

Stimulants Control Act

(Act No. 252 of June 30, 1951)

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Chapter I General Provisions

(Purpose of Act)

Article 1 The purpose of this Act is to implement necessary control of import, export, possession, manufacturing, assignment, acquisition and use of Stimulants and Stimulants' Raw Materials, so as to prevent health and sanitation hazards caused by abuse of stimulants.

(Definitions of Terms)

Article 2 (1) As used in this Act, the term "Stimulants" means the items listed in the following:

- (i) phenylaminopropane, phenylmethylaminopropane and their salts;
- (ii) a substance having a stimulating effect similar to the substances specified in the foregoing items, which are designated by Cabinet Order; or
- (iii) a substance containing any of the substances specified in the preceding two items.

(2) As used in this Act, the term "Stimulants Manufacturer" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to engage in the business of manufacturing Stimulants (including refining Stimulants, processing Stimulants into a different type of Stimulants, with or without the application of a chemical transformation process, and dividing Stimulants into small portions and placing them in containers, but excluding prescription; the same applies hereinafter) and assigning the manufactured Stimulants to a Stimulants Dispensing Facility or Stimulants

Researcher.

- (3) As used in this Act, the term "Stimulants Dispensing Facility" means a hospital or clinic which obtained a designation pursuant to the provisions of this Act as a facility permitted to dispense Stimulants.
- (4) As used in this Act, the term "Stimulants Researcher" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to use Stimulants, and to manufacture Stimulants limited only to the cases allowed by the Minister of Health, Labour and Welfare, for an academic research purpose.
- (5) As used in this Act, the term "Stimulants' Raw Materials" means the items listed in the Appended Table.
- (6) As used in this Act, the term "Stimulants' Raw Materials Importer" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to engage in the business of importing Stimulants' Raw Materials, or to import Stimulants' Raw Materials for a business purpose.
- (7) As used in this Act, the term "Stimulants' Raw Materials Exporter" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to engage in the business of exporting Stimulants' Raw Materials.
- (8) As used in this Act, the term "Stimulants' Raw Materials Manufacturer" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to engage in the business of manufacturing of Stimulants' Raw Materials (including refining of Stimulants' Raw Materials, and processing Stimulants' Raw Materials into a different type of Stimulants' Raw Materials, with or without the application of a chemical transformation process, and dividing Stimulants' Raw Materials into small portions and placing them in containers, but excluding prescription) or to manufacture Stimulants' Raw Materials for a business purpose (including refining of Stimulants' Raw Materials, and processing Stimulants' Raw Materials into a different type of Stimulants' Raw Materials, with or without the application of a chemical transformation process, and dividing Stimulants' Raw Materials into small portions and placing them in containers, but excluding prescription).
- (9) As used in this Act, the term "Stimulants' Raw Materials Handler" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to engage in the business of assigning Stimulants' Raw Materials or to use Stimulants' Raw Materials for a business purpose.
- (10) As used in this Act, the term "Stimulants' Raw Materials Researcher" means a person who obtained a designation pursuant to the provisions of this Act as a person permitted to manufacture or use Stimulants' Raw Materials for an academic research purpose.

Chapter II Designation and Notification

(Requirements for Designation)

Article 3 (1) A Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher is to be designated from among persons who satisfy the following qualifications and who are determined appropriate, by the Minister of Health, Labour and Welfare for each manufacturing site in the case of a Stimulants Manufacturer, or by the governor of the prefecture of the location of a hospital, clinic or research institute for each of such facility in the case of a Stimulants Dispensing Facility or Stimulants Researcher:

- (i) for a Stimulants Manufacturer, a person who has obtained permission for pharmaceuticals manufacturing and sales business under Article 12, paragraph (1) (Permission for Pharmaceuticals Manufacturing and Sales Business) of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Act No. 145 of 1960) (hereinafter referred to as "Act on Pharmaceuticals and Medical Devices") or permission for pharmaceuticals manufacturing business under Article 13, paragraph (1) (Permission for Pharmaceuticals Manufacturing Business) of the Act on Pharmaceuticals and Medical Devices (hereinafter collectively referred to as a "Pharmaceuticals Manufacturer and Distributor");
 - (ii) for a Stimulants Dispensing Facility, a mental hospital or any other hospital or clinic which requires the dispensing of Stimulants for a medical treatment purpose; or
 - (iii) for a Stimulants Researcher, a person with considerable knowledge of Stimulants who needs to use Stimulants for a research purpose.
- (2) The standard for designation of a Stimulants Dispensing Facility or Stimulants Researcher is provided by Order of the Ministry of Health, Labour and Welfare.

(Application Procedures for Designation)

Article 4 (1) A person who intends to obtain a designation of a Stimulants Manufacturer must submit to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the person's manufacturing site, a written application for each manufacturing site.

- (2) A person who intends to obtain a designation of a Stimulants Dispensing Facility or Stimulants Researcher must submit to the governor of the prefecture of the location of the person's hospital, clinic or research institute a written application for each of such facilities.

(Designation Certificate)

Article 5 (1) When a designation of a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher is granted, the Minister of Health, Labour and Welfare must deliver a designation certificate to the Stimulants Manufacturer, and the prefectural governor must deliver a designation certificate to the licensee for the establishment of the Stimulants Dispensing Facility or Stimulants Researcher.

(2) The delivery of the designation certificate to the Stimulants Manufacturer is to be made via the governor of the prefecture of the location of the manufacturer's manufacturing site.

(3) A designation certificate may not be assigned or loaned to any other person.

(Effective Period of Designation)

Article 6 The effective period of designation of a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher is from the day of designation to December 31 of the subsequent year.

(Lapse of Designation)

Article 7 For a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher, if the effective period of a designation expires or the designation is rescinded, or if any of the grounds specified in Article 9 (Notification of Discontinuance of Business) arise, the designation ceases to be in effect.

(Rescission of Designation and Suspension of Business)

Article 8 (1) If a Stimulants Manufacturer, a licensee for establishment of a Stimulants Dispensing Facility, an administrator (meaning an administrator of a hospital or clinic under the Medical Care Act (Act No. 205 of 1948) the same applies hereinafter) of a Stimulants Dispensing Facility, a physician engaged in medical treatment at a Stimulants Dispensing Facility or a Stimulants Researcher has violated any provisions of this Act, a disposition imposed under the provisions of this Act, or any conditions imposed on the designation or permission, or if a Stimulants Researcher no longer satisfies the qualification under Article 3, paragraph (1) (Requirements for Designation), item (iii), their designation may be rescinded, or an order for the business or research of such Stimulants Manufacturer or Stimulants Researcher relating to Stimulants and Stimulants Raw Materials to be suspended for a fixed period may be issued, by the Minister of Health, Labour and Welfare in case of a Stimulants Manufacturer, or by the prefectural governor in case of a Stimulants Dispensing Facility or Stimulants Researcher.

(2) A notice under Article 15, paragraph (1) or Article 30 of the Administrative Procedure Act (Act No. 88 of 1993) relating to the disposition under the

preceding paragraph must be given no later than two weeks before the hearing date or the deadline for submission of a written statement of explanation (or no later than two weeks before the date of oral presentation, when an opportunity for explanation by oral presentation is given).

(Notification of Discontinuance of Business)

Article 9 (1) When a Stimulants Manufacturer falls under any of the following items, the Stimulants Manufacturer must provide a notification to that effect, with a designation certificate attached, to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the Stimulants Manufacturer's manufacturing site, within 15 days from the day when the grounds for falling under the item arose:

- (i) when the manufacturer has discontinued the Stimulants manufacturing business at the manufacturing site;
 - (ii) when the manufacturer has not obtained a renewal upon the expiration of the effective period of a pharmaceuticals manufacturing and sales business permission pursuant to the provisions of Article 12, paragraph (2) (Effective Period of Permission) of the Act on Pharmaceuticals and Medical Devices, or upon the expiration of the effective period of a pharmaceuticals manufacturing business permission pursuant to the provisions of Article 13, paragraph (3) (Effective Period of Permission) of the Act on Pharmaceuticals and Medical Devices; or
 - (iii) when a pharmaceuticals manufacturing and sales business permission or pharmaceuticals manufacturing business permission is rescinded pursuant to the provisions of Article 75, paragraph (1) (Rescission of Permission) of the Act on Pharmaceuticals and Medical Devices.
- (2) When a licensee for establishment of a Stimulants Dispensing Facility falls under any of the following items, the licensee must provide a notification, with a designation certificate attached, to that effect to the governor of the prefecture of the location of the licensee's hospital or clinic, within 15 days from the day when the grounds for falling under the item arose:
- (i) when the licensee has discontinued the hospital or clinic which is a Stimulants Dispensing Facility;
 - (ii) when the licensee has discontinued the medical treatment at the medical department specified in the designation standard under Article 3, paragraph (2) (Standard for Designation) at the hospital or clinic which is a Stimulants Dispensing Facility; or
 - (iii) when the permission for establishment of the hospital or clinic which is a Stimulants Dispensing Facility is rescinded pursuant to the provisions of Article 29 (Rescission of Establishment Permission and Closure Order) of the Medical Care Act.

- (3) When a Stimulants Researcher discontinues research which requires the use of Stimulants at the research institute, the Stimulants Researcher must provide a notification to that effect, with a designation certificate attached, to the governor of the prefecture of the location of the research institute, within 15 days from the day of the discontinuance.
- (4) If a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher dies or is dissolved, the notification under the preceding three paragraphs must be provided by the relevant person's heir in the case of death, or by its liquidator or a corporation surviving or incorporated by a merger in the case of dissolution.

(Returning and Submission of Designation Certificate)

Article 10 (1) Except as provided in the preceding Article, when a designation of a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher ceases to be in effect, the designation certificate must be returned to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of such person's manufacturing site in the case of a person which formerly was a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a person which formerly was a licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher, within 15 days from the day when the designation ceased to be in effect.

- (2) When a Stimulants Manufacturer has received a disposition to suspend business under Article 8, paragraph (1) (Rescission of Designation and Suspension of Business) of this Act or Article 75, paragraph (1) (Rescission of Permission) of the Act on Pharmaceuticals and Medical Devices, a licensee for establishment of a Stimulants Dispensing Facility has received a closure order under Article 29 (Rescission of Establishment Permission and Closure Order) of the Medical Care Act, or a Stimulants Researcher has received a disposition to suspend research under Article 8, paragraph (1) of this Act, the designation certificate must be submitted to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the manufacturing site in the case of a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher, within 15 days from the day of the disposition.
- (3) In the case referred to in the preceding paragraph, the Minister of Health, Labour and Welfare or prefectural governor must state the summary of the disposition in the designation certificate, and must return the certificate to the Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher promptly after the expiration of

the period of suspension of business, period of closure or period of suspension of research.

