Medical Device Act, B.E. 2531 (1988)

Translation

BHUMIBHOL ADULYADEJ, REX.,

Given on the 13th day of May, B.E. 2531;

Being the 43rd Year of the Present Reign.

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

Whereas it is expedient to issue a law on medical device;

Be it, therefore, enacted by the King, by and with the advice and consent of the parliament as follows:

Section 1

This Act shall be called the "Medical Device Act, B.E. 2531 (1988)"

Section 2

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

Section 3

In this Act,

"Medical Device" means

(1) Equipment, products or articles used in the medical profession; the profession of nursing and midwifery, of the clinical practice of medicine or of veterinary as prescribed by the legislation concerned;

(2) Equipment, products or articles that have effects on the health, the structure or any functions of the human or animal body;

(3) Constituents, components, accessories or parts of the equipment, products or articles under (1) or (2);

(4) Other equipment, products or articles prescribed by the Minister as medical device by publication in the Government Gazette;

"Produce" means make, assemble or devise; repackage separately or collectively; as well as recycle by transmuting, modifying or sterilizing;

"Distribute" means sell, dispense, dispose of, trade or transfer the right or possession to other persons for commercial purpose, including having in possession for sale;

"Import" means bring or order to be brought into the Kingdom;

"Export means bring or send out of the Kingdom.

"Label" means any image, design, symbol or statement displayed on the medical device, its container or package;

"Accompanying Document" means the paper or any other material on which information about the medical device is displayed by and image, design, symbol or statement, inserted or included in the container or package of the medical device, including the manual.

"Licensee" means the person to whom the license is granted under this Act; in the case where the licensee is a juristic person, it includes the person(s) who is (are) authorized by the juristic person to do the business;

"Licensor" means the Secretary-General of the Food and Drug Administration or the person authorized by the Secretary-General of the Food and Drug Administration;

"Committee" means the Medical Device Committee;

"Competent official" means a person appointed by the Minister for the execution of the Act;

"Minister" means the Minister having charge and control of the execution of the Act;

Section 4

The Minister of Public Health shall have charge and control of the execution of the Act and is empowered to appoint competent officials, to issue the Ministerial Regulation imposing fees not exceeding those given in the attachment hereof, to grant fee exemptions and to determine other undertakings for the execution of this Act.

The Ministerial Regulation shall come into force after its publication in the Government Gazette.

CHAPTER I

THE MEDICAL DEVICE COMMITTEE

Section 5

There shall be a committee called "Medical Device Committee" consisting of the Permanent Secretary for Public Health as the chairman; the Director-General of the Medical Services Department of his/her representative; the Director-General of the Communicable Disease Control Department or his/her representative; the Director-General of the Medical Sciences Department or his/her representative; the Director-General of the Health Department of his/her representative; the Director-General of the Livestock Development Department or his/her representative; representatives of the Ministry of Defense, the Ministry of Science, Technology and Energy, the Ministry of Industry and the Ministry of University Affairs as members; and there shall be no fewer than seven but no more than nine qualified persons appointed members by the Minister. Among them, there shall be one physician, one professional person in nursing and midwifery, one first-class clinician in dentistry and one first-class veterinarian.

The Secretary-General of the Food and Drug Administration shall be member and secretary, and a Deputy Secretary-General of the Food and Drug Administration, who is assigned by the Secretary-General of the Food and Drug Administration, shall be a member and assistant secretary.

Section 6

A member appointed by the Minister shall hold office for a term of two years.

A member who vacates his/her office may be reappointed.

Section 7

Apart from, the expiration of the term of office under Section 6, a member appointed by the Minister shall vacate his/her office upon:

(1) Death

(2) Resignation

(3) Dismissal by the Minister,

(4) Being adjudged bankrupt,

(5) Being adjudged incompetent of quasi-incompetent, or

(6) Being imprisoned by a final judgment to imprisonment, except for an offence committed by negligence of petty offence.

In the case where a member appointed by the Minister vacates his/her office before the expiration of the term, the Minister may appoint any other person to fill the vacancy. The appointed member shall hold office for the remaining period of the term of the member he/she replaces.

