation for sale requires a certificate of herbal product formula registration;

(3) name, category, type or characteristics of herbal products whose production or importation for sale requires a notification receipt or a listing receipt;

(4) name, category, type or characteristics of herbal products whose production, importation or sale are prohibited;

(5) List of the National Thai Traditional Medicine Formulary, the Herbal Product Pharmacopoeia, the Thai Herbal Preparation Pharmacopoeia, the Thai Herbal Pharmacopoeia, and other pharmacopoeias related to herbal products.

(6) name of materials classified as herbal products, and name of the materials prohibited for use as ingredients in herbal products;

(7) name, quantity and condition of the materials that may be used as ingredients in herbal products for the herbal products applying for product listing;

(8) name, quantity and condition of materials with specific requirements or restrictions for use as ingredients in herbal products;

(9) name, category, type or characteristics of herbal products with controlled label and package insert;

(10) criteria, procedures and conditions for the production, importation, sale, and storage of herbal products, including the properties of the places for the production, importation, sale, and storage of herbal products, and necessary equipment to promote and support the potential of business operators as well as the quality and safety of herbal products that may affect consumers;

(11) criteria, procedures and conditions for the notification, licensing and for the production or importation of herbal products to be used as herbal product samples for the application for product registration, research, analysis, exhibition or donation purposes;

(12) criteria and procedures for herbal product disposal;

(13) qualifications, numbers, criteria, procedures and conditions for the operation of the persons on duty at the places of herbal product production, importation, sale and storage;

(14) the diseases that are prescribed as the prohibited characteristics of a licensee and a person on duty;

(15) any place in the Kingdom designated as an import inspection checkpoint of herbal products;

(16) duties that a licensee or a person on duty are required to perform under section 28, section 29, section 30, section 31, section 32 and section 33, as the case may be, for consumer protection purpose;

(17) required items for an application for the registration, notification and listing of herbal products;

(18) criteria, procedures and conditions for herbal product consideration process, including the maximum rates of fees and charges to be collected from the applicants;

(19) criteria, procedures and conditions for the registration, the maximum rates of registration fees, and registration fees to be collected from experts, expert organisations, state agencies or both domestic and international private agencies;

(20) standard criteria, purity indicators or other characteristics essential for product quality and the deviation limit indicated for herbal product that are registered, notified or listed;

(21) criteria, procedures and conditions for herbal product advertisement.

CHAPTER 1
The National Herbal Policy Committee

Section 7 There shall be a committee called the "National Herbal Policy Committee" consisting of:

(1) the Prime Minister or the Deputy Prime Minister assigned by the Prime Minister as Chairperson;

(2) the Minister of Public Health as the first Deputy Chairperson and the Minister of Agriculture and Cooperatives as the second Deputy Chairperson;

(3) twenty-one ex-officio members, namely, the Permanent Secretary of Finance, Permanent Secretary of Tourism and Sports, Permanent Secretary of Agriculture and Cooperatives, Permanent Secretary of Natural Resources and Environment, Permanent Secretary of Commerce, Permanent Secretary of Interior, Permanent Secretary of Science and Technology, Permanent Secretary of Education, Permanent Secretary of Public Health, Permanent Secretary of Industry, Secretary-General of the Council of State, Director-General of the Department of Medical Sciences, Secretary-General of the National Research Council of Thailand,

Secretary-General of the Food and Drug Administration, Director of the Health Systems Research Institute, President of the National Science and Technology Development Agency, President of the Medical Council of Thailand, President of the Thai Traditional Medical Council, President of the Pharmacy Council of Thailand, Chairman of the Federation of Thai Industries, Chairman of the Thai Chamber of Commerce;

(4) three qualified members appointed by the Minister from representatives of the state institutions of higher education and private institutions of higher education under the law on private institution of higher education providing education in the academic fields of pharmacy, Thai traditional medicine or applied Thai traditional medicine. The representatives shall select among themselves one member from each field;

(5) nine qualified members who are appointed by the Minister from persons with the knowledge, expertise and experiences in the fields of law, trade and investment, consumer protection, Thai traditional medicine, agriculture and plant variety, research and development, environment, herbs and industry, with one member from each field.

The Director-General shall be member and secretary of the Policy Committee and the Deputy Director-General assigned by the Director-General of the Department of Thai Traditional and Alternative Medicine, the Deputy Director-General assigned by the Director-General of the Department of Agricultural Extension, and the Deputy Secretary-General assigned by the Secretary-General of the Food and Drug Administration shall be assistant secretaries.

The selection and appointment of the committee members under (4) and (5) shall be in accordance with the criteria, procedures and conditions prescribed and notified by the Minister.

Section 8 The qualified members under section 7 (4) and (5) shall hold office for a term of three years from the date of their appointment. A qualified member who vacates office may be re-elected or re-appointed but he or she shall not hold office for more than two consecutive terms.

Upon the expiration of the term of office under paragraph one, if a new member has not yet been selected or appointed, the vacating member shall remain in office to perform his or her duties until a newly selected or appointed member takes up the office.

In the case where a committee member under paragraph one vacates office before the expiration of the term, there shall be a selection of a representative under section 7(4) and an appointment of a member under section 7(5), and the selected and

appointed member shall hold office for the remaining period of the term of office of the member whom he or she replaces, unless the remaining term under section 7 (4) or (5) is less than 90 days, such procedures to have a replacement may not be conducted. In such case, the Policy Committee shall consist of the remaining members.

Section 9 Apart from vacating office upon the expiration of the term, the members under section 7 (4) and (5) shall vacate office upon:

(1) death;

(2) resignation;

(3) being a bankrupt;

(4) being an incompetent or quasi-incompetent person;

(5) being removed from office by the Minister for negligence or dishonesty in the performance of duties, disgraceful behavior or incapability;

(6) having been sentenced to imprisonment by a final judgment, except for offences committed by negligence or petty offences;

(7) having a licence to practice the art of healing or a professional licence for practitioner suspended or revoked.

Section 10 The Policy Committee shall have the following duties and powers:

(1) to formulate the national herbal product policies and strategic plans every five years for submission to the Cabinet for consideration;

(2) to submit opinions or recommendations to the Cabinet on budgetary issues or other matters related to the policies and strategic plans under (1);

(3) to monitor and evaluate the performance of relevant agencies to ensure their compliance with the policies and strategic plans under (1), and to set up the criteria and procedures of performance report;

(4) to promote and support the Policy Committee performance in accordance with this Act;

(5) to determine preventive measures and solutions to problems of herbal products as well as to propose amendment or revision of the laws related to herbal products;

(6) to set up work plans or research projects for a comprehensive development of herbal product system;

(7) to formulate measures to promote herbal product cooperation between the public and private sectors;

(8) to determine the types of business operators and propose promotion rights and privileges for herbal product operators to the Minister or relevant agencies;

(9) to determine the criteria, procedures and conditions for the notification and promotion of operators under this Act, including measures for the promotion of herbal production as raw materials in the production of herbal products under the agricultural safety approach;

(10) to submit annual reports to the Cabinet;

(11) to perform any other tasks as prescribed by the law to be the duties and powers of the Policy Committee or as assigned by the Prime Minister or the Cabinet.

Section 11 At a meeting of the Policy Committee, the presence of no less than one-half of the total number of committee members is required to constitute a quorum.

At a meeting of the Policy Committee, if the Chairperson is not present or is unable to perform required duties, the first Deputy Chairperson shall preside over the meeting. If the first Deputy Chairperson is not present or is unable to perform required duties, the second Deputy Chairperson shall preside over the meeting. If the Chairperson and both Deputy Chairpersons are not present or are unable to perform their duties, the meeting shall choose one member to preside over the meeting.

The decision of a meeting shall be by a majority of votes and one member shall have one vote each. In case of an equality of votes, the person presiding over the meeting shall have an additional vote as the casting vote. The Policy Committee shall meet at least twice a year.