(Reissuance of Designation Certificate)

- Article 11 (1) When a designation certificate is damaged or lost, a Stimulants Manufacturer may submit an application for reissuance of the designation certificate to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the manufacturing site in the case of a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher.
- (2) When the lost designation certificate is discovered after the application for reissuance, the former designation certificate must be returned within 15 days, to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the manufacturing site in the case of a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher.

(Notification of Change of Name and Address)

- Article 12 (1) When a Stimulants Manufacturer has changed name (or corporate name, in case of a corporation), address or the name of the Stimulants Manufacturer's manufacturing site, the Stimulants Manufacturer must provide a notification to that effect, with a designation certificate attached, to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the Stimulants Manufacturer's manufacturing site, within 15 days from the day of the change.
- (2) When a licensee for establishment of a Stimulants Dispensing Facility has changed the name of the licensee's Stimulants Dispensing Facility, the licensee must provide a notification to that effect, with a designation certificate attached, to the governor of the prefecture of the location of the licensee's hospital or clinic, within 15 days from the day of the change.
- (3) When a Stimulants Researcher has changed the Stimulants Researcher's name or address, or the name of the Stimulants Researcher's research institute has changed, the Stimulants Researcher must provide a notification to that effect, with a designation certificate attached, to the governor of the prefecture of the location of the research institute, within 15 days from the day of the change.
- (4) In the case of the preceding three paragraphs, the Minister of Health, Labour and Welfare or prefectural governor must promptly amend and return the designation certificate.

Chapter III Prohibitions and Restrictions

(Prohibition of Import and Export)

Article 13 No person may import or export any Stimulants.

(Prohibition of Possession)

Article 14 (1) No person may possess Stimulants, except for a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or its administrator, a physician engaged in medical treatment at a Stimulants Dispensing Facility, Stimulants Researcher, or a recipient of delivery of Stimulants for a dispensing purpose from a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher.

(2) The provisions of the preceding paragraph do not apply to a case falling under any of the following items:

- (i) the case where a business assistant of a Stimulants Manufacturer, administrator of a Stimulants Dispensing Facility, a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher possesses Stimulants for a business purpose;
- (ii) the case where a Stimulants Manufacturer assigns Stimulants to a Stimulants Dispensing Facility or Stimulants Researcher or transfers custody of Stimulants, and where a person engaged in the service of transportation of mail or correspondence provided in Article 2, paragraph (2) of the Act on Correspondence Delivery by Private Business Operators (Act No. 99 of 2002) (referred to as "correspondence" in Article 24, paragraph (5) and Article 30-7, item (x)) or goods possesses Stimulants as necessary for performing the service;
- (iii) the case where a person who provides nursing care for a recipient of delivery of Stimulants for a dispensing purpose from a physician engaged in medical treatment at a Stimulants Dispensing Facility possesses Stimulants for the recipient; or
- (iv) the case of possession of Stimulants for any act conducted under laws and regulations.

(Prohibition and Restriction on Manufacturing)

Article 15 (1) No person may manufacture any Stimulants, except for the case of manufacturing by a Stimulants Manufacturer for a business purpose or the case of manufacturing by a Stimulants Researcher with the permission of the Minister of Health, Labour and Welfare for a research purpose.

(2) When a Stimulants Researcher intends to obtain permission for manufacturing Stimulants pursuant to the provisions of the preceding

paragraph, the Stimulants Researcher must submit a written application to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the Stimulants Researcher's research institute, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

- (3) The Minister of Health, Labour and Welfare may designate the manufacturing quantity of each Stimulants Manufacturer for each period from January to March, April to June, July to September, and October to December of each year.
- (4) A Stimulants Manufacturer may not manufacture Stimulants in excess of the quantity designated by the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph.

(Administrator of Stimulants Dispensing Facility)

Article 16 (1) Business affairs relating to acquisition of Stimulants to be dispensed at a Stimulants Dispensing Facility and management of Stimulants acquired by a Stimulants Dispensing Facility must be handled by the administrator of the dispensing facility.

- (2) A licensee for establishment of a Stimulants Dispensing Facility must have the administrator of the dispensing facility handle business affairs relating to the acquisition of Stimulants and the management of Stimulants acquired.

(Restriction and Prohibition of Assignment and Acquisition)

Article 17 (1) A Stimulants Manufacturer may not assign Stimulants manufactured by the Stimulants Manufacturer to any person other than a Stimulants Dispensing Facility and Stimulants Researcher.

- (2) A Stimulants Dispensing Facility or Stimulants Researcher may not acquire Stimulants from any person other than a Stimulants Manufacturer.
- (3) No person may assign or acquire Stimulants, except for the cases referred to in the preceding two paragraphs or the case where a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher delivers Stimulants for a dispensing purpose.
- (4) The provisions of the preceding three paragraphs do not apply to the case of assignment or acquisition of Stimulants for the execution of duties under laws and regulations, or to the case of assignment or acquisition of Stimulants by a Stimulants Researcher with the permission of the Minister of Health, Labour and Welfare.
- (5) When a Stimulants Researcher intends to obtain permission for assignment or acquisition of Stimulants pursuant to the provisions of the preceding paragraph, the Stimulants Researcher must submit a written application to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the Stimulants Researcher's research institute, pursuant to

the provisions of Order of the Ministry of Health, Labour and Welfare.

(Assignment Certificate and Acquisition Certificate)

Article 18 (1) When assigning or acquiring Stimulants (excluding the case where a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher delivers Stimulants for a dispensing purpose), the assignor must deliver to the assignee an assignment certificate prepared pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the assignee must deliver to the assignor an acquisition certificate prepared pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The assignee referred to in the preceding paragraph may provide information on the matters to be specified in the acquisition certificate under the preceding paragraph by a method using an electronic information processing system or any other method using information communication technology as specified by Order of the Ministry of Health, Labour and Welfare, with the approval of the assignor and pursuant to the provisions of Cabinet Order, in lieu of delivery of the acquisition certificate. In such case, the assignee is deemed to have delivered the acquisition certificate.

(3) The assignment certificate or acquisition certificate under paragraph (1), or electronic or magnetic record (meaning a record made in an electronic form, a magnetic form or any other form not recognizable to human perception, which is made available for information processing by computers and specified by Order of the Ministry of Health, Labour and Welfare; the same applies hereinafter) prepared by the method prescribed in the first sentence of the preceding paragraph must be kept by the recipient of the delivery or provision thereof for two years from the date of the acquisition or assignment of the Stimulants.

(4) The assignment certificate, acquisition certificate and electronic or magnetic record specified in the preceding paragraph may not be assigned to others, except for the assignment under paragraph (1) or (2).

(Prohibition of Use)

Article 19 Except for the cases specified in the following items, no person may use any Stimulants:

- (i) the case where a Stimulants Manufacturer uses Stimulants for a manufacturing purpose;
- (ii) the case where a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher dispenses Stimulants;
- (iii) the case where a Stimulants Researcher uses Stimulants for a research purpose;

- (iv) the case where a recipient of Stimulants delivered by a physician engaged in medical treatment at a Stimulants Dispensing Facility or Stimulants Researcher for a dispensing purpose dispenses the Stimulants; or
- (v) the case of use for the act conducted under laws and regulations.

(Restriction on Dispensing)

- Article 20 (1) A physician engaged in medical treatment at a Stimulants Dispensing Facility must not dispense, or deliver for a dispensing purpose, any Stimulants except for those managed by the administrator of a Stimulants Dispensing Facility where the physician engages in medical treatment.
- (2) The physician referred to in the preceding paragraph must not dispense, or deliver for a dispensing purpose, any Stimulants for any purpose other than the medical treatment of others.
 - (3) The physician referred to in paragraph (1) may not dispense, or deliver for a dispensing purpose, any Stimulants for the purpose of alleviation or treatment of addictive symptoms of stimulants addicts.
 - (4) In the case of delivery of Stimulants by the physician referred to in paragraph (1) for a dispensing purpose, the physician must affix the physician's signature on a document specifying the address, name and age of the recipient of delivery thereof as well as the dispensing method and period of dispensing, and must deliver the document upon the dispensing.
 - (5) A Stimulants Researcher must not dispense, or deliver for a dispensing purpose, any Stimulants to others for a research purpose, except for the cases permitted by the Minister of Health, Labour and Welfare.
 - (6) When a Stimulants Researcher intends to obtain permission for dispensing or delivery of Stimulants pursuant to the provisions of the preceding paragraph, the Stimulants Researcher must submit a written application to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the Stimulants Researcher's research institute, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
 - (7) The provisions of paragraph (4) apply mutatis mutandis to the case where a Stimulants Researcher delivers Stimulants for a dispensing purpose.

(Restriction on Advertisement)

Article 20-2 No person may make an advertisement concerning Stimulants except for a case of advertisement in newspapers or magazines for medical and pharmaceutical specialists, etc. (meaning medical and pharmaceutical specialists or persons engaged in research on natural science; the same applies in this Article) which publicizes articles relating to medical, pharmaceutical or natural science issues, or any other case of advertisement primarily targeting medical and pharmaceutical specialists, etc.

Chapter IV Handling

(Sealing by Revenue Stamp)

- Article 21 (1) A Stimulants Manufacturer must contain Stimulants manufactured by the Stimulants Manufacturer in a container and seal the container with a revenue stamp issued by the government, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.
- (2) A Stimulants Manufacturer, Stimulants Dispensing Facility and Stimulants Researcher may not assign or acquire any Stimulants unless they are kept sealed pursuant to the provisions of the preceding paragraph.
- (3) The provisions of the preceding paragraph do not apply to the case of assignment or acquisition of Stimulants for the execution of duties under laws and regulations.

