

**Tentative translation**

**ACT ON PROTECTION AND PROMOTION OF TRADITIONAL THAI  
MEDICINAL INTELLIGENCE, B.E. 2542**

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**BHUMIBOL ADULYADEJ REX.**

Given on the 19<sup>th</sup> Day of November, B.E. 2542

Being the 54<sup>th</sup> Year of the Present Reign.

His Majesty King Bhumibol Adulyadej is graciously pleased to proclaim that:

Whereas it is expedient to have a law on protection and promotion of traditional Thai medicinal intelligence;

This Act contains certain provisions that restrict the rights and liberties of the people, which are permissible under section 29, along with section 35, section 48 and section 50 of the Constitution of the Kingdom of Thailand;

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

**Section 1.** This Act shall be called the "Act on Promotion and Protection of Traditional Thai Medicinal Intelligence, B.E. 2542."

**Section 2.** This Act shall come into force as from 180 days after the date of its publication in the Government Gazette.

**Section 3.** In this Act,

"traditional Thai medicinal intelligence" means the basic knowledge and capability concerned with traditional Thai medicine;

"traditional Thai medicine" means the medicinal procedures concerned with examination, diagnosis, therapy, treatment or prevention of, or promotion and rehabilitation of the health of humans or animals, obstetrics, traditional Thai massage, and also includes the production of traditional Thai drugs and the invention of medical devices, (on the basis of knowledge or text that has been passed on from generation to generation);

"text on traditional Thai medicine" means technical knowledge concerned with traditional Thai medicine which has been written or recorded in Thai books, palm leaf, stone inscription or other materials or that have not been recorded but passed on from generation to generation;

"Thai traditional drugs" means medicines obtained directly from herbs or derived from mixture, blended or transformed herbs, and also includes Thai traditional drugs under laws on drugs;

"formula on traditional Thai drugs" means a formula stated as the production process and ingredients which contain Thai traditional drugs, no matter what form the ingredients are;

"herbs" means plants, animals, bacteria, minerals, extracts of plants or animals used, or transformed or mixed or blended as drugs or food for diagnosis, therapy, treatment or prevention of diseases, or for promotion of the health of humans or animals. The meaning also includes the origin or the areas in which the products exist;

"controlled herbs" means herbs that have been announced as controlled herbs under the Ministerial Notification;

"conservation areas" means national reserved forests and other conservation areas for reservation and protection of natural resources, as stated by law;

"original extracts" means natural extracts that have not been mixed or new substances obtained from addition of molecules under scientific procedures;

"rough transformation" means the mixture, blend or transformation of herbs or the quality of herbs in order to obtain substances as a whole by original procedures and newly developed procedures without differentiating the pure ingredients of different substances;

"successor of formula on traditional Thai drugs or text on traditional Thai medicine" means persons who have been passed on with the text on traditional Thai medicine or formulas on traditional Thai drugs from the discoverer, the improver, or the developer of the substance, or those who have learnt from generation to generation from the discoverer, the improver or the developer of the substance, or those who were given the above mentioned from others;

“right holder” means those who have registered their intellectual property rights on traditional Thai medical intelligence under this Act;

“sales” means selling, disposition, distribution or exchange and also includes possession for sales;

“export” means to bring or export out of the country.

“transform” means to dispense or transform, or change the quality of the herbs;

“members” means the members of the Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence;

“Committee” means the Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence;

“licensing authority” means the Permanent Secretary or person assigned by the Permanent Secretary;

“registrar” means the central registrar or the provincial registrar, as the case may be;

“competent officials” means the licensing authority, the registrar, and the person appointed for the execution of this Act by the Minister;

“Permanent Secretary” means the Permanent Secretary of the Ministry of Public Health;

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

**Section 4.** The Minister of Public Health shall have charge and control of the execution of this Act and shall have the authority to appoint competent officials, issue Ministerial Regulations to specify fees not exceeding the rate annexed to this Act, and outline other activities, including issuance of rules and notifications for the execution of this Act

The Ministerial Regulations, Rules and Notifications shall come into force upon their publication in the Government Gazette.

**CHAPTER 1**  
**The Committee on Protection and Promotion**  
**of Tradition Thai Medicinal Intelligence**

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**Section 5.** There shall be the Committee on Protection and Promotion of Traditional Thai Medicinal Intelligence comprising of the Permanent Secretary of the Ministry of Public Health as chairman, the Director-General of the Medical Services Department, Director-General of the Intellectual Property Rights Department, Director-General of the Livestock Department, Director-General of the Forestry Department, Director-General of the Department of Agriculture, Director-General of the Medical Sciences Department, Secretary-General of the Food and Drug Administration, Secretary-General of the Environment Policy and Planning Office, and Director of the Medical Registration Division as members *ex officio*, and the equal number of the qualified members appointed by the Minister, on the basis of selection from the practitioners, those with knowledge, capability and experience in traditional Thai medicine, the production or sales of traditional Thai drugs and plantation or transformation of herbs. The Director of the Institute for Traditional Thai Medicine shall be a member and secretary of the Committee.

