

# Narcotics and Psychotropics Control Act

(Act No. 14 of March 17, 1953)

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## Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to prevent the health and sanitation hazards caused by the abuse of narcotics and psychotropics and to thereby promote the public welfare, by setting in place the necessary controls on the import, export, manufacture, formulation of pharmaceutical preparations, transfer, and other handling of narcotics and psychotropics, as well as by taking action with regard to narcotics addicts such as establishing measures to provide them with the necessary medical treatment.

(Definitions of Terms)

Article 2 As used in this Act, the terms set forth in the following items have the meanings prescribed therein:

(i) "Narcotic" means a substance as set forth in Appended Table I;

(ii) "Opium" means opium as prescribed in the Opium Control Act (Act No. 71

- of 1954);
- (iii) "Opium Poppy" means an opium poppy as prescribed in the Opium Control Act;
  - (iv) "Plant Containing a Narcotic Raw Material" means a plant set forth in Appended Table II;
  - (v) "Exempt Narcotic" means a substance as prescribed in item (lxxvi)(a) of Appended Table I;
  - (vi) "Psychotropic" means a substance as set forth in Appended Table III;
  - (vii) "Narcotic or Psychotropic Raw Material" means a substance as set forth in Appended Table IV;
  - (viii) "Narcotics Handler" means a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, Primary Wholesaler of Narcotics, Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher;
  - (ix) "Commercial Narcotics Handler" means a Narcotics Handler other than a Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher;
  - (x) "Narcotics Importer" means a person that is in the business of importing Narcotics, having been licensed to do so by the Minister of Health, Labour and Welfare;
  - (xi) "Narcotics Exporter" means a person that is in the business of exporting Narcotics, having been licensed to do so by the Minister of Health, Labour and Welfare;
  - (xii) "Narcotics Manufacturer" means a person that is in the business of manufacturing Narcotics, having been licensed to do so by the Minister of Health, Labour and Welfare (this includes refining a Narcotic and turning a Narcotic into a different type of Narcotic by subjecting it to a chemical transformation; the same applies hereinafter);
  - (xiii) "Formulator of Narcotic Pharmaceuticals" means a person that is in the business of formulating pharmaceutical preparations of Narcotics (meaning processing a Narcotic into a different type of Narcotic without subjecting it to a chemical transformation; dispensation is excluded from this meaning; the same applies hereinafter) or of packaging Narcotics into small portions (meaning dividing Narcotics accepted from another person into small portions and placing them into containers; the same applies hereinafter), having been licensed to do so by the Minister of Health, Labour and Welfare;
  - (xiv) "Manufacturer of Exempt Narcotics" means a person that is in the business of manufacturing Exempt Narcotics, having been licensed to do so by the Minister of Health, Labour and Welfare;
  - (xv) "Primary Wholesaler of Narcotics" means a person that is in the business

- of transferring Narcotics to Narcotics Wholesalers, having been licensed to do so by the Minister of Health, Labour and Welfare;
- (xvi) "Narcotics Wholesaler" means a person that is in the business of transferring Narcotics to Narcotics Retailers, the operators of Medical Facilities at Which Narcotics Are Administered, and the operators of Narcotics Research Facilities, having been licensed to do so by the prefectural governor;
- (xvii) "Narcotics Retailer" means a person that is in the business of transferring Narcotics dispensed based on prescriptions for Narcotics that have been written by Persons Licensed to Administer Narcotics (hereinafter referred to as a "Narcotics Prescription"), having been licensed to do so by the prefectural governor;
- (xviii) "Person Licensed to Administer Narcotics" means a person that, in the course of business and as treatment for an illness, administers Narcotics, delivers a person Narcotics to administer, or deliver prescriptions for Narcotics, having been licensed to do so by the prefectural governor;
- (xix) "Narcotics Manager" means a person that, in the course of business, manages Narcotics that are administered or delivered to persons to administer at a Medical Facility at Which Narcotics Are Administered, having been licensed to do so by the prefectural governor;
- (xx) "Narcotics Researcher" means a person that, for academic research purposes, cultivates Plants Containing Narcotic Raw Materials, manufactures Narcotics, or makes use of Narcotics, Opium, or Opium Poppies, having been licensed to do so by the prefectural governor;
- (xxi) "Site of Operations Involving Narcotics" means a store, manufacturing site, formulation site, pharmacy, hospital, clinic (including the address of a physician or dentist as prescribed in Article 5, paragraph (1) of the Medical Care Act (Act No. 205 of 1948); the same applies hereinafter), veterinary facility for peoples' animals (meaning a veterinary facility as prescribed in Article 2, paragraph (2) of the Veterinary Medicine Act (Act No. 46 of 1992); including the address of a veterinary house call service as prescribed in Article 7, paragraph (1) of that Act; the same applies hereinafter), or research facility, at which a Narcotics Handler handles Narcotics in the course of business or research; provided, however, that if a Person Licensed to Administer Narcotics or Narcotics Researcher is engaged in treatment or research at two or more hospitals, clinics, veterinary facilities for peoples' animals (hereinafter referred to as a "Hospital or Similar Facility"), or research facilities within the boundaries of the same prefecture, only the primary Hospital or Similar Facility at which the person engages in medical treatment or the primary research facility at which the person engages in research is considered to be an Site of Operations Involving Narcotics;