In the case where the Minister appoints additional members during the serving term of the member who were previously appointed, the additional members shall hold office for the remaining period of the term of the previously-appointed members.

Section 8

In a Committee meeting, an attendance of not less than one-half of the total number of the members shall be required to constitute a quorum.

If the chairman is absent from or not present at the meeting, the members present shall elect one among themselves to preside over the meeting.

The decision of the meeting shall be taken by a majority of votes. Each member shall have one vote. In case of a tie, the person who presides over the meeting shall have another vote as the casting vote.

Section 9

The Committee shall have the following powers and duties:

(1) To provide advice or opinions to the Minister regarding the policies and measures for controlling medical device;

(2) To provide advice or opinions to the Minister on making announcements under Section 35;

(3) To give approval on the suspension and revocation of licenses;

(4) To perform other duties as prescribed in this Act;

(5) To perform other duties as assigned by the Minister.

Section 10

The Committee is empowered to appoint a Sub-committee to perform any duties assigned by the Committee and the provisions of Section 8 shall apply to the meeting of the Sub-Committee mutatis mutandis.

Section 11

In the performance of its duties under this Act, the Committee shall have power to summon any person to make a statement or to submit the concerned documents or anything else for consideration.

CHAPTER II

APPLICATION FOR AND GRANTING OF LICENCE

Section 12

It is prohibited to produce or import medical device prescribed by the announcement of the Minister under Section 35 (1) unless a license has been granted by the licensor.

The application for and granting of license shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

Section 13

It is prohibited to distribute medical device prescribed by the announcement of the Minister under Section 35 (1) unless a license has been granted by the licensor.

The application for and granting of license shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

The person who has been granted permission to produce and import under the first paragraph of Section 12 shall also have permission to distribute the medical device produced or imported by himself/herself.

Section 14

The licensor is empowered to issue a license to produce, import or distribute medical device prescribed by the announcement of the Minister under Section 35 (1) when it is evident that the applicant.

(1) Be the business owner and have sufficient wealth or status to establish and operate a business;

(2) Be no less then twenty years old;

(3) Have residence in Thailand;

(4) Have never been imprisoned by a final judgment of imprisonment or a legitimate order to imprisonment for any offences stipulated by law to include dishonesty or for the offences described in this Act, except for the cases where at least two years have passed subsequent to release from imprisonment on the date of application;

(5) Not be insane or mentally unfit, not be adjudged incompetent or quasi-incompetent;

(6) Not suffer from the illnesses prescribed by the Minister by publication in the Movement Gazette;

(7) Have premises for the production, importation or distribution of medical device, as well as the implement for the production, distribution or storage and control or quality control of the medical device, the characteristics and number of which are in accordance with those prescribed by the Ministerial Regulation;

(8) Not have the same commercial name with or a similar commercial name to that of a licensee whose license has been suspended or revoked for less than one year;

(9) Not be a licensee whose license is being suspended under this Act;

(10) Not be a licensee whose license has been revoked under this Act, except for the cases where at least two years have passed subsequent to the revocation on the date of application.

In the case where the applicant is a juristic person, the manager or the representative of the juristic person who is the business operator must have the qualifications under (2) and (3) and have no forbidden characteristics under (4) (5) (6) (9) or (10).

Section 15

After the Minister has made announcements of the medical device under 35 (1), the person who is producing, importing or distributing the medical device on that date shall submit an application for a license under Section 12 or Section 13 within one hundred and eighty days from the date of the announcement. Within that period, if the licensor issues an order of non-permission, the applicant shall no longer operate the business as from the date of acknowledgement of the order and the provisions of Section 55 shall apply mutatis mutandis.

Section 16

After the announcement under Section 35 (3) has been made, the producer, importer or distributor of medical device shall submit the list of particulars to the Secretary-General of the Food and Drug Administration or the person authorized by the Secretary-General of the Food and Drug Administration.

The list of particulars and the submission of such list under the first paragraph shall be in accordance with the periods of time, rules, procedure and conditions prescribed by the Ministerial Regulation.

Section 17

The provisions of Sections 12, 13, 15, and 16 shall not apply to;

(1) The production, importation or distribution of medical device by government ministries and departments of which duties include prevention, diagnosis, treatment or rehabilitation; and by the Thai Red Cross.