The selection of the qualified members under the first paragraph shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

**Section 6.** The Committee shall have the following power and duties to:

(1) provide consultation or advice to the Minister in issuing the Ministerial Regulations, Rules or Notifications under this Act;

(2) promote and develop the use of intellectual traditional Thai medicine and herbs;

(3) outline measures to strengthen stability and coordination between government agencies, state enterprises, communities and non government organizations on issues concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs;

(4) approve the withdrawal of registrations of intellectual property rights on traditional Thai medicine under section 39 (3);

withdrawal of registrations

(5) consider the appeal against the order or decision of the registrar or the licensing authority under this Act;

(6) lay down rules concerned with standards and procedures on lodging an appeal and consideration of appeal, registration of intellectual property rights on traditional Thai medicine, the administration and arrangement of benefits and expenses of the fund, and works concerned with protection and promotion of intellectuals on traditional Thai medicine and herbs;

(7) perform other activities as stated in this Act or under other laws as the authority of the Committee;

(8) perform other activities as assigned by the Minister.

**Section 7.** The qualified members appointed by the Minister shall hold office for a term of two years as from the day of the appointment. In case the qualified members vacate office before the end of their term subject to section 5 paragraph two, the Minister may appoint another person with similar qualifications as the qualified member, and the appointee shall hold office for the remaining term of the member he or she replaces.

The qualified members who vacates office at the expiration of term may be re-appointed.

**Section 8.** Apart from vacating office at the expiration of term under section 7, the qualified members appointed by the Minister shall vacate office upon :

- (1) deaths;
- (2) resignation;
- (3) being a bankrupt;
- (4) being incompetent or quasi-incompetent person;
- (5) being removed by the Minister for the reason of negligence, or dishonest to the duty, or indulge in unacceptable behavior;
- (6) being imprisoned by a final judgement, except for an offence committed through negligence or petty offence;
- (7) termination from being a practitioner in case the person was appointed under that criteria.

**Section 9.** At the meetings of the Committee, the presence of not less than one half of the total number of members is required to constitute a quorum.

If the chairman of the Committee is unable to attend any of the committee meeting sessions, the members shall select one among them selves to preside over meeting.

The decision of the meeting shall be by majority of votes. Each member shall have one vote. In case of an equality of votes, the person presiding over the meeting shall have an additional vote as the casting vote.

**Section 10.** The Committee shall have the power to appoint a sub-committee to consider or carry out any particular work as assigned by the Committee.

Section 9 shall apply *mutatis mutandis* the meeting of the sub-committee.

**Section 11.** In carrying out their duties under this Act, the Committee and sub-committee shall have the power to order any person to give or submit any evidence to supplement their considerations.

**Section 12.** There shall be the Institute for Traditional Thai Medicine under the Office of the Permanent Secretary, the Ministry of Public Health, having the authority to carry out duties concerned with protection and promotion of education, training, research, studies and development of intelligence on traditional Thai medicine and herbs and shall also be responsible for the administrative and technical works of the Committee.

**Section 13.** The Director of the Institute for Traditional Thai Medicine shall be the central registrar and the provincial health chiefs are the provincial registrars.

**CHAPTER 2**  
**Protection and Promotion of Intelligence on**  
**Traditional Thai Medicine**

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**Section 14.** The intellectual property rights on traditional Thai medicine to be protected under this Act shall be the right to intellectual property over the formula of traditional Thai drugs and text on traditional Thai medicine.

**Section 15.** The Institute for Traditional Thai Medicine shall be responsible for compiling information on traditional Thai medical intelligence concerned with formulas of traditional Thai drugs and text on traditional Thai medicine from throughout the country, for registration.

The registration of intellectual property rights on formulas of traditional Thai drugs and text on traditional Thai medicine under paragraph one shall be in accordance with the Rules issued by the Committee.

**Section 16.** There shall be three types of traditional Thai medicinal intellectual property rights as follows:

- (1) the national formula of traditional Thai drugs or the national text on traditional Thai Medicine;
- (2) general formula of traditional Thai drugs or general traditional Thai medicine document; and
- (3) personal formula of traditional Thai drugs or personal text on traditional Thai medicine.

**Section 17.** The Minister has the power to notify that formulas on traditional Thai drugs or text on traditional Thai medicine that is of benefit, or has special medical or public health value as the national formula on traditional Thai drug, or the national text on traditional Thai medicine, as the case may be.

The Notification under paragraph one shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

**Section 18.** The Minister has the power to notify the formulas of traditional Thai drugs or text on traditional Thai medicine that have been widely

used or whose intellectual property protection has expired under section 33, as general formula of traditional Thai drugs or general text on traditional Thai medicine, as the case may be.

