Unofficial Translation*

# DRUGS ACT (NO. 6), B.E. 2562 (2019)

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HIS MAJESTY KING MAHA VAJIRALONGKORN BODINDRADEBAYAVARANGKUN;

Given on the 15th Day of April B.E. 2562;

Being the 4th Year of the Present Reign.

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

Whereas it is expedient to amend the law on drugs;

Whereas this Act contains certain provisions in relation to the restriction of rights and liberties of persons, in respect of which section 26 in conjunction with section 37 and section 40 of the Constitution of the Kingdom of Thailand so permits by virtue of provisions of law;

Whereas the reasons and need for the restriction of rights and liberties of persons under this Act lie in prescribing procedures for granting drug permission in a manner suited to circumstances and technological development and also the growth in drug-related trade and industry, ensuring public safety from the use of drugs meeting quality and standards in conformity with international principles and formulating a framework for drug studies and research with a view to achieving efficiency protecting safety of volunteers participating in drug studies and research, and, in this regard, the enactment of this Act duly complies with the conditions provided 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.

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* Translation by Associate Professor Dr. Pinai Nanakorn under contract for the Office of the Council of State of Thailand. – Tentative Version – subject to final authorisation by the Office of the Council of State.

**Section 1.** This Act is called the "Drugs Act (No. 6), B.E. 2562 (2019)".

**Section 2.**[1] This Act shall come into force after one hundred eighty days as from the date of its publication in the Government Gazette.

**Section 3.** There shall be added a definition of "process for drug permission" between the definitions of "drug formula" and "medical practitioner" in section 4 of the Drugs Act, B.E. 2510 (1967) as amended by the Drugs Act (No. 3), B.E. 2522 (1979):

""process for drug permission" means" the consideration of an application, the examination of accuracy of documents, the appraisal of technical documents, analytical tests, the inspection of an establishment or the examination for the purpose of issuing a licence, a certificate of drug formula registration or a certificate, and any consideration in connection with drugs."

**Section 4.** The provisions of the definition of "practitioner of traditional arts of healing" in section 4 of the Drugs Act, B.E. 2510 (1967) as amended by the Drugs Act (No. 3), B.E. 2522 (1979) shall be repealed and replaced by the following:

""practitioner of traditional arts of healing" means a practitioner of Thai traditional medicine in Thai medicine, a practitioner of Thai traditional medicine in Thai pharmacy or a practitioner of applied Thai traditional medicine under the law on Thai traditional medicine professions or a medical practitioner in Chinese traditional medicine under the law on medical practice".

**Section 5.** The provisions of section 5 of the Drugs Act, B.E. 2510 (1967) shall be repealed and replaced by the following:

"**Section 5.** The Minister of Health shall have charge and control of the execution of this Act and shall have the power to appoint competent officials, issue Ministerial Regulations prescribing fees not exceeding the rates annexed hereto, reducing or exempting fees and prescribing other matters and also issue Notifications in the execution of this Act.

In issuing Ministerial Regulations prescribing fees under paragraph one, different rates of fees may be prescribed, having regard to types, kinds and descriptions of drugs or categories of drugs prescribed in licences or the size and business of operators.

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[1] Published in Government Gazette, Vol. 136, Part 50a, dated 16th April 2019.

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

**Section 6.** The provisions of section 11 of the Drugs Act, B.E. 2510 (1967) shall be repealed and replaced by the following:

"**Section 11.** The Commission shall have the power to appoint sub-committees for considering or conducting a study or research on matters falling within the duties and powers of the Commission and on the process for drug permission under section 11/2.

In appointing a sub-committee in the execution of section 11/2, there shall be at least a representative of the Office of the Public Sector Development Commission, a representative of an association or foundation having the object relating to consumer protection and a representative of an association or business operators having the object in connection with the manufacture of drugs, the sale of drugs or the import or ordering of drugs into the Kingdom. In this regard, in a sub-committee in charge of considering and prescribing listing fees and costs, there shall also be a representative of the Ministry of Finance as an additional member.

The provisions of section 9 shall apply to meetings of a sub-committee *mutatis mutandis*."

**Section 7.** The following provisions shall be added as Chapter I/I, Process for Drugs Permission, section 11/1, section 11/2, section 11/3 and section 11/4 of the Drugs Act, B.E. 2510 (1967):

"**CHAPTER I/I**

**PROCESS FOR DRUG PERMISSION**

**Section 11/1.** In the process for drug permission, apart from officials of the Office of the Food and Drug Administration and officials of agencies attached to the Ministry of Public Health who are entrusted to perform activities in the discharge of duties and powers of the Office of the Food and Drug Administration, there shall be specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries for performing duties in connection with the appraisal of technical documents, analytical tests, inspection of establishments or examination in order to facilitate expediency and efficiency of the process for drug permission. In this regard, such persons, agencies or organisations must be listed by the Office of the Food and Drug Administration.

