Act
Yum, 1967

Bhumibol Adulyadej, REX.

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

It is the 22nd year of the present reign.

His Majesty King Bhumibol Adulyadej His Majesty King Bhumibol Adulyadej to declare of the Royal Decree

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

Therefore, His Highness graciously graciously An Act shall be enacted with advice and consent. of the Constitution Drafting Assembly as a parliament as follows:

Section 1 This Act is called "The Medicine Act, B.E. 2510"

Section 2[1] This Act shall come into force upon the expiration of Sixty days from the date of announcement in the Government Gazette onwards

Section 3 to cancel (1) Drug Sales Act, B.E. 1950

(2) Drug Sales Act (No. 2), B.E. 1955

(3) Drug Sales Act (No. 3), B.E. 2499 (1956)

(4) Drug Sales Act (No. 4), B.E.

(5) Drug Sales Act (No. 5), B.E. 2502

Section 4[2] In this Act "drugs" means

(1) objects certified in the of the preparations announced by the Minister

(2) objects intended for for use in the diagnosis, treatment, mitigation, treatment or prevention of or human or animal sickness diseases decree

(3) pharmaceutical chemical substances or semi-finished pharmaceutical chemicals; or

(4) objects intended for for any effect on health, structure or function of the human or animal body

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1 Government Gazette, volume 84/part 101/special issue, page 7/20 October 1967

[y] Section 4 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

The objects under (1), (2) or (4) do not include

(a) objects intended for use in agriculture or industry as specified by the Minister announcement

(b) objects intended for for use as human food, sports equipment, tools, appliances for health promotion, cosmetics, or tools and components of equipment used for Practicing in the art of healing or the profession of medicine

(c) objects intended for for use in science rooms for research analysis or An autopsy that was not performed directly to the human body

"Modern drug" means a drug that is intended for for use in the medical profession Director, practicing modern art of healing or veterinary therapy

"Traditional medicine" means a drug that is intended for for use in the practice of the art of healing ancient plans or veterinary disease treatment which is in the list of ancient plans announced by the Minister or drugs prescribed by the Minister Announced as a traditional medicine or drugs that are permitted to be registered under for receiving medicines as traditional medicines

"Dangerous drug" means a modern drug or an ancient drug announced by the Minister. a dangerous drug

"Specially Controlled Drugs" means modern or traditional drugs prescribed by the Minister. Declared as a special controlled yam.

"Drugs for external use" 3 means that modern drugs or traditional drugs that are intended for external use, excluding topical

"Topical Drugs" 4 means that modern or traditional medicines intended for use Only on the ear, pound, nose, mouth, anus, vagina or urethra.

"general home drugs" means modern or traditional medicines prescribed by the Minister Declare it as a generic medicine for home use.

"Ready-packed medicine" 5 means a modern drug or an ancient drug that has been produced. Finished in pharmaceutical form, which are packaged in sealed or sealed containers or packages. and have complete labels under this Act

"Herbal medicine" means a drug derived from a plant, animal or mineral which is not mixed with or Transfiguration

"Pharmaceutical Chemicals" means organic chemical substances. or inorganic chemistry, which is a single substance used for flavoring, garnishing, preparing or mixing into a salad

"Semi-finished pharmaceutical chemicals" means organic chemicals or inorganic chemicals that It is a substance or mixture in a ready-to-use form. to be used in the production of finished medicines

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ÿ Section 4 defines the term "medicines for external use" as amended by the Medicines Act (No. 5), B.E. ÿÿÿÿ

ÿ Section 4 defines the term "medicine for topical use" as amended by the Drug Act (No. 5), B.E. ÿÿÿÿ

ÿ Section 4 The definition of "Ready Packed Medicines" was amended by the Medicines Act (No. 5), B.E. ÿÿÿÿ

“Professional medicine” means that the practice of medicine according to
Law on Medical Professions

“Practice of the modern art of healing” means the practice of the art of healing by
Relying on knowledge gained through scientific studies

“Practice of the traditional art of healing” means that the practice of the art of healing by
rely on knowledge from It is a study or succession study that is not a science-based education.

“Treatment of veterinary diseases” means that any action taken directly on the body
of animals for examination, treatment, prevention or elimination of disease

“Produce” 6 means to make, mix, cook or transform and includes
Transforming the salad, dividing the spicy salad with the intention to become the ready-packed salad, whether labeled or not.

“active ingredient” means the substance which is the constituent The importance of medicines that can contain
Therapeutic, relief, curative or preventive effects or human or animal sickness

“Strength of active ingredient” means

(1) Concentration of a drug with an active ingredient indicated by weight ,
weight per volume or the amount of active ingredient per unit of use; or

(2) the therapeutic effect of the drug as tested in the laboratory;
by appropriate means or has passed the control of the use of the disease effectively enough

"Sell" 7 means retail, wholesale, distribution, distribution, distribution, exchange for
commercial benefits and shall include having for sale.

"Wholesale" 8 means selling directly to a licensee to sell drugs. Licensee to sell
Ministry, Ta-buang, Department, Thai Red Cross Society, Pharmaceutical Organization Person authorized to operate
Hospital, medical practitioner Nursing Professionals Sustainability Practitioner.
Pregnant, nursing and midwifery practitioners Practitioner of modern arts, or
Veterinary practitioner

“Imports” 9 means any port or place in the Kingdom declared by the Minister.
in the Government Gazette as a checkpoint for drug inspection to lead or order into the Kingdom

“Label” includes any figure, invention, mark or message which
Shown on the container or package of medicine.

“Medicine documentation” includes: paper or any other object that makes it appear
Meaning with pictures Any fabricated mark, mark or statement relating to any drug inserted or included with
or packages containing medicines
Containers

“drug formulation” means a formulation which identifies a preparation ingredient that contains a drug, regardless of
What shape will it be cooked? and shall include drugs that are in the pharmaceutical industry which
ready to be used by humans or animals

ÿ Section 4 The definition of “production” was amended by the Medicines Act (No. 5), B.E. 2530.

ÿ Section 4 The definition of “selling” was amended by the Drug Act (No. 5), B.E. 2530.

ÿ Section 4 defines the word “wholesale” added by the Medicines Act (No. 5), B.E. 2530.

ÿ Section 4 defines the term “import checkpoint” added by the Medicines Act (No. 5), B.E. 2530.

"Permission Consideration Process" 10 means reviewing an audit request
the accuracy of the document Academic Document Assessment Analysis
Operate or audit to issue a license, certificate of registration medicine or certificate as well as any considerations
on medicines

"Medicine practitioner" means a medical practitioner
Law on Medical Professions

"Practice of the modern art of healing" means a practitioner of the modern art of healing.
Currently in the fields of dentistry, pharmacy, midwifery or nursing under the law on
control of the practice of the art of healing

"traditional healing arts practitioner" 11 means a practitioner of traditional medicine
Thai traditional medicine in Thai medicine Thai traditional medicine practitioner, Thai pharmaceutical practitioner
Applied Thai Traditional Medicine Profession in accordance with the Law on Profession of Thai Traditional Medicine or operator
Chinese Medicine

"First-class pharmacist" means a first-class practitioner in the modern art of healing in the branch.
pharmacy

"Second-class pharmacist" means a second-class practitioner in the modern art of healing in the branch.
Office of the Pharmacy

"Business operators first-class animal disease treatment" means that the licensee is
operator to provide first-class veterinary treatment according to the Animal Disease Control Act

"Business operators second-class animal disease treatment" means that the licensee is
operator second-class veterinary medicine
animal disease

"licensee" means a person licensed under this Act and in the case of
A juristic person is a licensed person. shall include the manager or representative of the juristic person who operates
business as well

"licensors" means that
(1) Secretary of the Food and Drug Administration or a person who is the secretary of the committee
Food and drug assignments. bring or order medicines into the Kingdom

(2) Secretary of the Food and Drug Administration or a person who is the secretary of the committee
Food and Drug Assignments For the license to sell medicines in Bangkok

(3) the provincial governor for granting permission to sell drugs in provinces that are under the jurisdiction.
other than Bangkok

"Committee" means the Medicine Committee under this Act.

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[99] Section 4 defines the term "the process of considering permitting drugs" added by the Medicines Act (Vol.
No. 6) B.E. 2019

[99] Section 4 defines the term "traditional healing arts practitioner" as amended by the
(No. 6) B.E. 2019

“Officer” means a person appointed by the Minister to act in accordance with
This Act

“Minister” means the Minister in charge of this Act.

Section 5 12 The Minister of Public Health shall maintain the affairs of this Act,
and have the power to appoint officials. water with the issuance of
ministerial regulations prescribing fees not exceeding the rate

at the end of this Act Reduce or exempt fees and determine other businesses, including issuing announcements
for the implementation of this Act

The issuance of Ministerial Regulations If the fees under paragraph one are set, the rates
Fees to be different taking into account the type, kind and nature of the prescribed drug or drug category.
in the license or the size and business of the operator

Ministerial Regulations and Announcements Once it has been published in the Government Gazette, it shall come into force.

Chapter 1

Drug Committee

Section 6 13 There shall be a committee called the “Medical Committee”.

consisting of the Permanent Secretary of the Ministry of Public Health as the chairman of the committee Director-General of the Medical Department Director-General of the Department
contagious disease control Director-General of the Department of Medical Sciences Director General of the Department of Health Board Secretary
Representative of the Ministry of Defense Representative of the Ministry of Agriculture and Cooperatives Representative of the university department
appointed from two deans of the Faculty of Pharmacy, representatives of the Board of Directors
Decree of the Director of the Division of Healing Arts Practices, Office of the Permanent Secretary Ministry of Public Health
being a director by position and not less than five qualified members appointed by the Minister but not more than
Nine people. Of these, at least two must be practitioners of the traditional art of healing.

Let the Deputy Secretary-General of the Food and Drug Administration be a member and secretary, and
Director of Division, Drug Control Division, Office of the Food and Drug Administration being a director and
Assistant secretary

State holding
the position for two years
Directors who are retired The position may be re-appointed.

Section 8. In addition to the expiration of Having held a position under section 7, the qualified director has expired.
from the position when

(1) death

(2) resignation

ÿÿ Section 5 amended by the Medicines Act (No. 6) B.E. 2019

ÿ Section 6 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

(3) to be dismissed by the Minister

(4) being bankrupt

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

(6) being imprisoned by a final judgment, except for a petty offense or offenses committed recklessly

(7) suspended or revoked a license to practice the art of healing.

When a qualified director is retired position before maturity to have the Minister appoint another person as Director instead and let that person be in the position to hold the position according to the terms of the director whom he/she replaces

Article 9 Board Meeting There must be at least one of the directors attending the meeting. Three of the total number of directors will constitute a quorum. If the chairman of the board is not present at the meeting The directors attending the meeting elect one director to be the chairman of the meeting.

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

One director shall have one vote. If the votes are the same, the chairman At the meeting, one more vote was cast as a casting vote.

Section 10 The Board of Directors has the duty to give advice or opinions on the following matters.

(1) Permission to produce drugs, sell drugs, or bring or order drugs into the Kingdom and the establishment of Recipe registration

(2) suspension of license Revocation of a license or drug registration revocation

(3) prescribing rules Methods and conditions related to drug production, drug sales, Bringing or ordering medicines into the Kingdom, taking medicines as samples for inspection and site inspections Manufacture of medicines, places to sell medicines, places to bring or order medicines into the Kingdom, and places where medicines are stored.

(4) the Minister's exercise of power under section 76 or section 77;

(5) other matters as assigned by the Minister.

Section 11 14 Let the Board have the power has the power to appoint a sub-committee to consider or research on matters that are in their duties and of the Board of Directors and the consideration process Drugs are permitted under section 11/2.

The appointment of a sub-committee to implement section 11/2 must at least Representative of the Office of the Government Development Board Representatives of associations or foundations whose objectives are consumer protection Representatives of associations or entrepreneurs with objectives in the manufacture of drugs, the sale Bringing or ordering medicines into the Kingdom. set up an account and expenses to have more representatives of the Ministry of Finance as sub-committees.

The provisions of section 9 shall apply mutatis mutandis to meetings of the sub-committees.