The Notification issued under paragraph one shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

**Section 19.** Whoever wishes to use the national traditional Thai drugs for registration and permission for production of drugs according to the Drug Law, or wishes to use it for research on improvement or development of new drug formulas [for commercial benefit,] or wish to research the national text on traditional Thai Drugs for development and improvement for commercial benefit, shall forward their application to obtain benefits and pay fees and the remuneration for making use there of to the licensing authority.

The application and permission, limitations to the rights and the remuneration shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial regulation.

**Section 20.** Personal formula of traditional Thai drugs or personal text on traditional Thai medicine under section 16(3) may be registered for protection of intellectual property rights and may be promoted according to the provisions of this Act by applying for registration to the registrar.

The application for registration of intellectual property rights on traditional Thai medicine under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in Ministerial Regulation.

**Section 21.** The persons who have the right to register for protection of intellectual property rights according to section 20 must be of Thai nationality and shall have the following qualifications:

- (1) being an inventor of the formula on traditional Thai drugs or text on traditional Thai medicine;
- (2) being an improver or developer of formula on traditional Thai drugs or text on traditional Thai medicine; or
- (3) being an inheritor of the formula on traditional Thai drugs or text on traditional Thai medicine.



**Section 22.** Registration for protection of intellectual property rights on traditional Thai medicine is prohibited if the registrar is of the opinion that:

(1) the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine, or is a general formula on traditional Thai drug, or general text on traditional Thai medicine, or

(2) the drug formula is a personal formula on traditional Thai drug that has been developed on non medical basis like the use of extracts of plants, animals or micro organisms that have not be obtained from natural extracts or the transformation that is not considered rough transformation.

**Section 23.** Any application for registration of intellectual property rights on traditional Thai medicine that is not made according to the requirements prescribed in the Ministerial Regulation issued under section 20 paragraph two be called for changes by the registrar within 30 days beginning from the date the applicant receives the request for changes.

If the applicant does not comply with the request of the registrar within the specified period mentioned in paragraph one, the registration shall be revoked.

**Section 24.** ~~After examining~~ the application, if the registrar is of the opinion that the applicant is qualified under section 21 and the application therefor is not prohibited under section 22, the registrar shall, without delay, announce the application at the Registration Office and at the office of the local administration organizations.

**Section 25.** In case many people jointly apply for registration on protection of intellectual property rights traditional Thai medicine, the registrar shall specify a date for inquiry and inform all the applicants.

Under the inquiry to be carried out according to paragraph one, the registrar may request any applicant for further questioning, more information or documents. After the inquiry has been made and the Permanent Secretary has made the decision, the registrar shall notify all the applicants the decision thereof the registrar.

The inquiry and consideration on the rulings shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

*Part-to-file*

**Section 26.** In case there is a separate application for protection of intellectual property rights on the same traditional Thai medicine by different applicants, the person who forwarded the application first shall have the right to register. If the application is forwarded at the same time, on the same date, the applicants shall have to decide on whether they would settle with any one person having full right over the registration or that they would jointly have equal rights within the time period specified by the registrar. If the case shall not be settled within the period specified by the registrar, the parties shall bring the case to the court within 90 days as from the date on which the registrar's specified time period ends. If the case is not take to court within the specified time period, the application for registration shall be revoked.

**Section 27.** If after examining the application for registration, the registrar is of the opinion that the applicant is not qualified according to section 21 and the intellectual property rights on traditional Thai medicine applied for is prohibited under section 22, the registrar shall refuse the registration and issue a letter to inform the applicant within 30 days from the date on which the refusal was made.

**Section 28.** In case the applicant for registration appeals against the ruling of the registrar according to section 27, and if the Committee rules that the rulings of the registrar is incorrect, the registrar shall proceed with the application process.

*objection procedure*

**Section 29.** After making publication on the application forwarded for registration according to section 24, people who feel they have the right over the intellectual property rights on traditional Thai medicine shall forward their objection to the registrar and provide evidence within 60 days from the date on which the publication was made under section 24.

**Section 30.** Before making the ruling, the registrar shall request the applicant and the person who object the registration to explain or provide evidence to supplement the consideration.

When the registrar has ruled on the application, a letter shall be issued to inform the applicant and the person who objected the application on the ruling of the registrar and the reasons thereof within 30 days from the ruling date.

**Section 31.** In case there is no objection as mentioned under section 29, or in case there is an objector and a final ruling has been made to enable the applicant or the objector have the right to register, the registrar shall issue an order authorizing the registration of protection of intellectual property rights on traditional Thai medicine to the applicant or the objector.

*grant*

Once the order for registration of intellectual property rights on traditional Thai medicine has been issued under paragraph one, the registrar shall issue a letter to inform the applicant or the objector of the application and ask for payment of fees for registration within 30 days from the date the letter is received. If the applicant for registration or the objector does not pay the fees within the time period specified, the registration will be revoked.

The registration certificate for intellectual property rights on traditional Thai medicine shall be in the form as prescribed in the Ministerial Regulation.