- (xxii) "Medical Facility at Which Narcotics Are Administered" means a Hospital or Similar Facility where a Person Licensed to Administer Narcotics provides medical treatment;
- (xxiii) "Narcotics Research Facility" means a research facility where a Narcotics Researcher engages in research;
- (xxiv) "Narcotics Addiction" means a chronic addiction to Narcotics, cannabis, or Opium;
- (xxv) "Narcotics Addict" means a person with a Narcotics Addiction;
- (xxvi) "Psychotropics Handler" means a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, Psychotropics Processor, Psychotropics Wholesaler, Psychotropics Retailer, operator of a Hospital or Similar Facility, or Operator of a Facility Conducting Experiments or Research Involving Psychotropics;
- (xxvii) "Commercial Psychotropics Handler" means a Psychotropics Handler other than the operator of a Hospital or Similar Facility or the Operator of a Facility Conducting Experiments or Research Involving Psychotropics;
- (xxviii) "Psychotropics Importer" means a person that is in the business of importing Psychotropics, having been licensed to do so by the Minister of Health, Labour and Welfare;
- (xxix) "Psychotropics Exporter" means a person that is in the business of exporting Psychotropics, having been licensed to do so by the Minister of Health, Labour and Welfare;
- (xxx) "Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals" means a person that is in the business of manufacturing Psychotropics (this includes refining a Psychotropic and turning a Psychotropic into a different type of Psychotropic by subjecting it to a chemical transformation; the same applies hereinafter), of formulating pharmaceutical preparations of Psychotropics (meaning turning a Psychotropic into a different type of Psychotropic without subjecting it to a chemical transformation; dispensation is excluded from this meaning; the same applies hereinafter), or of packaging Psychotropics into small portions (meaning dividing Psychotropics accepted from another person into small portions and placing them into containers; the same applies hereinafter), having been licensed to do so by the Minister of Health, Labour and Welfare;
- (xxxii) "Psychotropics Processor" means a person that is in the business of turning a Psychotropic into a substance other than a Psychotropic by subjecting it to a chemical transformation, having been licensed to do so by the Minister of Health, Labour and Welfare;
- (xxxiii) "Psychotropics Wholesaler" means a person that is in the business of transferring Psychotropics to Psychotropics Handlers (other than Psychotropics Importers), having been licensed to do so by the prefectural

- governor;
- (xxxiii) "Psychotropics Retailer" means a person that is in the business of transferring Psychotropics dispensed based on prescriptions for Psychotropics (hereinafter referred to as a "Psychotropics Prescription"), having been licensed to do so by the prefectural governor;
- (xxxiv) "Operator of a Facility Conducting Experiments or Research Involving Psychotropics" means the operator of a facility manufacturing or using Psychotropics for academic research purposes or for experimentation and testing (hereinafter referred to as a "Facility Conducting Experiments or Research Involving Psychotropics"), which is registered by the Minister of Health, Labour and Welfare or the prefectural governor;
- (xxxv) "Commercial Establishment at Which Psychotropics Are Handled" means a store, manufacturing site, formulation site, or pharmacy where a Commercial Psychotropics Handler handles Psychotropics in the course of business;
- (xxxvi) "Commercial Handler of Narcotic or Psychotropic Raw Materials" means an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Narcotic or Psychotropic Raw Materials, or Retailer of Narcotic or Psychotropic Raw Materials;
- (xxxvii) "Importer of Narcotic or Psychotropic Raw Materials" means a person that is in the business of importing Narcotic or Psychotropic Raw Materials;
- (xxxviii) "Exporter of Narcotic or Psychotropic Raw Materials" means a person that is in the business of exporting Narcotic or Psychotropic Raw Materials;
- (xxxix) "Manufacturer of Narcotic or Psychotropic Raw Materials" means a person that is in the business of manufacturing Narcotic or Psychotropic Raw Materials (this includes refining a Narcotic or Psychotropic Raw Material and turning a Narcotic or Psychotropic Raw Material into a different type of Narcotic or Psychotropic Raw Material, with or without subjecting it to a chemical transformation; dispensation is excluded from this meaning; the same applies hereinafter) or of packaging Narcotic or Psychotropic Raw Materials into small portions (meaning dividing Narcotic or Psychotropic Raw Materials accepted from another person into small portions and placing them into containers; the same applies hereinafter);
- (xl) "Manufacturer of Specified Narcotic or Psychotropic Raw Materials" means a person that is in the business of manufacturing the Narcotic or Psychotropic Raw Materials that Cabinet Order prescribes (hereinafter referred to as a "Specified Narcotic or Psychotropic Raw Material") or of packaging Specified Narcotic or Psychotropic Raw Materials into small portions;
- (xli) "Retailer of Narcotic or Psychotropic Raw Materials" means a person that