(Storage and Storage Transfer)

- Article 22 (1) A Stimulants Manufacturer, administrator of a Stimulants Dispensing Facility or Stimulants Researcher must store the Stimulants owned or managed by such person at the person's manufacturing site, hospital, clinic or research institute; provided, however, that if a Stimulants Manufacturer designates a business office where Stimulants are to be stored (hereinafter referred to as "Stimulants Storage Business Office") and provides a notification to that effect to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the business office, the Stimulants Manufacturer may store the Stimulants it owns at its Stimulants Storage Business Office, and transfer custody thereof between its manufacturing site and Stimulants Storage Business Office or two or more Stimulants Storage Business Offices.
- (2) The Stimulants Storage Business Office under the proviso to the preceding paragraph must be a business office of a Stimulants Manufacturer for which a pharmacist provided in the Act on Pharmaceuticals and Medical Devices is appointed.
- (3) The storage under paragraph (1) must be implemented at a locked and robust place.

(Disposal)

- Article 22-2 When a Stimulants Manufacturer, licensee for establishment of Stimulants Dispensing Facility or Stimulants Researcher intends to dispose of Stimulants owned by such person, the person must provide a notification to the governor of the prefecture of the location of the place of the person's manufacturing site (or a place of storage in case of Stimulants stored at a

Stimulants Storage Business Office), hospital, clinic or research institute, and must implement the disposal with the attendance of a prefectural official.

(Notification of Accident)

Article 23 When any of the Stimulants owned or managed by a Stimulants Manufacturer, administrator of Stimulants Dispensing Facility or Stimulants Researcher is lost or stolen, or its whereabouts become unknown, a notification on the item names and quantities of the Stimulants as well as any other information necessary to identify the situation of the accident must be promptly provided to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the manufacturing site (or the Stimulants Storage Business Office in case of Stimulants stored there) in the case of a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of an administrator of a Stimulants Dispensing Facility or Stimulants Researcher.

(Obligation to Take Measures upon Lapse of Designation)

Article 24 (1) When a designation of a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher ceases to be in effect (or, if the application for designation provided in the following Article is made, when the disposition to refuse the application is rendered), a report on the item names and quantities of Stimulants owned by the relevant person at the time when the designation ceased to be in effect, must be submitted to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the manufacturing site (or the Stimulants Storage Business Office in case of Stimulants stored there) in the case of a person which formerly was a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a person which formerly was a licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher, within 15 days from the day when the designation ceased to be in effect (or, if the application for designation provided in the following Article is made, from the day when the disposition to refuse the application was rendered; hereinafter the same applies in this Article).

(2) In the case referred to in the preceding paragraph, a person which was formerly a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher must assign Stimulants owned by the person to a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher, and submit a report on the item names and quantities of the Stimulants assigned as well as the name (or corporate name in case of a corporation) and address of the assignee, to the Minister of Health, Labour and Welfare, via the governor of the prefecture of

the location of the manufacturing site (or the Stimulants Storage Business Office in case of Stimulants stored there) in the case of a Stimulants Manufacturer, or to the governor of the prefecture of the location of the hospital, clinic or research institute in the case of a Stimulants Dispensing Facility or Stimulants Researcher, within 30 days from the day when the designation ceased to be in effect.

- (3) If the person which formerly was a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher was unable to assign the Stimulants within the period specified in the preceding paragraph, the person must promptly request the attendance of an official and dispose of the Stimulants in accordance with the official's instructions.
- (4) If the person which formerly was a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher dies or is dissolved, the report under paragraph (1), the assignment and report under paragraph (2) and the disposition under the preceding paragraph must be made by the relevant person's heir in the case of death, or by its liquidator or a corporation surviving or incorporated by a merger in the case of dissolution.
- (5) In the cases referred to in the preceding three paragraphs, the provisions of Article 14, paragraph (1) (Prohibition of Possession) do not apply to the person which formerly was a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher and the relevant person's heir or its liquidator or a corporation surviving or incorporated by a merger, for the period from the day when the designation ceased to be in effect to the date of the assignment or disposition under the paragraph. In such case, the provisions of Article 14, paragraph (2) (Exception to Prohibition of Possession), item (i) apply *mutatis mutandis* to their business assistant, and item (ii) of the paragraph to a person engaged in the service of transportation of mail, letters and goods.
- (6) In the case of paragraphs (2) and (4), the provisions of Article 17 (Restriction and Prohibition of Assignment and Acquisition) and Article 21, paragraph (2) (Prohibition of Assignment and Acquisition of Stimulants Not Sealed with Revenue Stamp) do not apply.

(Special Provisions on Re-designation)

Article 25 If the person which formerly was a Stimulants Manufacturer, licensee for establishment of a Stimulants Dispensing Facility or Stimulants Researcher makes an application for designation of a Stimulants Manufacturer, Stimulants Dispensing Facility or Stimulants Researcher again before the expiration of the effective period of designation provided in Article 6 (Effective

Period of Designation) or within 30 days from the expiration of the effective period of designation, the provisions of Article 14, paragraph (1) (Prohibition of Possession) and the preceding Article do not apply to that person or the person which formerly was an administrator of the Stimulants Dispensing Facility for the period until the Minister of Health, Labour and Welfare or prefectural governor renders a disposition to grant or refuse the application.

Article 26 Deleted

(Disposition of Stimulants Vested in National Treasury)

Article 27 The Minister of Health, Labour and Welfare may make dispositions regarding Stimulants vested in the national treasury pursuant to the provisions of laws and regulations.

Chapter V Record and Report Concerning Business

(Books)

Article 28 (1) A Stimulants Manufacturer, administrator of a Stimulants Dispensing Facility and Stimulants Researcher must keep books at their respective manufacturing sites, Stimulants Storage Business Offices, hospitals, clinics or research institutes, and enter the following matters in the books:

(i) the item names and quantities of the Stimulants manufactured, assigned, acquired, transferred to different custody, dispensed, delivered for the purpose of dispensing, or used for a research purpose, as well as the date thereof;

(ii) the name (or the corporate name in the case of a corporation) and address of the counterparty to assignment or acquisition, and the name and location of the manufacturing site, Stimulants Storage Business Office, Stimulants Dispensing Facility or research institute; and

(iii) the item names and quantities of the Stimulants concerning which notification was provided pursuant to the provisions of Article 23 (Notification of Accident).

(2) A person specified in the preceding paragraph must keep the books under the preceding paragraph for two years from the date of the last entry.

(Report of Stimulants Manufacturer)

Article 29 A Stimulants Manufacturer, via the governor of the prefecture of the location of the Stimulants Manufacturer's manufacturing site, must submit a report to the Minister of Health, Labour and Welfare on the following matters for each period from January to March, from April to June, from July to September, and from October to December, within 15 days from the expiration

of such period:

- (i) the item names and quantities of the Stimulants owned at the beginning of the relevant period, as well as the place of storage;
- (ii) the item names and quantities of the Stimulants manufactured during the relevant period;
- (iii) the item names and quantities of the Stimulants assigned during the relevant period; and
- (iv) the item names and quantities of the Stimulants owned at the end of the relevant period, as well as the place of storage.

(Reports of Administrator of Stimulants Dispensing Facility and Stimulants Researcher)

Article 30 No later than December 15 of each year, an administrator of a Stimulants Dispensing Facility or Stimulants Researcher must submit a report to the governor of the prefecture of the location of the administrator's hospital, clinic or research institute on the item names and quantities of the Stimulants acquired, dispensed, delivered for the purpose of dispensing, or used or manufactured for a research purpose for the period from the day of obtaining designation (or December 1 of the preceding year, in the case of the year subsequent to the year in which the designation was obtained, or in the case of the year in which the designation was granted to the application under Article 25 (Special Provisions on Re-Designation)) to November 30 of the same year, as well as the name and quantity of the Stimulants managed or owned as of November 30 of the same year.

Chapter V-2 Designation, Notification, Restriction, Prohibition and Treatment Relating to Stimulants' Raw Materials

(Requirements for Designation)

Article 30-2 A Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher is to be designated from persons satisfying the following qualifications as determined appropriate, by the Minister of Health, Labour and Welfare and for each business establishment or manufacturing site in the case of a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer, or by the governor of the prefecture of the location of a business establishment or research institute for each of those establishments in the case of a Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

- (i) in the case of a Stimulants' Raw Materials Importer, a Pharmaceuticals Manufacturer and Distributor or any other person who intends to engage in the business of importing Stimulants' Raw Materials, or a person who needs to import Stimulants' Raw Materials for a business purpose;
- (ii) in the case of a Stimulants' Raw Materials Exporter, a person who has obtained permission for establishing a pharmacy pursuant to the provisions of Article 4, paragraph (1) (Permission on Establishment of Pharmacy) of the Act on Pharmaceuticals and Medical Devices (hereinafter referred to as "Licensee for Establishment of Pharmacy"), a Pharmaceuticals Manufacturer and Distributor, a person who has obtained the permission of a retailer or wholesaler pursuant to the provisions of Article 26, paragraph (1) (Permission of Retail Business) or Article 34, paragraph (1) (Permission of Wholesale Business) (hereinafter referred to as "pharmaceuticals distributor" in this Article), or any other person who intends to engage in the business of exporting Stimulants' Raw Materials;
- (iii) in the case of a Stimulants' Raw Materials Manufacturer, Pharmaceuticals Manufacturer and Distributor, pharmaceuticals distributor or any other person who intends to engage in the business of manufacturing Stimulants' Raw Materials or a person who needs to manufacture Stimulants' Raw Materials for a business purpose;
- (iv) in the case of a Stimulants' Raw Materials Handler, a Licensee for Establishment of Pharmacy, Pharmaceuticals Manufacturer and Distributor or any other person who intends to engage in the business of assigning Stimulants' Raw Materials or a person who needs to use Stimulants' Raw Materials for a business purpose; or
- (v) in the case of a Stimulants' Raw Materials Researcher, a person with considerable knowledge of Stimulants' Raw Materials who needs to manufacture or use Stimulants' Raw Materials for a research purpose.

(Rescission of Designation and Suspension of Business)

Article 30-3 (1) If a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher has violated any provisions of this Act, a disposition imposed under the provisions of this Act, or any conditions imposed on the designation or permission, their designation may be rescinded, or an order for the business or research relating to Stimulants Raw Materials to be suspended for a fixed period may be issued, by the Minister of Health, Labour and Welfare in the case of a Stimulants Raw Materials Importer, Stimulants Raw Materials Exporter or Stimulants Raw Materials Manufacturer, or by the prefectural governor in the case of a Stimulants Raw Materials Handler or Stimulants Raw Materials Researcher.