Section 12 The Policy Committee may appoint a subcommittee to consider or perform any task as assigned by the Policy Committee.

The provisions of section 11 shall apply, *mutatis mutandis*, to the meetings of subcommittees.

CHAPTER 2
The Herbal Product Committee

Section 13 There shall be a committee called the "Herbal Product Committee" consisting of:

(1) the Permanent Secretary of Public Health as Chairperson;

(2) fourteen ex-officio committee members, namely, the Director-General of the Department of Thai Traditional and Alternative medicine; Director-General of the Department of Disease Control, Director-General of the Royal Forest Department, Director-General of the Department of Agriculture, Director-General of the Department of Medical Sciences, Director-General of the Department of Agricultural Extension, Director-General of the Department of Health Service Support, Secretary-General of the National Research Council of Thailand, Secretary-General of the Food and Drug Administration, Secretary-General of the National Bureau of Agricultural Commodity and Food Standards, and one representative each from the Medical Council of Thailand, the Thai Traditional Medical Council, the Pharmacy Council of Thailand, and the Federation of Thai Industries with the knowledge, expertise and experiences in the field of herb as Committee members.

(3) six qualified members who are appointed by the Minister from persons with the knowledge, expertise and experiences in the fields of law, consumer protection, Thai traditional medicine, science, food science or food chemistry, herb and environment. There shall be one qualified member from each of these fields.

A Deputy Secretary-General entrusted by the Secretary-General of the Food and Drug Administration shall be member and secretary and a representative of the Department of Thai Traditional and Alternative Medicine and a representative of the Food and Drug Administration shall be assistant secretaries.

Appointment of the members under (3) shall be in accordance with the criteria, procedures and conditions prescribed and notified by the Minister.

Section 14 For the term of office and the vacating of office of the members under section 13 (3) as well as the meetings of the Committee, the provisions of section 8, section 9, and section 11 shall apply, *mutatis mutandis*.

Section 15 The Committee shall have the following duties and powers:

(1) to submit recommendations to the Minister on the issuance of the notifications under section 6;

(2) to submit recommendations to the Policy Committee on the herbal product policies;

(3) to submit recommendations, opinions or approvals to the licensing authority regarding permission to produce, import, sell, register, notify and list herbal products, suspend and revoke a licence suspension or licence revocation order;

(4) to prescribe and notify the criteria and methods for the conducting of researches on a comprehensive development of herbal product system under the work plans or research projects specified in section 10 (6);

(5) to prescribe and notify the criteria, procedures and conditions for the inspection of places of herbal product production, importation, sale and storage, including the display of premise signages and licences of a licensee and a person on duty;

(6) to prescribe and notify the criteria, procedures and conditions for the preparation of a list of raw materials used in the production of herbal products and records of the production, importation and sale of herbal products;

(7) to prescribe and notify the criteria, procedures and conditions for a display of herbal product name for the application of product registration, notification or listing as well as the display of herbal product labels and package inserts;

(8) to prescribe and notify the criteria and methods for the stating of health benefit, instruction for use, quality and safety of herbal products;

(9) to prescribe and notify the quality control methods and specifications of herbal products;

(10) to prescribe and notify the criteria, procedures and conditions for the issuance of certificate of free sale or the registration of herbal product formula ;

(11) to prescribe and notify the criteria, procedures and conditions for the monitoring, vigilance, evaluation and reporting of adverse effects resulting from the use of herbal products;

(12) to prescribe and notify the criteria, procedures and conditions for the issuance of certificate of analysis of herbal products;

(13) to approve the licensing authority's orders to reject application for herbal product registration, to refuse the amendment of particulars in an herbal product dossier, to refuse the renewal of an herbal product registration licence, and approve the amendment of particulars in an herbal product dossier in order to safeguard consumer safety, to monitor herbal product safety and to revoke herbal product registration licence;

(14) to prescribe and notify the criteria, procedures and conditions for the issuance of fines under this Act;

(15) to perform any other tasks as prescribed by the law to be the duties and powers of the Committee or as assigned by the Prime Minister, the Cabinet, the Policy Committee or the Minister.

The notifications under paragraph one shall come into force upon their publication in the Government Gazette.

Section 16 The Committee may appoint a subcommittee or a working group to consider or perform any task as assigned by the Committee.

The provisions of section 11 shall apply, *mutatis mutandis*, to the meetings of subcommittees and working groups.

CHAPTER 3

Application for and Issuance of licences

Section 17 Any person who wishes to engage in the production, importation or sale of the herbal products notified by the Minister under section 6 (1) shall apply for a licence and when the licensing authority has issued a licence, such person shall then be able to produce, import or sell herbal products.

Application for and issuance of licences under paragraph One shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 18 The provisions of section 17 shall not apply to:

(1) the production, importation or sale of herbal products by ministries, bureaus, departments or public institutions of higher education for the studies in the fields of pharmacy, Thai traditional medicine or applied Thai traditional medicine, or other public bodies which have a duty to prevent or treat of diseases as prescribed and notified by the Minister and the Thai Red Cross Society;

(2) the compounding of a Thai traditional medicine preparation for a particular patient by a Thai traditional medicine practitioner, an applied Thai traditional medicine practitioner, or a folk healer certified under the law on the Thai traditional medical profession. The compounding of drug, based on alternative medicine knowledge, for a particular patient shall be in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(3) the repacking of herbal products for use by a particular patient by medical and healthcare professionals or folk healers certified under the law on the Thai traditional medical profession;

(4) the sale of herbal products or herbal products repacked under (3) for use by a particular patient by medical and healthcare professionals or folk healers certified under the law on the Thai traditional medical profession;

(5) retailers who sell the materials used as ingredients for the production of herbal products as prescribed by the Secretary-General and notified in the Government Gazette;

(6) the importation of herbal products for personal use at the amount necessary for use for no longer than ninety days;

(7) the production, importation or sale of herbal products as prescribed and notified by the Minister for the benefit of the prevention or solving of domestic and international health problems;

(8) the sale of herbal products at the places of drug sales under the law on drugs.

A person who has been granted an exemption under (1), (2), (3), (4), (5), (6) or (7) must comply with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee.

Section 19 The licensing authority shall issue a licence for the production, importation or sale of herbal products when it appears that the applicant has the required qualifications and none of the prohibited characteristics as follows:

(1) being a business owner who wishes to apply for a licence;

(2) being no less than 20 years of age;

(3) has a residence in Thailand;

(4) has a place for the production, importation sale or storage of herbal products and has necessary equipment for such activities as prescribed and notified by the Minister upon the recommendation of the Committee;

(5) has a person on duty who is not afflicted with any of the diseases prescribed and notified by the Minister upon the recommendation of the Committee;

(6) not being a bankrupt;

(7) not being a person of unsound mind, an incompetent or quasi-incompetent person;

(8) not being afflicted with any of the diseases prescribed and notified by the Minister upon the recommendation of the Committee;

(9) has never been sentenced to imprisonment by a final judgement, except for offences committed through negligence or petty offenses, or the applicant has been released for no less than five years prior to the date of licence application;

(10) has never had a licence to produce, import or sell of herbal products under this Act revoked within a period of two years prior to the date of licence application;

(11) does not use the same or similar trade name to the one used by a licensee whose licence has been suspended or revoked for less than two years;

An applicant and a person on duty may be the same person.

In the case where an applicant is a juristic person, the representative of the juristic person or the person authorized by the juristic person to act on his or her behalf must have the qualifications specified in (2) and (3) and none of the prohibited characteristics specified in (6), (7), (8), (9) or (10).

Section 20 Herbal product licences can be classified as follows:

(1) licence to produce herbal products;

(2) licence to import herbal products;

(3) licence to sell herbal products.

The licensees under (1) or (2) shall also be deemed the licensees for the sale of the herbal products they produce or import.