- is in the business of transferring Narcotic or Psychotropic Raw Materials;
- (xlii) "Retailer of Specified Narcotic or Psychotropic Raw Materials" means a person that is in the business of transferring Specified Narcotic or Psychotropic Raw Materials;
- (xliii) "Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled" means a store, manufacturing site, or pharmacy where a Commercial Handler of Narcotic or Psychotropic Raw Materials handles Narcotic or Psychotropic Raw Materials in the course of business.

## **Chapter II Control of Narcotics**

### **Section 1 Licensing**

(Licensing)

Article 3 (1) For each Site of Operations Involving Narcotics, the Minister of Health, Labour and Welfare handles the licensing of Narcotics Importers, Narcotics Exporters, Narcotics Manufacturers, Formulators of Narcotic Pharmaceuticals, Manufacturers of Exempt Narcotics, and Primary Wholesalers of Narcotics; and prefectural governors handle the licensing of Narcotics Wholesalers, Narcotics Retailers, Persons Licensed to Administer Narcotics, Narcotics Managers, and Narcotics Researchers.

(2) It is not permissible for a person other than as follows to be licensed:

- (i) a person that has obtained a business permit for pharmaceutical manufacturing and sales pursuant to the Act to Ensure the 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 the "Act on Pharmaceuticals and Medical Devices"), for licensing as a Narcotics Importer;
- (ii) a person that has obtained a business permit for pharmaceutical manufacturing and sales or pharmaceutical sales pursuant to the Act on Pharmaceuticals and Medical Devices; and that is either personally a pharmacist, or that employs a pharmacist, for licensing as a Narcotics Exporter;
- (iii) a person that has obtained a business permit for pharmaceutical manufacturing and sales or pharmaceutical sales pursuant to the Act on Pharmaceuticals and Medical Devices, for licensing as a Narcotics Manufacturer or as a Formulator of Narcotic Pharmaceuticals;
- (iv) a person that has obtained a business permit for pharmaceutical manufacturing pursuant to the Act on Pharmaceuticals and Medical Devices, for licensing as a Manufacturer of Exempt Narcotics;
- (v) a person that has obtained a permit to operate a pharmacy pursuant to the Act on Pharmaceuticals and Medical Devices, or that has obtained a business

- permit for pharmaceutical sales pursuant to the Act on Pharmaceuticals and Medical Devices; and that is either personally a pharmacist or that employs a pharmacist, for licensing as a Primary Wholesaler of Narcotics or Narcotics Wholesaler;
- (vi) a person that has obtained a permit to operate a pharmacy pursuant to the Act on Pharmaceuticals and Medical Devices, for licensing as a Narcotics Retailer;
  - (vii) a physician, dentist, or veterinarian, for licensing as a Person Licensed to Administer Narcotics;
  - (viii) a physician, dentist, veterinarian, or pharmacist, for licensing as a Narcotics Manager;
  - (ix) a person that needs to cultivate a Plant Containing a Narcotic Raw Material; manufacture Narcotics; or make use of Narcotics, Opium, or Opium Poppies for academic research purposes, for licensing as a Narcotics Researcher.
- (3) It is permissible not to grant licensing to a person falling under one of the following items:
- (i) a person whose licensing has been rescinded pursuant to Article 51, paragraph (1), if three years have not passed since the day of the rescission;
  - (ii) a person that has been sentenced to a fine or heavier punishment, if three years have not passed since the day on which the person completed the sentence or ceased to be subject to its enforcement;
  - (iii) a person not otherwise falling under one of the preceding two items, that has violated this Act, the Cannabis Control Act (Act No. 124 of 1948), the Opium Control Act, the Pharmacists Act (Act No. 146 of 1960), the Act on Pharmaceuticals and Medical Devices, the Medical Practitioners' Act (Act No. 201 of 1948), the Medical Care Act, any other laws and regulations relating to pharmaceutical or medical affairs, or an administrative disposition based on any of these laws and regulations, if two years have not passed since the day of the violation;
  - (iv) an adult ward;
  - (v) a person that Order of the Ministry of Health, Labour and Welfare prescribes as one that is incapable of appropriately engaging in the business operations of a Narcotics Handler due to a physical or mental disorder;
  - (vi) a Narcotics Addict or a stimulants addict;
  - (vii) a corporation or organization that has a person falling under one of the preceding items among the officers engaged in its business operations.