(2) The provisions of Article 8, paragraph (2) (Special Provisions on Method of Hearing) apply mutatis mutandis to the disposition under the preceding paragraph.

(Notification of Discontinuance of Business)

Article 30-4 (1) When a Stimulants' Raw Materials Importer has discontinued the business of importing Stimulants' Raw Materials at the business establishment, a Stimulants' Raw Materials Exporter has discontinued the business of exporting Stimulants' Raw Materials at the business establishment, a Stimulants' Raw Materials Manufacturer has discontinued the business of manufacturing Stimulants' Raw Materials at the manufacturing site, a Stimulants' Raw Materials Handler has discontinued the business relating to the assignment or use of Stimulants' Raw Materials at the business establishment, or a Stimulants' Raw Materials Researcher has discontinued the research which requires the manufacturing or use of Stimulants' Raw Materials at the Stimulants' Raw Materials Researcher's research institute, a notification to that effect, with a designation certificate attached, must be provided to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the business establishment or manufacturing site in the case of a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer, or to the governor of the prefecture of the location of the business establishment or research institute in the case of a Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher, within 15 days from the day of the discontinuance.

(2) If a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher dies or is dissolved, the notification under the preceding paragraph must be provided by the relevant person's heir in the case of death, or by its liquidator or a corporation surviving or incorporated by a merger in the case of dissolution.

(Application, Mutatis Mutandis, Relating to Designation and Notification)

Article 30-5 The provisions of Articles 4 to 7 (Application Procedures for Designation, Designation Certificate, Effective Period of Designation, and Lapse of Designation) and Articles 10 to 12 (Returning and Submission of Designation Certificate, Reissuance of Designation Certificate, and Notification of Change of Name and Address) apply mutatis mutandis to a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants' Raw Materials Handler or Stimulants' Raw Materials Researcher. In such case: in these provisions, the term

"Stimulants Manufacturer" is deemed to be replaced with "Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer, the terms "Stimulants Dispensing Facility" (excluding the case of Article 12, paragraph (2)) and "licensee for establishment of Stimulants Dispensing Facility" are deemed to be replaced with " Stimulants' Raw Materials Handler," the term "Stimulants Researcher" is deemed to be replaced with "Stimulants' Raw Materials Researcher"; in Article 4, paragraph (1), Article 5, paragraph (2), Article 10, paragraphs (1) and (2), Article 11 and Article 12, paragraph (1), the term "manufacturing site" is deemed to be replaced with "business establishment or manufacturing site"; in Article 4, paragraph (2), Article 10, paragraphs (1) and (2), Article 11 and Article 12, paragraph (2), the term "hospital or clinic" is deemed to be replaced with "business establishment"; in Article 5, paragraph (1), the term "manufacturer" is deemed to be replaced with "importer, exporter or manufacturer," the term "licensee for establishment of the dispensing facility" is deemed to be replaced with "handler"; in Article 6, the term "the subsequent year" is deemed to be replaced with "the year in which the fourth anniversary of the date of designation falls"; in Article 7 and Article 10, paragraph (1), the terms "Article 9" and "the preceding Article" are deemed to be replaced with "Article 30-4"; in Article 10, paragraph (2), the terms "under Article 8, paragraph (1) (Rescission of Designation and Suspension of Business) or Article 75, paragraph (1) (Rescission of Permission) of the Act on Pharmaceuticals and Medical Devices" and "under Article 8, paragraph (1)" are deemed to be replaced with "Article 30-3, paragraph (1)," the term "a closure order under Article 29 (Rescission of Permission of Establishment and Closure Order) of the Medical Care Act" is deemed to be replaced with "a disposition of suspension of business under Article 30-3, paragraph (1)"; in Article 10, paragraph (3), the term "the period of suspension of business, period of closure or" is deemed to be replaced with "the period of suspension of business or"; and in Article 12, paragraph (2), the term "the name of the licensee's Stimulants Dispensing Facility" is deemed to be replaced with "the name (or the corporate name, in the case of a corporation) or address or name of business establishment."

(Restriction and Prohibition of Import and Export)

Article 30-6 (1) No person may import any Stimulants' Raw Materials, except for the case of import by a Stimulants' Raw Materials Importer with the permission of the Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare for a business purpose.

(2) No person may export any Stimulants' Raw Materials, except for the case of export by a Stimulants' Raw Materials Exporter with the permission of the

Minister of Health, Labour and Welfare pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare for a business purpose.

- (3) When a Stimulants' Raw Materials Importer or Stimulants' Raw Materials Exporter intends to obtain permission for import or export of Stimulants' Raw Materials pursuant to the provisions of the preceding two paragraphs, the importer or exporter must submit a written application to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the person's business establishment, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Indications for Export)

Article 30-6-2 When a Stimulants' Raw Materials Exporter exports Stimulants' Raw Materials, the exporter must not make a false indication for the item names and quantities.

(Prohibition of Possession)

Article 30-7 Except for the cases specified in the following items, no person may possess any Stimulants' Raw Materials:

- (i) the case where a Stimulants' Raw Materials Importer possesses Stimulants' Raw Materials for a business purpose;
- (ii) the case where a Stimulants' Raw Materials Exporter possesses Stimulants' Raw Materials for a business purpose;
- (iii) the case where a Stimulants' Raw Materials Manufacturer or Stimulants Manufacturer possesses Stimulants' Raw Materials for a business purpose;
- (iv) the case where a Stimulants' Raw Materials Handler possesses Stimulants' Raw Materials for a business purpose;
- (v) the case where a Stimulants' Raw Materials Researcher or Stimulants Researcher possesses Stimulants' Raw Materials for a research purpose;
- (vi) the case where a licensee for establishment of a hospital or clinic, a physician or dentist specified in Article 5, paragraph (1) (Special Provisions on House-Visiting Physician) of the Medical Care Act (hereinafter referred to as "House-Visiting Physician, etc.") or a licensee for establishment of a human-reared animal treatment facility (meaning a treatment facility specified in Article 2, paragraph (2) of the Veterinary Practice Act (Act No. 46 of 1992), and including the address of a person engaging veterinarians in medical treatment of human-reared animals solely through house-calls; the same applies hereinafter) (including a veterinarian engaged in medical treatment of human-reared animals solely through house-calls; the same applies hereinafter) possesses Stimulants' Raw Materials which are pharmaceuticals for a business purpose;
- (vii) the case where a Licensee for Establishment of Pharmacy possesses

- Stimulants' Raw Materials which are pharmaceuticals prescribed by a pharmacist in accordance with the prescription of a physician, dentist or veterinarian and Stimulants' Raw Materials which are pharmaceuticals to be used for the prescription;
- (viii) the case where a pharmacist engaged in prescription at a pharmacy, hospital or clinic, an administrator of a hospital or clinic, a physician or dentist engaged in medical treatment at a hospital or clinic, an administrator specified in Article 5, paragraph (2) of the Veterinary Practice Act (including the case where it applied mutatis mutandis pursuant to Article 7, paragraph (2) of the Act) (hereinafter referred to as "Veterinarian Administrator") or a veterinarian (limited to a veterinarian who is a licensee for establishment of a human-reared animal treatment facility or a veterinarian employed by a licensee for establishment of human-reared animal treatment facility; the same applies hereinafter) engaged in medical treatment of human-reared animals (meaning human-reared animals provided in Article 2, paragraph (1) of the Veterinary Practice Act; the same applies hereinafter) possesses Stimulants' Raw Materials which are pharmaceuticals for a business purpose;
 - (ix) the case where a business assistant of a person specified in the preceding items possesses Stimulants' Raw Materials for a business purpose;
 - (x) the case where a person engaged in the service of transportation of mail, correspondence or goods possesses Stimulants' Raw Materials as necessary for performing the businesses;
 - (xi) the case where a recipient of delivery of Stimulants' Raw Materials which are pharmaceuticals for a dispensing purpose from a physician or dentist engaged in medical treatment at a hospital or clinic, a House-Visiting Physician, etc. or a veterinarian engaged in medical treatment of human-reared animals possesses the Stimulants' Raw Materials, or a case where a person who provides nursing care for the recipient of delivery possesses the Stimulants' Raw Materials for the recipient; or
 - (xii) the case where a recipient of delivery of a prescription by a physician, dentist or veterinarian possesses Stimulants' Raw Materials which are pharmaceuticals prescribed by a pharmacist in accordance with the prescription, and a case where a person who provides nursing care for the recipient possesses Stimulants' Raw Materials which are pharmaceuticals prescribed by a pharmacist in accordance with the prescription for the recipient; or
 - (xiii) the case of possession of Stimulants' Raw Materials for any act conducted under laws and regulations.

(Prohibition of Manufacturing)

Article 30-8 Except for the cases specified in the following items, no person may manufacture any Stimulants' Raw Materials:

- (i) the case where a Stimulants' Raw Materials Manufacturer or Stimulants Manufacturer manufactures Stimulants' Raw Materials for a business purpose; or
- (ii) the case where a Stimulants' Raw Materials Researcher or Stimulants Researcher manufactures Stimulants' Raw Materials for a research purpose.

(Restriction and Prohibition of Assignment and Acquisition)

Article 30-9 Except for the cases specified in the following items, no person may assign or acquire any Stimulants' Raw Materials:

- (i) the case where a person specified in Article 30-7 (Prohibition of Possession), items (i) to (v) assigns or acquires Stimulants' Raw Materials to or from another person falling under those items for a business or research purpose;
- (ii) the case where a person specified in Article 30-7, item (vi) or (vii) acquires Stimulants' Raw Materials which are pharmaceuticals from a person specified in item (i) or items (iii) to (v) of the Article for a business purpose;
- (iii) the case where a physician or dentist engaged in medical treatment at a hospital or clinic, a House-Visiting Physician, etc. or a veterinarian engaged in medical treatment of human-reared animals delivers, for a dispensing purpose, Stimulants' Raw Materials which are pharmaceuticals, and a case where a Licensee for Establishment of Pharmacy or a licensee of establishment of a hospital or clinic assigns Stimulants' Raw Materials which are pharmaceuticals prescribed by a pharmacist in accordance with a prescription by a physician, dentist or veterinarian to a holder of the prescription;
- (iv) the case where a Stimulants' Raw Materials Importer or Stimulants' Raw Materials Exporter imports or exports Stimulants' Raw Materials for a business purpose with the permission of the Minister of Health, Labour and Welfare under Article 30-6 (Restriction and Prohibition of Import and Export), paragraph (1) or (2); or
- (v) the case of assignment or acquisition of Stimulants' Raw Materials for the execution of duties under laws and regulations.