(2) The production of medical device by the physicians, the clinicians or the professional persons in nursing and midwifery for use with specific patients, or the production of medical device by the veterinarians for use with specific animal patients.

(3) The production or importation of medical device for personal use or as examples for use in the research, analyses or test of quality and standard in limited quantity as necessary.

(4) The production or importation of medical device as examples for applying for license.

(5) The production of medical device as examples for exportation. Those who have been granted exemption shall submit the list of particulars of the medical device to the Secretary-General of the Food and Drug Administration in accordance with the rules, procedure and conditions prescribed by the Minister.

Section 18

For the benefit of exportation and when it it necessary for the licensee to produce medical device under Section 35(1) for export, the licensor shall grant temporary permission to the licensee to produce such medical device according to a foreign country standard, or an international standard in accordance with the rules and conditions prescribed by the Committee.

Section 19

If, after the inspection or analysis by competent officials, it is evident that the quality or standard of any medical device is below that prescribed by the Minister's announcement, rendering the medical device unsafe to use, for the users, likely to be detrimental to health or having modified standard, the licensor, with the advice of the Committee, shall be empowered to:

(1) Issue a written order to a licensee under Section 12 or Section 13 to alter or improve the medical device the licensee produced, imported or distributed in case it is the medical device prescribed by the Minister's announcement under Section 35(1);

(2) Issue a written order to a person who submits the list of particulars under Section 16 to alter or improve the medical device the person who submits the list of particulars produced, imported or distributed in case it is the medical device prescribed under Section 35 (3);

(3) Issue a written order to a licensee under Section 12 or 13, or a person who submits the list of particulars under Section 16 to cease to produce, import or distribute the medical device in case he/she did not obey the order issued under (1) or (2);

(4) Publicize the results of the inspection or analysis of the medical device to which the following information should be included:

a. In the case where the producer or importer can be clearly identified, the name of the producer or the importer, together with the type and characteristics of the medical device, and, if available its trade name, numbers and letters indicating its lot number of production;

b. In the case where the producer or importer cannot be clearly identified but the distributor is known, the name of the distributor, the place of distribution, together with the type and characteristics of the medical device.

Section 20

The license under Section 12 and Section 13 shall also provide coverage to the employees and the agents of the licensee.

The action of the employee or the agents of the licensee, to whom the license also provides coverage under the first paragraph, shall be deemed as the action of the licensee unless the licensee can prove that it is impossible for him/her to have any knowledge of or control upon such action.

Section 21

The license under Section 12 shall be valid until the 31st of December of the fifth year as from the year of issuance.

The license under Section 13 shall be valid until the 31st December of the year of issuance.

Section 22

If the licensee wishes to renew his/her license, he/she shall submit an application of renewal prior to the expiry date of the license. After he/she has submitted the application together with a renewal fee, he/she may continue to operate the business until the licensor issues a non-permission order of renewal.

The application for and granting of the renewal of license shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

The licensee whose license has expired for no longer than one month may submit a request for a grace period giving the reason why he/she could not submit the request within the prescribed period. The request for grace, however, shall not relieve him/her from being an offender under Section 63.

The application for the renewal of license shall not be made after one month has passed as from the expiry date of the license.

In the event that the licensor issues a non-permission order of the renewal of the license, the renewal fee shall be returned pro rata to the applicant, calculating on a monthly basis as from the date of the non-permission order to the expiry date of the license in question, except for the case where an appeal is made against the non-permission order and the Minister issues an order permitting the applicant for the renewal of license to continue temporally with his business. If the Minister issues an order to dismiss the appeal, calculation shall be made from the date of the dismiss of the appeal. Fifteen days or more shall be counted as a whole month.

Section 23

The Licensee under Section 12 or Section 13 is prohibited to move from the premises indicated in the license, unless the permission to do so has been granted by the licensor.