ÿÿ Section 11 amended by the Medicines Act (No. 6) B.E. 2019

Chapter 1/1

The process of considering permitting [15]

Section 11/116 In the process of considering a permit other than the office staff Food and Drug Administration and officials from agencies under the Ministry of Public Health who have been assigned to operate the business in the duties and powers of the Food and Drug Administration to have experts , the professional organization government agency or non-governmental organizations both domestically and internationally, acting in Academic Document Assessment Analysis establishment inspection or inspection In order for the approval process to be convenient, speedy and efficient, such person, agency or organization must be listed by the Office of the Registrar. Office of the Food and Drug Administration

Section 11/217 For the benefit of the approval process, the Minister The recommendation of the Board of Directors has the power to declare as follows:

(1) rules, procedures and conditions for acquiring and listing an expert organization; expert government agency or non-governmental organizations both domestically and internationally under section 11/1. to define qualifications, standards, and operations of individuals, agencies or such organizations

(2) the accounting value that is important for The Food and Drug Administration will collect from the experts. professional organization government agency or private organizations both in the country and abroad which can be stored Must not exceed the maximum bookkeeping rate

(3) types and expenses that are important of the Food and Drug Administration or the agency of the state assigned to to carry out the duties and powers of the Food and Drug Administration, the As the case may be, it will be collected from the applicant. to request in the approval process which can be stored not more than Maximum cost

(4) rules, procedures and conditions in the approval process

The highest billing rate and the highest expense rate under (2) and (3) upon receipt of approval approved by the Cabinet to come into force

The announcement under paragraph one may prescribe the exemption of rules, procedures and conditions. under (1), accounting values under (2), or categories and expenses under (3), in whole or in part, or Set up accounts or expenses to vary according to necessary and appropriate

Section 11/318 Account balance collected under section 11/2 (2) shall belong to Office of the Food and Drug Administration for expenses collected under section 11/2 (3) shall be

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[ÿÿ] Chapter 1/1 Procedures for Approving Drugs Sections 11/1 to Section 11/4 added by Medicine Act (No. 6) B.E. 2562

[ÿÿ] Section 11/1 added by the Medicines Act (No. 6) B.E. 2019

[ÿÿ] Section 11/2 added by the Medicines Act (No. 6) B.E. 2019

of the Food and Drug Administration or an agency assigned to Doing business in duty

powers of the Office of the Food and Drug Administration that have been collected, as the case may be, without having to be sent to the treasury. and the

as land income and shall be paid for the following purposes:

(1) as compensation for an expert, an expert organization or a non-governmental organization under Section 11/1

(2) it is an operating expense Implementation of a plan or project that is beneficial Public Health for the Protection of Consumers in Medicines

(3) It is an expense for the development of the competency of the agency and the officer to develop Work systems related to the approval process and increase operational efficiency

(4) are other related expenses and necessary concerning the conduct carry out the consideration process Permit as prescribed by the Minister

Section 11/419 Receipt of money under Section 11/2 (2) and (3) Payment under Section 11/3 and the collection of money shall be in accordance with the rules, procedures and conditions announced by the Minister. Determined with the approval of the Ministry of Finance

Chapter 2

Applying for and issuing licenses for modern medicines

Section 12. No one shall produce, sell, or bring or order into the Kingdom of At present, unless a license has been obtained from the licensor

Permissions and permissions are in accordance with the rules. Methods and conditions that stipulated in the ministerial regulations

Section 13 20 The provisions of section 12 do not apply to

(1) production of drugs produced by ministries, bureaus, or departments in charge of prevention or treatment, the Office of the Council of State, the Office of the Council of State, the Office of ordinance committee The Thai Red Cross Society and the Government Pharmaceutical Organization

(2) the manufacture of drugs according to the prescription of a medical practitioner or of a disease practitioner; art to order for specific patients or according to the prescription of the operator veterinary disease treatment for animals individual

(3) Sales of herbal medicines that are not dangerous drugs Sale of generic drugs at home Sales of medicines which a medical professional or a practitioner of the art of healing in the field of dentistry for patients of himself or the sale of drugs which the operator animal disease treatment for animals to treat or prevent disease or

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ýý Section 11/3 added by the Medicines Act (No. 6) B.E. 2019

ýý Section 11/4 added by the Medicines Act (No. 6) B.E. 2019

ýý Section 13 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

Sale of medicines sold by ministries, bureaus, departments in charge of prevention or treatment. The Thai Red Cross and
Pharmaceutical Organization

(4) bringing drugs with you into the Kingdom, which does not exceed the necessary amount;
for thirty days

(5) bringing or ordering drugs into the Kingdom by ministries, bureaus, or departments in their duties;
Preventing or treating diseases, the Thai Red Cross Society and the Government Pharmaceutical Organization

Persons exempted under (1) and (5) must comply with the rules, procedures and conditions prescribed by
stipulated in the Ministerial Regulation 21

Section 1422 A licensee shall issue a license to produce, sell or bring or order into
the kingdom that modern medicine can when it appears that the applicant for permission

(1) being the owner of the business and having assets or status sufficient to establish and operate able to operate

(2) being at least twenty years of age;

(3) have a residence in Thailand;

(4) never having been imprisoned by a final judgment or to give a lawful order
imprisonment for an offense that the law provides for an act as a constituent or in the wrong
under the law on narcotics The Law on Psychotropic Substances
with the sale of drugs or this Act unless the punishment has been passed for not less than two years prior to the date of application for a permit

(5) not being a person of unsound mind or an incompetent or a quasi-incompetent person

(6) not having a disease as announced by the Minister; prescribed in the Government Gazette

(7) there is a place for drug production, a place to sell drugs, a place to bring or order medicines into the Kingdom; or a
place where medicine is stored and equipment used in drug production, drug sales, or drug storage and control; or
maintain the quality of medicine which have the characteristics and amount as prescribed in the Ministerial Regulation

(8) to use a name in a commercial operation uniquely of or similar to the name used in the assembly

The business of the licensee who has been suspended or whose license has been revoked has not yet
one year

(9)23 There are persons who will act under Section 38, Section 39, Section 40, Section 40 bis.
Section 41, Section 42, Section 43 or Section 44, as the case may be.

Persons with duty to operate under (9) must be stationed at the place of drug production, place of sale of the drug, or
State can be the only place to bring or order medicines into the Kingdom.

In the case of a juristic person applying for permission, a manager or a representative of the juristic person who operates
The business must have the qualifications under (2) and (3) and must not have any prohibited characteristics under (4), (5) or (6).

Section 1524 Types of licenses The current plans for medicinal products are as follows:

ÿÿ Section 13, paragraph two, added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 14 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 14 (9) as amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 15 was amended by the Medicines Act (No. 5), B.E. 2530.

(1) a license to produce modern medicine;

(2) License to sell modern drugs

(3) a license to sell modern medicines;

(4) a license to sell modern drugs, only ready-packed drugs that are not dangerous drugs or drugs; special control

(5) a license to sell modern medicine only for ready-packed medicine for animals;

(6) a license to bring or order modern drugs into the Kingdom;

It shall be deemed that a person licensed under (1) or (6) is a person licensed under (3) for Drugs that they produce or bring or order into the Kingdom as the case may be.

It shall be deemed that a person licensed under (2) is also a person licensed under (3), (4) and (5).

It shall be deemed that the licensee under (3) is also a licensee under (4) and (5), but can only be sold by wholesale

Section 16. A license issued under section 15 shall provide protection to an employee or representative of licensee as well

shall be deemed that the of the employee or the agent of the licensee who is immune to Paragraph one is also the act of the licensee. unless the licensee can prove that doing so It is beyond their knowledge or control.

Section 17ÿÿ The license under section 15 is valid until the 31st of December of the year the licensor issues the license. A licensee wishes to renew the license to submit The request must be paid before the license expires.

when filed has already made such request may continue to operate the business until the licensor orders not to renew the license

Requests for renewal of licenses and permissions shall be in accordance with the rules, procedures and Conditions set forth in the Ministerial Regulations

A licensee whose license has expired within one month will submit a waiver request together with with reasons for the renewal of the license, but the submission of this waiver is not a cause for acquittal Business that has been done before applying for a license renewal, which is considered an undertaking Expiration license

Requesting a license renewal upon expiration for a period of one month from the date of expiration of the license age is impractical

Section 18. In the case where the licensor does not issue a license or does not grant permission to renew the license, An applicant for a license or an applicant for a renewal of a license has the right to appeal in writing to the Minister within thirty days from the date of Date of receipt of the licensee's notice of refusal to issue a license or not to allow renewal of license of State The decision of the Minister shall be final.

ÿÿ Section 17 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

In the event that the licensor does not allow the renewal of the current drug production license before the minister shall have a
decision on the appeal under paragraph two, the Minister has the power to order permission to carry out business. The
At the request of the appellant

Chapter 3
Duties of licensees in relation to modern medicines

Section 1926. A licensee is prohibited from

(1) produce or sell modern medicines outside the designated place; provided for in the license, unless
Wholesale

(2) produces or sells modern medicines that do not match the type of license;

(3) selling modern drugs that are dangerous or specially controlled drugs; to the licensee
under section 15 (4)

Section 2027 Licensees to produce modern medicines must have at least two first-class pharmacists.
Persons are responsible for the operations under section 38 and at least one pharmacist must be stationed.
all the time we are open

In case of necessity for the benefit of modern drug production control, the licensor will
Requires licensees to produce modern medicines to have first-class pharmacists is responsible for the operation under Sections of the
38 more than the amount specified in the first paragraph. according to the criteria set out prescribed in the Ministerial Regulation 28

Section 2129 Licensee to sell modern drugs Must have a first-class pharmacist or pharmacist
The second floor is the person who has the duty to operate under section 39 and section 40, always in operation

Section 21 bis30 A licensee to sell modern medicine must have a first-class pharmacist who has
The duty to perform duties under section 40 bis is stationed at the place of sale of modern medicines or at the place of storage of medicines.
all the time we are open

Section 2231 Licensees to sell modern drugs only for prepackaged drugs that are not medicines
Dangerous or specially controlled drugs Must have a first-class pharmacist second-class pharmacist medical practitioner who

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ÿÿ Section 19 amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 20 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 20, paragraph two, added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 21 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 21 bis added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 22 amended by the Medicines Act (No. 3), B.E. 2522

Practicing first-class modern arts in the field of dentistry Midwifery or nursing is a person who has

The duty to perform duties under Section 41 is always on duty during the business hours.

Section 2332 Licensee to sell modern drugs only ready-packed drugs for for animals must

There is a first-class pharmacist second-class pharmacist operator a first-class veterinary practitioner or a practitioner

Second Class, is responsible for the operations under Section 42 and Section 43, always on duty. the

Section 2433 Licensee who bring or order modern medicines into the Kingdom must have

first class pharmacist is a person who has the duty to operate under section 44 stationed at the place where the medicine is brought in or ordered into

Kingdom or drug storage facility all the time we are open

Section 2534. A licensee for the production of modern drugs shall comply with the following practices:

(1) provide a signboard at the disclosure of the place of manufacture specified in the license which is easily visible;

from outside the building is

(a) a sign indicating that the drug is manufactured;

(b) a sign showing the name, surname and academic status of the person having the duty to operate and the time

Operation

In this regard, the material used for making the label, the appearance, color, size of the label, the size of the letters and

The text displayed on the label shall be as specified in the prescribed in the ministerial regulations

(2) arrange for an analysis of raw materials and drugs produced before taken out of the manufacturing facility with

Evidence provides details of all analyzes Which must be maintained for at least five years.

(3) provide a label as registered under The medicine receipt is sealed in the container and packaged medicine that is

produced and on the label must show

(a) Yum name

(b) certificate number or code important for registration of medicinal formulas

(c) quantity of medicines contained

(d) the name and quantity or strength of the active ingredient which is the essential ingredient;

of medicines which must be in accordance with the registered medicinal formulas

(e) number or letter indicating the time of manufacture or analysis

(f) the name of the manufacturer of the drug and the province where the place of manufacture of the drug is located

(g) Date,

month, year of drug production

(h) the terms “dangerous drug”, “specially controlled drug”, “external drug” or “medicine for use;

specific" as the case may be, with red letters clearly visible in the case of a dangerous drug. Yum, special control, yam used

for external or topical use drugs

ÿÿ Section 23 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 24 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 25 amended by the Medicines Act (No. 5), B.E. 2530

(i) the term “homemade medicine” in case of generic home use medicine;

(j) The term “veterinary drug” in the case of veterinary drugs.

(k) the word “Expired Yam” and showing the date, month, and year the Yam has expired; In the case of a yum that

The Minister announced under section 76 (7) or (8).

(4) use labels and documents in the form of medicinal herbs registered in the medicinal formula and the text in

Labels and documents The information on the medicine must be clearly legible. The document containing the medicine must be translated into a foreign language.

in Thai language as well

(5) provide a warning on drug use in the label and on the drug leaflet for drugs prescribed by the Minister.