(Assignment Certificate and Acquisition Certificate)

Article 30-10 (1) When assigning or acquiring Stimulants' Raw Materials (excluding the cases of items (iii) and (iv) of the preceding Article), the assignor must deliver to the assignee an assignment certificate prepared pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the assignee must deliver to the assignor an acquisition certificate prepared pursuant to the provisions of Order of the Ministry of Health, Labour and

Welfare.

- (2) The assignee as referred to in the preceding paragraph may provide information on the matters to be specified in the acquisition certificate under the preceding paragraph by a method using an electronic information processing system or any other method using information communication technology as specified by Order of the Ministry of Health, Labour and Welfare, with the approval of the assignor and pursuant to the provisions of Cabinet Order, in lieu of delivery of the acquisition certificate. In such case, the assignee is deemed to have delivered the acquisition certificate.
- (3) The acquisition certificate and assignment certificate under paragraph (1), or an electronic or magnetic record prepared by the method prescribed in the first sentence of the preceding paragraph must be kept by the recipient of the delivery or provision thereof for two years from the date of the acquisition or assignment of the Stimulants' Raw Materials.

(Prohibition of Use)

Article 30-11 Except for the cases specified in the following items, no person may use any Stimulants' Raw Materials:

- (i) the case where a person specified in Article 30-7 (Prohibition of Possession), items (iii) to (v) uses Stimulants' Raw Materials for a business or research purpose;
- (ii) the case where a House-Visiting Physician, etc. and a person specified in Article 30-7, item (viii) dispenses, or uses for the purpose of prescription, Stimulants' Raw Materials which are pharmaceuticals for a business purpose;
- (iii) the case where a recipient of delivery of, for a dispensing purpose, Stimulants' Raw Materials which are pharmaceuticals by a physician or dentist engaged in medical treatment at a hospital or clinic, a House-Visiting Physician, etc. or a veterinarian engaged in medical treatment of human-reared animals dispenses the Stimulants' Raw Materials, and a case where a recipient of delivery of a prescription by a physician, dentist or veterinarian acquires Stimulants' Raw Materials which are pharmaceuticals prescribed by a pharmacist in accordance with a prescription from a Licensee for Establishment of Pharmacy or a licensee of establishment of a hospital or clinic and dispenses the Stimulants' Raw Materials; or
- (iv) the case of use for an act conducted under laws and regulations.

(Storage)

Article 30-12 (1) A person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii) (or an administrator in the case of a hospital or clinic, or a Veterinarian Administrator in the case of a human-reared animal treatment

facility; hereinafter the same applies in Article 30-14) must store Stimulants' Raw Materials owned or possessed by the person at the places specified in the following:

- (i) in the case of a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer or Stimulants Manufacturer, such person's business establishment or manufacturing site, or the place on which notification is provided to the Minister of Health, Labour and Welfare in advance, via the prefectural governor, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare;
 - (ii) in the case of a Stimulants' Raw Materials Handler, the handler's business establishment or the place on which notification is provided to the prefectural governor in advance pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare;
 - (iii) in the case of a Stimulants' Raw Materials Researcher or Stimulants Researcher, the relevant research institute;
 - (iv) in the case of a Licensee for Establishment of Pharmacy, the licensee's pharmacy;
 - (v) in the case of an administrator of a hospital or clinic, the administrator's hospital or clinic, or in the case of a House-Visiting Physician, etc., the address of the House-Visiting Physician, etc.; or
 - (vi) in the case of a Veterinarian Administrator of a human-reared animal treatment facility, the Veterinarian Administrator's facility, or in the case of a veterinarian engaged in the service of medical treatment of human-reared animals only by house-visit, the veterinarian address.
- (2) The storage under the preceding paragraph must be implemented at a locked place.

(Disposal)

Article 30-13 When a person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii) intends to dispose of Stimulants' Raw Materials owned by the person, the person must provide a notification to the governor of the prefecture of the location of the place of storage of the Stimulants' Raw Materials, and must implement the disposal with the attendance of a prefectural official.

(Notification of Accident)

Article 30-14 When any of the Stimulants' Raw Materials owned or possessed by a person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii) is lost, stolen or its whereabouts becomes unknown, a notification on the item names and quantities of the Stimulants' Raw Materials as well as any other information necessary to identify the situations of the accident must be promptly provided, to the Minister of Health, Labour and Welfare, via the

governor of the prefecture of the location of the place of storage of the Stimulants' Raw Materials in the case of a person specified in items (i) to (iii) of the Article, or to the governor of the prefecture of the location of the place of storage of the Stimulants' Raw Materials in the case of any other person.

(Obligation to Take Measures upon Lapse of Designation)

Article 30-15 (1) When any of the events specified in the following items occurs, a person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii) (in the case of a hospital or clinic established by the state or local government, its administrator, or, if an administrator is not appointed, an official designated by the licensee for establishment; or in the case of a human-reared animal treatment facility established by the state or local government, its Veterinarian Administrator) must submit a report on the item and quantity of Stimulants' Raw Materials owned or possessed by the person at the time of such event within 15 days from the day when the event occurred, to the Minister of Health, Labour and Welfare, via the prefectural governor of the place of storage of the Stimulants' Raw Materials in the case of a person specified in items (i) to (iii) of the Article, or to the governor of the prefecture of the location of the place of storage of the Stimulants' Raw Materials in the case of any other person:

- (i) when a designation of a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants Manufacturer, Stimulants' Raw Materials Handler, Stimulants' Raw Materials Researcher or Stimulants Researcher ceases to be in effect (or, when a disposition to refuse an application for designation under Article 25 (Special Provisions on Re-Designation) (including the case where it is applied *mutatis mutandis* pursuant to Article 30-16, paragraph (1)) is rendered);
- (ii) if a Licensee for Establishment of Pharmacy closed the licensee's pharmacy, if the effective period of the licensee's permission expires but the licensee does not obtain renewal, or if the permission of the licensee is rescinded pursuant to the provisions of Article 75, paragraph (1) (Rescission of Permission) of the Act on Pharmaceuticals and Medical Devices;
- (iii) if the licensee for establishment of a hospital or clinic closed the licensee's hospital or clinic, if the permission for establishment of the licensee's hospital or clinic is rescinded pursuant to the provisions of Article 29, paragraph (1) (Rescission of Permission of Establishment and Closure Order) of the Medical Care Act, or if a House-Visiting Physician, etc. discontinues medical treatment; or
- (iv) if a licensee for establishment of a human-reared animal treatment facility closes the licensee's facility or discontinues the medical treatment of human-reared animals.

- (2) In the case referred to in the preceding paragraph, the person who is required to submit the report must assign Stimulants' Raw Materials owned or possessed by the person to a person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii), and must report on the item names and quantities of the assigned Stimulants' Raw Materials as well as the name (or corporate name, in the case of a corporation) and address of the assignee within 30 days from the day when any of the situations specified in the items of the preceding paragraph occurs, to the Minister of Health, Labour and Welfare, via the prefectural governor, or to the prefectural governor, in accordance with the categories specified in the paragraph.
- (3) If the person specified in the preceding paragraph is unable to assign the Stimulants' Raw Materials within the period specified in the paragraph, the person must promptly request the attendance of an official and dispose of or conduct other treatment of the Stimulants' Raw Materials in accordance with the official's instructions.
- (4) Except for the case where the licensee for establishment of the hospital, clinic or human-reared animal treatment facility in item (iii) or (iv) of paragraph (1) is a state or local government, the provisions of Article 24, paragraph (4) (Obligation to Take Measure upon Lapse of Designation) apply mutatis mutandis to a person required to submit a report, assign, dispose of or otherwise conduct treatment of Stimulants' Raw Materials pursuant to the provisions of the preceding three paragraphs in relation to the report, assignment, disposal or any other treatment under the provisions.
- (5) In the cases referred to in the preceding three paragraphs, the provisions of Article 30-7 do not apply to a person required to assign, dispose of or otherwise conduct treatment of Stimulants' Raw Materials pursuant to the provisions of paragraph (2) or (3) or the person's heir, liquidator or a corporation surviving or incorporated by a merger, as well as business assistants of the aforementioned persons, for the period from the day when the grounds specified in the items of paragraph (1) arose until the assignment, disposal or other treatment under the preceding three paragraphs is completed.
- (6) In the case of paragraphs (2) and (4), the provisions of Article 30-9 (Restriction and Prohibition of Assignment and Acquisition) do not apply.

(Application, Mutatis Mutandis)

Article 30-16 (1) The provisions of Article 25 (Special Provisions on Re-Designation) apply mutatis mutandis to a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer, Stimulants' Raw Materials Handler and Stimulants' Raw Materials Researcher. In such case, the term "person which formerly was a Stimulants Manufacturer" is deemed to be replaced with "person which formerly was a Stimulants' Raw

Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer," the term "licensee for establishment of Stimulants Dispensing Facility" is deemed to be replaced with "Stimulants' Raw Materials Handler," the term "Stimulant Researcher" is deemed to be replaced with "Stimulants' Raw Materials Researcher," the term "Article 6" is deemed to be replaced with "Article 6 as applied mutatis mutandis pursuant to Article 30-5 (Application, Mutatis Mutandis, Relating to Designation and Notification)," the term "Stimulants Manufacturer" is deemed to be replaced with "Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter, Stimulants' Raw Materials Manufacturer," the term "Stimulants Dispensing Facility or" is deemed to be replaced with "Stimulants' Raw Materials Handler or," and the phrase "the provisions of Article 14, paragraph (1) (Prohibition of possession) and the preceding Article do not apply to that person or the person which formerly was an administrator of the Stimulants Dispensing Facility" is deemed to be replaced with "the provisions of Article 30-7 (Prohibition of Possession) and the preceding Article do not apply to that person or that person's business assistant."

- (2) The provisions of Article 27 (Disposition of Stimulants Vested in National Treasury) apply mutatis mutandis to Stimulants' Raw Materials.