(Licenses)

Article 4 (1) When licensing a Narcotics Handler pursuant to the preceding Article, the Minister of Health, Labour and Welfare or prefectural governor

must issue that Narcotics Handler a license.

- (2) A license must give the name and address of the Narcotics Handler and the information that Order of the Ministry of Health, Labour and Welfare prescribes.
- (3) A license must not be transferred or loaned to any other person.

(Licensing Validity)

Article 5 A Narcotics Handler's licensing is valid from the licensing date to December 31 of the year two years after that in which the licensing date falls.

(Lapse of Licensing)

Article 6 A Narcotics Handler's licensing lapses at the end of its validity, if it is rescinded pursuant to Article 51, paragraph (1), or if:

- (i) the Narcotics Handler files a notification as referred to in paragraph (1) of the following Article;
- (ii) the Narcotics Handler comes to lack the qualifications referred to the items of Article 3, paragraph (2).

(Notification of Discontinuation of Business Operations)

Article 7 (1) A Narcotics Handler must file a notification within 15 days, accompanied by its license, if, while its license is valid, it discontinues business operations or research involving Narcotics at the Site of Operations Involving Narcotics for which it has been licensed; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must file this notification and accompanying license with the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, it must file this notification and accompanying license with the prefectural governor.

- (2) The provisions of the preceding paragraph apply mutatis mutandis if a Narcotics Handler comes to lack a qualification referred to in one of the items of Article 3, paragraph (2).
- (3) If a Narcotics Handler dies, the heir or a person administering the estate on behalf of the heir must file a notification of this within 15 days, accompanied by the handler's license; and if a Narcotics Handler that is a corporation is dissolved, its liquidator or bankruptcy trustee, or the representative of the corporation that survives or is incorporated in a merger, must do the same; if the Narcotics Handler that dies or is dissolved is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of



Narcotics, this notification and accompanying license must be filed with the Minister of Health, Labour and Welfare; and if the Narcotics Handler that dies or is dissolved is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, this notification and accompanying license must be filed with the prefectural governor.

(Return of Licenses)

Article 8 At the end of the validity of licensing or if licensing is rescinded pursuant to Article 51, paragraph (1), a Narcotics Handler must return the license within 15 days; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must return its license to the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, it must return its license to the prefectural governor.

(Notification That Information Specified on a License Has Changed)

Article 9 (1) If information that is specified on its license changes, a Narcotics Handler must file a notification of this within 15 days, accompanied by its license; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must file this notification and accompanying license with the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, it must file this notification and accompanying license with the prefectural governor.

(2) On receipt of a notification as referred to in the preceding paragraph, the Minister of Health, Labour and Welfare or the prefectural governor must promptly update the license and deliver it to the Narcotics Handler.

(Reissuance of Licenses)

Article 10 (1) If its license is damaged or lost, a Narcotics Handler must file an application for reissuance within 15 days, specifying the loss or damage as the reason and including the license, if the reason for reissuance is damage; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must file this with the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a

Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, it must file this with the prefectural governor.

- (2) If, after being reissued a license pursuant to the preceding paragraph, a Narcotics Handler finds the license it had lost, it must return this within 15 days; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must return the license to the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher, it must return the license to the prefectural governor.

Article 11 Deleted

## **Section 2 Prohibitions and Restrictions**

(Prohibited Conduct)

Article 12 (1) It is prohibited for any person to import, export, manufacture, formulate into a pharmaceutical preparation, package, transfer, accept, deliver, administer, be in possession of, or dispose of diacetylmorphine, diacetylmorphine salt, or a Narcotic containing one of these (hereinafter referred to as "Diacetylmorphine or a Similar Substance"); provided, however, that this does not apply if the operator of a Narcotics Research Facility transfers, accepts, or disposes of Diacetylmorphine or a Similar Substance with the permission of the Minister of Health, Labour and Welfare, or if a Narcotics Researcher manufactures, formulates into a pharmaceutical preparation, packages, administers, or is in possession of Diacetylmorphine or a Similar Substance for research purposes, with the permission of the Minister of Health, Labour and Welfare.

- (2) It is prohibited for any person to import or export powdered opium.
- (3) It is prohibited for any person to cultivate a Plant Containing a Narcotic Raw Material; provided, however, that this does not apply if a Narcotics Researcher cultivates a Plant Containing a Narcotic Raw Material for research purposes, with the permission of the Minister of Health, Labour and Welfare.
- (4) It is prohibited for any person to be administered Diacetylmorphine or a Similar Substance as prohibited pursuant to paragraph (1).

(Import)

Article 13 (1) It is prohibited for a person that is not a Narcotics Importer to import a Narcotic (other than Diacetylmorphine or a Similar Substance or the

Narcotic prescribed in paragraph (2) of the preceding Article; the same applies hereinafter in this Article through Article 19-2); provided, however, that this does not apply if persons entering Japan import a Narcotic by bringing it with them as treatment for an illness from which they suffer, with the permission of the Minister of Health, Labour and Welfare.