**Section 32.** In case the Permanent Secretary rules according to Section 25 (2) that many people jointly have the right to register, or in case many people apply for registration of the same product and have joint ownership of the intellectual property rights on traditional Thai medicine, or a final ruling on joint ownership of the intellectual property rights on traditional Thai medicine is made by the court in accordance with section 26, the concerned parties should have equal rights for registration over protection of intellectual property rights on traditional Thai medicine.

*joint-ownership*

In the joint registration on protection of intellectual property rights on traditional Thai medicine, the concerned parties shall jointly outline a memorandum as to how they would jointly share the registration rights and forward it to the registrar along with the registration.

**Section 33.** The right to intellectual property on traditional Thai medicine under this section should be valid for a life time of the bearer of the registration and extend for another 50 years from time the owner of the registration has deceased.

*Term:  
50 pma*

In case there is joint ownership of the registration right under section 32, the intellectual property rights on traditional Thai medicine shall be valid for a life time of the bearer and extended for another 50 years from the date on which the last joint owner of the registration deceases.

SD pma

At the end of the period specified under paragraph one or two the Minister shall publish in the Government Gazette, specifying the formula on traditional Thai drug or text on traditional Thai medicine as a general formula on traditional Thai drug or general text on traditional Thai medicine in accordance with to section 16 (2), as the case may be

expiration of term → general formula

**Section 34.** The right holder would have the sole ownership on the production of the drug and have sole right over the research, distribution, improvement or development of formulas on traditional Thai drugs or intellectual property rights of traditional Thai medicine under the registered text on traditional Thai medicine.

Scope of rights

exemptions:

The provisions of paragraph one shall not apply to:

- (1) any act that is of benefit for studies, findings, tests or research according to the regulation specified by the Minister; or
- (2) preparation of specific drugs according to prescription of holders of registration certificate on traditional Thai medicine, or
- (3) production of drugs for household use or production of drugs by state hospitals or government or state agencies, for use in state hospitals, or the use of text on traditional Thai medicine for benefits in treatment of patients in state hospitals, provided that it shall be in accordance with the Rules issued by the Minister.

**Section 35.** The intellectual property right on traditional Thai medicine under this section shall not be transferred to others, except for the case in which it is passed on by succession.

The successor on traditional Thai medicine through inheritance according to paragraph one must forward their request for registration to the registrar within 2 years from the date the right holder deceases.

In case there is no request for registration of rights on traditional Thai medicine passed on by inheritance within the time period specified in paragraph two the right to be protected under this Act shall be terminated and section 33 (3) shall apply herewith *mutatis mutandis*.

transfer of rights

**Section 36.** The right holder may permit any person to use their right under section 34. *license*

The permit for use of the right under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

**Section 37.** The registrar has the right to revoke the registration of intellectual property rights on traditional Thai medicine under the following cases:

(1) the right holder misuses the right against the public order and good morals;

(2) the right holder violates or does not comply with the conditions or limitations outlined by the registrar in registration of the intellectual property rights on that traditional Thai medicine; or

(3) the right holder exercised the right that may cause severe damage to the registered intellectual property on traditional Thai medicine.

**Section 38.** The concerned party or the public prosecutor may file complaints with the court to revoke registration over intellectual property right on traditional Thai medicine that had been registered in contrary to unfairly under section 21 or section 22.

**Section 39.** Before revoking the registration of intellectual property rights on traditional Thai medicine under section 37, the registrar shall conduct an inquiry and inform the right holder, so that the person can provide an explanation within 30 days from the acknowledgement date. *Revocation*

In conducting an inquiry under paragraph one, the registrar may permit the concerned parties explain or provide evidence required for consideration.

After having conducted an inquiry if the registrar is of the opinion that the registration of the intellectual property rights on traditional Thai medicine shall be revoked, the registrar shall seek approval from the Committee. After the Committee has approved the revoke the registration of intellectual property rights on traditional Thai medicine, the registrar shall order the revoke and issue a letter stating the decision made and the reasons therefor to the right holder within 30 days from the date on which the order was issued by the registrar.

**Section 40.** The right holder whose registration has been revoked under section 39 may re-apply for a registration in accordance with section 20 after the expiration of one year from the date the registration of intellectual property rights on traditional Thai medicine has been revoked.

**Section 41.** In case the person permitted with the intellectual property right on traditional Thai medicine exercise their rights against public order or good morals or violate or not comply with the conditions specified in the Ministerial Regulation issued under section 36 paragraph two or exercise their rights which may cause serious damage to intellectual property right on traditional Thai medicine that has been registered, the registrar shall have the power to revoke the permission to the intellectual property rights on the traditional Thai medicine.

The revoke of the permission to the intellectual property right on traditional Thai medicine under this section shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

**Section 42.** Before ordering the revoke on the permission of intellectual property rights on traditional Thai medicine under section 41, the registrar shall issue a letter to inform the right holder on traditional Thai medicine to give a statement within 15 days from the date on which the letter from the registrar has been received, and section 39 paragraph two shall apply herewith *mutatis mutandis* .