(Books)

Article 30-17 (1) A person specified in Article 30-7 (Prohibition of Possession), item (i) or (ii) must keep books at the person's respective business establishment and enter the following matters in the books:

- (i) the item names and quantities of the Stimulants' Raw Materials imported, exported, assigned or acquired, as well as the date thereof;
- (ii) the name and address of the counterparty to the import or export of Stimulants' Raw Materials; and
- (iii) the item names and quantities of Stimulants' Raw Materials notified pursuant to the provisions of Article 30-14 (Notification of Accident).

(2) A person specified in Article 30-7, items (iii) to (v) must keep books at the person's respective business establishment, manufacturing site or research institute and enter the following matters in the books:

- (i) the item names and quantities of the Stimulants' Raw Materials manufactured, assigned, acquired or used for a business or research purpose, as well as the date thereof; and
- (ii) the item names and quantities of Stimulants' Raw Materials notified pursuant to the provisions of Article 30-14.

(3) A person specified in the preceding two paragraphs must keep the books under the preceding two paragraphs for two years from the date of the last entry.

Chapter VI Supervision

(Request for Report)

Article 31 When it is necessary for the Minister of Health, Labour and Welfare or the prefectural governor for the purpose of Stimulants or Stimulants' Raw Materials control, the minister or prefectural governor may request a necessary report from a Stimulants Manufacturer, a licensee for establishment of a Stimulants Dispensing Facility or its administrator, a Stimulants Researcher, a person specified in Article 30-7 (Prohibition of Possession) items (i) to (vii) (in the case of a hospital or clinic, including its administrator, and in the case of a human-reared animal treatment facility, including its Veterinarian Manager) and any other related persons.

(On-Site Inspection, Sampling and Questioning)

- Article 32 (1) When it is necessary for the Minister of Health, Labour and Welfare or the prefectural governor for the purpose of Stimulants control, the minister or prefectural governor may instruct officials to enter the premises of a manufacturing site or Stimulants Storage Business Office of a Stimulants Manufacturer, a hospital or clinic which is a Stimulants Dispensing Facility, a research institute of a Stimulants Researcher or any other place relating to Stimulants, inspect books or any other articles, take a sample of any items which are or are suspected to be Stimulants limited to the minimum quantity necessary for testing, or to ask a Stimulants Manufacturer, licensee or administrator of a Stimulants Dispensing Facility or an administrator thereof, a physician engaged in medical treatment at a Stimulants Dispensing Facility, a Stimulants Researcher or any other related persons questions.
- (2) When it is necessary for the Minister of Health, Labour and Welfare or the prefectural governor for the purpose of Stimulants' Raw Materials control, the minister or prefectural governor may instruct officials to enter a place specified in the items of Article 30-12 (Storage) relating to a person specified in the Article (excluding the location of a House-Visiting Physician, etc. and veterinarian engaged in medical treatment of human-reared animals solely through house-calls), inspect books or any other articles, take a sample of any items which are or are suspected to be Stimulants' Raw Materials limited to the minimum quantity necessary for testing, or to ask a person specified in Article 30-7 (Prohibition of Possession), items (i) to (vii) or any other related persons questions.
- (3) The provisions of the preceding two paragraphs must not be construed to have been granted for the purpose of criminal investigation.

(Stimulants Inspector)

Article 33 (1) The authority of the officials provided in Article 22-2 (Disposal), Article 24, paragraph (3) (Disposition of Stimulants Owned at Time of Lapse of Designation), Article 30-13 (Disposal), Article 30-15, paragraph (3) (Disposition of Stimulants' Raw Materials Owned at Time of Lapse of Designation), and paragraphs (1) and (2) of the preceding Article are to be exercised by the persons specified in the following items:

- (i) a narcotics agent or pharmaceutical affairs inspector designated in advance by the Minister of Health, Labour and Welfare; or
- (ii) a prefectural narcotics agent or pharmaceutical affairs inspector designated in advance by the prefectural governor.

(2) A person designated pursuant to the provisions of item (i) or (ii) of the preceding paragraph is called a stimulants inspector.

(3) When a stimulants inspector attends the disposition of Stimulants under Article 22-2 or Article 24, paragraph (3) or the disposition of Stimulants' Raw Materials under Article 30-13 or Article 30-15, paragraph (3), or enters the premises or makes inspection or sampling or asks questions pursuant to the provisions of paragraph (1) or (2) of the preceding Article, the stimulants inspector must carry an identification card and present it when requested by the persons involved.

(Submission of Opinion by Prefectural Governor)

Article 34 If a prefectural governor finds it necessary to render any disposition specified in Article 8, paragraph (1) or Article 30-3, paragraph (1) (Rescission of Designation and Suspension of Business) to a Stimulants Manufacturer, Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer, the governor must submit the opinion to the Minister of Health, Labour and Welfare.

Chapter VII Miscellaneous Provisions

(Conditions for Designation or License)

Article 34-2 (1) A designation or permission prescribed in this Act may be subjected to certain conditions, and such conditions may be amended.

(2) The condition referred to in the preceding paragraph must be within the minimum extent necessary for the prevention of occurrence of health and sanitation hazards caused by abuse of Stimulants or Stimulants' Raw Materials, and must not result in the person who receives such designation or license being bound by undue obligations.

(Exemption of Application regarding Stimulants for Crime Forensic

Investigation)

- Article 34-3 (1) Notwithstanding the provisions of this Act, the Minister of Health, Labour and Welfare may import, manufacture or acquire Stimulants or Stimulants' Raw Materials to be used for the crime forensic investigation relating to Stimulants or Stimulants' Raw Materials.
- (2) The Minister of Health, Labour and Welfare provides the Stimulants or Stimulants' Raw Materials imported, manufactured or acquired pursuant to the provisions of the preceding paragraph to a national or prefectural institution engaged in criminal forensic investigation relating to Stimulants or Stimulants' Raw Materials.
- (3) The head of the institution which obtained Stimulants or Stimulants' Raw Materials delivered from the Minister of Health, Labour and Welfare pursuant to the provisions of the preceding paragraph must keep books, and must enter in the books the item names and quantities of the Stimulants or Stimulants' Raw Materials used for the purpose of the criminal forensic investigation relating to Stimulants or Stimulants' Raw Materials, as well as the date thereof and any other matters specified by Order of the Ministry of Health, Labour and Welfare.
- (4) Notwithstanding the provisions of this Act, if the Minister of Health, Labour and Welfare receives a request from a foreign government on the import of Stimulants or Stimulants' Raw Materials used for the purpose of criminal forensic investigation relating to Stimulants or Stimulants' Raw Materials, the minister may export to the foreign government the Stimulants or Stimulants' Raw Materials imported, manufactured or acquired pursuant to the provisions of paragraph (1) or the Stimulants or Stimulants' Raw Materials vested in the national treasury pursuant to the provisions of laws and regulations.

(Designation Procedures of Stimulants Dispensing Facility Established by State or Prefecture)

- Article 35 (1) Notwithstanding the provisions of the portion of Article 3, paragraph (1) (Requirements for Designation) relating to a person authorized to grant designation and Article 4, paragraph (2) (Application Procedures for Designation), the Minister of Health, Labour and Welfare may grant a designation of a Stimulants Dispensing Facility to a hospital or clinic established by the state, in consultation with the competent minister.
- (2) Notwithstanding the provisions of Article 4, paragraph (2), a prefectural governor may grant a designation of a Stimulants Dispensing Facility to a hospital or clinic established by the prefecture.
- (3) If the Minister of Health, Labour and Welfare grants the designation of a Stimulants Dispensing Facility to a hospital or clinic established by the state pursuant to the provisions of paragraph (1), the minister delivers to an

administrator of the dispensing facility a designation certificate, via the governor of the prefecture of the location, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Change of Entity Required to Provide Notification on Stimulants Dispensing Facility Established by State or Prefectural Government)

Article 36 (1) For a Stimulants Dispensing Facility established by the state or local government, the following notification, returning of designation certificate and report must be provided and conducted by the administrator of the dispensing facility (or if an administrator is not appointed, an employee designated by the licensee for establishment of the facility), to the Minister of Health, Labour and Welfare, via the governor of the prefecture of the location of the administrator's hospital or clinic, in the case of a Stimulants Dispensing Facility established by the state, or to the governor of the prefecture of the location of the administrator's hospital or clinic in the case of a Stimulants Dispensing Facility established by the local government:

- (i) a notification under Article 9, paragraph (2) (Notification of Discontinuance of Medical Treatment);
 - (ii) returning of designation certificate under Article 10, paragraph (1) (Returning of Designation Certificate upon Lapse of Designation);
 - (iii) returning of a former designation certificate under Article 11, paragraph (2) (Returning of Former Designation Certificate Discovered after Making Reissuance Application);
 - (iv) a notification under Article 12, paragraph (2) (Notification of Change of Name); and
 - (v) a report under Article 24, paragraph (1) (Report on Item Names and Quantities of Stimulants Owned at Time of Lapse of Designation) and paragraph (2) (Assignment of Stimulants Owned at Time of Lapse of Designation and Report Thereof).
- (2) In the case of a Stimulants Dispensing Facility established by the state or local government, the assignment or disposition of Stimulants under Article 24, paragraph (2) (Assignment of Stimulants Owned at Time of Lapse of Designation and Report Thereof) or paragraph (3) (Disposition of Stimulants Owned at Time of Lapse of Designation) must be implemented by the administrator of the dispensing facility (or if the administrator is not appointed, an employee designated by the licensee for establishment of the facility).
- (3) The provisions of Article 24, paragraph (5) (Exception to Prohibition of Possession) and paragraph (6) (Exception to Restriction and Prohibition of Assignment and Acquisition) apply mutatis mutandis to the case referred to in the preceding paragraph.

(Delegation of Special Provisions on Stimulants Dispensing Facility
Established by State)

Article 37 In addition to what is provided in this Act, the special provisions necessary for the application of the provisions of this Act to a Stimulants Dispensing Facility established by the state are to be provided by Order of the Ministry of Health, Labour and Welfare.

(Charges)

Article 38 A person specified in the following items must pay to the national treasury the charges in the amount specified by Cabinet Order considering the actual costs required for the examination by the state of the applications specified in the relevant item:

- (i) an applicant for designation of a Stimulants Manufacturer;
 - (ii) an applicant for designation of a Stimulants' Raw Materials Importer;
 - (iii) an applicant for designation of a Stimulants' Raw Materials Exporter;
 - (iv) an applicant for designation of a Stimulants' Raw Materials Manufacturer;
- or
- (v) an applicant for re-issuance of a designation certificate of a Stimulants Manufacturer, Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer.