**Section 11/2.** For the purpose of the process for drug permission, the Minister with the recommendation of the Commission has the power to issue a Notification prescribing the following:

(1) rules, procedures and conditions for the acquisition and listing of specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries under section 11/1, provided that the Notification shall prescribe qualifications, standards and work operation of such persons, agencies or organisations;

(2) listing fees to be collected by the Office of the Food and Drug Administration from specialists, specialists' organisations, State agencies or private agencies in the country or from foreign countries, provided that they shall not exceed maximum rates of listing fees;

(3) types and the amount of costs to be collected by the Office of the Food and Drug Administration or a State agency entrusted to carry out missions within the duties and powers of the Office of the Food and Drug Administration, as the case may be, from applicants in the process of drug permission, provided that they shall not exceed maximum rates of costs;

(4) rules, procedures and conditions for the process of drug permission.

The maximum rates of listing fees and the maximum rates of costs under (2) and (3) shall come into force upon their approval by the Council of Ministers.

The Notification under paragraph one may prescribe exemption from rules, procedures and conditions under (1), listing fees under (2) or the types and amount of costs under (3) in whole or in part or may prescribe listing fees or costs differently as justified by necessity and appropriateness.

**Section 11/3.** Proceeds from listing fees collected under section 11/2 (2) shall vest in the Office of the Food and Drug Administration, while proceeds from costs collected under section 11/2 (3) shall vest in the Office of the Food and Drug Administration or the agency entrusted to carry out affairs within the duties and powers of the Office of the Food and Drug Administration, as the case may be, without being required to be remitted to the Treasury as State revenue, and shall be expended for the following purposes:

(1) funding remuneration of specialists, specialists' organisations or private agencies under section 11/1;

(2) funding expenses incurred in the operation of wok in pursuit of action plans or projects which are beneficial to the public, for the purpose of consumer protection in relation to drugs;

(3) funding expenses incurred in the development of potential of agencies and officials, with a view to developing work systems relating to the process for drug permission and enhancing efficiency of operations;

(4) funding other relevant and necessary expenses in connection with the pursuit of the process for drug permission, as prescribed in the Notification of the Minister.

**Section 11/4.** The receipt of proceeds under section 11/2 (2) and (3), the disbursement of proceeds under section 11/3 and the retention of money shall be in accordance with the rules, procedures and conditions prescribed in the Notification of the Minister with the approval of the Ministry of Finance."

**Section 8.** The following provisions shall be added as section 77 *quarter* and section 77 *quinque* of the Drugs Act, B.E. 2510 (1967):

"**Section 77 *quarter*.** In the interest of promoting, supporting and developing research for the purpose of considering drug formula registration with a view to achieving efficiency and standards of human research, the Minister has the power to issue a Notification, by publication in the Government Gazette, prescribing rules, procedures and conditions for drug research. In this regard, in such Notification, there shall also be the protection of safety of volunteers participating in drug research.

Drug researchers shall comply with the rules, procedures and conditions under paragraph one.

In the case where failure to comply with the rules, procedures and conditions under paragraph one results in lack of safety and danger to persons, the environment or the public on account of the process or steps relating to drug research, the Secretary-General of the Food and Drug Administration shall have the power to order improvement of the drug research, temporary suspension of the drug research or cessation of the drug research, in accordance with the gravity of such lack of safety and danger.

"**Section 77 *quinque*.** In the interest of developing and promoting drug-related industries, the Minister may issue a Notification prescribing rules, procedures and conditions in connection with standards for the manufacture of drugs, sale of drugs or import or ordering of drugs into the Kingdom. In this regard, requirements may be prescribed to the effect of applying or making reference to foreign standards or international standards and, in the case of necessity, applying or making reference to standards documented in foreign-language documents, provided

that such standards shall not be lower than those recognised by the Office of the Food and Drug Administration."

**Section 9.** The following provisions shall be added as (6/1) of section 80 of the Drugs Act, B.E. 2510 (1967):

"(6/1) documents indicating the reference number of the application for a patent or a petty patent already published under the law on patents or information on the registration of rights in personal Thai traditional medicine wisdom, wisdom comprising a general Thai traditional drug formula or a general Thai traditional medicine text or the acquisition of permission for the exploitation of a national Thai traditional drug formula or a national Thai traditional medicine text under the law on the protection and promotion of Thai traditional medicine wisdom."

**Section 10.** The provisions of section 86 *bis* of the Drugs Act, B.E. 2510 (1967) as amended by the Drugs Act (No. 3), B.E. 2522 (1979) shall be repealed and replaced by the following:

"**Section 86/1.** For the protection of safety of drug users, the Minister with the recommendation of the Commission shall have power to order alteration of a registered drug formula as may be deemed appropriate or as is necessary or order a review of a registered drug formula, in accordance with rules and procedures prescribed."

**Section 11.** The following provisions shall be added as section 86/2 of the Drugs Act, B.E. 2510 (1967):

"**Section 86/2.** A certificate of registration of a drug formula shall be valid for a term of seven years as from the date of issuance thereof.