Section 21 A licensee who wishes to amend the particulars of his or her licence shall file an application to the licensing authority, except for a temporary relocation or change of places for the importation, sale or storage of herbal products due to an urgent need that makes prior application for permission inexecutable.

Application for and issuance of permission to amend the particulars in a licence and to relocate or change the places under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 22 Licenses under section 20 shall be valid for a period of five years from the date of issue.

Section 23 A licensee who wishes to renew a licence shall file an application to the licensing authority before its expiration date.

A licensee whose licence has expired for no longer than one month may file an application for a renewal and for an exemption, stating a sound reason for failing to file the renewal application within the prescribed period. However, an application for exemption shall not cause the licensee to be acquitted under section 94. In the case where more than one month has passed since the expiration date of the licence, the licence shall not be renewed.

Upon filing an application under paragraph one and payment of the licence renewal fees, the licence shall continue to be valid until a refusal order for licence renewal is issued.

Application for licence renewal and permission for licence renewal under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

In the case where a refusal order for licence renewal is issued, the licensing authority shall notify the licensee and refund the renewal fees proportionately, by calculating on a monthly basis from the date issue of the refusal order until the expiration date of the five-year period. If the licence is granted a renewal, the fraction of one month that is fifteen days or more shall be counted as one month.

Section 24 In the case where a licence is lost, destroyed or substantially damaged, the licensee shall file an application for a substitute licence within fifteen days of the date that such loss, destruction or substantial damage is known.

Application for and issuance of a substitute licence under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

CHAPTER 4
Duties of Licensees and Persons on Duty

Section 25 A licensee must supervise and ensure that the persons on duty shall perform the duties prescribed in this Act.

Section 26 A licensee, who wishes to conduct business during the period when a person on duty is temporarily unable to perform the duties, must notify the licensing authority about such inability of the person on duty, and the licensee must arrange to have a person with the same qualifications as the person on duty perform the duties on behalf of the person on duty.

The person who performs the duties instead of the person on duty under paragraph one shall have the same duties and responsibilities as the person on duty

whom he or she substitutes for, and shall perform the duties for no longer than ninety days from the initial date of substitution. The licensee must notify the licensing authority within three days from the initial date of substitution.

The required notification under paragraph one and paragraph two shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

Section 27 In the case where a person on duty does not wish to continue performing the duties, the person on duty shall notify the licensing authority in writing no less than seven days prior to the date that he or she shall stop performing the duty. Such person shall be released from said duties and responsibilities from that day onward.

Section 28 Licensees shall have the following duties:

(1) arrange to have the person(s) on duty, with the qualifications and at the number prescribed and notified by the Minister under section 6 (13), upon the recommendation of the Committee and not having been afflicted with the disease specified in section 6 (14), to perform the duties throughout the specified period of working hours;

(2) arrange to have the herbal products produced, imported, sold and stored in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(3) arrange to have the herbal products produced, imported, sold and stored at the places specified in the licence;

(4) arrange to have a sign showing that it is the places for the production, importation or sale of herbal products and the licences of the licensees and the persons on duty on display in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(5) arrange to have a list of raw materials used in the production of herbal products and records of the production, importation or sale of herbal products prepared in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(6) arrange to have the samples of produced or imported herbal products collected and stored in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

Section 29 Licensees with a licence to produce or import herbal products shall have the following duties:

(1) in case of production, the licensee must arrange to have the quality inspection of raw materials and herbal products produced or have evidence showing details of the inspection before moving the herbal products out of the place of

production, in accordance with the criteria, procedures and conditions prescribed and notified by the Secretary-General upon the recommendation of the Committee and

notified in the Government Gazette. Such evidences shall be kept for no less than five years;

(2) in case of importation, the licensee must arrange to have a certificate of analysis of herbal products and keep such certificate for no less than five years, and to have the products passed the inspection at an inspection checkpoint of imported herbal products as prescribed and notified by the Minister upon the recommendation of the Committee;

(3) arrange to have herbal product labels and package inserts as permitted in the licence. In this regard, a display of such labels and package inserts shall be in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(4) perform any other duty as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 30 Licensees with a licence to sell herbal products shall have the following duties:

(1) arrange to keep herbal products properly separated according to their categories;

(2) ensure availability of herbal product labels and package inserts provided by the licensees with the licensces to produce or import;

(3) perform any other duty as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 31 The persons on duty at the places [ให้ตรงกับข้ออื่น ๆ] of herbal product production shall have the following duties:

(1) to be on duty at the place of production provided by the licensee under section 28 (3);

(2) produce herbal products according to the formula registered under section 34 or notified or listed under section 45;

(3) produce herbal products in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(4) ensure that the display of herbal product labels and package inserts is in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(5) perform any other duty as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 32 The persons on duty at the place of herbal product importation shall have the following duties:

(1) to be on duty at the place for the storage or importation of herbal products provided by the licensee under section 28 (3);

(2) handle imported herbal products in accordance with this Act;

(3) handle the importation of herbal products in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(4) ensure that the storage and disbursement of herbal products is in compliance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(5) perform the duty to ensure that the provision of herbal product labels and package inserts are complete and accurate before sale;

(6) perform any other duty as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 33 The persons on duty at the place of herbal product sale shall have the following duties:

(1) to be on duty at the place of storage or sale of herbal products provided by licensees under section 28 (3);

(2) store and keep herbal products properly separated in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(3) sell herbal products in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(4) perform any other duty as prescribed and notified by the Minister upon the recommendation of the Committee.

CHAPTER 5
Registration of Herbal Products

Section 34 Any person, who wishes to produce or import for sale of the herbal products notified by the Minister under section 6 (2), shall first file application for the registration of herbal product to the licensing authority, and upon receiving a certificate of product registration, the licensee can then produce or import such herbal product for sale.

Applicants for product registration under paragraph one must have the qualifications specified in section 19 (2) and (3) and none of the prohibited characteristics specified in section 19 (6), (7), (8) or (9).

In the case where an applicant is a juristic person, the representative of the juristic person or the person authorized to act on behalf of the juristic person must have the required qualifications and none of the prohibited characteristics under paragraph two.

Application for herbal product registration and issuance of a certificate of product registration under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 35 The provisions of section 34 shall not apply to:

(1) samples of an herbal product to be produced or imported for the application of product registration;

(2) herbal products to be produced or imported for research, analysis, exhibition or donation purposes;

(3) the materials used as a composition in the production of an herbal product;

(4) the production or importation of an herbal products for the treatment of a particular patient as prescribed and notified by the Minister upon the recommendation of the Committee.

In case of the production or importation of herbal product samples under (1) or the production or importation of herbal products for the specified purposes in (2), the manufacturers or importers shall notify the licensing authority in writing. In this regard, such notification and the production or importation must be in accordance with the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee.

Section 36 The application for product registration under section 34 requires the following particulars:

(1) herbal product name given in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(2) name and address of the registration applicant;

(3) herbal product formula;

(4) health benefit of the herbal product;

(5) documents or evidences of the health benefit, instruction for use, quality, and safety of the herbal product;

(6) details of the containers and content sizes;

(7) quality control method and specifications of the herbal product as prescribed and notified by the Committee;

(8) a certificate of free sale or a certificate of product registration, for imported herbal products only, which is issued in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(9) herbal product label;

(10) herbal product package insert;

(11) other particulars as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 37 The licensing authority, with the approval of the Committee, shall have the power to issue a refusal order of the application for product registration when it deems that:

(1) the particulars submitted for product registration do not comply with the provisions of section 36;

(2) the herbal product applied for registration is the herbal product of which its certificate of product registration was previously revoked;

(3) the herbal product applied for registration contains a material which is technically unsuitable as an ingredient, has unreliable health benefit, or is probably unsafe for consumers;

(4) the name of the herbal product applied for registration is boastful, impolite, inappropriately against good culture or possibly misleading.