(Price of Revenue Stamp)

Article 39 A person who needs a revenue stamp provided in Article 21, paragraph (1) (Sealing of Manufactured Stimulants with Revenue Stamp) must pay to the national treasury the price in the amount specified by Order of the Ministry of Health, Labour and Welfare considering the actual costs.

(Special Provisions on Time Limit When Procedure Is Made Via Prefectural Governor)

Article 40 For a notification, returning or submission of designation certificate or report to be directed to the Minister of Health, Labour and Welfare via the prefectural governor pursuant to the provisions of this Act, if the written notification, designation certificate or written report is submitted to the prefectural governor within the time limit specified in the relevant provision, such acts are deemed to have been conducted within the prescribed time limit.

(Categories of Business Affairs)

Article 40-2 Business affairs to be administered by a prefecture pursuant to the provisions of Article 4, paragraph (1) (Application for Designation via Prefectural Governor) (including the case where it is applied mutatis mutandis

pursuant to Article 30-5), Article 5, paragraph (2) (Delivery of Designation Certificate via Prefectural Governor) (including the case where it is applied mutatis mutandis pursuant to Article 30-5), Article 9, paragraph (1) (Notification of Discontinuance of Business via Prefectural Governor), Article 10, paragraph (1) (Returning of Designation Certificate via Prefectural Governor) and paragraph (2) (Submission of Designation Certificate via Prefectural Governor) (limited to the portion pertaining to a Stimulants Manufacturer, and including the case where these provisions are applied mutatis mutandis pursuant to Article 30-5), Article 11, paragraph (1) (Re-Issuance of Designation Certificate via Prefectural Governor) and paragraph (2) (Returning of Former Designation Certificate via Prefectural Governor) (limited to the portion pertaining to a Stimulants Manufacturer, and including the case where these provisions are applied mutatis mutandis pursuant to Article 30-5), Article 12, paragraph (1) (Notification of Change of Name or Address via Prefectural Governor) (including the case where it is applied mutatis mutandis pursuant to Article 30-5), Article 15, paragraph (2) (Application for Permission for Manufacturing via Prefectural Governor), Article 17, paragraph (5) (Application for Permission for Assignment or Acquisition via Prefectural Governor), Article 20, paragraph (6) (Application for Permission for Dispensing and Delivery via Prefectural Governor), Article 22, paragraph (1) (Notification of Storage Business Office via Prefectural Governor), Article 22-2 (Disposal), Article 23 (Notification of Accident), Article 24, paragraph (1) (Report on Item Names and Quantities of Stimulants Owned at Time of Lapse of Designation) and paragraph (2) (Assignment of Stimulants Owned at Time of Lapse of Designation and Report Thereof), Article 29 (Report of Stimulants Manufacturer), Article 30 (Reports of Administrator of Stimulants Dispensing Facility and Stimulants Researcher), Article 30-4, paragraph (1) (Notification of Discontinuance of Business of Stimulants' Raw Materials Importer) (limited to the portion pertaining to a Stimulants' Raw Materials Importer, Stimulants' Raw Materials Exporter or Stimulants' Raw Materials Manufacturer), Article 30-6, paragraph (3) (Application for Permission of Import and Export of Stimulants' Raw Materials via Prefectural Governor), Article 30-12, paragraph (1), item (i) (Notification of Place of Storage of Stimulants' Raw Materials via Prefectural Governor) and item (ii) (Notification of Place of Storage of Stimulants' Raw Materials), Article 30-13 (Disposal of Stimulants' Raw Materials), Article 30-14 (Notification of Accident Relating to Stimulants' Raw Materials), Article 30-15, paragraph (1) (Report on Item Names and Quantities of Stimulants' Raw Materials Owned at Time of Lapse of Designation) and paragraph (2) (Assignment of Stimulants' Raw Materials Owned or Possessed at Time of Lapse of Designation and Report Thereof), Article 31 (Request for Report), Article 32, paragraph (1) (On-Site

Inspection, Sampling and Questioning Relating to Stimulants) and paragraph (2) (On-Site Inspection, Sampling and Questioning Relating to Stimulants' Raw Materials), Article 35, paragraph (3) (Delivery of Designation Certificate to Stimulants Dispensing Facility Established by the State via Prefectural Governor) and Article 36, paragraph (1) (Notification of Stimulants Dispensing Facility Established by the State via Prefectural Governor) are treated as Item 1 statutory entrusted functions prescribed in Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947).

(Delegation of Authorities)

Article 40-3 (1) The authorities of the Minister of Health, Labour and Welfare prescribed in this Act may be delegated to the head of a Regional Bureau of Health and Welfare, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the head of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may be delegated to the head of a Regional Bureau of Health and Welfare Branch Office or to the head of a regional narcotics control office, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Transitional Measures)

Article 40-4 In the case of legislation, revision or repeal of a Cabinet Order pursuant to the provisions of this Act, transitional measures as may be necessary (including transitional measures relating to penal provisions) may be provided in the Cabinet Order, to the extent deemed reasonably necessary for the legislation, revision or repeal.

Chapter VIII Penal Provisions

(Criminal Punishment)

Article 41 (1) A person who imported or exported any Stimulants to or from Japan or a foreign country or who manufactured any Stimulants without due cause (excluding a person who falls under Article 41-5, paragraph (1), item (ii)) is punished by imprisonment with required labor for a definite term not less than one year.

(2) A person who committed the offense referred to in the preceding paragraph for the purpose of profit is punished by life imprisonment with required labor or imprisonment with required labor for a term not less than three years, or, depending on the circumstance of the offense, by a life imprisonment with required labor or imprisonment with required labor for a term not less than three years and a fine not exceeding 10,000,000 yen.

(3) An attempt to commit the offenses mentioned in the preceding two paragraphs is punished.

Article 41-2 (1) A person who possessed, assigned or acquired any Stimulants without due cause (excluding a person who falls under Article 42, item (v)) is punished by imprisonment with required labor for a term not exceeding ten years.

(2) A person who committed the offense referred to in the preceding paragraph for the purpose of profit is punished by imprisonment with required labor for a definite term not less than one year, or, depending on the circumstance of the offense, by an imprisonment with required labor for a definite term not less than one year and a fine not exceeding 5,000,000 yen.

(3) An attempt to commit the offenses mentioned in the preceding two paragraphs is punished.

Article 41-3 (1) A person who falls under any of the following items is punished by imprisonment with required labor for a term not exceeding ten years:

(i) a person who violated the provisions of Article 19 (Prohibition of Use);

(ii) a person who violated the provisions of Article 20, paragraph (2) or (3) (Restriction on Dispensing for Any Purpose Except for Medical Treatment of Others or Restriction on Dispensing for Purpose of Alleviation or Treatment of Addiction);

(iii) a person who violated the provisions of Article 30-6 (Restriction and Prohibition on Import and Export); or

(iv) a person who violated the provisions of Article 30-8 (Prohibition of Manufacturing).

(2) A person who committed the offense referred to in the preceding paragraph for the purpose of profit is punished by imprisonment with required labor for a definite term not less than one year, or, depending on the circumstance of the offense, by an imprisonment for a definite term not less than one year and a fine not exceeding 5,000,000 yen.

(3) An attempt to commit the offenses mentioned in the preceding two paragraphs is punished.

Article 41-4 (1) A person who falls under any of the following items is punished by imprisonment with required labor for a term not exceeding seven years:

(i) a person who violated the provisions of Article 20, paragraph (1) (Restriction on Dispensing of Stimulants Not under Management of Administrator);

(ii) a person who violated the provisions of Article 20, paragraph (5) (Restriction on Dispensing by Stimulants Researcher);

(iii) a person who violated the provisions of Article 30-7 (Prohibition of

- Possession);
- (iv) a person who violated the provisions of Article 30-9 (Restriction and Prohibition on Assignment and Acquisition); or
 - (v) a person who violated the provisions of Article 30-11 (Prohibition of Use).
- (2) A person who committed the offense referred to in items (ii) to (v) of the preceding paragraph for the purpose of profit is punished by imprisonment with required labor for a term not exceeding ten years, or, depending on the circumstance of the offense, by an imprisonment for a term not exceeding ten years and a fine not exceeding 3,000,000 yen.
- (3) An attempt to commit the offenses referred to in items (ii) to (v) of paragraph (1) and the preceding paragraph (limited to the parts pertaining to items (ii) to (v) of paragraph (1)) is punished.

Article 41-5 (1) A person who falls under any of the following items is punished by imprisonment with required labor for a term not exceeding three years or fine not exceeding 500,000 yen, or both:

- (i) a person who violated the order to suspend business or research under Article 8, paragraph (1) (Rescission of Designation and Suspension of Business);
 - (ii) a person who violated the provisions of Article 15, paragraph (4) (Restriction on Manufacturing);
 - (iii) a person who violated the provisions of Article 20-2 (Restriction on Advertisement); or
 - (iv) a person who violated the order to suspend business or research under Article 30-3, paragraph (1) (Rescission of Designation and Suspension of Business).
- (2) An attempt to commit the offenses mentioned in the preceding two items is punished.

Article 41-6 A person who made a preparation with a purpose to commit the offense under Article 41, paragraph (1) or (2) is punished by imprisonment with required labor for a term not exceeding five years.

Article 41-7 A person who made a preparation with a purpose to commit the offense under Article 41-3, paragraph (1), item (iii) or (iv) or paragraph (2) (limited to the portion pertaining to item (iii) or (iv) of paragraph (1) of the Article) is punished by imprisonment with required labor for a term not exceeding five years.

Article 41-8 (1) The Stimulants or Stimulants' Raw Materials pertaining to the offenses under Article 41 to the preceding Article which are owned or possessed

by an offender are confiscated; provided, however, that the Stimulants or Stimulants' Raw Materials may not be confiscated if owned by a person other than the offender.

(2) In relation to the committing of the offense specified in the preceding paragraph (excluding the offenses under Article 41-3 to Article 41-5 and the preceding Article), a vessel, aircraft or vehicle made available for carrying the Stimulants may be confiscated.

Article 41-9 A person who knowingly provided or carried funds, land, building, vessel, aircraft, vehicle, equipment, machine, device or raw material (excluding Stimulants' Raw Materials) necessary for any act which constitutes an offense under Article 41, paragraph (1) or (2) is punished by imprisonment with required labor for a term not exceeding five years.