(2) To apply the proviso to Article 24, paragraph (1); the proviso to Article 27, paragraph (1); and the proviso to Article 28, paragraph (1); persons importing a Narcotic by carrying it on their person pursuant to the proviso to the preceding paragraph are deemed to have been delivered that Narcotic to administer by a Person Licensed to Administer Narcotics.

(Permission for Import)

Article 14 (1) On each occasion that a Narcotics Importer seeks to import Narcotics, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(2) A person seeking the permission referred to in the preceding paragraph must submit a written application for permission to the Minister of Health, Labour and Welfare, giving the following information:

(i) the product name and quantity of the Narcotics it seeks to import;

(ii) the name and address of the exporter;

(iii) the import period;

(iv) the means transportation;

(v) the name of the port of entry.

(3) If a person that has obtained the permission referred to in paragraph (1) seeks to change a piece of information referred to in one of the items of the preceding paragraph, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(4) It is permissible for the Minister of Health, Labour and Welfare not to grant the permission referred to in paragraph (1) or the preceding paragraph upon finding it to be inappropriate to do so, considering domestic demand and stockpiles of that Narcotic.

(5) When granting the permission referred to in paragraph (1), the Minister of Health, Labour and Welfare delivers an import permit and certificate of permission for import bearing the applicant's name and address, as well as the information set forth in paragraph (2).

(6) When granting the permission referred to in paragraph (3), the Minister of Health, Labour and Welfare delivers an updated import permit and certificate of permission for import.

(Submitting Certificates of Permission for Export)

Article 15 Having imported a Narcotic, a Narcotics Importer must submit the

certificate of permission for export issued by the country of export to the Minister of Health, Labour and Welfare, within 10 days after the date of import of the Narcotic or receipt of the certificate of permission for export.

(Returning Import Permits)

Article 16 If a Narcotics Importer does not import the Narcotic within the permitted import period, it must return the import permit to the Minister of Health, Labour and Welfare within 10 days after the end of that period.

(Export)

Article 17 It is prohibited for a person that is not a Narcotics Exporter to export a Narcotic; provided, however, that this does not apply if persons leaving Japan export a Narcotic by bringing it with them as treatment for an illness from which they suffer, with the permission of the Minister of Health, Labour and Welfare.

(Permission for Export)

Article 18 (1) On each occasion that a Narcotics Exporter seeks to export Narcotics, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(2) A person seeking the permission referred to in the preceding paragraph must submit a written application for permission to the Minister of Health, Labour and Welfare giving the following information, accompanied by a certificate of permission for import issued by the country of import:

(i) the product name and the quantity of Narcotics it seeks to export;

(ii) the name and address of the importer;

(iii) the export period;

(iv) the means of transportation;

(v) the name of the port of departure.

(3) If a person that has obtained the permission referred to in paragraph (1) seeks to change a piece of information referred to in one of the items of the preceding paragraph, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(4) When granting the permission referred to in paragraph (1), the Minister of Health, Labour and Welfare delivers an export permit and certificate of permission for export bearing the applicant's name and address, as well as the information set forth in the items of paragraph (2).

(5) When granting the permission referred to in paragraph (3), the Minister of Health, Labour and Welfare delivers an updated export permit and certificate of permission for export.

(6) When exporting a Narcotic, a Narcotics Exporter must send the certificate of

permission for export along with that Narcotic.

(Returning Export Permits and Certificates of Permission for Export)

Article 19 If a Narcotics Exporter does not export the Narcotic within the permitted export period, it must return the export permit and certificate of permission for export to the Minister of Health, Labour and Welfare within 10 days after the end of that period.

(Indications at the Time of Export)

Article 19-2 When exporting a Narcotic, a Narcotics Exporter must not give a false indication as regards the product name and quantity.

(Manufacturing)

Article 20 (1) It is prohibited for a person that is not a Narcotics Manufacturer to manufacture a Narcotic (other than Diacetylmorphine or a Similar Substance; the same applies hereinafter in this Section other than in Article 29-2); provided, however, that this does not apply if a Narcotics Researcher manufactures Narcotics for research purposes.

(2) It is prohibited for a person that is not a Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, or Manufacturer of Exempt Narcotics to manufacture an Exempt Narcotic; provided, however, that this does not apply if a Narcotics Researcher manufactures Narcotics for research purposes.

(Permission for Manufacture)

Article 21 (1) Before manufacturing a Narcotic or Exempt Narcotic, a Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, or Manufacturer of Exempt Narcotics must obtain the permission of the Minister of Health, Labour and Welfare for the product name and quantity of the Narcotics or Exempt Narcotics it seeks to manufacture, as well as for the product name and quantity of any Narcotics, Opium, or Opium Poppy it would use to manufacture them, for each of the periods from January through June and from July through December (hereinafter referred to as a "Semiannual Period").