Section 38 Holders of a certificate of product registration, who wish to amend particulars in the product registration document, shall file an application to the licensing authority.

Application for amendment and permission of amendment application of particulars in the product registration document under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

The consideration for the approval of the amendment of a product registration document shall comply with the provisions of section 37, *mutatis mutandis*.

Section 39 Certificates of product registration shall be valid for five years from the date of issue.

Section 40 Holders of a certificate of product registration, who wish to renew the certificate, shall file an application to the licensing authority before the expiration date of the certificate.

Holders of a certificate of product registration that has expired no longer than one month may file an application for renewal and for extension, stating a sound reason for failing to file the application for renewal within the prescribed period. However, an application for exemption shall not cause the certificate holder to be acquitted under section 94. In the case where more than one month has passed since the expiration date of the certificate of product registration, the certificate shall not be renewed.

Upon filing an application under paragraph one and payment of the renewal fees, the certificate of product registration shall continue to be valid until a refusal order for the renewal of a certificate of product registration is issued.

Application for renewal and permission for the renewal of a certificate of product registration under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

In the case where a refusal order for the renewal of a certificate of product registration is issued, the licensing authority shall notify the certificate holder and refund the renewal fees proportionately, by calculating on a monthly basis from the date of issue of the refusal order until the expiration date of the five-year period. If the certificate of product registration is granted a renewal, the fraction of one month that is fifteen days or more shall be counted as one month.

Section 41 In the case where a certificate of product registration is lost, ก estroyed or substantially damaged, the holder of the certificate of product registration shall file an application for a duplicate copy of the certificate within fifteen days of the date that such loss, destruction or substantial damage is known.

Application for and issuance of a substitute certificate of product registration under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 42 To safeguard consumer safety, the licensing authority, with the approval of the Committee, shall have the power to issue an order in writing to the holder of the certificate of product registration to amend the particulars in the product registration document or to monitor the safety of the herbal product, as prescribed in the said order.

Section 43 The licensing authority, with the approval of the Committee, shall have the power to revoke a certificate of product registration by informing the holder of the certificate of product registration and publish such revocation in the Government Gazette when it is appears that:

(1) an herbal product has been altered into an object intended for use as a medical device, cosmetic, drug, narcotic, psychotropic substance, hazardous substance or food;

(2) the advertisement of an herbal product is a violation of the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(3) the herbal product does not have the health benefit as stated in the product registration document, is not safe for the consumers, or is a fake herbal product under section 59;

(4) the holder of a certificate of product registration lacks the required qualifications or has any of the prohibited characteristics under section 34, paragraphs two or paragraph three;

(5) the holder of a certificate of product registration fails to make an amendment of the particulars in the product registration document or fails to monitor the safety of herbal product as ordered by the licensing authority under section 42.

Section 44 A refusal order for product registration, a disapproval order for the amendment of particulars in the product registration document, a disapproval order for the renewal of the certificate of product registration, or the orders to amend particulars in the product registration document, to monitor herbal product safety or to revoke a certificate of product registration shall be final.

CHAPTER 6
Notification and Listing of Herbal Products

Section 45 Any person, who wishes to produce or import for sale an herbal product notified by the Minister under section 6 (3), shall first file application for the notification or listing of an herbal product to the licensing authority, and after the herbal product notification receipt or herbal product listing receipt is granted, such herbal product can then be produced or imported for sale.

Applicants for herbal product notification or herbal product listing under paragraph one must have the qualifications under section 19 (2) and (3) and none of the prohibited characteristics under section 19 (6), (7), (8) or (9).

In the case where an applicant for herbal product notification or listing is a juristic person, the representative of the juristic person or the person authorized to act on behalf of the juristic person must also have the required qualifications and none of the prohibited characteristics under paragraph two.

The notification and the issuance of herbal product notification receipt, the listing and the issuance of herbal product listing receipt under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 46 Herbal product notification or listing under section 45 shall comply with the provision of section 35, *mutatis mutandis*.

Section 47 The notification or listing of an herbal product under section 45 requires the following particulars:

(1) name of a notified or listed herbal product shall be in accordance with the criteria, procedures and conditions prescribed by the Committee;

(2) name and address of the applicant for product notification or listing;

(3) herbal product formula;

(4) details of the herbal product containers and content sizes;

(5) certificate of analysis of the herbal product in accordance with the criteria, procedures and conditions prescribed and notified by the Committee;

(6) herbal product label;

(7) herbal product package insert;

(8) other particulars as prescribed and notified by the Minister upon the recommendation of the Committee.

Section 48 The application for product notification, the application for product listing, the amendment of product notification document, the amendment of product listing document shall comply with the provisions of section 37 and section 38, *mutatis mutandis*.

Section 49 The receipt of product notification or the receipt of product listing shall be valid for five years from the date of issue.

The renewal of a notification receipt or listing receipt shall comply with the provisions of section 40, *mutatis mutandis*.

Section 50 In the case where a notification receipt or a listing receipt is lost, destroyed or substantially damaged, the holder of the notification receipt or a listing receipt shall file an application for a duplicate copy of the notification receipt or a listing receipt within fifteen days of the date that such loss, destruction or substantial damage is known.

Application for and issuance of a duplicate copy of notification receipt or listing receipt under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 51 To safeguard consumer safety, the licensing authority, with the approval of the Committee, shall have the power to issue an order in writing to the holder of a notification receipt or a listing receipt to amend the particulars in the product notification document or product listing document, or to monitor the safety of an herbal product as prescribed in the said order.

Section 52 The licensing authority, with the approval of the Committee, shall have the power to revoke a notification receipt or a listing receipt by informing the holder of said notification receipt or listing receipt and published such revocation in the Government Gazette when it appears that:

(1) an herbal product has been altered into an object intended for use as a medical device, cosmetic, drug, narcotic, psychotropic substance, hazardous substance or food;

(2) the advertisement of an herbal product is a violation of the criteria, procedures and conditions prescribed and notified by the Minister upon the recommendation of the Committee;

(3) an herbal product is not safe for consumers;

(4) the holder of a notification receipt or a listing receipt of an herbal product lacks the required qualifications or have any of the prohibited characteristics under section 45, paragraphs two or paragraph three;

(5) the holder of a notification receipt or a listing receipt of an herbal product fails to amend the particulars in the product notification document or product listing document or fail to monitor the safety of an herbal product as ordered by the licensing authority under section 51.

Section 53 A refusal order for product notification of for product listing, a disapproval order for the amendment of particulars in product notification or listing document, a disapproval order for the renewal of a notification or listing receipt, or the orders to amend particulars in product notification document or listing document, to monitor herbal product safety or to revoke a notification receipt or a listing receipt shall be final.

CHAPTER 7
Herbal Product Consideration Process

Section 54 In the herbal product consideration process, the following officials, persons, organizations or agencies shall have the duties of herbal product evaluation, inspection and consideration:

(1) officials of the Food and Drug Administration who are assigned by the Secretary-General;

(2) officials of an agency under the Ministry of Public Heath who are assigned by the Minister or by a person assigned by the Minister;

(3) experts, expert organizations, state agencies or private organizations both in and out of the country, who are registered with the Thai Food and Drug Administration and assigned by the Secretary-General to perform said duties;

In the case of herbal products that are Thai traditional drugs, only the experts, expert organizations, state agencies or private organizations in Thailand who are registered with the Thai Food and Drug Administration and assigned by the Secretary-General shall perform such duties.

Section 55 For the benefit of the herbal product consideration process, the Minister, upon the recommendation of the Committee, shall have the power to prescribe and issue notifications on the following matters:

(1) criteria, procedures and conditions for the registration of experts, expert organizations, state agencies or private organizations in and out of the country. In this regard, the notification must prescribe the qualifications, standards and performance of said persons, agencies or organizations.

(2) the registration fees that the Food and Drug Administration shall collect from experts, expert organizations, state agencies or private organizations both in and out of the country; the collected fee must not be higher than the maximum rates of registration fees.