Notification under section 76 (9) in the case of a documented label Medication warnings are listed at

Any part of the label or documentation of the medicine may be

(6) to make samples of raw materials used in the manufacture of medicines; List of yam produced and sold and collecting

In this regard, as stipulated in the Ministerial Regulations

(7) other acts as prescribed prescribed in the ministerial regulations

In the case that the container of medicine is so small that it cannot show the label with the text under (3)

In all, the licensee to produce modern medicinal products shall be exempted from having to show any statement under (3) (c) (d) (e) (f) (g) (i) or (j). one

or all After receiving permission from the licensee

in the case of drugs produced for export outside the Kingdom Text on labels and documents

The medicine label must also specify the name of Thailand. Other messages, if wishing to request an exemption, must be granted permission from

first licensee

In the case where a licensee for the production of modern drugs wishes to amend the label concerning the date, month , year

in which the drug has expired under (3) (k), must submit an application for a license in accordance with the rules, procedures and conditions prescribed in

ministerial regulations

Section 2635 Licensees to sell modern drugs shall comply with the following:

(1) provide a sign at the disclosure of the place where the drug is sold as specified in the license; easily seen

from outside the building is

(a) a sign indicating that it is a place where medicine is sold;

(b) a sign showing the name, surname and academic status of the person having the duty to operate and the time

Operation

In this regard, the material used for making the label, the appearance, color, size of the label, the size of the letters and

The text displayed on the label shall be as specified in the prescribed in the ministerial regulations

(2) arrange for a separate storage of medicines; for animals as a proportion from other medicines

(3)

provides for the separation of drugs into the following proportions:

(a) dangerous drugs

(B) Specially Controlled

Drugs

(c) other spicy salads

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Section 26 amended by the Medicines Act (No. 3) B.E. 2522

(4) to provide a proportionate place for the preparation of prescription drugs by medical practitioners Practitioner of modern arts or operators animal disease treatment and for the storage of medicines used therein too

(5) provide labels on the containers and packages for medicinal herbs as specified as prescribed in section 25 (3), there shall be intact

(6) to make a list of drugs purchased and sold as prescribed by prescribed in the ministerial regulations

(7) other acts as prescribed prescribed in the ministerial regulations

The provisions of paragraph one shall apply to a licensee who has been granted a license to sell drugs under section 15 (4) and (5) mutatis mutandis.

Section 26 bis [7] A licensee to sell modern medicines shall comply with Section 26 paragraph one, mutatis mutandis, except that there is no need to provide a proportionate place. for seasoning the spicy salad according to (4)

Section 2738 The licensee making or ordering modern medicines into the Kingdom Do the following

(1) provide a signboard at the disclosure of the location; bring or order medicines into the specified kingdom contained in the license, which is easily seen from outside the building, is

(a) a sign indicating that it is a place bring or order medicines into the Kingdom

(b) a sign showing the name, surname and academic status of the person having the duty to operate and the time Operation

In this regard, the material used for making the label, the appearance, color, size of the label, the size of the letters and The text displayed on the label shall be as specified in the prescribed in the ministerial regulations

(2) At the time of import, a manufacturer's certificate showing details of the drug analysis must be provided. who brought or ordered into the kingdom which must be kept for not less than five years The cave manufacturer's certificate is Foreign languages must also translated into Thai and have a label as specified prescribed in section 25 (3) that Containers and packaging for medicinal products Unless in (f) specify the name of the city and country where the place of manufacture of medicine is located instead. province name

(3) Before selling the medicine, labels shall be provided with the container and packaging of the medicinal product having the characteristics and The information is complete as set out in specified in section 25 (3), except in (f) specifving the names of cities and countries; Location of the place where the medicine is produced instead of the name of the province and specify the name of the leader bring or order medicines into the Kingdom; and Province or ordering spicy salads as well

(4) use labels and documents in the form of medicinal herbs registered in the medicinal formula and the text in Labels and documents The information on the medicine must be clearly legible. The document containing the medicine must be translated into a foreign language. in Thai language as well

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[ÿÿ] Section 26 paragraph two, amended by the Medicines Act (No. 5), B.E. 2530.

[ÿÿ] Section 26 bis added by the Medicines Act (No. 5), B.E. 2530

[ÿÿ] Section 27 amended by the Medicines Act (No. 5), B.E. 2530

(5) provide a warning on drug use in the label and on the drug leaflet for drugs prescribed by the Minister.
Announcement under section 76 (9). Warning for use of the drug if it is in a foreign language. translated into Thai

also in the case that the label has a document Medication warnings are listed in any section.
label or document

(6) to make a list of drugs brought in or ordered into the Kingdom and sold; and collect samples at
to bring or order into the Kingdom as stipulated in the Ministerial Regulations

(7) pharmacists as prescribed prescribed in the ministerial regulations

In the case of medicines imported under (2) or medicines to be sold under (3) are packed in containers with
so small that it may not be able to show all the labels with the text under section 25 (3), the licensee shall give or order
Modern medicine entering the Kingdom is exempted from the need to show a statement under section 25 (3) (c) (d) (e) (f) (g) (i) or (j)
Any or all of the following, when permitted by the licensor

Section 27 bis 39 Modern medicines To bring or order into the kingdom, it must be passed.
Competent staff inspection at the entry point
Competent officers' audits are carried out in accordance with established rules and procedures.
in the ministerial regulations

Section 28 in the event of a license loss or material damage the licensee
notify the licensor and submit a request A license substitute must be filed within fifteen days from the date of acknowledgment of the loss.
or was destroyed as such

Requesting a substitute for a license The formulation and issuance of a substitute license shall be in accordance with
Criteria, methods and conditions prescribed prescribed in the ministerial regulations

Section 2940 A licensee must present his or her license and that of a pharmacist, a practitioner
professional medicine A first-class practitioner of the modern arts in the field of dentistry Midwifery or
a nurse or veterinary practitioner, put it in a conspicuous place easily visible at the drug production facility
selling medicines or places bring or order medicines into the Kingdom, as the case may be.

Section 30. A licensee is prohibited from moving to a place of drug production, place of sale of a drug, place of delivery or
Order medicines into the Kingdom or a place where medicines are stored. unless authorized by the licensor

Permission and Permission to be in accordance with the rules Methods and conditions that
stipulated in the ministerial regulations

Section 31. A licensee is prohibited from producing modern drugs in a drug production facility during
Pharmacists are not on duty in such places.

[ÿÿ] Section 27 bis, added by the Medicines Act (No. 5), B.E. 2530

[ÿÿ] Section 29 amended by the Medicines Act (No. 3), B.E. 2522

Section 32. Licensees are prohibited from selling dangerous or specially controlled drugs during

Pharmacist or operator Veterinary disease treatment is not on duty.

Section 33 When the licensee wishes to change the person having the duty to perform the duties under section 38

Section 39 Section 40 Section 40 Bis Section 41 Section 42 Section 43 or Section 44 to notify

It is a letter to the licensor. and can be substituted with permission from the licensee.41

In the case where the licensee does not have the duty to perform the duties under paragraph one to the licensee

notify in writing to the licensor within seven days from the date that no person has the duty to operate

Section 33 bis 42. In the case of a person having duty to operate in a drug production facility a place that sells medicine or

The place of bringing or ordering medicines into the Kingdom shall not be able to function temporarily for a period of not more than sixty days.

The licensee appoints a person with the same qualifications as a person operating in that location to act on his behalf.

Yes, by letting the licensee notify it is a letter to the licensee first. and shall be regarded as the person acting on behalf of the person who has

Functions under Section 38, Section 39, Section 40, Section 40 bis, Section 41, Section 42

Section 43 or Section 44, as the case may be.

The notification in writing under paragraph one shall be in accordance with the regulations prescribed by the Board.

Section 3443 Persons having duties under Section 38 Section 39 Section 40 Section 40

40 bis, section 41, section 42, section 43 or section 44 who wishes to not perform their duties Must notify in writing to the licensor for

information no later than seven days from the date of termination of duty.

Section 35. Any licensee who ceases any business permitted under this Act The termination of business must be

notified in writing to the licensor not exceeding fifteen days from the date of termination of business and it shall be deemed that

The
license has expired from the date of business dissolution as stated.

Section 36 The licensee who has notified the dissolution of the business shall sell his remaining drug to the recipient.

granting other permissions or to whom the licensor deems appropriate within ninety days from the date of cessation of business except the licensee

will extend the said period

Section 37 If a licensee dies and there is a person who is qualified to be a licensee

In accordance with this Act, express the intention to the licensee within thirty days from the date of the licensee's death.

in order to continue the business that the deceased has been given permission to may allow the person expressing his intention to continue his business

until the license expires In such case, it shall be deemed that the Employed as a licensee under

This Act since the licensee's death

ÿÿ Section 33, paragraph one, amended by the Medicines Act (No. 5), B.E. 2530.

ÿÿ Section 33 bis, amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 34 as amended by the Medicines Act (No. 5), B.E. 2530

Chapter 4

Pharmacist duties medical practitioner practitioner

First-class current plan in dentistry Midwifery or nursing

or operators animal disease treatment 44

Section 3845 A first-class pharmacist under section 20 shall be stationed at a drug production place.
throughout the business hours and to perform the following duties:

(1) to control the production of drugs in accordance with the regulations of medicines that have been registered under Section 79

(2) to control the practice of labels and documents; Act on medicines under section 25 (3) (4) and (5)

(3) to control the packaging of medicines and the labeling of drug containers and packages to be in accordance with in accordance with this Act

(4) to control the sale of drugs to be in accordance with Section 39.

(5) to control drug accounting and sample storage under section 25 (6).

(6) other acts as prescribed prescribed in the ministerial regulations

Section 3946 A first-class pharmacist under section 21 shall be present at the place of sale of prescription drugs.
present throughout the business hours and are obliged to perform the following duties:

(1) control the separation of drug storage under section 26 (2) and (3);

(2) to control the practice of labels under section 26 (5);

(3) to control the sale of drugs in accordance with this Act;

(4) to concoct drugs in a place arranged by a licensee to sell drugs under section 26 (4);

(5) provide labels on the containers and packages containing the medicines prepared according to the manufacturer's prescription;
professional medicine Practitioner of modern arts or veterinary practitioners in accordance with
Criteria, methods and conditions prescribed prescribed in the ministerial regulations

(6) to control the delivery of dangerous drugs; Yum Special Control or spicy salad according to the prescription of the person
professional medicine Practitioner of modern arts or veterinary practitioners

(7) supervises the accounting of drugs under section 26 (6).

(8) other acts as prescribed prescribed in the ministerial regulations

Section 40 Second-class pharmacists under Section 21 shall comply with Section 39 as well as
first class pharmacist except in regards to improvement Sales and delivery of specially controlled drugs are prohibited.

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44 Title of Chapter 4 amended by the Medicines Act (No. 3) B.E. 2522

ÿÿ Section 38 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 39 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

Section 40 bis 47 A first-class pharmacist under section 21 bis shall be stationed at the place of sale.

(1) To deliver modern medicines or to a drug storage facility during all hours of operation and to perform the following duties:

controls the separation of medicines in accordance with Section 26 (2) and (3).

(2) to control the practice of labels under section 26 (5);

(3) to control the accounting of drugs under section 26 (6);

(4) to control the sales of modern drugs

(5) other acts as prescribed prescribed in the ministerial regulations

Section 4148 A first-class pharmacist second-class pharmacist or

A first-class practitioner of the modern arts in the field of dentistry Midwifery or follow-up care

Section 22 stationed at the place where the modern drug is sold, only for ready-to-pack medicines that are not dangerous drugs or drugs.

special control at all times during the business hours and are obliged to perform the following duties:

(1) supervises the practice of labels under section 26 (5).

(2) to control the distribution of ready-to-pack medicines that are different from the original condition produced by the manufacturer;

(3) to control the accounting of drugs under section 26 (6);

(4) other acts as prescribed prescribed in the ministerial regulations

Section 4249 A first-class pharmacist or to treat veterinary diseases under section 23 ,

stationed at the place that sells the current drug, only ready-packed medicine for and

shall have the duty to perform the following: (1) supervising the separation of medicines

in accordance with section 26 (3)

(2) to control the practice of labels under section 26 (5);

(3) to control the distribution of ready-to-pack medicines for sale for animals different from the original condition that the manufacturer have produced

(4) to control the delivery of packaged medicines for for animals that are dangerous or controlled drugs special

(5) to control the accounting of drugs under section 26 (6).

(6) Other acts as prescribed prescribed in the ministerial regulations

Section 43. A second-class pharmacist or to treat second-class veterinary diseases under section 23

Comply with section 42, the same as a first-class pharmacist. or operators to treat first-class veterinary diseases, except

with respect to the control of delivery of prepackaged drugs for For animals that are specially controlled drugs, it is not possible.

Section 4450 A first-class pharmacist under section 24 shall be present at the place of delivery or ordering.

Medicines enter the Kingdom or to a drug storage facility at all times when they are open. and to have duties as follows:

ÿÿ Section 40 bis, added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 41 amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 42, amended by the Medicines Act (No. 3), B.E. 2522 (1979)

(1) control the medicines brought in or ordered into the Kingdom to be in compliance with the medicinal formula;
that have been registered under Section ÿÿ

(2) to control the practice of labels under section 27 (2) (3) and (5).