The application for and granting of the permission shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

The provision in the first paragraph shall not apply to a move or change of premises that is made urgently and temporarily. However the move or change shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

Section 24

The entrepreneur under Section 16 is prohibited to move the premises for the production, importation, distribution or storage of the medical device unless notification has been made to the Secretary-General of the Food and Drug Administration or the person authorized by the Secretary-General of the Food and Drug Administration in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

Section 25

In the event of loss, destruction or change of the license, the licensee shall apply for a substitute of the license within fifteen day as from the date of knowledge of the loss, destruction or damage thereof.

The application for and the granting of a substitute for license shall be made in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation.

CHAPTER III

DISSOLUTION AND ASSIGNMENT

Section 26

Any licensee who dissolves the business which has been granted license under this Act shall submit a written notification of the dissolution of the business to the licensor within thirty days as from the date of the dissolution and it shall be deemed that the license expires on the date of the dissolution.

Section 27

The licensee who has notified the dissolution of his/her business may sell the rest of his/her medical device to other persons within one hundred and eighty day as from the date of the dissolution, unless permission to extend the period is granted by the licensor.

Section 28

If the licensee under Section 12 or Section 13 passes away and his/her successor of a person qualified to be a licensee under the provisions of this Act expresses his/her wish to the licensor within sixty days as from the date of the date of the licensee's death, or within the period of extension granted by the licensor as may be necessary, to continue the operation of the business of the licensee. The one who expresses such a wish may continue the operation of the business to the expiry date of the license. In such a case, it shall be deemed that the one who expresses the wish becomes a licensee under this Act as from the date of the licensee's death.

CHAPTER IV

DUTIES OF LICENSEE AND THE ENTREPRENEUR

Section 29

The licensee is prohibited to produce, import, distribute or store medical device outside the premises indicated in the license, except for

(1) Temporary storage with permission granted by the licensor;

(2) Separate or collective repackage of the medical device temporarily imported in accordance with the rules, procedure and conditions prescribed by the Ministerial Regulation;

(3) Direct sale to a physician, a modern science clinician, a professional person in nursing and midwifery and a veterinarian as prescribed by the Minister by publication in the Government Gazette.

Section 30

The licensee under Sections 12 and Section 13 and the entrepreneur under Section 16 shall submit reports on the production, importation or distribution, as well as the reports on the adverse reactions of the medical device he/she produces, imports or distributes, to the Secretary-General of the Food and Drug Administration in accordance with rules and procedure prescribed by the Ministerial Regulation.

Section 31

In the even that the Minister has made an announcement on medical device under Section 35 (9), the licensee under Section 12 and Section 13 shall arrange for a controller of the production, importation or distribution as the case may be within the period as prescribed in the announcement.

The qualification, the number and the duties of the controller under the first paragraph shall be as prescribed by the Minister by publication in the Government Gazette.

Section 32

The licensee under Section 12 and Section 13 shall display the license or the substitute for the license as the case may be, and also a sign indicating the name, surname and qualifications of the controller of the production, importation or distribution as the case may be in an open and easily seen place within the premises indicated in the license.

CHAPTER V

LABELS AND ACCOMPANYING DOCUMENTS OF MEDICAL DEVICE

Section 33

The medical device for sale or in possession for sale shall have labels bearing the following information in Thai on its container or package:

(1) Name, category and type of the medical device;

(2) Name and premises of the producer or the importer as the case may be. In case of the importer, the name of the producer and the source of production of the medical device must be given;

(3) Content;

(4) The numbers or letters indicating its lot number of production;

(5) The number of the license;

(6) The use of, instruction for use and instruction for storage/maintenance of medical device;

(7) For disposable medical device, the word "for single use" in red must be clearly displayed;

(8) Warnings and precautions for handling the medical device as prescribed by the Minister by publication in the Government Gazette under Section 35 (5);

(9) The expiry date of the medical device as prescribed the Minister by publication in the Government Gazette Under Section 35 (8)

(10) Other information as prescribed by the Minister by publication in the Government Gazette.

The label may bear information in other languages than Thai but it must correspond with that in Thai and appears in size no bigger than the Thai.

Section 34

The accompanying document that comes with medical device shall bear the information as prescribed in Section 33 (6) and Section 33 (8) in legible print. If the information is in other languages than Thai, there shall also be corresponding Thai statements.