(2) The provisions of Article 14, paragraph (4) apply mutatis mutandis to the permission referred to in the preceding paragraph.

(3) On finding it to be necessary to do so when granting the permission referred to in paragraph (1), the Minister of Health, Labour and Welfare may designate the capacity of containers into which the Narcotic being manufactured must be placed.

(Formulation of Pharmaceutical Preparations; Packaging)

Article 22 It is prohibited for a person that is not a Narcotics Manufacturer or a

Formulator of Narcotic Pharmaceuticals to formulate a pharmaceutical preparation of Narcotics or to package a Narcotic; provided, however, that this does not apply if a Narcotics Researcher formulates a pharmaceutical preparation of a Narcotic or packages it for research purposes.

(Permission to Formulate Pharmaceutical Preparations; Permission for Packaging)

- Article 23 (1) Before formulating a pharmaceutical preparation of Narcotics or packaging them, a Narcotics Manufacturer or Formulator of Narcotic Pharmaceuticals must obtain the permission of the Minister of Health, Labour and Welfare for the product name and quantity of the Narcotics it seeks to formulate pharmaceutical preparations of or package, as well as for the product name and quantity of Narcotics it would use to formulate pharmaceutical preparations of them, for each Semiannual Period.
- (2) The provisions of Article 14, paragraph (4) and Article 21, paragraph (3) apply mutatis mutandis to the permission referred to in the preceding paragraph.

(Transfer)

- Article 24 (1) It is prohibited for a person that is not a Commercial Narcotics Handler to transfer a Narcotic; provided, however, that this does not apply if:
- (i) the operator of a Medical Facility at Which Narcotics Are Administered transfers a Narcotic that is delivered to a person to administer;
  - (ii) a person that has been delivered a Narcotic to administer by a Person Licensed to Administer Narcotics or a person that has accepted a Narcotic dispensed by a Narcotics Retailer based on a Narcotics Prescription transfers the Narcotic to the operator of a Medical Facility at Which Narcotics Are Administered or to a Narcotics Retailer because the person no longer needs to administer the Narcotic;
  - (iii) a person that has been delivered a Narcotic to administer by a Person Licensed to Administer Narcotics or a person that has accepted a Narcotic dispensed by a Narcotics Retailer based on a Narcotics Prescription dies, and the heir or a person administering the estate on behalf of the heir transfers the Narcotic that is owned or administered thereby to the operator of a Medical Facility at Which Narcotics Are Administered or a Narcotics Retailer.
- (2) The proviso to the preceding paragraph does not apply if a Narcotic that is delivered to a person to administer is delivered in violation of Article 27, paragraph (1), (3), or (4), nor does it apply if a Narcotics Prescription is delivered in violation of paragraph (3) or (4) of that Article.
- (3) A Narcotics Importer must not transfer a Narcotic to a person other than a Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Primary

Wholesaler of Narcotics, or Narcotics Wholesaler; provided, however, that this does not apply to the transfer of codeine, dihydrocodeine, or the salts of either of these to a Manufacturer of Exempt Narcotics.

- (4) A Narcotics Exporter must not transfer Narcotics except when exporting them.
- (5) A Narcotics Manufacturer must not transfer a Narcotic to a person other than a Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Primary Wholesaler of Narcotics, or Narcotics Wholesaler; provided, however, that this does not apply to the transfer of codeine, dihydrocodeine, or the salts of either of these to a Manufacturer of Exempt Narcotics.
- (6) A Formulator of Narcotic Pharmaceuticals must not transfer a Narcotic to a person other than a Narcotics Exporter, Formulator of Narcotic Pharmaceuticals, Primary Wholesaler of Narcotics, or Narcotics Wholesaler.
- (7) A Manufacturer of Exempt Narcotics must not transfer Narcotics.
- (8) A Primary Wholesaler of Narcotics must not transfer a Narcotic to a person other than a Primary Wholesaler of Narcotics or Narcotics Wholesaler.
- (9) A Narcotics Wholesaler must not transfer a Narcotic to a person other than a Narcotics Wholesaler, Narcotics Retailer, operator of a Medical Facility at Which Narcotics Are Administered, or operator of a Narcotics Research Facility within the boundaries of the prefecture containing the locality of the Site of Operations Involving Narcotics for which it has been granted its license.
- (10) The provisions of the preceding paragraphs do not apply if Narcotics are transferred with the permission of the Minister of Health, Labour and Welfare.
- (11) A Narcotics Retailer must not transfer a Narcotic other than to a person in possession of a Narcotics Prescription (excluding one that has been delivered in violation of Article 27, paragraph (3) or (4)).
- (12) The provisions of the preceding paragraph do not apply if Narcotics are transferred with the permission of the person prescribed in one of the following items, in the category of case set forth in that item:
  - (i) if a Narcotics Retailer transfers a Narcotic to another Narcotics Retailer: prefectural governor;
  - (ii) in a case other than as set forth in the preceding item: the Minister of Health, Labour and Welfare.