The recipient of a certificate of registration of a drug formula who intends to apply for renewal of the term of validity thereof shall submit an application to the permission grantor prior to the date of its expiry

The recipient of a certificate of registration of a drug formula whose certificate expires for a term not exceeding one month may submit an application for renewal of its term of validity and for relaxation and shall, for this purpose, indicate a due reason for failure to submit an application for renewal of its term of validity within the time limit. But, the application for relaxation does not have the effect of precluding liability under section 123 *quarter* and in the case where the one-month period elapses as from the expiry of the certificate of registration of a drug formula, no renewal of the term of validity is permissible.

Upon submission of the application under paragraph two or paragraph three and payment of the fee for renewal of the term of validity, the certificate of registration of a drug formula shall remain valid until an order is issued for refusing to grant permission for renewal of its term of validity.

The renewal of the term of validity and the granting of permission for renewal of the term of validity of a certificate of registration of a drug formula shall be in accordance with rules, procedures and conditions prescribed in the Ministerial Regulation. In this regard, such Ministerial Regulation may also provide for a review of the registration of a drug formula.

In the case where an order is issued for refusing to grant permission for renewal of the term of validity of a certificate of registration of a drug formula, the permission grantor shall notify it to the recipient of the certificate of registration of a drug formula and the fee for renewal of the term of validity shall be returned to the applicant for the renewal *pro rata* by reference to the calculation on a monthly basis as from the date of the refusal order up to the date of the expiration of the seven-year period if such certificate of registration of a drug formula is otherwise permitted to be renewed. A fraction of one month, if it reaches a period of fifteen days, shall be reckoned as one month."

**Section 12.** The following provisions shall be added as section 122 *ter* of the Drugs Act, B.E. 2510 (1967):

"**Section 122 *ter*.** Any drug researcher who fails to comply with an order of the Secretary-General of the Food and Drug Administration under section 77 *quarter* paragraph three shall be liable to a fine not exceeding one hundred thousand Baht."

**Section 13.** The following provisions shall be added as section 123 *quarter* of the Drugs Act, B.E. 2510 (1967):

"**Section 123 *quarter*.** Any recipient of a certificate of registration of a drug formula who submits an application for renewal of its term of validity after the certificate of registration of a drug formula has expired for a term not exceeding one month under section 86/2 shall be liable to a daily fine not exceeding five hundred Baht a day throughout the period in which the failure to submit an application for renewal of its term of validity continues."

**Section 14.** Rates of fees annexed to the Drugs Act, B.E. 2510 (1967) shall be repealed and replaced by rates of fees annexed hereto.

**Section 15.** All applications for permission, applications for registration of a drug formula or any applications submitted prior to the date on which this Act comes into force and pending consideration shall be deemed to be applications under this Act *mutatis mutandis* and if such applications contain different particulars from those required under this Act, the permission grantor shall have the power to order amendment to the applications to ensure conformity with this Act.

**Section 16.** A certificate of registration of a drug formula issued under the Drugs Act, B.E. 2510 (1967) prior to the date on which this Act comes into force shall be valid for a term as follows:

(1) a certificate of registration of a drug formula as registered before 1st January 1997 shall expire at the expiration of a period of five years as from the date on which this Act comes into force;

(2) a certificate of registration of a drug formula as registered from 1st January 1997 to 31st December 2007 shall expire at the expiration of a period of seven years as from the date on which this Act comes into force;

(3) a certificate of registration of a drug formula as registered from 1st January 2008 to the date on which this Act comes into force shall expire at the expiration of a period of nine years as from the date on which this Act comes into force.

**Section 17.** Ministerial Regulations, Notifications or Rules issued under the Drugs Act, B.E. 2510 (1967) as in force on the day prior to the date on which this Act comes into force shall continue to be in force insofar as they are not contrary to or inconsistent with this Act until Ministerial Regulations or Notifications issued under the Drugs Act, B.E. 2510 (1967) as amended by this Act come into force.

The issuance of Ministerial Regulations or Notifications under paragraph one shall be completed within two years as from the date on which this Act comes into force. If their completion cannot be achieved, the Minister shall report the reasons therefor to the Council of Ministers.

**Section 18.** Notifications issued under the Order of the Head of the National Council for Peace and Order No. 77/2016 Re: Enhancement of Efficiency in the Process for Health Product Permission, dated 27th December B.E. 2559 (2016) in respect of drugs, as in force on the day prior to the date on which this Act comes into force, shall apply to the process for drug permission under the provisions of Chapter I/I, Process for Drug Permission, of the Drugs Act, B.E. 2510 (1967) as amended by this Act insofar as they are not contrary to or inconsistent with the

Drugs Act, B.E. 2510 (1967) as amended by this Act until Notifications issued under the Drugs Act, B.E. 2510 (1967) as amended by this Act come into force.

When Notifications issued under the Drugs Act, B.E. 2510 (1967) as amended by this Act come into force, the Notifications issued under the Order of the Head of the National Council for Peace and Order No. 77/2016 Re: Enhancement of Efficiency in the Process for Health Product Permission, dated 27th December B.E. 2559 (2016) in respect of drugs shall be repealed.

**Section 19.** The Minister of Public Health shall have charge and control of the execution of this Act.

Countersigned by:

General Prayut Chan-o-cha
Prime Minister