The medical device that has the information under Section 33(6) given in it accompanying document may not display that same information in the label.

CHAPTER VI

THE CONTROL OF MEDICAL DEVICE

Section 35

For the purpose of controlling medical device the Minister shall have the power, by publication in the Government Gazette, to prescribe;

(1) The name, category, type and characteristics of the medical device of which producer, importer or distributor needs to require a license;

(2) The quality and standard of the medical device under (1) according to the name, category, type and characteristics of the medical device, as well as the rules, procedure and conditions of its production and importation;

(3) The name, category, type and characteristics of the medical device of which particulars its producer, importer or distributor needs to made notification under Section 16;

(4) The name, category, type and characteristics of the medical device of which production, importation or distribution is prohibited;

(5) The name, category, type and characteristics of the medical device that needs warning and precautions in handing and such warnings and precautions need to be displayed in statements, signs or images;

(6) The quality and standard of the container, the way to use the container, as well as the materials that are not allowed to be used as a container of the medical device;

(7) The method of transport, storage or destruction or rendering unusable of the medical device;

(8) The name, category, type and characteristics of the medical device of which expiry date needs to be indicated in the label;

(9) The name, category, type and characteristics of the medical device of which the licensee must arrange for a controller in its production, importation or distribution.

Section 36

It is prohibited to produce, import or distributed the following medical device;

(1) Counterfeit medical device;

(2) Sub-standard medical device;

(3) Deteriorated medical device;

(4) Medical device that is unsafe to use

Section 37

Counterfeit medical device means the medical device that has the following characteristics:

(1) The medical device which is wholly or partly counterfeit or imitative;

(2) The medical device which bears the name, category, type or characteristics different from those granted by the license or those in the list of particulars submitted to the licensor;

(3) The medical device which bears false statements of the producer's name, of the source of production, of the date of production or of the place of production.

Section 38

Sub-standard medical device means the medical device of which quality or standard is below that prescribed by the Minister's announcement under Section 35 (2)

Section 39

Deteriorated medical device means the medical device of which condition has so deteriorated that its quality is below standard, or the medical device that is beyond its prescribed expiry date.

Section 40

Medical device that is unsafe to use means the medical device that has the following characteristics;

(1) Disposable medical device which has already been used;

(2) Medical device that is produced or kept un-hygienically;

(3) Medical device that is contaminated with foreign or potentially health-hazardous substances;

(4) Medical device that includes degradable substances and may be toxically harmful to the user;

(5) medical device of which effectiveness is still doubtful.

CHAPTER VII

ADVERTISING

Section 41

It is prohibited to advertise falsely or fraudulently the benefit, quality, quantity, standard or source of the medical device.

Section 42

The advertisement of medical device for commercial purpose must have the approval of the licensor regarding the statement, the audio or the video aspects of the advertisement and must be in accordance with the conditions prescribed by the licensor.

Section 43

The licensor is authorized to issue a written order suspending the advertisement that is considered violating or failing to comply with this Act.

CHAPTER VIII

COMPETENT OFFICIALS

Section 44

In the performance of duties, a competent official shall have the following powers:

(1) To enter the premises of production, importation, distribution and storage of the medical device during working hours to inspect or control for the execution of this Act;

(2) To take as samples a reasonable amount of the medical device for examination or analysis;

(3) In the event that there is reasonable cause of suspicion that violation of this Act has occurred, to confiscate or attach the medical device, as well as other equipment or instrument involved with the violation, including the containers, the packages, the labels, the accompanying documents and other relating documents of such medical device.

Section 45

In the performance of duties, the competent official shall present his/her official identity card to the person(s) concerned.

The identity card of the competent official shall be in the form prescribed by the Ministerial Regulation.

Section 46

The licensee and the persons who are involved with the production, importation, distribution and storage of the medical device shall accord facility to the competent official who performs his/her duty under Section 44.

Section 47

The property confiscated or attached under Section 44 (3) shall be vested in the Ministry of Public Health if it is evident that

(1) The owner is non-existent, or the owner or possessor does not claim for it within ninety days as from the date of confiscation or attachment, or

(2) The public prosecutor has issued a non-prosecution order, or the court has passed a judgment not to confiscate, and the owner or possessor does not claim for it within ninety days as from the date the non-prosecution order is known or the date of the final judgment, as the case may be.