(3) to control the practice of the manufacturer's certificate showing the analytical details of the drug;
pursuant to section 27 (2) and drug documentation under section 27 (4)

(4) to regulate the sale of
drugs to be in accordance with Section 39.

(5) to control drug accounting and sample storage under section 27 (6).

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

(7) control the storage of medicines bring or order into the Kingdom at a drug storage facility

(8) other acts as prescribed prescribed in the ministerial regulations

Section 4551 prohibits pharmacists medical practitioner practitioner
First-class current plan in dentistry Midwifery or nursing Veterinary practitioners perform the duties of those in charge of the place where the drug is produced, where the drug is sold, or where the drug is brought or prescribed into the facility.
Kingdom without him being the one responsible for the work in that place.

Chapter 5

Permission and issuance of a license for traditional medicines

Section 46. No person shall produce, sell, or bring or order into the Kingdom any drug.
Ancient plans, unless a license has been obtained from the licensor.

Permission and Permission to be in accordance with the rules Methods and conditions that
stipulated in the ministerial regulations

Section 47 The provisions of Section 46 do not apply to

(1) production of drugs produced by ministries, bureaus, or departments in charge of prevention or treatment, the
The Thai Red Cross Society and the Government Pharmaceutical Organization

(2) the preparation of traditional medicines according to The list of drugs announced by the Minister under section 76 (1) by the person
Practicing traditional healing arts for sale only for their patients or for retail

(2 bis)52 Sales of traditional drugs by
licensees to sell modern drugs, licensees
Wholesale the current plan of yam. and licensees to sell modern drugs, only ready-packed drugs that are not dangerous drugs or
Yum Special Control

(3) Sales of herbal medicines that are not dangerous drugs or sales of generic medicines at home.

ÿÿ Section 44 amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 45 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 47 (2 bis) added by the Medicines Act (No. 5) B.E. 2530

(4) bringing with you drugs into the Kingdom that does not exceed the amount necessary to be used;

or ordering of medicines into the Kingdom by ministries, bureaus, departments in for thirty days, and the importation

Duty to prevent or treat disease The Thai Red Cross and the Pharmaceutical Organization

Section 4853 A licensee shall issue a license to produce, sell, or bring or order into

The kingdom where traditional medicine can be when it appears that the applicant for permission

(1) being the owner of the business and having assets or status sufficient to establish and operate able to operate

(2) being at least twenty years of age;

(3) have a residence in Thailand;

(4) never having been imprisoned by a final judgment or to give a lawful order

imprisonment for an offense that the law provides for an act as a constituent or in the wrong

under the law on narcotics The Law on Psychotropic Substances

with the sale of drugs or this Act unless the

punishment has been passed for not less than two years prior to the date of application for a permit

(5) not being a person of unsound mind or an incompetent or a quasi-incompetent person

(6) not having a disease as announced by the Minister; prescribed in the Government Gazette

(7) there is a place for drug production, a place to sell drugs, a place to bring or order medicines into the Kingdom;

or a place where medicine is stored clean and hygienic

(8) to use a name in a commercial operation uniquely of or similar to the name used in the assembly

The business of the licensee who has been suspended or whose license has been revoked has not yet

one year

(9) having a person to act under section 68, section 69 or section 70;

Persons with duties under (9) must be stationed at the drug production facility. a place that sells medicine or

There is only one place to bring or order medicines into the Kingdom.

In the case of a juristic person applying for permission Manager or representative of the juristic person who operates

The business must have the qualifications under (2) and (3) and must not have any prohibited characteristics under (4), (5) or (6).

Section 49 Types of licenses The guidelines for traditional medicines are as follows:

(1) License to

produce traditional medicines

(2) a license to sell traditional medicines;

(3) a license to bring or order traditional medicines into the Kingdom

It shall be deemed that the licensee under (1) or (3) is the licensee under (2) for the drug.

that they produce or or order to enter the Kingdom as well, as the case may be.

Section 50 A license issued under Section 49 provides protection to an employee or representative of

licensee as well

Section 48 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

shall be deemed that the of the employee or the agent of the licensee who is immune to
the act of the licensee. Unless the licensee can prove that doing so, paragraph one, is also
It is beyond their knowledge or control.

5154 , a license under section 49 shall be valid until the date that ÿÿ December of that year
issues the license. If you wish to request for a license renewal, you must submit an application
before the license expires.

Age when filing has already made such request may continue to operate the business until the licensor gives an order not to renew
that license

Requesting a license renewal and permission to be in accordance with the rules, procedures and
Conditions set forth in the Ministerial Regulations

A licensee whose license has expired within one month will submit a waiver request together with
With the reason for requesting a license renewal, it can only be submitted The request for a waiver is not a cause for acquittal.
Business that has been done before applying for a license renewal, which is considered an undertaking
Expiration license

Requesting a license renewal upon expiration for a period of one month from the date of expiration of the license
age is impractical

Section 52. In the case where the licensor does not issue a license or does not grant permission to renew a
license,
An applicant for a license or an applicant for a renewal of a license has the right to appeal in writing to the Minister within thirty days from the date of
Date of receipt of the licensee's notice of refusal to issue a license or notice of the renewal of license
of State The decision of the
Minister shall be final.

In the event that the licensor does not allow the renewal of the license to produce traditional medicines before the minister
There will be a decision on the appeal under paragraph two, the Minister has the power to order permission to carry out the business for a
while. upon the request of the appellant

Chapter 6

Duties of Licensees in Traditional Medicines

Section 5355. The licensee is prohibited from producing or selling traditional medicines outside the premises.
set forth in the license except for wholesale

Section 5456 Licensee to produce traditional medicines Must have a practitioner in the art of traditional medicine
The ancients have the duty to comply with Section 68 regularly throughout the business hours.

ÿÿ Section 51 amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 53 as amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 54 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

The number of licensees under paragraph one who produces more than fifty recipes or more shall have a number of entrepreneurs.

The ancient art of healing has the duty to perform the duties under Section 68 as prescribed in the Ministerial Regulations.

Section 54 bis 57 A licensee for the manufacture of traditional drugs which produces traditional drugs by hammering method pelletizing, coating method or other similar methods and use pharmaceutical chemicals or semi-finished pharmaceutical chemicals in Tablet pressing, coating or similar operations including the addition of preservatives to traditional medicines must comply with the rules and procedures prescribed prescribed in the ministerial regulations

Section 5558 Licensee to sell traditional medicines Must have a practitioner in the art of traditional medicine The ancients have the duty to perform the duties under section 69 on a regular basis throughout the business hours.

Section 5659 Licensee In order to bring or order traditional medicines into the Kingdom, there must be Practitioner of the traditional art of healing is the person who performs duties under Section 70 stationed at the place of treatment or ordering traditional medicines into the kingdom or a place where medicine is stored all the time we are open

Section 5760 The licensee for the manufacture of traditional medicines shall comply with the followings:

(1) provide a signboard at the disclosure of the place of manufacture specified in the license which is easily visible; from outside the building is

(a) a sign indicating that the drug is manufactured

(b) a badge showing the name and surname of the person having the duty to operate and the time of operation

In this regard, the material used for making the label, the appearance, color, size of the label, the size of the letters and The text displayed on the label shall be as specified in the prescribed in the ministerial regulations

(2) provide a label as registered under The medicine receipt is sealed in the container and packaged medicine that is produced and on the label must show

(a) Yum name

(b) certificate number or code important for registration of medicinal formulas

(c) quantity of medicines contained

(d) Number or letter indicating the time of manufacture of the drug

(e) the name of the manufacturer and the province where the medicine is produced

(f) Date, month, year of manufacture of the drug

(g) the word “traditional medicine” clearly visible.

(h) the words “medicine for external use” or “medicine for topical use”, as the case may be; with red letters Obviously, in the case of external use or topical use

(i) the term “homemade medicine” in the case of generic medicine

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ÿÿ Section 54 bis, added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 55 amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 56 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 57 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

(j) the term “veterinary medicine” in case of veterinary medicine;

(3) use labels and documents; in accordance with the medicinal products that have been registered under and the message in

Labels and documents The information on the medicine must be clearly legible. If the medicine document is in a foreign language, it must contain the words

Thai translation too

(4) to make a list of drugs produced and sold in accordance with the prescribed in the ministerial regulations

(5) Other acts as stipulated prescribed in the ministerial regulations

In the case that the container of medicine is so small that it cannot show the label with the text under (2)

In all, the licensee to produce traditional medicines shall be exempted from having to show the statement under (2) (c) (d) (e) (g) (h) (i) or (j) clause. any one

or all of them after receiving permission from the licensee 61

in the case of drugs produced for export outside the Kingdom Text on labels and documents

The medicine label must also specify the name of Thailand. Other messages, if wishing to request an exemption, must be granted permission from

the licensee first, and the provisions of (2) (g) (h) and (i) shall not apply.

Section 5862 Licensees to sell traditional medicines shall comply with the following practices:

(1) provide a signboard at the disclosure of the place where the drug is sold as specified in the license, which can be easily seen;

from outside the building is

(a) A sign indicating that the drug is sold.

(b) a badge showing the name and surname of the person having the duty to operate and the time of operation

In this regard, the material used for making the label, the appearance, color, size of the label, the size of the letters and

The text displayed on the label to be in accordance with prescribed in the ministerial regulations

(2) provide labels that containers and packages of medicines as prescribed in section 57 (2) remain;

completely

(3) other acts as prescribed prescribed in the ministerial regulations

Section 5963. The licensee importing or ordering traditional medicines into the Kingdom

Do the following

(1) provide a signboard at the disclosure of the location; bring or order medicines into the specified kingdom

contained in the license, which is easily seen from outside the building, is

(a) a sign indicating that it is a place bring or order medicines into the Kingdom

(b) a badge showing the name and surname of the person having the duty to operate and the time of operation

In this regard, the labeling material, the nature, the color, the size of the label, the size of the letters and the text

displayed on the sign as specified in prescribed in the ministerial regulations

(2) at the time of import, the label shall be provided as specified provided in section 57 (2) that the container and

packaged salad Except in (e) specify the name of the city and country where the place of manufacture of medicine is made instead of the name of the province.

ýÿ Section 57, paragraph two, amended by the Medicines Act (No. 5), B.E. 2530.

ÿÿ Section 58 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ýÿ Section 59 amended by the Medicines Act (No. 5), B.E. 2530

(3) Before selling the medicine, labels shall be provided with the container and packaging of the medicinal product having the characteristics and

The information is complete as set out
in as provided in section 57 (2), except in (e) specifying the name of city and country;

Location of the place where the medicine is produced instead of the name of the province and specify the name of the leader bring or order medicines into the Kingdom; and

Province or ordering spicy salads as well

(4) use labels and documents in the form of medicinal herbs registered in the medicinal formula and the text in

Labels and documents The information on the medicine must be clearly legible. The document containing the medicine must be translated into a foreign language.

in Thai language as well

(5) to make a list of drugs brought in or ordered into the Kingdom and sold; and collect samples at

to bring or order into the Kingdom as stipulated in the Ministerial Regulations

(6) other acts as prescribed prescribed in the ministerial regulations

In the case of medicines imported under (2) or medicines to be sold under (3) are packed in containers with

so small that it may not be able to show the label containing the text under section 57 (2) at all, to the licensee or order

Traditional medicines entering the Kingdom are exempt from having to show a statement under section 57 (2) (c) (d).

(e) (g) (h) (i) or (j) any or all of the clauses, when permitted by the licensor.

Section 59 bis. 64 Traditional medicines used An order to come into the Kingdom must go through

inspection of the competent officer at the point of entry

Competent officers' audits are carried out in accordance with established rules and procedures.

in the ministerial regulations

Section 60. In the event of a license loss or material damage, the licensee

notify the licensor and submit a request A license substitute must be filed within fifteen days from the date of acknowledgment of the loss.

or was destroyed as such

Requesting a substitute for a license The formulation and issuance of a substitute license shall be in accordance with

Criteria, methods and conditions prescribed prescribed in the ministerial regulations

Section 61 A licensee must present his or her license and that of a practitioner of the art of healing.