When the registrar issues an order revoking the permission of intellectual property right on traditional Thai medicine, a letter shall be issued to inform the right holder and the person to whom the permission of intellectual property rights of traditional Thai medicine has been granted within 30 days from the date of the issuance of the revoking order.

**Section 43.** Persons with the nationality of other nations who agree to permit persons with Thai nationality to have the protection of intellectual property rights on traditional Thai medicine may seek registration of intellectual property rights protection on the local traditional medicine in their country under this Act.

Reciprocity  
A.3, TRIPS

**Section 36.** The right holder may permit any person to use their right under section 34. *license*

The permit for use of the right under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

**Section 37.** The registrar has the right to revoke the registration of intellectual property rights on traditional Thai medicine under the following cases:

(1) the right holder misuses the right against the public order and good morals;

(2) the right holder violates or does not comply with the conditions or limitations outlined by the registrar in registration of the intellectual property rights on that traditional Thai medicine; or

(3) the right holder exercised the right that may cause severe damage to the registered intellectual property on traditional Thai medicine.

**Section 38.** The concerned party or the public prosecutor may file complaints with the court to revoke registration over intellectual property right on traditional Thai medicine that had been registered in contrary to unfairly under section 21 or section 22.

**Section 39.** Before revoking the registration of intellectual property rights on traditional Thai medicine under section 37, the registrar shall conduct an inquiry and inform the right holder, so that the person can provide an explanation within 30 days from the acknowledgement date. *Revocation*

In conducting an inquiry under paragraph one, the registrar may permit the concerned parties explain or provide evidence required for consideration.

After having conducted an inquiry if the registrar is of the opinion that the registration of the intellectual property rights on traditional Thai medicine shall be revoked, the registrar shall seek approval from the Committee. After the Committee has approved the revoke the registration of intellectual property rights on traditional Thai medicine, the registrar shall order the revoke and issue a letter stating the decision made and the reasons therefor to the right holder within 30 days from the date on which the order was issued by the registrar.

**Section 40.** The right holder whose registration has been revoked under section 39 may re-apply for a registration in accordance with section 20 after the expiration of one year from the date the registration of intellectual property rights on traditional Thai medicine has been revoked.

**Section 41.** In case the person permitted with the intellectual property right on traditional Thai medicine exercise their rights against public order or good morals or violate or not comply with the conditions specified in the Ministerial Regulation issued under section 36 paragraph two or exercise their rights which may cause serious damage to intellectual property right on traditional Thai medicine that has been registered, the registrar shall have the power to revoke the permission to the intellectual property rights on the traditional Thai medicine.

The revoke of the permission to the intellectual property right on traditional Thai medicine under this section shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

**Section 42.** Before ordering the revoke on the permission of intellectual property rights on traditional Thai medicine under section 41, the registrar shall issue a letter to inform the right holder on traditional Thai medicine to give a statement within 15 days from the date on which the letter from the registrar has been received, and section 39 paragraph two shall apply herewith *mutatis mutandis*.

When the registrar issues an order revoking the permission of intellectual property right on traditional Thai medicine, a letter shall be issued to inform the right holder and the person to whom the permission of intellectual property rights of traditional Thai medicine has been granted within 30 days from the date of the issuance of the revoking order.

**Section 43.** Persons with the nationality of other nations who agree to permit persons with Thai nationality to have the protection of intellectual property rights on traditional Thai medicine may seek registration of intellectual property rights protection on the local traditional medicine in their country under this Act.

Reciprocity  
A.3, TRIPS



The application for registration, the issuance of a certificate of registration, and the revocation of the registration under paragraph one shall be in accordance with the rules, procedure and conditions prescribed the Ministerial Regulation.

### CHAPTER 3

#### Protection of Herbs

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**Section 44.** For the purpose of herbs protection, the Minister, with the advice of the Committee, shall have the power to issue a Notification in the Government Gazette to specify the kind, characteristic, type, and names of herbs that are of study and research value, or have important economic significance, or may become extinct, as controlled herbs.

**Section 45.** For the purpose of the protection of controlled herbs, the Minister shall, with the advice of the Committee, notify in the Government Gazette:

(1) specifying the amount or quantity of controlled herbs under possession, to make use of, under care, under conservation or under transportation which needs to be informed the registrar;

(2) specifying rules, procedure and conditions in informing under (1);

(3) specifying rules, procedure and conditions on the possession, to make use of, under care, under conservation or for transportation of controlled herbs;

(4) specifying rules, procedure and conditions on studying and researching the controlled herbs;

(5) specifying rules, procedure and conditions on exporting controlled herbs for commercial and noncommercial purposes, or distribution or transformation of controlled herbs for commercial purposes;

(6) specifying other requirements to conserve, prevent or prohibit or reduce dangers or damage that may be caused to controlled herbs.

**Section 46.** No person shall research or export controlled herbs or sell or transform them for commercial purposes, unless a licence has been obtained from the licensing authority.