(Transfer by Narcotics Retailers)

Article 25 When transferring a Narcotic to a person in possession of a Narcotics Prescription, a Narcotics Retailer must not transfer a Narcotic other than the one dispensed based on that prescription.

(Acquisition)

Article 26 (1) It is prohibited for a person that is not a Commercial Narcotics

Handler, owner of a Medical Facility at Which Narcotics Are Administered, or owner of a Narcotics Research Facility to accept a Narcotic; provided, however, that this does not apply if:

- (i) the operator of a Medical Facility at Which Narcotics Are Administered accepts a Narcotic delivered by a Person Licensed to Administer Narcotics;
  - (ii) a person that has been delivered a Narcotics Prescription accepts the Narcotic dispensed based on that prescription from a Narcotics Retailer.
- (2) The proviso to the preceding paragraph does not apply if the Narcotic delivered by the Person Licensed to Administer Narcotics is delivered in violation of paragraph (3) or (4) of the following Article or if the Narcotics Prescription is delivered in violation of those provisions.
- (3) A Commercial Narcotics Handler, operator of a Medical Facility at Which Narcotics Are Administered, or operator of a Narcotics Research Facility must not become the other party to a transfer of Narcotics that is prohibited pursuant to Article 24.

(Administering Narcotics; Giving Persons Narcotics to Administer; Narcotics Prescriptions)

- Article 27 (1) It is prohibited for a person that is not a Person Licensed to Administer Narcotics to administer a Narcotic, deliver a person a Narcotic to administer, or deliver a prescription for a Narcotic; provided, however, that this does not apply if:
- (i) a Narcotics Researcher administers a Narcotic for research purposes;
  - (ii) a person that has been delivered a Narcotic to administer by a Person Licensed to Administer Narcotics administers that Narcotic;
  - (iii) a person that has accepted a Narcotic dispensed based on a Narcotics Prescription from a Narcotics Retailer, administers that Narcotic.
- (2) The proviso to the preceding paragraph does not apply if either the Narcotic delivered by the Person Licensed to Administer Narcotics or the Narcotics Prescription is delivered or delivered in violation of paragraph (3) or (4).
- (3) A Person Licensed to Administer Narcotics must not administer a Narcotic, deliver a person a Narcotic to administer, or deliver a prescription for a Narcotic for any other purpose than as treatment for an illness; provided, however, that this does not apply if a mental health doctor dispenses N-allylnormorphine, its salts, a Narcotic that contains either of these, or a Narcotic that Cabinet Order prescribes, in order to conduct a medical examination under Article 58-6, paragraph (1).
- (4) Notwithstanding the preceding paragraph, a Person Licensed to Administer Narcotics must not administer a Narcotic, deliver a person a Narcotic to administer, or deliver a prescription for a Narcotic to alleviate the symptoms of addiction in a person addicted to Narcotics or Opium or to otherwise treat the



addiction; provided, however, that this does not apply if a Person Licensed to Administer Narcotics providing medical treatment at a hospital that Order of the Ministry of Health, Labour and Welfare prescribes under Article 58-8, paragraph (1) administers 6-dimethylamino-4,4-diphenyl-3-heptanone, its salts, a Narcotic that contains either of these, or a Narcotic that Cabinet Order prescribes to a person hospitalized in that hospital pursuant to that Article.

- (5) It is prohibited for any person to be administered a Narcotic as prohibited pursuant to paragraph (1), (3), or (4).
- (6) When issuing a prescription for a Narcotic, a Person Licensed to Administer Narcotics must write the name of the patient (or, if the patient is an animal, the type of animal and the name of its owner or handler) and the product name, quantity, usage, and dosage of the Narcotic, the name and license number of the Person Licensed to Administer Narcotics, and the information that Order of the Ministry of Health, Labour and Welfare prescribes, on a prescription sheet that bears either the name and seal or the signature of that person.

(Possession)

Article 28 (1) It is prohibited for any person that is not a Narcotics Handler, the owner of a Medical Facility at Which Narcotics Are Administered, or the owner of a Narcotics Research Facility to have possession of a Narcotic; provided, however, that this does not apply if:

- (i) a person that has been delivered a Narcotic to administer by a Person Licensed to Administer Narcotics or a person that has accepted a Narcotic dispensed by a Narcotics Retailer based on a Narcotics Prescription, has possession of that Narcotic;
- (ii) a person that has been delivered a Narcotic to administer by a Person Licensed to Administer Narcotics or a person that has accepted a Narcotic dispensed by a Narcotics Retailer based on a Narcotics Prescription dies, and the heir or a person administering the estate on behalf of the heir has possession of a Narcotic that is owned or administered thereby.
- (2) The proviso to the preceding paragraph does not apply if the Narcotic that is delivered or Narcotics Prescription that is delivered by the Person Licensed to Administer Narcotics is delivered in violation of paragraph (3) or (4) of the preceding Article.
- (3) A Manufacturer of Exempt Narcotics must not have possession of a Narcotic other than codeine, dihydrocodeine, or their salts.