(3) the types of services and service charges that the Food and Drug Administration or the state agencies assigned to perform a mission within the duties and powers of the Food and Drug Administration, as the case may be, shall collect from applicants for the herbal product consideration process; the collected service charges must not be higher than the maximum rates of expenses.

(4) criteria, procedures and conditions of the herbal product consideration process, taking into account the protection of the Thai traditional medicine wisdom and the safeguarding of trade secret as well.

The maximum rates of registration fees and service charges under (2) and (3) shall be effective upon approval by the Cabinet.

The notifications in paragraph one may notify an exemption of the criteria, procedures and conditions prescribed in (1), the registration fees in (2) or the service charges in (3), in all or in parts, or may notify different rates of registration fees or service charges as deemed necessary and appropriate.

Section 56 The registration fees collected under section 55 (2), shall belong to the Food and Drug Administration, while the charges collected under section 55 (3) shall belong to the Food and Drug Administration or the state agencies entrusted with the performance of such missions, which are within the duties and powers of the Food and Drug Administration, as the case may be. Such income shall not be transferred to the treasury as public revenue, but shall be spent for the following purposes:

(1) as renumerations for experts, expert organizations or private organizations under section 54 (3);

(2) as expenses for the operation of the work plans or projects for the public benefit of the protection of herbal product consumers;

(3) as capacity-building expenses for agencies and officials for the movement of the work system of the herbal product consideration process and the enhancement of its efficiency;

(4) as other applicable and necessary expenses for the implementation of the herbal product consideration process as prescribed and notified by the Minister.

Section 57 Acceptance of money under section 55, disbursement of money under section 56 and the safekeeping of such money shall be in accordance with the criteria, procedures and conditions prescribed and notified by the Minister with the approval of the Ministry of Finance.

CHAPTER 8
Herbal Product Control

Section 58 A person shall be prohibited from producing, importing or selling the following herbal products:

(1) fake herbal products;

(2) substandard herbal products;

(3) deteriorated herbal products;

(4) herbal products that are not registered, notified, or listed, as the case may be;

(5) herbal products of which the certificate of registration, the notification receipt, or the listing receipt was revoked.

Section 59 Fake herbal products are products with the following characteristics:

(1) an herbal product or an object which is wholly or partly an imitation of a genuine herbal product;

(2) an herbal product which shows the name or expiration date which is false;

(3) an herbal product which shows manufacturer name, manufacturer trademark, or place of production which is false;

(4) an herbal product which shows labels or package insert which is false;

(5) an herbal product which shows that it is an herbal product produced in accordance with a previously registered, notified or listed formula which is false;

(6) an herbal product of which the production does not meet the standards specified in the product's registered, notified or listed formula or has a deviation values that is different from the criteria prescribed and notified by the Minister upon the recommendation of the Committee.

Section 60 Substandard herbal products are products with the following characteristics:

(1) have the quantity or strength of active ingredients lower or higher than the minimum or the maximum limits specified in the formulae of the registered herbal products or have the deviation values that are different from the criteria prescribed and notified by the Minister, upon the recommendation of the Committee, but that are lower than the levels prescribed under section 59 (6);

(2) have the purity values or other characteristics essential for the product quality that are different from the limits specified in the formulae of registered herbal products or from the standard criteria prescribed and notified by the Minister, upon the recommendation of the Committee;

(3) contain ingredients that are different from those previously registered, notified, or listed.

Section 61 Deteriorated herbal products are products with the following characteristics:

(1) an herbal product that is expired as indicated by the expiration date on the labels;

(2) an herbal product that, after production, is so denatured as to have the same characteristics as the fake herbal products under section 59 (6) or the substandard herbal products under section 60;

Section 62 No licensee shall produce herbal products when the person on duty in charge of the place of production is not present therein to perform the duties.

Section 63 No person on duty shall perform the duties in different places of production, importation or sale of herbal products at the same period of time.

Section 64 In the case where it is suspected that any herbal product does meet the required quality, is inefficacious or unsafe, the Secretary-General shall have the power to order the licensees with a licence to produce or import such herbal product, holder of the certificate of product registration, holders of the product notification receipt, or holders of the product listing receipt to submit supporting documents or evidences to prove product quality, efficacy or safety.

During the operation under paragraph one, the Secretary-General shall have the power to order a temporary cessation of the production, importation or sale until it is proven that the herbal product has the required quality, efficacy or safety.

Section 65 When it appears that the quality or efficacy of an herbal product does not conform with what was previously registered, notified or listed or is unsafe, the Secretary-General shall have the following powers:

(1) to issue a written order to the licensed manufacturers, importers or sellers, holders of the certificate of product registration, holders of the notification receipt or holder of the listing receipt to suspend their production, importation or sale of herbal products or other related activities as prescribed and notified by the Committee;

(2) to promptly announce the results of the test or quality analysis of the herbal product to the public;

(3) to recall herbal products from licensed manufacturers, importers or sellers of the herbal products, possessors of the herbal products, holders of the certificate of product registration, or holders of the notification receipt, or holders of the listing receipt; or to issue an order to licensed manufacturers, importers or sellers of the

herbal products, holders of the certificate or product registration, or holders of the notification receipt, or holders of the listing receipt to collect the herbal products that they produced, imported or sold from the market or from the possessors of such products within a specified period of time;

(4) to order licensed manufacturers, importers or sellers, possessors of the herbal products, holders of the certificate of product registration, holders of the notification receipt, holders of the listing receipt or an authorized person to destroy or deal with the herbal product as appropriate for each individual case when the herbal product is found to be the product under section 58.

Licensed manufacturers, importers, sellers, possessors of the herbal products, holders of the certificate of product registration, holders of the notification receipt, or holders of the listing receipt shall be responsible for the expenses incurred from the operations under (3) and (4).

CHAPTER 9
Business Termination and Transfer

Section 66 While a licence is still valid, any licensee under section 17 who wishes to terminate a licensed business shall notify the licensing authority in writing of the business termination at least fifteen days prior to the intended termination date of the business, as well as declare the place of storage and the remaining quantity of herbal products that may be harmful.

Any licensee under section 17 who does not wish to renew the licence and wishes to terminate the business shall notify the licensing authority in writing of the business termination at least fifteen days prior to the intended termination date of the business, as well as declare the place of storage and the remaining quantity of herbal products that may be harmful.

In the case where any licensee under section 17 is denied the renewal of the licence, such person shall declare the place of storage and the quantity of the remaining herbal products that may be harmful within fifteen days from the date of being informed of the denial of licence renewal.

The notification (of business termination) given under this section shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

Section 67 In the case where a licensee under section 17 – who has notified a business termination, whose licence has expired, or who is denied the renewal of the licence by the licensing authority , as the case may be –wishes to sell his or her remaining herbal products, the licensee must sell to another licensee or to the person

whom the licensing authority deems appropriate within ninety days of the business termination date, the licence expiration date, or the date the licensee is informed of the denial of licence renewal. In this regard, the licensing authority may extend such period as deems appropriate.

Section 68 Any licensee under section 17, who wishes to transfer the licence to a transferee who has the required qualifications and none of the prohibited characteristics under section 19, shall file a licence transfer application to the licensing authority. The transfer shall be effective when the permission is granted by the licensing authority.

The application for licence transfer and the permission of a licence transfer shall be in accordance with the criteria, procedures and conditions prescribed in the Ministerial Regulations.

Section 69 In the case where a licensee under section 17 dies, if the heir or a person who has the consent of the heir states an intention to continue the business to the licensing authority within ninety days from the date that the licensee died; and the licensing authority has verified that such person has the required qualifications and none of the prohibited characteristics under section 19, the said heir or the person who has the consent of the heir shall continue the business operation until the licence expires, and shall be deemed the licensee under this Act from the date that the previous licensee died.