The application for a license and the issuance thereof under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

The licence issued under paragraph one shall be valid up to 31 December of the third year as from the year in which the licence is issued.

**Section 47.** The licence issued under section 46 shall cover the employees or representative of the licensee.

It shall be deemed that the act of the employee or representative of the licensee under paragraph one is the act of the licensee unless the licence can prove that the act has been committed without his or her knowledge or beyond his or her control.

**Section 48.** The provisions of section 46 shall not apply to research on controlled herbs which have been carried out by state agencies, but such agencies must inform the registrar and comply with the rules, procedure and conditions prescribed by the Minister under section 45(4).

**Section 49.** The application for renewal of a licence issued under section 46 shall be made by the licensee before the expiration of the licence, and upon such application, the licensee can continue his or her business until the licensing authority refuses the renewal thereof.

The application for renewal of a licence and the permission thereof shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

**Section 50.** In case the licence issued under section 46 is lost or destroyed, the licensee may apply for a licence substitute within 30 days from the date of knowledge of the loss or destruction.

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

**Section 51.** The person who possesses controlled herbs beyond the amount or quantity notified by the Minister under section 45(1) on the date on which the Notification on controlled herbs is made in the Government Gazette, shall inform the registrar of the possession of controlled herbs as required under this Act, within the period of time specified in the Notification.

**Section 52.** In case any licensee under section 46 does not comply with this Act or the Ministerial Regulations, Rules or Notifications issued under this Act, the licensing authority shall have the power to suspend the licence for not more than 90 days each time.

The licensee whose licence has been suspended must stop all the performances permitted under the licence and, within the suspension period, no application for other licence under this Act shall be made.

**Section 53.** The licensing authority shall have the power to revoke the order suspending the licence before the period specified, when satisfied that the licensee whose the licence has been revoked has complied with the provisions of this Act or the Ministerial Regulations, Rules or Notifications issued under this Act.

**Section 54.** If the licensee under section 46 does not comply with the provisions of this Act or Ministerial Regulations, Rules or Notifications issued under this Act and indulges in severe fault, the licensing authority shall have the power revoke the licence.

The licensee whose the licence has been revoked must stop all the performances permitted under the licence and shall not apply for any other licence under this Act until a period of two years, from the date the licence is revoked has elapsed and the licensing authority may issue such other licence as he or she deems appropriate.

**Section 55.** The order to suspend the licence under section 52 and the order to revoke the licence under section 54 shall be made in writing and notified the licensee. In case the licensee can not be found or the licensee refuse to accept the document, the order shall be posted at a conspicuous areas that can be easily seen at the place specified in the licence and it is deemed that the licensee has acknowledged the order from the date on which the order has been posted.

**Section 56.** The licensee whose the licence has been revoked under section 54 may sell the controlled herbs under their possession to other licensees or other person who the licensing authority deems appropriate, within 60 days from the date the notice is acknowledged. In case an appeal is made, the days shall be counted from the date on which the decision is made by the Committee, unless the licensing authority has extended the time period, but it shall not more than 60 days.

**Section 57.** For the purpose of conserving herbs and the areas from where the herbs naturally originate in the ecological system, or has biological diversity, or may have been easily effected by humans, in areas which have been specified as conservation areas, the Minister, with advice of the Committee, shall outline a plan entitled "Plan for Conservation of Herbs" to be forwarded to the Council of Ministers for approval.

Plans for conservation of herbs according to paragraph one may be made as a short term plan, medium term plan or long term plan according to appropriateness and has to include work plans and procedures leading to the following matters:

(1) stipulation of conditions in permitting a person to enter conservation areas as specified under the law on such matter for the compliance of the government agency concerned in order to conserve natural resources or the value of herbs or not to effect the natural, ecological system, or biological diversity in the areas where the herbs originated;

(2) laying down of procedures in handling particularly with the areas from where the herbs originated and also outlining the duties and responsibilities of the government agency concerned, for maximum benefit in coordination, in order to bring about efficiency in conserving the nature, the ecological system, biological diversity and the value of the herbs in that area;

(3) survey and research on herbs and the areas from where they originate for benefits in outlining procedures to conserve herbs and the place of their origin;

(4) the inspection, follow-up and analysis in entering into the conservation areas for benefits in carrying out the works as planned and enforcement of the laws concerned.

Plans for conservation of herbs under paragraph one shall be published in the Government Gazette.

**Section 58.** For benefits in outlining plans for conservation of herbs under section 57, the competent officials shall have the power to enter the specified conservation areas in order to inspect and research the herbs and the areas from where the herbs originate. This shall have to be done with support and coordination from other concerned state authorities, as specified by Rules prescribed by the Council of Ministers.

**Section 59.** After the publication of the plan on conservation of herbs under section 57, the protection and management of conservation area shall be carried out according to the plan on conservation of herbs and the law on such matter.