The ancient plan was posted in a conspicuous place, easily visible at the drug production site. a place that sells medicine or a place ordering or ordering medicines

come to the Kingdom, as the case may be

Section 62. A licensee is prohibited from moving to a place of drug production, place of sale of a drug, place of delivery or

Order medicines into the Kingdom or a place where medicines are stored. unless authorized by the licensor

Permission and Permission to be in accordance with the rules Methods and conditions that

stipulated in the ministerial regulations

Section 59 bis added by the Medicines Act (No. 5), B.E. 2530

Section 63 When the licensee wishes to change the person having the duty to act in accordance with Section 68
Section 69 or Section 70 shall be notified in writing to the licensor and will be able to substitute upon receipt.

permission from the licensee

In the case where the licensee does not have the duty to perform the duties under paragraph one to the licensee

notify in writing to the licensor within seven days from the date that no person has the duty to operate

Section 63 bis[65] In the case of persons having the duty to operate in a drug production place, a place where the drug is sold ,

or a place to bring or order medicines into the Kingdom may not perform his duties temporarily for not more than sixty

date, the licensee shall arrange for those who have the same qualifications as those in charge of operating in that place to act.

replaceable duty by having the licensee notify in writing to the licensee first and shall be deemed to be acting on behalf of

having the duty to perform the duties under Section 68, Section 69 or Section 70, as the case may be;

Notification in writing under the first paragraph to be in accordance with the regulations set by the Board

Section 64 Persons having duties under Section 68, Section 69 or Section 70 ,

wishing not to continue to perform duties Must notify in writing to the licensor for information no later than seven days from the date of lapse.

duty

Section 65. Any licensee who dissolves the business which is permitted under this Act.

must notify in writing of the termination of business to the licensor not exceeding fifteen days from the date of termination of business and shall be considered

that the license has expired from the date of business dissolution

Section 66 Licensee who has notified the termination of business will sell his leftovers to

other licensee or to whom the licensor deems appropriate within ninety days from the date of cessation of business, except

allowed to extend the said period for

Section 67 If a licensee dies and there is a person qualified to be a licensee

In accordance with this Act, express the intention to the licensee within thirty days from the date of the licensee's death in order to

to continue the business that the deceased has been given permission to may allow the person expressing his intention to continue his business

until the license expires In such a case It shall be deemed that the person expressing Employed as a licensee under

this Act from the date of the licensee's death

Chapter 7

Duties of practitioners in the traditional art of healing

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[65] Section 63 bis, added by the Medicines Act (No. 3), B.E. 2522 (1979)

Section 6866. A practitioner of the traditional art of healing under Section 54 shall be present at a drug production place during all hours of operation and shall have the following duties:

(1) to control the production of drugs in accordance with the regulations of medicines that have been registered under Section 79

(2) Supervising the practice of labels and documents. with drugs under section 57 (2) and (3)

(3) to control the repacking and labeling of drug containers and packages so that is correct under this Act

(4) to control the sale of drugs to be in accordance with section 69.

(5) to control the accounting of drugs under section 57 (4)

(6) Other acts as prescribed prescribed in the ministerial regulations

Section 6967 A practitioner of the traditional art of healing under section 55 shall be present at a place that sells medicines during its opening hours and shall have the following duties:

(1) to control the practice of labels under section 58 (2);

(2) to control the sale of drugs in accordance with this Act;

(3) other acts as prescribed prescribed in the ministerial regulations

Section 7068. Practitioners of the traditional arts of healing under section 56 shall be present at Places to bring or order medicines into the Kingdom or a place where medicines are stored at all times when they are open and that The duties are as follows.

(1) to control the medicines brought or ordered into the Kingdom to be in accordance with the regulations; to receive the medicine that has been made registered under section 79

(2) to control the practice of labels under section 59 (2)

(3) supervising the practice of documents with drugs under section 59 (4)

(4) to control the sale of drugs to be in accordance with section 69;

(5) supervises the accounting of drugs under section 59 (5).

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

(7) control the storage of medicines bring or order into the Kingdom at a drug storage facility

(8) other acts as prescribed prescribed in the ministerial regulations

Section 7169. A practitioner of the traditional arts of healing is prohibited from performing the duties of a person who has the duty. Operate in a drug manufacturing facility, a place where the drug is sold, or where drugs are brought or ordered into the Kingdom by themselves. is not named as a person in charge of operating in that place

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ÿÿ Section 68 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 69 as amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 70 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 71 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

Chapter 8

counterfeit drugs, illegal drugs, deteriorating drugs

Section 7270. No person shall produce, sell, or bring or order into the Kingdom any drug.
the following

(1) fake salad

(2) illegal drugs

(3) the drug has deteriorated quality;

(4) Drugs that are not registered
as a medicinal formulation.

(5) spicy salad registered under the Drug production has been canceled for licensees to produce medicines and licensees to produce medicines.
Bringing or ordering medicines into the Kingdom or spicy salad The prescription has been canceled for more than six months for the recipient.
permits to sell drugs

(6) a drug for which the Minister has ordered the revocation of the medicinal recipe registration.

The provisions of (4) shall not apply to ministries, bureaus, or departments for the prevention or treatment of disease.
The Thai Red Cross Society and the Government Pharmaceutical Organization

Section 73 The following drugs or substances are counterfeit drugs:

(1) Drugs or objects that All or part of the artificial medicine is authentic.

(2) a medicine labeled as another medicine or showing the month and year that the medicine has expired; which is not true

(3) a drug showing the name or mark of the manufacturer or the location of the drug production facility which is not true;

(4)71 Yum that shows that it is a stipend. of the registered medicinal products which is not true
(5)72 Drugs that
are not manufactured according to standards as to the size, quantity or strength of the substance.
whose active action is absent or more than twenty percent from the lower threshold the final or the highest, which is defined in the recipe formulated
registered under section 79

Section 7473 The following drugs are non-standard drugs.

(1) a drug that is not produced according to the standard by the dosage or strength of the active ingredient;
lack or exceed the threshold The latest or the highest stipulated in the drug formula registered under Sections 79 but not
up to the size mentioned in section 73 (5).

(2) medicines produced by purity or other characteristics which are important to the quality of the medicine
deviating from the criteria prescribed in the drug formula registered under section 79 or the drug formula ordered by the Minister
edit registration has received the drug under section 86 bis

ÿÿ Section 72 as amended by the Medicines Act (No. 3), B.E. 2522
ÿÿ Section 73 (4) amended by the Medicines Act (No. 3), B.E. 2522
ÿÿ Section 73 (5) as amended by the Medicines Act (No. 3), B.E. 2522
ÿÿ Section 74 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

Section 75 The following drugs are deteriorated drugs.

(1) medicines that have expired as shown on the label;

(2) a drug that has been altered to have the same characteristics as a counterfeit drug under section 73 (5), or

Drugs that violate the standards under section 74

Section 75 bis 74. No person shall sell packaged drug in bulk, arranged in batches from time to time.

the same, with the intent for the purchaser to use them together to treat, treat, cure or prevent disease or symptoms of disease
any particular disease

The contents of the first paragraph not applicable to first-class pharmacists Medical Practitioners

or a practitioner in the art of healing in the field of dentistry that sells only for their patients and practitioners
animal diseases that are sold for the animals he treated

Chapter 9

Drug declaration

Section 7675 The Minister shall have
the powers As announced in the Government Gazette,

(1) Drug recipe

(2) medicinal substances

(3) dangerous drugs

(4) drugs that are specially controlled drugs

(5) a medicine that is an ordinary medicine for home use;

(6) drugs that are traditional medicines

(7) spicy salad which must be notified expired on the label

(8) shelf life of some drugs

(9) Drugs requiring notification Warnings for the use of medicines are provided on the label and on the drug leaflet and the message.
of the warning

In the event that the Minister has announced The shelf life of any drug is prescribed under (8) if the recipient
Any licensed drug can prove or test with explicit evidence from research that its drug may contain.
The validity period exceeds the period of use announced by the Minister, then the Minister with the approval of the
The Board has has the power to extend the shelf life of that drug for which it has been proven or tested
announced in the Government Gazette.

Section 77 The Minister has the power with the authority to announce in the Government Gazette specifying disease or condition
of a disease that is forbidden to advertise that it can be used to treat, relieve, treat or prevent disease or its symptoms

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ÿÿ Section 75 bis, added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 76 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

Section 77 bis 76 For the purpose of protecting the welfare of the people, the Minister, with the advice of the Committee, has the power to determine the number of to allow it to be set in in any area by announcing in the Government Gazette

Section 77 ter 77 for the benefit of controlling drugs brought in or ordered into The Kingdom of Ministers has the power to declare in the Government Gazette prescribing entry points.

Section 77 quarter 78 for the benefit of promoting, supporting and developing Research to consider registration to obtain effective medicines and meet research standards In person, the Minister has the power to announce in the Government Gazette. to set rules, procedures and conditions for In this announcement, the safety of the volunteers must at least be protected. who also participated in the medicinal research study

The drug researcher 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 causes Unsafe and dangerous to people, the environment or the public as a result of the process or procedures related to drug research studies The Secretary of the Food and Drug Administration has the power to order Improve drug research studies Temporarily suspend drug research studies or discontinue drug research studies the severity of the insecurity and the danger

Section 77 Benja79 For the benefit of the development and promotion of the pharmaceutical industry The minister may announce to prescribe rules, procedures and conditions relating to standards for for the manufacture of medicines, the sale of medicines, or the importation or ordering of medicines into the Kingdom, which may be required to use or refer to the standards of foreign or international standards and in case there is a need As necessary, use or refer to standards. that is a foreign language document, provided that such standard must not be above the standard at the office Food and Drug Administration approved

Section 78. Notifications of the Minister under this Chapter may be made upon advice from Board

Chapter 10

Registration of medicinal formulas

ýÿ Section 77 bis, added by the Medicines Act (No. 3), B.E. 2522 (1979)

ýÿ Section 77 ter Added by the Medicines Act (No. 5), B.E. 2530

ýÿ Section 77 quarter, added by the Medicines Act (No. 6) B.E. 2019

ýÿ Section 77 quince, added by the Medicines Act (No. 6) B.E. 2019

Section 7980 Licensee to produce drugs or a licensee bring or order medicines into
wishes to produce or bring or order into the Kingdom any modern drug or Yum whoever

The ancient plan had to bring the medicinal formula to be registered to the competent official. and when receiving the certificate
Registration of a drug formula can then be produced or brought or ordered into the Kingdom.

Section 79 bis 81 The provisions
of section 79 shall not apply to

(1) medicines that are pharmaceutical chemicals; or semi-pharmaceutical chemicals ready-made products that are not packaged

(2) herbal salad

(3) a sample drug that is permitted to be produced or brought or ordered into the Kingdom to request
Registration of drug formulas in accordance with the rules, procedures and conditions prescribed by prescribed in the ministerial regulations

(4) Drugs that are permitted to be used to bring or order into the Kingdom in accordance with the rules,
and conditions announced by the Minister with the approval of the Committee prescribed in the Government Gazette

Section 80 Application for registration In order to receive medicines under section 79, details must be given.
the following

(1) Yum name

(2) Names and quantities of
medicinal substances

(3) packing size

(4) standard analytical methods of modern drugs; In the case of analytical methods outside of the formula
Minister announced

(5) label

(6) Documents accompanying medicines.

(6/1)83 Document showing No. C. to apply for a patent or a petty patent that has been published in the advertisement
then according to the law with patent or registered information on intellectual property rights of Thai traditional medicine
Person, ingenuity General or local Thai traditional salad of general Thai traditional medicine or receiving
allowed to take advantage of or of the national Thai traditional medicine
Law on Protection and Promotion of Thai Traditional Medicine Wisdom

(7) other items as prescribed
prescribed in the ministerial regulations

Section 81. Amendment to the registration of medicinal formulas may be made with permission from
officer

ÿÿ Section 79 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 79 bis, added by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 79 bis (4) added by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 80 (6/1) added by the Medicines Act (No. 6) B.E. 2019

Section 82 Application for registration or amendment of the list of drug formula registration and issuance

Certificate of registration or amendment of the registration of medicinal formulas to be in accordance with the rules, procedures and

Conditions set forth in the Ministerial Regulations

Section 8384. Officials are prohibited from registering medicinal formulas when the Committee
saw that

(1) It is a drug specified in section 72 (1) or (6).

(2) an application for registration of The receipt of medicines is not in accordance with Section 80 and Section 82.

(3) the drug applied for registration under the medicinal formula cannot be trusted in its properties or may

not safe for users

(4) It is a medicine that uses its name in the sense of boasting, not being polite, or possibly misleading from the truth.

(5) a medicine whose name is inappropriate with the good culture of Thailand. or lead to destruction

Value of Thai language

Order not accepting registration to receive the medicines of the officials to be the most

Section 84. The provisions of Section 83 shall apply to amendments to the registration of medicinal formulas.

mutatis mutandis

Section 8585 The licensee to produce drugs or licensee bring or order medicines into

The Kingdom sends a regular report. year on the production or importation or ordering of medicines into the Kingdom of

Each recipe has been registered in accordance with the form prescribed in the Ministerial Regulations within the date ÿÿ March of the year

next

Yam that

has been registered already received the medicine any receipt that is not produced or brought or ordered into

the Kingdom for two consecutive years, the registration of such medicinal formulas shall be cancelled.