Article 41-10 A person who knowingly provided or carried funds, land, building, vessel, aircraft, vehicle, equipment, machine, device or raw material necessary for any act which constitutes an offense under Article 41-3, paragraph (1), item (iii) or (iv) or paragraph (2) (limited to the portion pertaining to item (iii) or (iv) of paragraph (1) of the Article) is punished by imprisonment with required labor for a term not exceeding five years.

Article 41-11 A person who acted as an intermediary for the assignment and acquisition of Stimulants, which constitutes the offense under Article 41-2, is punished by imprisonment with required labor for a term not exceeding three years.

Article 41-12 The offenses under Article 41, Article 41-2, Article 41-6, Article 41-9 and the preceding Article are governed by the provisions of Article 2 of the Penal Code.

Article 41-13 A person who acted as an intermediary for the assignment and acquisition of Stimulants' Raw Materials prohibited pursuant to the provisions of Article 30-9 (Restriction and Prohibition of Assignment and Acquisition) is punished by imprisonment with required labor for a term not exceeding three years.

Article 42 A person who falls under any of the following items is punished by imprisonment with required labor for a term not exceeding one year or a fine not exceeding 200,000 yen, or both:

(i) a person who violated the provisions of Article 5, paragraph (3) (Prohibition of Assignment and Lending of Designation Certificate);

- (ii) a person who violated the provisions of Article 16 (Administrator of Stimulants Dispensing Facility);
- (iii) a person who failed to deliver an assignment certificate or acquisition certificate in violation of the provisions of Article 18, paragraph (1) (Delivery of Assignment Certificate and Acquisition Certificate), made a false statement on these certificates, or made a false entry on the electronic or magnetic records specified in paragraph (3) of the Article (Assignment Certificate and Acquisition Certificate, and Storage of Electronic or Magnetic Records);
- (iv) a person who violated the provisions of Article 18, paragraph (4) (Assignment Certificate and Acquisition Certificate, and Prohibition of Assignment of Electronic or Magnetic Records);
- (v) a person who violated the provisions of Article 21, paragraph (1) (Sealing by Revenue Stamp) or paragraph (2) (Prohibition of Assignment and Acquisition of Stimulants Not Sealed by Revenue Stamp);
- (vi) a person who violated the provisions of Article 22 (Storage and Storage Transfer);
- (vii) a person who violated the provisions of Article 22-2 (Disposal);
- (viii) a person who failed to provide a notification or submitted a false notification under Article 23 (Notification of Accident);
- (ix) a person who failed to submit a report or submitted a false report under Article 24, paragraph (1) (Report on Item Names and Quantities of Stimulants Owned at Time of Lapse of Designation), paragraph (2) (Assignment of Stimulants Owned at Time of Lapse of Designation and Report Thereof) or paragraph (4) (Change of Party Obligated to Submit Report in Case of Death or Dissolution), or a person who failed to submit a report or submitted a false report under Article 36, paragraph (1) (Change of Entity Obligated to Provide Notification Relating to Stimulants Dispensing Facility Established by State or Local Government) in relation to Article 24, paragraphs (1) and (2);
- (x) A person who violated the provisions of Article 24, paragraph (3) (Disposition of Stimulants Owned at Time of Lapse of Designation) or paragraph (4) (Change of Party Obligated to Submit Report in Case of Death or Dissolution), or the provisions of Article 36, paragraph (2) (Change of Party Obligated to Make Disposition Relating to Stimulants Dispensing Facility Established by State or Local Government) in relation to Article 24, paragraph (3);
- (xi) a person who failed to keep or make entries in a book, or who made a false entry in the book under Article 28, paragraph (1) (Keeping and Entry of book);
- (xii) a person who failed to submit a report or submitted a false report under

- Article 29 (Report of Stimulants Manufacturer);
- (xiii) a person who failed to submit a report or submitted a false report under Article 30 (Reports of Administrator of Stimulants Dispensing Facility and Stimulants Researcher);
 - (xiv) a person who violated the provisions of Article 5, paragraph (3), as applied mutatis mutandis pursuant to Article 30-5 (Application, Mutatis Mutandis, Relating to Designation and Notification);
 - (xv) a person who violated the provisions of Article 30-6-2 (Indications for Export);
 - (xvi) a person who failed to deliver an assignment certificate or acquisition certificate in violation of the provisions of Article 30-10, paragraph (1) (Delivery of Assignment Certificate and Acquisition Certificate), made a false statement on these certificates, or made a false entry on the electronic or magnetic records under paragraph (3) of the Article (Assignment Certificate and Acquisition Certificate, and Storage of Electronic or Magnetic Records);
 - (xvii) a person who violated the provisions of Article 30-12 (Storage);
 - (xviii) a person who violated the provisions of Article 30-13 (Disposal);
 - (xix) a person who failed to provide a notification or submitted a false notification under Article 30-14 (Notification of Accident);
 - (xx) a person who failed to submit a report or submitted a false report under Article 30-15, paragraph (1) (Report on Item Names and Quantities of Stimulants' Raw Materials Owned at Time of Lapse of Designation) or paragraph (2) (Assignment of Stimulants' Raw Materials Owned at Time of Lapse of Designation and Report Thereof), or Article 24, paragraph (4) (Change of Party Obligated to Submit Report in Case of Death or Dissolution) as applied mutatis mutandis pursuant to Article 30-15, paragraph (4);
 - (xxi) a person who violated the provisions of Article 30-15, paragraph (3) (Disposition or Other Treatment of Stimulants' Raw Materials Owned or Possessed at Time of Lapse of Designation) or Article 24, paragraph (4) (Change of Party Obligated to Submit Disposition in Case of Death or Dissolution) as applied mutatis mutandis pursuant to Article 30-15, paragraph (4);
 - (xxii) a person who failed to keep or make entries in a book, or who made a false entry in the book under Article 30-17, paragraph (1) or (2) (Keeping and Entry of Book).

Article 42-2 A person who falls under any of the following items is punished by a fine not exceeding 200,000 yen:

- (i) a person who violated the provisions of Article 9 (Notification of Discontinuance of Business), or Article 36, paragraph (1) (Change of Entity

- Obligated to Provide Notification Relating to Stimulants Dispensing Facility Established by State or Local Government) in relation to Article 9, paragraph (2);
- (ii) a person who violated the provisions of Article 18, paragraph (3) (Assignment Certificate and Acquisition Certificate, and Storage of Electronic or Magnetic Records);
 - (iii) a person who violated the provisions of Article 28, paragraph (2) (Storage of Books);
 - (iv) a person who violated the provisions of Article 30-4 (Notification of Discontinuance of Business);
 - (v) a person who violated the provisions of Article 30-10, paragraph (3) (Assignment Certificate and Acquisition Certificate, and Storage of Electronic or Magnetic Records);
 - (vi) a person who violated the provisions of Article 30-17, paragraph (3) (Storage of Books);
 - (vii) a person who failed to submit a report or submitted a false report under Article 31 (Request for Report); or
 - (viii) a person who refused, obstructed or evaded inspection or sampling under Article 32, paragraph (1) or (2) (On-Site Inspection, Sampling and Questioning), or who failed to answer or made a false statement in response to questions under the provisions of the paragraphs.

(Administrative Punishment)

Article 43 A person who falls under any of the following items (or, in the case of a corporation, its representative) is punished by a non-criminal fine not exceeding 100,000 yen:

- (i) a person who violated the provisions of Article 10, paragraph (1) (Returning of Designation Certificate) or paragraph (2) (Submission of Designation Certificate), or Article 36, paragraph (1) (Change of Entity Obligated to Provide Notification Relating to Stimulants Dispensing Facility Established by State or Local Government) in relation to Article 10, paragraph (1);
- (ii) a person who violated the provisions of Article 11, paragraph (2) (Returning of Former Designation Certificate), or Article 36, paragraph (1) relating to Article 11, paragraph (2);
- (iii) a person who violated the provisions of Article 12 (Notification of Change of Name or Address), or Article 36, paragraph (1) relating to Article 12, paragraph (2);
- (iv) a person who violated the provisions of Article 20, paragraph (4) (Procedure for Delivery for Purpose of Dispensing) (including the case where it is applied mutatis mutandis pursuant to paragraph (6) of the Article);
- (v) a person who violated the provisions of Article 10, paragraph (1) or (2) as

- applied mutatis mutandis pursuant to Article 30-5 (Application, Mutatis Mutandis, Relating to Designation and Notification);
- (vi) a person who violated the provisions of Article 11, paragraph (2), as applied mutatis mutandis pursuant to Article 30-5; or
 - (vii) a person who violated the provisions of Article 12, as applied mutatis mutandis pursuant to Article 30-5.

(Dual Criminal Liability Provision)

Article 44 If a representative of a corporation, or an agent, employee or other worker of a corporation or an individual person committed an offense under Article 41, paragraph (2) or (3) or Article 41-2, paragraph (2) or (3), or committed a violation of Article 41-3, paragraph (2) or (3), Article 41-4, paragraph (2) or (3), Article 41-5, Article 42 or Article 42-2, in relation to the business of the corporation or individual person, in addition to punishing the person who committed the act in question, the corporation or individual person is also punished by a fine as respectively prescribed in the relevant Article.

Appended Table

- (i) 1-phenyl-2-methylaminopropanol-1, its salts, and a substance containing any of these, excluding any substance containing 10% or less 1-phenyl-2-methylaminopropanol-1;
- (ii) 1-phenyl-1-chloro-2-methylaminopropane, its salts, and a substance containing any of these;
- (iii) 1-phenyl-2-dimethylaminopropanol-1, its salts, and a substance containing any of these, excluding any substance containing 10% or less 1-phenyl-2-dimethylaminopropanol-1;
- (iv) 1-phenyl-1-chloro-2-dimethylaminopropane, its salts, and a substance containing any of these;
- (v) 1-phenyl-2-dimethylaminopropane, its salts, and a substance containing any of these;
- (vi) phenylacetic acid, its salts, and a substance containing any of these, excluding any substance containing 10% or less phenylacetic acid;
- (vii) phenylacetoacetonitrile and a substance containing it;
- (viii) phenylacetone and a substance containing it; and
- (ix) any raw material substance of Stimulants specified by Cabinet Order.