**Section 60.** If any conservation area is inappropriately managed or has problems concerned with inappropriate conservation of herbs, or has caused destruction of herbs, or areas in which the herbs originated, leading to severe crisis which needs to be tackled immediately and the state authorities concerned do not have the authority to do so under the law, or can not solve the problem, the Minister, with the advice of the Committee shall propose the Council of Ministers to permit the Ministry of Public Health to take action in conservation as outlined under the Plan for Conservation of Herbs as stated under section 57, as necessary and appropriate, to control and solve the problems.

**Section 61.** In case any area in which the herbs originated have natural ecology system or biological diversity that may be destroyed or may be easily effected by humans or the entry into the area for use of herbs has caused risk to extinction or degradation or reduction of species of herbs, or the state aims at increasing public involvement in the management, development and making use of herbs in the area, and the area has not been notified as conservation area, the Minister, with the advice of the Committee, has the power to issue Ministerial Regulation notifying the area as a herb conservation area.

The land within the specified area shall to be notified as herb conservation area under paragraph one shall not be the area under the right

ownership or possession under the Land Code of individuals who are not the state entities.

The Ministerial Regulation under paragraph one shall have a plan indicating the land area specified as herb conservation area attached therewith.

**Section 62.** In issuing a Ministerial Regulation according to section 61, at least one or many of the following protection measures shall be outlined in the Ministerial Regulation:

(1) The use of herb should maintain nature and value of the herb, or should not effect the natural ecology or biological diversity in the area;

(2) Any act that may be of danger or cause effects that could lead to change in the ecology system within the area, or biological diversity, or effect the value of the herbs, shall be prohibited;

(3) The imposition of specific management measures for those areas, along with outlining duties and areas of responsibility of the state, for effective cooperation and coordination in working towards conservation of natural resources and maintaining the value of the herbs, or the ecological system or biological diversity within the area.

(4) Outlining of other conservation measures as seen necessary and appropriate with the environment in the area.

**Section 63.** In the herb conservation areas, no person shall own or possess land, or plant or construct anything, or cut, clear, burn, or destroy trees or other plants, or destroy biological diversity or the ecology system, or carry out digging of minerals, stones, soil or change in the water ways or any act that results in pollution or causes flood or running dry of water, stream, canals, ponds, or causes danger to herbs, except for the act that is done to administer the area with the objective of conserving herbs or to make use of herbs, with permission from the licensing authority.

The application for and the issuance of the permit under paragraph one shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

The permit issued under paragraph one shall be valid up to 31 December of the third year after the year in which the permit is issued.

Section 49 and section 50, and section 52 up to section 55 shall apply *mutatis mutandis* to the renewal of permit, application for the substitute, suspension and revocation of the permit issued under paragraph one.

**Section 64.** In order to support the participation of the private sector in conservation, promotion and development of herbs, the owner or the possessor of the land from where the herbs originate or the land used for plantation of the herbs have the right to register the land with the registrar, in order to obtain assistance or support under this Act.

The obtainment of registration, the issuance of certificate of registration and the revocation of the registration shall be in accordance with the rules, procedure and conditions prescribed in the Ministerial Regulation.

**Section 65.** The owner or the possessor of the land that has been registered under section 64 has the right to obtain assistance or support as prescribed in the Rules issued by the Minister.

#### **CHAPTER 4**

#### **Conservation**

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**Section 66.** In case the registrar rejects the application for registration of intellectual property rights on traditional Thai medicine under section 27, the person who seeks registration has the right to appeal the order with the Committee within 30 days from the date on which the order was received from the registrar.

**Section 67.** In case the registrar has made a decision on the right of the applicant over the registration for intellectual property rights under section 30 paragraph two, the applicant or the objector, as the case may be, has the right to appeal to the Committee within 30 days, from the date of receiving of the decision of the registrar.

**Section 68.** In case the registrar issues an order revoking the registration on intellectual property rights on traditional Thai medicine as stated

under section 39 paragraph three, the right holder has the right to appeal the order to the Minister within 30 days from the date on which the notice has been received from the registrar.

The decision of the Minister shall be final.

The appeal under paragraph one shall not entail a stay of the execution the order to revoke the registration of intellectual property rights on traditional Thai medicine.

**Section 69.** In case the registrar issues an order to revoke the permission to exercise the intellectual property rights on traditional Thai medicine under section 41, the person who has the right to exercise the rights thereof may appeal the order to the Committee within 30 days from the date the notice of the registrar has been received.

The appeal under paragraph one shall not entail a stay of the execution of the revoke order on permission to exercise the intellectual property rights on traditional Thai medicine.

**Section 70.** In case the licensing authority orders the suspension of the permit under section 52 or orders the revocation of the permit under section 54, the person whose permit has been suspended or revoked has the right to appeal the order to the Committee within 30 days from the date the notice from the registrar has been received.

The appeal under paragraph one shall not entail a stay of the execution of the suspension or revocation of the permit.