Section 8686 Any drug registered under already received the medicine If later it appears that the drug

No properties as registered or may not be safe for users or a counterfeit drug under section 72 (1)

or the drug has been transformed into an object that is intended for for use as food or cosmetics under a license

Produced for the distribution of regulated food or received a certificate It is important to register cosmetics according to

the law on that The Minister, with the advice of the Committee, has the power to order to revoke the registration

that recipe revocation to act which is published in the Royal Gazette

of State Ministers' orders

shall be final.

ÿÿ Section 83 amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 85 as amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 86 as amended by the Medicines Act (No. 5), B.E. 2530

Section 86/187 to protect the safety of drug users to the Minister with advice

of the Board of Directors power to order amendments to the registration to receive registered medicinal products as it deems appropriate or as

Necessity or order a review of medicines that have already been registered according to the established rules and procedures

Section 86/288 Certificate of Registration The shelf life of the medicinal product shall be seven years from the date of issuance.
for registration
of medicinal formulas

Recipient of the certificate of registration under for medicines that wish to renew the certificate registration is important

Medicine recipe, the application must be submitted to the licensee before the date of the certificate. important for registration Expired medicine

Recipient of the certificate of registration under in which the certificate of It is important to register their drug formulas.

After the expiration of one month, an application for renewal and a waiver will be filed. by showing reasonable reasons for not doing

submitted an application for an extension of time within the specified period, but the request for a waiver was not a cause for acquittal under section 123

and in the event that when the bird has passed a period of one month from the date of the warrant important for registration Expired medicine

will not be able to proceed with the renewal

when filed The application under paragraph two or paragraph three has been paid and the renewal fee has been paid. The

Give a certificate of registration The medicinal product shall continue to be used until the The order does not allow the renewal of the warrant.

Registration of the drug formula

Application for renewal and permission to renew the certificate It is important to register the drug formula to be

according to the rules, procedures and conditions prescribed prescribed in the Ministerial Regulations.
State

requires a review of the registration You can take the salad as well.

In the event that there is an order refusing to renew the certificate important for the registration of drug formulas for the licensor

notify the recipient It is important to note the registration of the medicinal formula and to return the renewal fee to the applicant.

pro-rata renewal expiration date of each year from the date of Orders are not permitted until the

If the registration certificate is The prescription of the medicine is permitted to be renewed. Fractions of one month cave to fifteen days.

to be counted as one month

Section 87 In the case of a certificate of registration Medication receipts are lost or destroyed in

Importantly, the licensee shall notify the competent official and submit a request. requesting a replacement certificate

Register a drug formula within fifteen days from the date of becoming aware of such loss or damage.

Requesting a replacement certificate important for registration for the receipt of medicines and the issuance of a substitute for a warrant

according to the rules Methods and conditions set forth prescribed in the ministerial regulations

Chapter 11

Advertising Council

Section 88 Advertising for the sale of drugs must

ÿÿ Section 86/1 amended by the Medicines Act (No. 6) B.E. 2019

ÿÿ The Office of the Council of State, Section 86/2, added by the Medicines Act (No. 6) B.E. 2019

(1) not exaggerating the medicinal properties or substances which are components of the medicine that it can

treat, cure or cure a disease or sickness, or use words

any other having the same meaning

(2) not showing false or exaggerated medicinal properties;

(3) fails to understand whether any substance is a medicinal substance or a component of a medicinal product; which the truth is not

There is that object or component in the salad. or but not as much as it makes me understand

(4) does not make it understood that it is a medicine causing a miscarriage or strong menstrual pills

(5) not to be understood as yam oral contraceptives

(6) not showing properties of dangerous or specially controlled drugs;

(7) There is no endorsement or

recognition of the medicinal properties of any other person.

(8) not showing medicinal properties that it can treat, relieve, cure or prevent disease; or

Symptoms of diseases announced by the Minister under section 77

The provisions in (5) and (6) shall not apply to the text on the label or the accompanying documents of medicines and

The contents of (1), (4), (5), (6), (7) and (8) shall not apply to advertisements which directly to the practitioner

art, medical practitioner or operators animal disease treatment 89

Section 88 bis 90 Advertising for the sale of rubber via radio broadcasting amplifier radio

Television, projection or cinematography or the publication must

(1) has received approval of the text, sound, or image used in advertising from the licensor;

(2) complying with the conditions prescribed by the licensee;

Section 89. Advertising is prohibited to sell drugs inappropriately. or by singing or making music; or

show the suffering of the patient

Section 90. Advertising is prohibited from selling drugs by means of free-to-carry or issuance of prizes.

Section 90 Bis 91 Secretary of the Food and Drug Administration Pledge to order in writing

Stop advertising for the sale of drugs deemed to be advertisements in violation of this Act.

Chapter 12

officer

 Section

9192 in the performance of duties Authorized officers as follows:

ÿÿ Section 88 paragraph two, amended by the Medicines Act (No. 5), B.E. 2530.

ÿÿ Section 88 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 90 bis, added by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 91 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

(1) enter a place of drug production, place where drugs are sold, places where drugs are brought or ordered;

The Office of the Council of State or the Office of the Royal Decree during business hours to check, control, to ensure compliance

This Act

(2) to take medicines in reasonable quantities as samples for examination or analysis;

(3) in the case where there is a reasonable ground to suspect that there has been an act committing an offense under this Act may enter any facility to inspect the drug and may seize or freeze the drug; and tools that related to action prosecution as well as containers or packages of medicines and documents related thereto;

can

(4) Announcement of the results of the inspection or quality analysis of the drug taken for examination, or analyze according to (2) to the public for acknowledgment with the approval of the Board of Directors.

to the protection of the safety of drug users

(5) in the case where it appears to the official that any drug is unsafe for drug users , the Office of the Council of State, the Office of the Commission; Decree Office of the Council of State or may be harmful to drug users Let the officers have the authority to to collect or order the licensee to produce medicines

Licensee to sell medicines or licensee bring or order medicines into the Kingdom to store such yam of their own returned within the period specified by the competent officer and has the power to destroy the said drug

Criteria and methods established prescribed in the ministerial regulations

In the performance of the officials under paragraph one, the licensee and

Those involved in the manufacture of medicines, the sale of medicines, or the importation or ordering of medicines into the Kingdom in such a place provide convenience as appropriate in the case

Section 92. In the performance of duties, the officer must present his/her identity card.

when the person concerned requests

Employee identification card shall be in accordance with the form prescribed by prescribed in the ministerial regulations

Section 93 Medicines, including drug containers or packages and documents seized under section 91, if the owner is not present or the public prosecutor orders absolute non-prosecution or the court does not convict and the person

The owner or possessor does not request a refund within ninety days from the date of seizure. or the date of acknowledgment of the order Absolutely not to prosecute or the date of the final judgment, as the case may be, shall be vested in the Ministry of Public Health.

The cave that was seized was low. or if it is delayed, it will be a risk of damage. Office of the Council of State or will incur costs for keeping in excess of the market price of the drug The staff will manage the sales.

To market the medicine, including the container or package of the medicine and the documents before the due date, the amount of money may be obtained. whatever the net amount, the money shall be retained instead.

Article 94 In the implementation of this Act Let the officers be

Employees under the Criminal Code

Chapter 13

License suspension and license revocation

Section 95 when it appears to the licensee that any licensee does not comply
This Act or the Ministerial Regulation issued under this Act licensee with the advice of
The Board has A warrant can suspend a license by not exceeding one hundred and twenty days each time, or in the case of A
lawsuit was filed against the licensee to the court that committing an offense under this Act will order to suspend the license
a final judgment

A licensee whose license is suspended must stop the drug production, sale or importation.
or ordering drugs into the Kingdom, as the case may be, and during the suspension period the license shall apply
no more licenses under this Act

Section 96. When it appears to the licensee that the licensee is disqualified under section 14 , the
or Section 48, the person authorized by the recommendation of the Board has the power to order the revocation of a license.

Licensees whose licenses have been revoked must stop producing the drug. selling drugs or bringing
or ordering drugs into the Kingdom, as the case may be, and will apply for any further licenses under this Act
Not until two years have elapsed from the date the license is revoked. and the licensor will issue a license or not
may, at its discretion, deem appropriate.

Section 97 Order of suspension of license and order to revoke the license to be made in writing
Notify the licensee and in the event that the ordered person is not found or the person ordered does not accept When ordering such an order, close the order.
Keep it conspicuously visible at the place where the drug is manufactured, where the drug is sold, or where the drug is brought in or ordered.
Kingdom and it is deemed that the licensee is aware of the that order has been placed since the closing date of the order

Order to suspend the license and license revocation order to advertise in newspapers or
by other means as well

Section 98. The person authorized by the recommendation of the Board has the power to withdraw the suspension order.
The license may be terminated prior to the expiration date when it is satisfied that the suspended licensee has taken action.
under this Act or Ministerial Regulations already issued under this Act

Section 99 A licensee whose license has been suspended or revoked has the right to:
Appeal to the Minister within thirty days from the date of acknowledgment of the order.
Amend the licensor's order in a favorable manner to the appellant.

The decision of the Minister shall be final.

An appeal under paragraph one shall not suspend the enforcement of the license suspension
or a license revocation order

Section 100. A person whose license has been revoked will sell his remaining drug to the licensee.
or any other person who the
licensor deems appropriate within sixty days from the date of acknowledgment. license revocation order
or the date of acknowledgment Minister's decision unless the licensor grants a waiver to extend the said period

Chapter 14
State Penalties

Section 101. Any person who violates section 12 shall be liable to imprisonment for not more than five years and no fine over ten thousand baht

Section 10293 Any licensee who violates section 19 or section 30 shall be liable to punishment.
fine from
two thousand baht to fifty thousand baht

Section 103 94 Any licensee who fails to comply with section 20, section 21, section 21 bis,
section 22, section 23 or section 24 shall be liable to imprisonment for not more than three months or a fine not exceeding five thousand baht, or both, and shall be fined daily for an additional five hundred baht per day until it is properly complied with.

Section 10495 Any licensee who produces or sells drugs or brings or orders drugs into
the Kingdom after the license has expired without submitting An applicant for a license renewal must be punished.
Daily adjustment of one hundred baht per day all the time the license is expired

Section 10596 Any licensee who fails to comply with Section 25 Section 26 Section 26
bis or section 27 shall be liable to a fine from two thousand baht to ten thousand baht.

Section 105 bis 97 Any person who fails to comply with section 27 bis or section 59 bis must
liable to a fine from two thousand baht to ten thousand baht

Section 106 Any licensee who fails to comply with Section 28
Section 29 Section 33 Section 35, Section 60, Section 61, Section 63, Section 65, Section 81 or Section 87
a fine not exceeding one thousand baht

ÿÿ Section 102, amended by the Office of the Council of State, Medicines Act (No. 3), B.E. 2522.

ÿÿ Section 103 as amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 104 as amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 105 as amended by the Medicines Act (No. 5), B.E. 2530

ÿÿ Section 105 bis, added by the Medicines Act (No. 5), B.E. 2530

Section 107 Any person who violates section 31 , or section 32 shall be liable to a fine of one thousand to fifty thousand baht

Section 107 bis 98 Any licensee who fails to notify the establishment of an operator on behalf of the person in charge complying with section 33 bis shall be liable to a fine not exceeding five hundred baht.

Section 108 Any person having the duty to act who fails to comply with Section 34 or Section 64 , shall be liable to a fine not exceeding five hundred baht

Section 10999 Any person having the duty to act who fails to comply with Section 38, Section 39 , Section 40 Section 40 Bis Section 41 Section 42 Section 43 or Section 44 shall be punished fine from one thousand baht to fifty thousand baht

Section 110 100 Any person who violates section 45 shall be liable to a fine of one thousand baht to fifty thousand baht

Section 111. Any person who violates section 46 shall be liable to imprisonment for not more than three years and a fine over fifty thousand baht

Section 1112101 Any licensee who violates section 53 or section 62 shall be liable to punishment. fine from one thousand baht to three thousand baht

Section 113 102 Any licensee who fails to comply with Section 54, Section 55 or Section 56 Must be punished Imprisonment for not more than one month or a fine not exceeding two thousand baht, or both, and on a daily basis for another hundred baht per day until the correct implementation

Section 113 bis103 Any licensee who fails to comply with section 54 bis shall be punished a fine not exceeding fifty thousand baht

Section 114 Any licensee who fails to comply with Section 57, Section 58 or Section 59 shall be liable to a fine of one thousand to five thousand baht.

ÿ Section 107 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿ Section 109 was amended by the Medicines Act (No. 5), B.E. 2530.

ÿÿ Section 110 amended by the Medicines Act (No. 3), B.E. 2522

ÿÿ Section 112 amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿ Section 113 as amended by the Medicines Act (No. 3), B.E. 2522

ÿ Section 113 Bis, added by the Medicines Act (No. 5), B.E. 2530

Section 114 bis 104 Any licensee who fails to notify the establishment of an operator on behalf of the person in charge
complying with section 63 bis shall be liable to a fine not exceeding five hundred baht.