The statement of intention and its verification under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

CHAPTER 10
Advertisement

Section 70 No person shall advertise an herbal product or the benefits of an herbal product unless he or she is granted a licence by the licensing authority.

Application for and issuance of the licence under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette. In this regard, the Secretary-General may prescribe specific conditions for the advertisement or restrict the use of advertising media.

Section 71 Advertising licences under section 70 shall be valid for three years from the date of issue.

Section 72 For the amendment of particulars in advertising licence, the provisions of section 21 shall be applied, *mutatis mutandis*.

Section 73 In the case where an advertising licence is lost, destroyed or substantially damaged, the advertising licensee shall apply for a substitute licence within fifteen days of the date that such loss, destruction or substantial damage is known.

Application for and issuance of a substitute licence under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

Section 74 No person shall advertise an herbal product in the following manners:

(1) boasting that its health benefit or a material that is an ingredient of an herbal product is able to miraculously cure, treat, relieve or prevent a disease or an illness, or which is based on personal belief, or is able to completely cure a disease or using any wording to imply the same meaning;

(2) claiming a health benefit that is false, exaggerating, or giving misleading information about the health benefit of the herbal product;

(3) creating an understanding that an herbal product contains a particular material as an ingredient, when actually, there is no such material or ingredient in the herbal product, or it is present in the product but not as much as the amount led to perceive in the advertisement;

(4) the health benefit of an herbal product is guaranteed or praised by any person, any group of persons or any institution;

(5) acting in any manner that is a violation of the criteria, procedures and conditions for advertisement prescribed and notified by the Minister upon the recommendation of the Committee.

The provisions of (4) shall not apply to an advertisement directed to medical practitioners, dental practitioners, pharmacy practitioners, Thai traditional medicine practitioners, and applied Thai traditional medicine practitioners. An advertisement directly to the practitioners of said professions requires a licence under section 70.

Section 75 In the case where the licensing authority deems any advertisement to be a violation of section 74, the licensing authority shall have the power to order the advertiser to perform one of the following acts:

(1) to correct the statement or method of advertisement;

(2) to refrain from using a particular statement or method of advertisement;

(3) to cease the advertisement.

In issuing an order under paragraph one, the licensing authority may also order the advertiser to disseminate the correct information, all the expenses thereof shall be borne by the advertiser.

CHAPTER 11
Promotion of Business Operators

Section 76 For the benefit of the promotion of the capability of the producers or sellers of herbal products, the producers or sellers who are the business operators under section 10 (8) shall apply to the Secretary-General for such promotion under section 77.

Application for promotion under paragraph one shall be in accordance with the criteria, procedures and conditions prescribed by the Secretary-General and notified in the Government Gazette.

Section 77 Promotion of business operators who apply for the promotion under section 76 shall include:

(1) support business operation based on the readiness and the needs of business operators, whether through herbal product promotion and development or research assistance on different aspects of technological development, including the promotion of herbal cultivation, herbal culture, improvement of production quality, management, and marketing;

(2) promotion of business coalition or cooperation between business operators and other business sectors or industries;

(3) reduction or exemption of the prescribed fees hereto attached;

(4) providing technical consultation on the compliance with relevant criteria and standards, or on the preparation of technical documents on herbal product production or sale purposes as well as the application for certification assessment, application for registration, notification, or listing of an herbal product to be produced; all of these measures are provided at no cost.

(5) organizing training for capacity-building on business operation to ensure its compliance with the standards required by law, at no cost for participation. Such trainings shall be in accordance with the courses prescribed and notified by the Director-General;

(6) giving free documents, e.g. guidance, handbooks, technical documents, or any other documents prepared by government agencies to disseminate knowledge and to strengthen business operator potential;

(7) other rights and privileges as prescribed by the Policy Committee; promotion measures in (1), (2), (4), (5), (6) and (7) shall be in accordance with the criteria, procedures and conditions prescribed by Policy Committee and notified in the Government Gazette.

CHAPTER 12
Competent Officials

Section 78 For the performance of official duties in accordance with this Act, competent officials shall have the following powers:

(1) to enter into a place of production, importation, sale, or storage of herbal products during the working hours of such places, or to enter into a vehicle used for the transportation of herbal products, for the purposes of inspection or control as deemed necessary under this Act;

(2) to take a reasonable quantity of herbal products as samples for testing or analysis;

(3) in the case where there are reasonable grounds to suspect that an offence under this Act has been committed, competent officials may enter any place or vehicle to inspect, search, seize or confiscate the herbal products, equipment, tools, as well as the containers, packaging, labels, package inserts or any item related to the suspected herbal products or having reasonable grounds to believe that they are related to an offence;

(4) to summon a person to give a statement or submit necessary documents or evidences for the consideration by competent officials.

In the performance of official duties under paragraph one, licensees and all persons involved in the production, importation or sale of herbal product shall properly facilitate the operation of the competent officials.

In the performance of official duties under (3), a search warrant must be presented unless there are reasonable grounds to believe that a delay in obtaining the search warrant shall result in the moving, concealing, alteration or destruction of the evidence related to an offence, the competent officials may carry out a search without a search warrant. However, they must comply with the Criminal Procedure Code on search procedures.

Section 79 Items seized or confiscated under section 78 (3) shall become the properties of the Ministry of Public Health when it appears that:

(1) no owner or no person has come forward to claim ownership or possession of such items within ninety days from the date of seizure or confiscation;

(2) where the case is not prosecuted and the owner or possessor of such items has not claimed them within ninety days of the date that they are informed of the non-prosecution order;

(3) where the case is prosecuted and the public prosecutor gives a final order not to proceed with the case or the Court has not passed a sentence forfeiture, and the owner or possessor of such items has not claimed them within ninety days of the date that they are informed of the non-prosecution order or the date that the Court passes its final judgement, as the case may be.

Section 80 In the case where the items seized or confiscated under section 78 (3) are perishable or are near expiry or their storage would create a risk of damage or from the storage costs being higher than their worth, the competent officials who seized or confiscated such items may sell the items by auction before the case is finalized or before they become the property of the Minister of Public Health. The resulting net proceeds from the sale deducted by all expenses and incumbrance, shall be seized in lieu of the items and deposited into a government bank account.

Section 81 In the performance of their duties, competent officials must show their identity cards to the persons concerned.

The identity cards of competent officials shall be in the form prescribed and notified by the Minister.

Section 82 For the performance of their duties in accordance with this Act, competent officials shall become the officials under the Penal Code.

CHAPTER 13
Suspension and Revocation of a Licence

Section 83 When any licensee under section 17 violates or fails to comply with this Act, the licensing authority, with the approval of the Committee, shall have the power to order a suspension of his or her licence for not longer than one hundred and twenty days at a time. In the case where a licensee is prosecuted for an offence committed under this Act, the licence may be suspended pending a final judgement of the Court.

A licensee whose licence has been suspended must cease the operation specified by the licence suspension order. During licence suspension, the licensee shall not be able to apply for any other licence under this Act.

Section 84 The licensing authority under section 17, with the approval of the Committee, shall have the power to order a revocation of a licence if it appears that a licensee lacks the required qualifications or has any of the prohibited characteristics under section 19, or violates the licence suspension order under section 83.

Section 85 A licence suspension order and licence revocation order shall be notified in writing to the licensee. If the licensee cannot be located or refuses to accept the order, the order shall be posted in an open and conspicuous location at the place of production, importation or sale of herbal products. The licensee shall be deemed to have acknowledged the said order from the date of its posting.

The order of a licence suspension and the order of a licence revocation under paragraph one may be notified by publishing in a daily newspaper or via any other means.

Section 86 The licensing authority, with the approval of the Committee, shall have the power to withdraw a licence suspension order when it appears that the licensee, whose licence has been suspended, has properly complied with the provisions of this Act.