Section 48

In case the property confiscated or attached under Section 44 (3) is perishable or at risk if kept for a long time, or the expenses of its keeping exceeds its value, the Food and Drug Administration may auction it prior to the finalization of the case or prior to its being vested in the Ministry of Public Health. The net proceeds of the sale, after expenses and encumbered charged have been deducted, shall be deposited in a government's bank in lieu of the property.

Section 49

In the performance of duties under this Act, the competent official shall be a competent officer under the Penal Code.

CHAPTER IX

THE SUSPENSION AND REVOCATION OF THE LICENSE

Section 50

In the event that a licensee violates or fails to comply with the Act, or any Ministerial Regulations, or the announcement issued under this Act, the licensor, with the approval of the Committee, is empowered to suspend his/her license for no longer than on hundred and twenty days at a time. In the case where action has been taken to the court charging the licensee against violating this Act, the licensor may suspend the license until the final judgment has been passed.

The licensee, whose license has been suspended, is prohibited from operating the business granted permission by the license.

Section 51

The licensor is empowered to cancel the suspension order before the expiration of the period if it is evident that the licensee, whose license has been suspended, has complied with this Act, or any Ministerial Regulation or announcements issued under this Act.

Section 52

The licensor, with the approval or the Committee, is empowered to revoke the license when it is evident that the licensee lacks the qualifications under Section 14 or is declared by a final judgment that he/she has violated this Act or the suspension order of his license.

Section 53

The order to suspend or revoke the license shall be notified, in a written order, to the licensee. In the event that the licensee cannot be found or refuse to accept such on order, it shall be posted in an open and easily seen place at the premises indicated in the license, and it shall be deemed that the licensee acknowledges the order as from the date of the posting of the order.

The order to suspend or revoke the license may also be advertised in the newspapers or publicized in any other ways.

Section 54

Subject to Section 36, the licensee whose license was revoked may distribute the rest of his/her medical device to other licensees, or to the persons deemed appropriate by the licensor within one hundred and eighty days as from the date of acknowledgement of the revocation order or of the decision of the Minister, unless the extension of such period has been granted by the licensor.

CHAPTER X

APPEAL

Section 55

In the event the licensor does not issue a license or does not grant permission to renew the license, the applicant for or for renewal of the license shall have the right to appeal in writing to the Minister within thirty days as from the date of receiving the notification of non-issuance or non-renewal as the case may be.

The decision of the Minister shall be final.

In case where the licensor does not grant permission for renewal of license, before the Minister makes a decision on the appeal under the second paragraph, the Minister is empowered to grant permission for temporary operation of the business upon request by the applicant.

Section 56

The licensee whose license has been suspended or revoked shall have the right to appeal in writing to the Minister within thirty days as from the date of acknowledgement of the order.

The appeal under the first paragraph shall not imply an abatement of the suspension or revocation order.

The decision of the Minister shall be final.

CHAPTER XI

PENALTY PROVISIONS

Section 57

Any person fails to comply with the Committee's order issued under Section 11 shall be liable to imprisonment for a term not exceeding one month or a fine not exceeding five thousand Baht, or both.

Section 58

Any person who violates the first paragraph of Section 12 or the first paragraph of Section 13 shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding one hundred and fifty thousand Baht, or both

Section 59

Any person who fails to comply with Section 16 shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding twenty five thousand Baht, or both.

Section 60

Any licensee who produces medical device under Section 35 (1) according to a foreign country standard or the international standard without permission under Section 18 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding fifty thousand Baht, or both.

Section 61

Any licensee who provides medical device produced under Section 18 for sale in the Kingdom shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding one hundred and fifty thousand Baht, or both.

Section 62

Any person who fails to comply with the licensor's order issued under Section 19 (1), (2) or (3) shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding fifty thousand bath, or both.

Section 63

Any licensee who produces, imports or distributes medical device after the expiry date of his/her license without having submitted a request for its renewal shall be liable to a fine of five hindered Baht per day until the license has been renewed.