Section 115 Any practitioner of the traditional art of healing who fails to comply with Section 68, Section 69
or section 70 shall be liable to a fine of five hundred baht to two thousand baht.

Section 116105. Any practitioner of the traditional art of healing who violates section 71 must be
fine from five hundred baht up to two thousand and five hundred baht

Section 117 Any person who produces a counterfeit drug in violation of section 72 (1) shall be punished with imprisonment.
Imprisonment from three years to life and a fine from ten thousand baht to fifty thousand baht

Manufacture of counterfeit drugs with characteristics under section 73 (2), (3) or (4) which is a violation
Section 72 (1) If the manufacturer is able to prove that the drug is not dangerous to the drug user shall be punished.
Imprisonment for not more than five years and a fine not exceeding twenty thousand baht 106

Section 1118107. Any person who produces a drug that does not conform to the standard or a drug whose registration has been revoked by the Minister
Drug formula in violation of section 72 (2) or (6) shall be liable to imprisonment from two years to five years; and
fine from four thousand baht to twenty thousand baht

Any person who produces medicinal products registered under The receipt of medicines is canceled in violation of section 72 (5).
Imprisonment for not more than two years or a fine not exceeding twenty thousand baht, or both

Section 119 Whoever sells or brings or orders into the Kingdom a counterfeit drug which is
Violation of section 72 (1) shall be liable to imprisonment from one year to twenty years and fined from two thousand baht to
thousand baht ten

If the person acting under paragraph one commits without knowing that it is a fake salad must be fined
but from one thousand to fifty thousand baht

Section 120108 Any person who sells or brings or orders into the Kingdom of illegal drugs
or spicy salad that the Minister has ordered the revocation of the registration in violation of section 72 (2) or (6) shall be subject to
Imprisonment for not more than three years and a fine not exceeding fifty thousand baht

Who sells or sells importing or ordering into the Kingdom of drugs registered under The prescription of the medicine was cancelled.
which is a violation of section 72 (5) shall be liable to imprisonment for not more than one year or a fine not exceeding ten thousand baht, or both

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ÿÿÿ Section 114 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿÿ Section 116 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿÿ Section 117 paragraph two, added by the Medicines Act (No. 5), B.E. 2530

ÿÿÿ Section 118 amended by the Medicines Act (No. 5), B.E. 2530

ÿÿÿ Section 120, amended by the Act (No. 5), B.E. 2530.

If the person doing the act under paragraph one and paragraph two commits without knowing that it is a drug that violates the standard

formula or the medicine registered under the The prescription of the medicine was cancelled. The Minister ordered the revocation of the registration of the medicinal shall be liable to a fine not exceeding fifty thousand baht

Section 121. Any person who sells or brings or orders into the Kingdom the deteriorated drug

is a violation of section 72 (3) shall be liable to imprisonment for not more than one year or a fine not exceeding three thousand baht, or both

both fine

If the person acting under paragraph one commits Doing it without knowing that it is a drug that has deteriorated in quality must be punished.

a fine of not more than three thousand baht

Section 122. Any person who produces, sells, or brings or orders into the Kingdom a drug that is not

Registration of drug formula in violation of section 72 (4) shall be liable to imprisonment for not more than three years or not more than thousand baht, or both.

Section 122 bis 109 Whoever violates section 75 bis shall be punished with imprisonment for not more than five years

or a fine not exceeding fifty thousand baht, or both

Section 122 ter 110. Any drug researcher who fails to comply with the secretary's order

The Food and Drug Administration under section 77 quarter paragraph three shall be liable to a fine not exceeding one hundred thousand baht.

Section 123 Any licensee who fails to comply with Section 79 shall be punished with imprisonment not exceeding

three years or a fine not exceeding fifty thousand baht, or both

Section 123 bis111 Any licensee who fails to comply with Section 85 paragraph one must:

liable to a fine from one thousand to five thousand baht and to be adjusted daily for another hundred baht per day until

act right

Section 123 ter 112 Any licensee submitting a regular report annual report on production or lead

or ordering drugs into the Kingdom under Section 85 paragraph one which is false, shall be punished with imprisonment not exceeding

three months or a fine not exceeding fifty thousand baht, or both

Section 123 quartet 113 Recipient of the certificate of registration under who receives a prescription for renewal

registration certificate receiving the medicine after receiving the certificate important for registration not more than

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ÿÿÿ Section 122 bis, added by the Medicines Act (No. 5), B.E. 2530

ÿÿÿ Section 122 ter Added by the Medicines Act (No. 6) B.E. 2019

ÿÿÿ Section 123 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿÿ Section 123 ter Added by the Medicines Act (No. 3) B.E. 2522

ÿÿ Section 123 quarter, added by the Medicines Act (No. 6) B.E. 2562

one month under section 86/2 shall be liable to a daily fine of not more than five hundred baht per day throughout the time

have not filed a request request for renewal of certificate important for registration of medicinal formulas

Section 124114 Any person who advertises the sale of drugs in violation of section 88, section 88 bis, section 89 or section 90 shall be liable to a fine not exceeding one hundred thousand baht.

Section 124 bis 115. Any person who violates an order to suspend the sale of drugs by the secretary Food and Drug Administration which is ordered under section 90 bis shall be liable to imprisonment for not more than three months, or a fine not exceeding fifty thousand baht, or both, and shall be fined on a daily basis for an additional five hundred baht per day until complies with the said order.

Section 1225116 Whoever obstructs or does not provide convenience to the officials who to perform duties or not to comply with An official order of an official under section 91 shall be punished Imprisonment for not more than one month or a fine not exceeding one thousand baht, or both

Section 125 bis 117 Any licensee to manufacture medicines, sell medicines, or bring or order medicines came into the kingdom a chakra while a license to produce medicine, sell medicine, or bring or order medicine into The Kingdom, as the case may be, is suspended from Section 95, shall be punished imprisonment for not more than five years and fine not more than ten thousand baht

Section 126 when penalties under Section 126 101 Section 111 Section 117 Section 118 Section 119 Section 120 Section 121 or Section 122 Drugs, tools and equipment used in the manufacture of medicines, including containers or packages of medicines related to crimes for the Ministry public health to destroy or deal with it as it deems appropriate

Section 126 bis 118 of the offenses under this Act that are punishable by a fine of only one place to the Secretary of the Food and Drug Administration or the person assigned by the Secretary of the Food and Drug Administration. have adjustable comparative power

In the event of drug seizure Containers or packages containing medicines and documents related to commit an offense, the Secretary to the Food and Drug Administration or the person who is the Secretary of the Food Committee and the prescription will be compared to the fine only if the offender guilt permits the confiscated belonging to Ministry of Public Health 119

ÿÿÿ Section 124 as amended by the Medicines Act (No. 5), B.E. 2530

ÿÿÿ Section 124 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿÿ Section 125 as amended by the Medicines Act (No. 3), B.E. 2522 (1979)

ÿÿÿ Section 125 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿÿ Section 126 bis, added by the Medicines Act (No. 3), B.E. 2522

ÿÿÿ Section 126 bis, paragraph two, added by the Medicines Act (No. 5), B.E. 2530

special chapter

Section 127 Drug sales business license under the law on drug sales

Before the date this Act comes into force, it will continue to be valid until its expiration. If the licensee is wishing to continue to produce medicines, sell drugs, or to bring or order medicines into the Kingdom and have filed an application license under this Act shall be able to continue the business that has been permitted under the previous license until a new license is obtained or the licensor has notified of the refusal. and in the case of receiving new license The act to be correct under this Act shall be completed within one hundred and twenty days from the date of License date

If the licensee under the first paragraph does not wish to engage in the business continue that business or have filed a complaint A person who is licensed under this Act is not permitted to sell medicines. of his remaining to another licensee or to whom the licensee deems appropriate within ninety days from the date of The original license has expired. or the date that the licensor notifies that the license is not permitted, as the case may be, unless the licensor has to extend such period to

Section 128 Certificate of Registration for the receipt of medicines issued under the law on selling medicinal products before the date this Act comes into force shall be of the following ages:

(1) certificate of registration for the receipt of drugs registered in 1962 and 1963 , shall be valid until 31 December B.E. 2512

(2) registration certificate for the receipt of drugs registered in 1964 and 1965 , shall be valid until 31 December B.E. 2513

(3) registration certificate The prescription of drugs registered after 1965 shall be Age up to 31 December 1971

Section 129 Within three years from the date this Act comes into force, the scene produced , or brought or ordered into the Kingdom of the Kingdom under the law on the sale of drugs before the date of This Act comes into force. exempt from labeling practices as stipulated prescribed in section 25 (3). Section 26 (5), Section 27 (3), Section 57 (2), Section 58 (2) and Section 59 (2) of This Act

Countersigned by His Majesty the King

Field Marshal Thanom Kittikachorn

Prime Minister

fee 120

(1) Production license for modern medicine 50,000 baht each

(2) a license to sell modern drugs , 5,000 baht

Each (4) a license to sell modern medicines only for ready-packed 10,000 baht

that are not dangerous or specially 5,000 baht per copy

controlled drugs State for

animals 5,000 baht each

(6) a license to bring in or order a modern drug;

In the Kingdom, each 100,000 baht

(7) each license for the manufacture of traditional medicines, 25 baht each 10,000 baht

(9) a license to bring in or order an ancient drug;

in the kingdom 100,000 baht per copy

(10) registration certificate for the receipt of 25,000 baht per copy

modern medicine (11) certificate of registration 25,000 baht per copy

(12) License substitute (13)

Certificate of for the receipt of modern 1,000 baht per copy

drug (14) A replacement certificate, certificate of registration, 1,000 baht traditional 1,000 baht

(15) Each renewal of a license equals one half.

of fees for that type of license

each

(16) Renewal of certificates important for registration The amount of each dose is equal to

Half of the fee for vouchers

Registration of for each type of medicine

ÿÿ Fee Amended by the Medicines Act (No. 6) B.E. 2562

Note :- The reason for promulgating this Act is due to the law on the sale of drugs.

which is now in force There are also business controls on drug production, sale of drugs, and the importation or prescribing of drugs into the country.

The Kingdom as well as regulating the presence of pharmacists responsible for the sale of dangerous drugs and other sections . bundle
another that is not yet concise and suitable for the current situation Therefore, it is expedient to revise the law on
Sale of medicines for the safety and welfare of the people

Announcement of the Revolutionary Council No. 321 dated ÿÿ December 1971

Whereas the Medicines Act B.E. 2510 (1967) stipulated that the Permanent Secretary of the Ministry of Public Health was

Licensee for drug production, importation or ordering of medicines into the Kingdom and the sale of medicines in the metropolitan Bangkok.

Thonburi now deems appropriate to transfer to powers and duties of the Director-General of the Department of Public Health Promotion

Office of the Council of State, Office of the Council of State No. 2 This announcement of
the Revolutionary Council does not affect the license issued by the Permanent Secretary .

Public health was issued under the Medicine Act B.E. 2510 (1967)

Article 3 The Minister of Public Health shall maintain the affairs of the Faculty
this revolution

Article 4 This Announcement of the Revolutionary Council shall come into force as from the day following the date of its proclamation.

Gazette onwards

Medicine Act (No. 2) B.E. 2518122

Section 2 This Act shall come into force as from the day following the date of its publication in the Government Gazette.

Noun onwards

Section 4 This Act does not affect the license. at the Director-General of the Department of Promotion
Public health was issued under the Medicine Act B.E. 2510 (1967), amended by the Announcement of the Revolutionary Council.
No. 321, dated ÿÿ December 1972

Section 5. The Minister of Public Health shall take care of the affairs under this Act.

Note :- The reason for promulgating this Act is due to Section 3 places

The Act amending the Announcement of the Revolutionary Council No. 216 dated 29 September 1972 , the
(No. 3) B.E. 1974, revised department-level government agencies under the Ministry of Public Health and

Section 15 of the Act on the Transfer of Powers, Businesses, Assets, Debts, Government Officials, Employees and Money

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ÿÿÿ Government Gazette, Volume 89/Part 190/Special Issue, page 92/13, December 1972.