**Section 71.** The decisions of the Committee under section 66, section 67, section 69 and section 70 shall be final.

**Section 72.** The appeal and procedure to consider the appeal shall be in accordance with the rules and procedure prescribed in the Ministerial Regulation.

## CHAPTER 5

### Competent Officials

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**Section 73.** In carrying out their duties, the competent officials shall have the power to:

(1) enter any place during the working hours to inspect and control of the execution of this Act;

(2) inspect any place or vehicles between the time when the Sun rises until the Sun sets or during working hours, in case there is suspicion that this Act has been violated, and in case there is a reasonable ground to believe that the delay in issuing search warrant may lead to removal or hide or destruction of documents or products concerned with the commission of offence, and if the inspection during the specified time is not complete, it can be continued;

(3) confiscate or take into custody the documents or products concerned with violation of this Act, as evidence in taking action against the case;

(4) request for any person for questioning or submitting documents or evidence in case there is a reasonable ground to believe that the statements, documents or evidence is of benefit to find or use as evidence in proving the violation of this Act;

(5) request any person to move out of the herb conservation area or avoid any act in violation of section 63.

In carrying out their duties in accordance with paragraph one, the concerned parties shall facilitate the competent officials as necessary.

**Section 74.** In carrying out their duties, the competent officials must produce their identity cards for identification.

The identity cards of the competent officials shall be in the Form as prescribed by the Minister by publication it in the Government Gazette.

**Section 75.** In carrying out their duties under this Act, the competent officials shall be the officials under the Penal Code.

## CHAPTER 6

### Fund on Traditional Thai Medicine Intelligence

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**Section 76.** A fund entitled "Fund on Traditional Thai Medicine Intelligence" shall be set-up in the Office of the Permanent Secretary, Ministry of

Public Health, as a revolving fund for expenses concerned with works on conservation and promotion of intelligence on traditional Thai medicine.

The fund shall include the following money and property;

- (1) subsidy from the state;
- (2) money or property received from the private sector from within and outside the country, foreign governments or international organizations;
- (3) interests and benefits obtained from the fund.
- (4) other earnings obtained from the functioning of the fund.

The earnings of the fund shall not be considered as earnings that must be remitted to the Finance Ministry under the law on the treasury balance and the law on the budgetary procedures.

The Office of the Permanent Secretary, Ministry of Public Health is responsible for maintaining the money and property of the fund, and shall withdraw the money in the fund in accordance with the provisions of this Act.

The administration, management of benefits and use of money in the fund shall be in accordance with the rules prescribed by the Committee, with the approval of the Finance Ministry.

## CHAPTER 7

### Penalties

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**Section 77.** Any person who violates the orders of the Committee or Sub-committee appointed under section 11 together with section 6(5) or order of the registrar under section 39 paragraph two or the order of the competent officials under section 73(4) shall be liable to imprisonment for a term of not more than one month, or a fine of not more than 2,000 baht, or both.

**Section 78.** Any person who violates section 19, section 46, section 52 paragraph two, section 54 paragraph two, or section 63 paragraph one or does not comply with the orders of the competent officials under section 73(5) shall be liable to imprisonment for a term of not more than one year, or a fine of not more than 20,000 baht, or both.

**Section 79.** Any person who violates section 51 shall be liable to imprisonment for a term of not more than six months, or a fine of not more than 10,000 baht, or both.

**Section 80.** Any person who violates the protection measures specified under the Ministerial Regulation issued under section 62(2) shall be liable to imprisonment for a term of not more than two years, or a fine of not more than 40,000 baht, or both.

**Section 81.** Any person who does not facilitate the competent officials under section 73 paragraph two shall be liable to a fine of not more than 2,000 baht.

**Section 82.** In case the wrongdoer who has to be liable under this Act is a juristic person, the managing director, manager, or representative of the juristic person shall be liable to the penalty imposed thereto, unless they can prove that the act of the juristic person have been committed without their knowledge or consent.

Countersigned by:

Chuan Leekpai

Prime Minister.

### RATE OF FEES

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(1) Licence to research on the controlled herbs or the renewal thereof	10,000	baht each
(2) Licence for sales, export or transformation of controlled herbs for commercial purpose or the renewal thereof	20,000	baht each
(3) Permit to administer the herbs control area or make use of herbs therein for commercial purpose or the renewal thereof	10,000	baht each
(4) Substitute of the licence or permit under (1) (2) or (3)	100	baht each
(5) Certificate of registration of land of herbs origin	1,000	baht each
(6) Substitute of the certificate of registration of land of herbs origin	100	baht each
(7) Permit for making use of formula of the national traditional Thai drugs or national traditional Thai medicine under section 19	20,000	baht each
(8) Objection of the registration of intellectual property rights on traditional Thai medicine	500	baht each
(9) Certificate of registration of intellectual property rights on traditional Thai medicine	1,000	baht each
(10) Substitute of the registration certificate of intellectual property rights on traditional Thai medicine	100	baht each
(11) Application form for a licence or permit or the renewal thereof, or for the registration, under this Act	500	baht each