Section 87 A person, whose licence has been revoked, who wishes to sell the remaining herbal products, must sell to another licensee or to a person deemed appropriate by the licensing authority within a period of ninety days from the received date of the licence revocation order or the received date of the written notice of the Minister's decision under section 89, paragraph two. In this regard, the licensing authority may extend the said period as deems appropriate.

CHAPTER 14
Appeal

Section 88 In the case where the licensing authority does not issue or grant a licence renewal, the applicant for a licence or for a licence renewal shall have the right to appeal in writing to the Minister within thirty days from the received date of the written notice of refusal to issue a licence or to grant a licence renewal, as the case may be.

The decision of the Minister shall be final.

During the Minister's consideration of an appeal of the refusal order to grant a licence renewal, the Minister, at the request of the appellant, shall have the power to permit the applicant of a licence renewal to produce, import or sell of herbal products, as the case may be, for the time being.

Section 89 The licensee whose licence has been suspended or revoked shall have the right to appeal in writing to the Minister within thirty days of the received date of the written notice of licence suspension or revocation, as the case may be.

The decision of the Minister shall be final.

The appeal under paragraph one shall not be used as a cause for a stay of the enforcement of the licence suspension or revocation order.

Section 90 In considering an appeal under section 88 or section 89, the Minister shall finish the consideration within sixty days of the received date of the appeal. In case of necessity where the appeal consideration cannot be completed within the said period, a written notice shall be sent to the appellant for acknowledgement before the specified completion date. In this regard, the appeal consideration period shall not be extended for more than sixty days from the said completion date.

CHAPTER 15
Penalties

Section 91 Any person who produces, imports or sells herbal products without a licence under section 17, paragraph one shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding three hundred thousand baht or to both.

Section 92 Any person who produces, imports or sells herbal products with granted exemptions under section 18, paragraph one (2), (3), (4), (5), (6) or (7) but fails to comply with the notification issued under section 18 paragraph two shall be liable to a fine not exceeding fifty thousand baht.

Section 93 Any licensee under section 17 or any holder of a certificate of product registration, any holder of notification receipt or listing receipt, or any advertisement licensee who fails to comply with section 21 paragraph one, section 38 paragraph one, section 48 or section 72, as the case may be, shall be liable to a fine not exceeding ten thousand baht.

Section 94 Any licensee under section 17 or any holder of a certificate of product registration, any holder of notification receipt or listing receipt, who files an application for a licence renewal, a certificate of product registration, a notification receipt or a listing receipt after the licence, the certificate of product registration, notification receipt or listing receipt has expired for no longer than one month under section 23 paragraph two, section 40 paragraph two or section 49 paragraph two, as the case may be, shall be liable to a daily fine not exceeding one thousand baht per day as long as the application for a licence renewal, certificate of product registration, notification receipt or listing receipt has not yet been filed.

Section 95 Any licensee under section 17 or any holder of a certificate of product registration, any holder of notification receipt or listing receipt, or any advertisement licensee who fails to comply with section 24 paragraph one, section 41 paragraph one, section 50 paragraph one or section 73 paragraph one, as the case may be, shall be liable to a fine not exceeding five thousand baht.

Section 96 Any licensee under section 17 who fails to comply with section 25 or section 26 paragraph one or any person on duty who fails to comply with section 27, as the case may be, shall be liable to a fine not exceeding five thousand baht.

Section 97 Any licensee under section 17 who fails to comply with section 28 (1) shall be liable to imprisonment for a term not exceeding three months or to a fine not exceeding thirty thousand baht, or to both, and to an additional daily fine not exceeding one thousand baht per day until the licensee has properly complied with such provisions.

Section 98 Any licensee under section 17 who fails to comply with section 28 (2), (3), (4), (5) or (6), section 29 or section 30, as the case may be, shall be liable to a fine not exceeding fifty thousand baht.

Section 99 Any person on duty who fails to comply with section 31, section 32 or section 33, as the case may be, shall be liable to a fine not exceeding twenty thousand baht.

Section 100 Any person who has been granted an exemption under section 35 (1) or (2) and fails to notify the licensing authority in writing under section 35 paragraph two shall be liable to a fine not exceeding fifty thousand baht.

Any licensed manufacturer or importer, any research sponsor or any researcher on herbal products, who fails to comply with the notification issued under section 35 paragraph two shall be liable to a fine not exceeding one hundred thousand baht.

Any benefactor or any recipient of herbal product donation, who fails to comply with the notification issued under section 35 paragraph two, shall be liable to a fine not exceeding fifty thousand baht.

Section 101 Any person who produces or imports fake herbal products, which is a violation of section 58 (1), shall be liable to imprisonment for a term not exceeding ten years or to a fine not exceeding one million baht.

For the production or importation of fake herbal products with the characteristics specified in section 59 (2), (3), (4), (5) or (6), which is a violation of section 58 (1), if the producers or importers can prove that such herbal products are not harmful to the consumers, they shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand baht, or to both.

Section 102 Any person who sells fake herbal products, which is a violation of section 58 (1), shall be liable to imprisonment for a term not exceeding three years and to a fine not exceeding three hundred thousand baht.

For the sale of fake herbal products with the characteristics specified in section 59 (2), (3), (4), (5) or (6), which is a violation of section 58 (1), if the sellers can prove that such herbal products are not harmful to the consumers, they shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand baht, or to both.

Section 103 Any person who produces or imports substandard herbal products or herbal products of which the certificate of registration, notification receipt or listing receipt has been revoked, which is a violation of section 58 (2) or (5), shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding two hundred thousand baht.

Section 104 Any person who sells substandard herbal products or herbal products of which the certificate of registration, notification receipt or listing receipt has been revoked, which is a violation of section 58 (2) or (5), shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding fifty thousand baht, or to both.

Section 105 Any person who imports or sells deteriorated herbal product, which is a violation of section 58 (3), shall be liable to imprisonment for a term not exceeding three months or to a fine not exceeding thirty thousand baht, or to both.

Section 106 Any person who produces, imports or sells an herbal product which has not been registered, notified, or listed, as the case may be, which is a violation of

section 58 (4), shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand baht, or to both.

Section 107 Any licensed manufacturer of herbal products who violates section 62 shall be liable to a fine not exceeding fifty thousand baht.

Section 108 Any person on duty who violates section 63 shall be liable to a fine from five thousand and twenty thousand baht.

Section 109 Any licensee under section 17, who fails to comply with an order issued by the Secretary-General under section 64 paragraph two, shall be liable to imprisonment for a term not exceeding one month or to a fine not exceeding ten thousand baht, or to both.

Section 110 Any licensee under section 17 or any holder of a certificate of product registration, any holder of notification receipt or listing receipt, who fails to comply with the order issued by the Secretary-General under section 65 (1) or (3), shall be liable to imprisonment for a term not exceeding three months or to a fine not exceeding thirty thousand baht, or to both.

Section 111 Any licensed manufacturer, importer, or seller of herbal products or any person who possesses or is assigned to destroy herbal products, who fails to comply with section 65 (4), shall be liable to a fine not exceeding fifty thousand baht.

Section 112 Any licensee under section 17, who terminates business operation without complying with section 66, shall be liable to a fine not exceeding ten thousand baht.

Section 113 Any licensee under section 17, who notified the licensing authority of business termination, whose licence expired, or who the licensing authority refused licence renewal or revoked the licence under section 84, who sold the remaining herbal products after the expiration of the period specified in section 67 or section 87, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand baht, or to both.

Section 114 Any person, who advertises an herbal product without a licence under section 70 paragraph one or who violates section 74, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand baht, or to both.

Section 115 Any advertiser, who fails to comply with the order of the licensing authority under section 75, shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding one hundred thousand baht, or to both, and to an additional daily fine not exceeding five thousand baht per day until the advertiser properly complies with the order.