Section 64

Any licensee who violates the first paragraph of Section 23 or Section 29 shall be liable to a fine not exceeding five thousand Baht.

Section 65

Any entrepreneur under Section 16 who violates Section 24 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding fifty thousand bath, or both.

Section 66

Any licensee who fails to comply with Section 25, Section 26 or Section 32 shall be liable to a fine not exceeding one thousand Baht.

Section 67

Any licensee or entrepreneur under Section 16 who fails to submit a report under Section 30 shall be liable to a fine not exceeding five thousand Baht.

Section 68

Any licensee or entrepreneur under Section 16 who submits an untruthful report under Section 30 shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding twenty five thousand bath, or both.

Section 69

Any licensee who fails to arrange for a controller of production, importation or distribution, as the case may be, according to the qualification, number and period prescribed by the Minister's announcement under Section 31 shall be liable to a fine not exceeding ten thousand Baht.

Section 70

Any controller of production, importation or distribution under Section 31 who fails to observe one's duties prescribed by the Minister's announcement under the second paragraph of Section 31 shall be liable to a fine not exceeding ten thousand Baht.

Section 71

Any licensee who fails to comply with Section 33 shall be liable to a fine not exceeding ten thousand Baht.

Section 72

Any licensee who fails to comply with the first paragraph of Section 34 shall be liable to a fine not exceeding five thousand Baht.

Section 73

Any person who produces, imports, or distributes the medical device prohibited by the Minister's announcement under Section 34 (4) shall be liable to imprisonment for a term not

exceeding five years or to a fine not exceeding two hundred and fifty thousand Baht, or both.

Section 74

Any person who produces, imports, or distributes counterfeit medical device under Section 36 (1) shall be liable to imprisonment for a term not exceeding five years or to a fine not exceeding two hundred and fifty thousand bath, or both.

Section 75

Any person who produces, imports, or distributes sub-standard medical device under Section 36 (2) or the medical device that is unsafe to use under Section 36 (4) shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding one hundred and fifty thousand Baht, or both.

Section 76

Any person who produces, imports, or distributes deteriorated medical device under Section 36 (3) shall be liable to imprisonment for a term not exceeding five years or to a fine not exceeding two hundred thousand Baht, or both.

Section 77

Any person who advertises medical device in violation of Section 41 shall be liable to imprisonment for a term not exceeding six months or to a fine not exceeding twenty-five thousand Baht, or both.

Section 78

Any person who fails to comply with Section 42 shall be liable to a fine not exceeding ten thousand Baht.

Section 79

Any person who violates the licensor's order issued under Section 43 shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding fifty thousand Baht, or both, and to a daily fine of one thousand until he/she complies with the order.

Section 80

Any person who obstructs or falls to accord facility to the competent official who performs his/her duty under Section 44 shall be liable to imprisonment for a term not exceeding one month or to a fine not exceeding five thousand Baht, or both.

Section 81

Any licensee who violates the second paragraph of Section 50 shall be liable to imprisonment for a term not exceeding three years or to a fine not exceeding one hundred and fifty thousand Baht, or both.

Section 82

For each of the offences under this Act liable to only fining, the Secretary-general of the Food and Drug Administration shall be empowered to settle the offence.

Countersigned by

General Prem Tinasulanon

Prime Minister

Rate

(1) A license for production of medical device 10,000 Baht

(2) A license for importation of medical device 20,000 Baht

(3) A license for distribution of medical device 3,000 Baht

(4) Each permission, for transferring the premises of production, importation, distribution or storage of medical device 1,000 Baht

(5) A substitution for a license 100 bath

(6) The fee for each renewal of license is equal to that of the license.

Note: The reason for the legislation of this Act was that, despite the advancement of the medical technology has increased the activities in the production, distribution, importation and exportation of medical device. Thailand still lacked a law that would provide direct enforcement to medical device. The legislation on pharmaceuticals, which was applied *mutatis mutandis*, sometimes provided insufficient enforcement. For the sake of the public welfare, for the control of quality, standard, and for the safety in the use of medical device, it is essential to enact this Act.

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