ÿÿ Government Gazette volume 92/part 42/special issue, page 60/20 February 1975

Budget of the Department of Medicine and Health and the Department of Public Health Promotion to the office
State, Permanent
Secretary, Department of Medicine, Department of Communicable Disease Control, Department of Health, and the Office of the Commission
Food and Medicine, Ministry of Public Health, B.E.
Promoting public health and the authorities of the Department of Public Health Promotion only in relation to
Food and Drug Control Division to the Food and Drug Administration or of officials
Office of the Food and Drug Administration, as the case may be. authority of the licensor
2510 as amended by the Announcement of the Revolutionary Council No. 321, dated the Office of the Council of State,
the Office of the Council of
ÿÿ December 1972. In this regard, it was necessary to amend the definition of the term “licensor” to be in accordance with the duties.
of the government agencies in the Ministry of Public Health that have been renovated, it is necessary to enact this Act

Medicine Act (No. 3), B.E. 2522123

Section 2 This Act shall come
into force as from the day following the date of its publication in the Government Gazette.

Noun onwards

come under 45 within three years from the date this Act comes into force Named supper
or the recipe is in the in the receipt of drugs announced by the Minister under section 76 (1), the licensee may continue to
produce, sell, or bring or order into the Kingdom. by exemption from compliance with Section 79
of the Medicines Act, B.E. 2510 (1967), as amended by this Act and shall not be regarded as a violation
Section 72 (4) of the Medicine Act, B.E. 2510 (1967), as amended by this Act.

Section 46 Registration certificate for the receipt of medicines issued prior to the date of this Act
It shall continue to be valid until the expiration of the validity specified in the certificate of registration of the drug formula.
In the case where the licensee wishes to apply for registration for receiving medicines that have previously been issued a certificate
Registration of drug formula under paragraph one must be submitted prior to the registration certificate. when receiving the medicine expires
such request has been submitted may continue to operate the business until the official gives an order not to accept registration
that recipe

Section 47 During the period of five years from the date this Act comes into force, in the case of
that the licensee to sell modern medicine or the licensee to sell modern medicine only for ready-packed medicine that is not medicine
any dangerous or specially controlled drug which has been licensed prior to the date this Act comes into force, has not yet
may procure persons under Section 21 or Section 22 of the Medicines Act B.E. 2510 (1967) as amended
Added by this Act, as the case may be, is the person having duty to perform duties at the place of sale of medicines.
Throughout the business hours, the licensee to sell such drugs shall do the following:

ÿÿÿ Government Gazette Volume 96/Chapter 79/Special Issue, page 29/13, May 1979.

(1) for a licensee to sell current drug to provide pharmacists as specified in

Section 21 of the Medicines Act, B.E. 2510 (1967), as amended by this Act, is at

A place that sells medicines for at least three consecutive hours a day during business hours.

(2) for a licensee to sell modern drugs, only ready-packed drugs that are not dangerous drugs;

or specially controlled salads There shall be an operator under section 22 of the Medicines Act B.E. 2510 (1967).

as amended by this Act shall be present at the place of sale of medicines for not less than three hours a day.

keep in touch during business hours

Section 48 In the case where the licensee sells modern drugs only for prepackaged drugs that are not medicines

dangerous or specially controlled drugs Who has been licensed prior to the date this Act comes into force?

unable to procure persons under Section 22 of the Medicines Act B.E. 2510 (1967) as amended by

This Act becomes a person who has the duty to work at a place that sells medicines throughout the time that it is open for business.

Let the licensee to sell such drugs to attend the training. or assign it to another person to receive

Training from the Ministry of Public Health and when the training has been completed, the course

Such training are located only at places where modern medicines are sold, only ready-to-eat, non-hazardous drugs; or

its own specially controlled drugs or those of a licensee who has been assigned to that person for training only. By

being the person having the duty to perform the duties under Section 41 of the Medicine Act, B.E. 2510 (1967), as amended.

by this Act

The training under paragraph one shall be completed within five years from the date of

This Act comes into force.

Training course Qualifications of trainees and expenses that the recipient

Training must be paid in accordance with the regulations prescribed by the Minister.

Section 49 The Minister of Public Health shall take care of the maintenance under this Act.

Note :- The reason for promulgating this Act is that the provisions in the Medicines Act

1967 with respect to the protection of drug users both in terms of the licensee and the authority of the officer and in

relation to the quality of medicines including quality control methods and

Advertising for the sale of drugs It is not appropriate for the circumstances to protect and provide security to

People who use drugs with sufficient medicine should be amended to be more appropriate.

This Act

Medicines Act (No. 4) B.E. 2527124

Section 2 This Act shall come into force as from 14 May 1984.

onwards

Section 3. The period of enforcement of Section 47 (1) of the Medicines Act (No. 3) B.E. 2522 (1979) shall be extended with respect to the waiver for the licensee. Selling the current plan which has been already approved before the date the Medicines Act (No. 3), B.E. 2522 came into force, must provide a pharmacist. pursuant to section 21, being in charge of operating at a place selling drugs for not less than three consecutive hours per day in opening hours, extended until September 30, 1986.

During the extension of the period of enforcement under paragraph one If the Minister The Ministry of Public Health, with the recommendation of the Medicines Committee, sees that in any locality It is expedient that the recipient For permission to sell modern drugs under paragraph one, there must be a regular pharmacist. always available during business hours Section 21. The Minister of Public Health shall have the power to Publishing in the Government Gazette The locality is the area where a pharmacist is required. at all times during the business hours under section 21 by having effective on the date specified in the said notification. but shall come into force ninety days from the date of publication in the Government Gazette. noun

Section 4. The Minister of Public Health shall take care of the affairs under this Act.

NOTE
Under Section 47 of the Medicines Act (No. 3) B.E.

Sale of modern drugs that have already been approved before the date of the Drug Act (No. 3) that has not yet come into force Pharmacists may be assigned to perform duties at the pharmacy location during all hours of operation. State as stipulated in Section 21, but must provide a full-time pharmacist. at least three places that sell medicines per day Consecutive hours during the opening hours will end on May 13, 1984, but the situation in Currently, the number of pharmacists available is insufficient, causing licensees to sell modern medicines. allowed Already before the date of the Drug Act (No. 3), B.E. 2522 (1979) came into force in large numbers, unable to supply pharmaceuticals to be present at all times that it is open for business under section 21 of the said Act, it is expedient to expand The period of entry into force of the provisional provisions with respect to the granting of licensees to the sale of modern drugs shall be established. A pharmacist under section 21 shall be present at the place of sale for not less than three consecutive hours per day in Opening hours will be out for a while. If the Minister of Public Health sees that any area has a pharmacist enough to Requires licensees to sell modern medicines to arrange for a full-time pharmacist always open Able to act in accordance with Section 21, the Minister shall have the power to designate such locality by publishing in the Government Gazette, therefore it is necessary to enact an Act. this

Medicines Act (No. 5), B.E. 2530125

Section 45 Licensees to sell modern drugs only ready-to-pack drugs that are not dangerous drugs or specially controlled salads If still unable to recruit persons under Section 22 of the Medicines Act B.E. 2510 (1967), the Office of the Council of State

to become an officer who works at the drug sales facility during the time that it is open for the licensee

Such persons have the right to receive training. or assign other people to receive training from the Ministry of Public Health After receiving the training, those who have completed the training course located only at the place where the medicinal herbs are sold

At present, only ready-to-pack medicines that are not dangerous or specially controlled drugs for themselves or those of licensees who have

Assign that person to attend training only. by being the person having the duty to operate under section 41

Medicine Act, B.E. 2510 (1967)

The training under paragraph one shall be to be completed within five years from the date

This Act shall come into force. After the expiration of such period, training may not be held again.

Training course Qualifications of the trainees and expenses that the trainees have to pay

in accordance with the regulations prescribed by the Minister

In the case where a licensee sells modern drugs only for ready-to-pack drugs that are not dangerous drugs, or

Special controlled drugs, which have successfully completed the training course, are responsible for the operation under paragraph one, relocated.

the place where the drug is sold, or in the case where the licensee sells the modern drug only for ready-packed drugs that are not dangerous drugs

or specially controlled drugs with evidence showing that they are the business of selling drugs after the licensee to sell drugs

The current plan is only for prepackaged drugs that are not dangerous drugs or the former specially controlled drugs, which have successfully completed the

Trained to be responsible for performing the duties under the first paragraph. It shall be deemed that the place of sale of the drug relocated, or the place of sale of the drug at

The licensee has such evidence. It is a place that sells medicines for Successful completion of the regular training course

under the first paragraph

In order to protect the welfare of the people, the Minister has the power to prescribe that the recipient

The training was completed in accordance with Section 48 of the Medicines Act (No. 3), B.E. 2522 and according to

This Act may receive training to increase knowledge from time to time as it deems appropriate.

Section 46. Section 29 of the Medicines Act, B.E. 2510 (1967) shall apply to:

Licensee to sell modern drugs, only ready-to-pack drugs that are not dangerous or specially controlled drugs, which have

Those who have completed the training course under Section 48 of the Medicines Act (No. 3) B.E. 2522 or

Section 45 of this Act is responsible for the operation under Section 41 of the Medicines Act, B.E. Those who have completed the training

course are posted at the place where the drug is sold.

consent

Section 47. Section 45 of the Medicines Act, B.E. 2510 (1967) shall apply to:

Those who have completed the training course under Section 48 of the Medicines Act (No. 3) B.E. 2522 or

Section 45 of this Act In performing the duties of an operator in a facility that sells the planned medicines

At present, only ready-to-pack medicines that are not dangerous drugs or specially controlled drugs, mutatis mutandis.

Section 48 The Minister of Public Health shall take care of this Act.

Note :- The reason for promulgating this Act is because the Act governing

The Standard for Biological Materials, B.E. 2440 (1940), contains duplicate provisions. The overlap with the law on drugs should be repealed.

The Act And while the law on drugs does not have a provision to provide protection to People who use drugs are sufficient, for example there is no provision prohibiting the sale of drug kits. There is no control over the production of medicinal products. antiques using modern technology, etc., and the provisions in respect of permits and controls. It is not appropriate to manufacture, sell, bring or order medicines into the Kingdom. should be amended further More appropriate, it is necessary to enact this Act.

Medicine Act (No. 6) B.E. 2562126

Section 2 This Act shall come into force upon the expiration of one hundred and eighty days from the date of announced in the Government Gazette onwards

Section 15. Any application for a license, an application for registration of a medicinal formula, or an application that has been submitted before the date this Act comes into force and is still under consideration, it shall be deemed as a request under this Act, mutatis mutandis, and if such request is different from the to request under this Act, Let the licensee have to order to amend the may request for compliance with this Act.

Section 16 Registration certificate 2510 before the date this Act comes into force shall be of the following ages:

(1) certificate of registration The prescription for drug receipt registered prior to 1997 shall expire after five years from the date this Act comes into force. 1 January B.E.

(2) Registration certificate for the receipt of registered drugs between 1997 and the date of 107 be expired after seven years from the date of this Act. apply 1 January B.E.

(3) Registration certificate for the receipt of drugs registered between 2008 and the date this Act comes into force shall expire after nine years from the date of this Act. apply 1 January B.E.

Section 17 Ministerial Regulations, Notifications or Rules issued under the Medicines Act, B.E. 2510 (1967), which was in force on the day before the date this Act came into force. shall continue to be enforceable as long as it is not contrary to or contrary to this Act Until there is a ministerial regulation or announcement issued under the Medicine Act B.E. 2510 (1967) as amended by this Act comes into force.

to issue Ministerial Regulations or announcements under paragraph one to be completed within two years from the date this Act comes into force If this cannot be done, the Minister must report the reason for the inability to do so. can proceed to the Cabinet

Article 18. Notification issued by order of the Head of the National Council for Peace and Order at No. 77/2559 on Enhancement of Efficiency in the Health Product Approval Process, dated the 27 December 2016 in regards to medicines in force on the day before the date of this Act Apply, apply to the approval process. in accordance with the provisions of Chapter 1/1, the process of considering a permit of the Medicine Act, B.E. 2510 (1967), as amended by This Act to the extent that it is not contrary to or inconsistent with the Medicines Act, B.E. 2510, as amended by This Act Until there is an announcement issued under the Medicine Act B.E. 2510 (1967) as amended by This Act comes into force.

When the announcement issued under the Medicine Act, B.E. 2510, as amended by This Act has come into force. give the notification issued under the Order of the Head of the National Council for Peace and Order No. 77/2559 on Enhancement of Efficiency in the Health Product Approval Process, dated 27 December 2016, the part relating to drugs has been cancelled.

Section 19. The Minister of Public Health shall take care of the affairs under this Act.

Note :- The reason for promulgating this Act is because the Medicines Act Decree 1967 has been in force for a long time. Some provisions are inconsistent with the current situation. which has the development of technology and the expansion of the pharmaceutical trade and industry, and to What is the process of consideration? effective It is expedient to revise the provisions relating to the definitions. Add method rules and conditions for drug research studies Reference to international standards Certificates Important registration of drug formulas, process for approval of drugs, penalties and adjust the rate of fees to be more suitable, therefore it is necessary to enact this Act

Office of the Council of State

Black Print/more

24 April 2019

Nusara/Examination

25 April 2019