Section 116 Any person, who fails to come forward to give a statement, fails to submit the necessary documents or evidences under section 78 paragraph one (4) without a sensible reason, shall be liable to a fine not exceeding five thousand baht.

Section 117 Any person, who fails to properly facilitate the operation of a competent official under section 78 paragraph two, shall be liable to imprisonment for a term not exceeding one month, or to a fine not exceeding ten thousand baht, or to both.

Section 118 Any licensee under section 17, who fails to comply with the order issued by the licensing authority under section 83, shall be liable to imprisonment for a term not exceeding two years, or to a fine not exceeding two hundred thousand baht, or to both, and to an additional daily fine not exceeding five thousand baht per day until the licensee properly complies with the order.

Section 119 In the case where an offender is a juristic person, if the offence committed by the juristic person is due to an order or action of a director or manager or any person who is responsible for the operation of said juristic person, or in the case where such person has a duty to order or execute such action but has refrained from issuing the order or executing such action to the extent that it causes the said juristic person to commit an offence, such person shall be liable to the penalty prescribed for such offence.

Section 120 When the Court passes a judgement to penalize any person for an offence under section 58, the Court shall order a forfeiture of all herbal products, tools and equipment used for their production as well as labels, containers or packaging that are related to the offence, unless such properties belong to another person who was not a party to the offence.

In the case where the Court has ordered a forfeiture of the properties under paragraph one but it subsequently appears, through a request of the *bona fide* owner of such properties, that the *bona fide* owner was not a party to the offence, the Court shall order a return of such properties. In this regard, the *bona fide* owner must file an application to the court within ninety days from the date that the Court passed the final judgement.

The properties forfeited by the court order under paragraph one shall become the properties of the Ministry of Public Health to subsequently be destroyed or to deal with the properties as it deems appropriate.

Section 121 For offences under this Act with a penalty of fine only or a penalty of imprisonment for a term not exceeding six months, the Secretary-General or a person assigned by the Secretary-General shall have the power to impose a fine in accordance with the criteria, procedures and conditions prescribed and notified by the Committee.

After the offender has paid the fine at the amount imposed within thirty days from the date that the fine was imposed, the case shall then be absolved under the Criminal Procedure Code.

In the case where the herbal products, tools, equipment, containers, packaging, labels, package inserts or any materials related to the offense have been seized or confiscated, the Secretary-General or a person assigned by the Secretary-General shall be able to impose a fine when the offender agrees to have the seized or confiscated items become the properties of the Ministry of Public Health.

The items that have become the properties of the Ministry of Public Health under paragraph three shall be destroyed or dealt with as it deems appropriate under the criteria, procedures and conditions prescribed and notified by the Minister.

In the case where a person, who claims to be the owner of the seized or confiscated items under paragraph three or paragraph four, has shown to the Secretary-General or a person assigned by the Secretary-General, within ninety days from the date of that the fine was imposed, that he or she is the *bona fide* owner of the items and was not a party to the offence, and the seized or confiscated items still remain in the possession of the competent officials, the Secretary-General or a person assigned by the Secretary-General shall order a return of such items to the *bona fide* owner.

TRANSITORY PROVISIONS

Section 122 During the initial period, the Policy Committee shall consist of the members under section 7 (1), (2) and (3) and the Director-General shall be the Policy Committee member and secretary. They shall temporarily perform the duties of the Policy Committee under this Act until the members under section 7 (4) and (5) are appointed, which shall not exceed ninety days from the date that this Act comes into force. In this regard, the Deputy Director-General of the Department of Thai Traditional and Alternative Medicine assigned by the Director-General, the Deputy Director-General of the Department of Agricultural Extension assigned by the Director-General, and the Deputy Secretary-General of the Food and Drug Administration assigned by the Secretary-General shall be the Policy Committee assistant secretaries.

Section 123 During the initial period, the Committee shall consist of the members under section 13 (1) and (2), and the Deputy Secretary-General of the Food and Drug Administration assigned by the Secretary-General shall be the Committee member and secretary. They shall temporarily perform the duties of the Committee under this Act until the members under section 13 (3) are appointed, which shall not exceed ninety

days from the date that this Act comes into force. In this regard, a representative of the Department of Thai Traditional and Alternative Medicine, and a representative of the Food and Drug Administration shall be the Committee assistant secretaries.

Section 124 All licences to produce, import or sell drugs or food that are herbal products under this Act, which were issued under the Drugs Act, B.E. 2510 (1967) or the Food Act, B.E. 2522 (1979) prior to the date that this Act comes into force, shall continue to be valid until such licences expire.

Section 125 All certificates of drug registration and certificates of food registration of the drugs and food that are herbal products under this Act, which were granted under the Drugs Act, B.E. 2510 (1967) and the Food Act, B.E. 2522 (1979) prior to the date that this Act comes into force, shall continue to be valid until such certificates expire. The drugs or food produced or imported before the said certificates expire shall continue to be on sale until such drugs or food are expired or until the licensing authority orders a revocation.

Section 126 Applications for a licence, applications for a certificate of drug registration or any other application relating to herbal products under this Act, which have been filed under the Drugs Act, B.E. 2510 (1967) or the Food Act, B.E. 2522 (1979), and are still under consideration shall be deemed the applications filed under this Act, *mutatis mutandis*. If such applications differ from the applications prescribed under this Act, the licensing authority shall have the power to order a correction and amendment of the applications in order to comply with this Act.

Section 127 All Ministerial Regulations, Notifications or Regulations issued under the Drugs Act, B.E. 2510 (1967) or the Food Act, B.E. 2522 (1979), in relation to the herbal products under this Act, which exist prior to the date that this Act comes into force, shall remain in force as long as they do not conflict with or contradict this Act until the Ministerial Regulations or notifications issued under this Act come into force.

The issuance of the Ministerial Regulations or notifications under this Act shall be completed within two years of the date that this Act comes into force. If this cannot be accomplished, the Minister shall report the reasons why the said mission is not accomplished to the Cabinet for acknowledgement.

Countersigned by

General Prayuth Chan-ocha

Prime Minister

RATES OF FEES

(1) Licence to produce an herbal product	10,000 baht per copy

(2) Licence to import an herbal product	100,000 baht per copy
(3) Licence to sell an herbal product	2,500 baht per copy
(4) Licence to advertise an herbal product	5,000 baht per copy
(5) Certificate of herbal product registration	25,000 baht per copy
(6) Herbal product notification receipt	5,000 baht per copy
(7) Herbal product listing receipt	1,000 baht per copy
(8) Certificate	1,000 baht per copy
(9) Substitute licence, substitute certificate of herbal product registration, substitute notification receipt, and substitute listing receipt	1,000 baht per copy
(10) Licence renewal fee is half of the fee for the issuance of each type of licence	
(11) Renewal fee for a Certificate of herbal product registration is half of the fee for the issuance of each certificate of herbal product registration	
(12) Renewal fee for a notification receipt or listing receipt is half of the fee for the issuance of each notification receipt or listing receipt.	

Remark:- The rationale for the promulgation of this Act is as follows: whereas there is currently no specific law for the control and regulation of herbal products, as a result the provisions of laws on drugs and food are therefore enforced for the regulation of herbal products. However, such laws are not suitable for the control and regulation of herbal products and are incongruent with the policy on the promotion and development of herbal products. Therefore, it is deemed expedient to have the laws on the control and regulation of herbal products for humans to solve these problems with the National Herbal Policy Committee being responsible for the formulation of national herbal policies and strategic plans and the Herbal Product Committee being responsible for providing advice to the Minister of Public Health on the formulation of criteria for the control and regulation of herbal products. This is to ensure that the systems of licensing, registration, notification, and listing of herbal products would be efficient. In addition, there shall also be the provisions of law on the promotion of systematic and comprehensive development and promotion of herbal products to ensure that Thai herbal products will be safe, of good quality and meet internationally accepted standards for better global recognition and increased export value. It is therefore necessary to enact this Act.