(Disposal)

Article 29 A person seeking to dispose of a Narcotic must file a notification with the prefectural governor giving the product name and quantity of the Narcotic as well as the means of disposal, and must dispose of it in the presence of a

prefectural official; provided, however, that this does not apply if a Narcotics Retailer or the operator of a Medical Facility at Which Narcotics Are Administered disposes of a Narcotic that has been dispensed based on a Narcotics Prescription pursuant to Order of the Ministry of Health, Labour and Welfare.

(Advertising)

Article 29-2 It is prohibited for any person to advertise a Narcotic other than in a newspaper or journal for medical and pharmaceutical specialists or researchers (meaning medical and pharmaceutical specialists or persons engaged in research in the natural sciences; the same applies hereinafter in this Article) which prints articles about medicine, pharmaceuticals, or the natural sciences, or in a way that otherwise primarily targets medical and pharmaceutical specialists or researchers.

### **Section 3 Handling**

(Sealing Receptacles with Certification Stickers)

- Article 30 (1) When a Narcotics Importer, Narcotics Manufacturer, or Formulator of Narcotic Pharmaceuticals transfers Narcotics it has imported, manufactured, formulated into a pharmaceutical preparation, or packaged, it must seal the container into which it has placed the Narcotics or the container's immediate wrapper with a certification sticker issued by the government, pursuant to Order of the Ministry of Health, Labour and Welfare.
- (2) A Commercial Narcotics Handler (other than a Narcotics Retailer) must not transfer a Narcotic unless it remains sealed pursuant to the preceding paragraph.
- (3) It is prohibited for a Person Licensed to Administer Narcotics or Narcotics Retailer to deliver or transfer a Narcotic that remains sealed pursuant to paragraph (1).
- (4) The provisions of the preceding three paragraphs do not apply if a Narcotic is transferred with the permission under Article 24, paragraph (10) or (12).

(Labeling of Containers and Packaging)

- Article 31 A Commercial Narcotics Handler (other than a Narcotics Retailer) must not transfer a Narcotic other than one bearing the mark "((麻))" (an abbreviation of the word "narcotic", which is pronounced "ma") and the following information on its container and the packaging directly surrounding that container; provided, however, that this does not apply if it is transferring a Narcotic with the permission under Article 24, paragraph (10):
- (i) the date of import, manufacturing, formulation into a pharmaceutical

- preparation, or packaging;
- (ii) the product name of the ingredient Narcotic as well as its quantity or content;
- (iii) the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(Proof of Acquisition and Proof of Transfer)

Article 32 (1) When transferring a Narcotic, a Commercial Narcotics Handler (other than a Narcotics Retailer; the same applies in the following paragraph) must not deliver the Narcotic until after receiving from the acquirer a proof of acquisition that the acquirer has prepared pursuant to Order of the Ministry of Health, Labour and Welfare, or unless it delivers the Narcotic in exchange for the proof of acquisition; and when delivering a Narcotic, a Commercial Narcotics Handler must deliver the acquirer of the Narcotic a proof of transfer prepared pursuant to Order of the Ministry of Health, Labour and Welfare at the same time; provided, however, that this does not apply if it is transferring a Narcotic with the permission under Article 24, paragraph (10).

(2) With the consent of the acquirer and pursuant to Cabinet Order, in lieu of being delivered proof of acquisition under the preceding paragraph, a Commercial Narcotics Handler as referred to in that paragraph may be provided with the information that is required to be given in the proof of acquisition through one of the means of employing an electronic data processing system or otherwise making use of information communication technology which Order of the Ministry of Health, Labour and Welfare prescribes. In that case, a Commercial Narcotics Handler is deemed to have received proof of acquisition.

(3) The proof of acquisition or proof of transfer as referred to in paragraph (1), or, if the means prescribed in the first clause of the preceding paragraph are used, the electronic or magnetic record that is created using those means (meaning a record created in electronic form, magnetic form, or any other form that cannot be perceived by the human senses, which Order of the Ministry of Health, Labour and Welfare prescribes as being put to use in computerized data processing), must be kept on file with the recipient for two years, beginning on the date of its receipt.

(Management of Narcotics at Medical Facilities at Which Narcotics Are Administered and at Narcotics Research Facilities)

Article 33 (1) The operator of a Medical Facility at Which Narcotics Are Administered that has two or more Persons Licensed to Administer Narcotics providing medical treatment must have one Narcotics Manager; provided, however, that this does not apply if the operator is a Narcotics Manager.

- (2) A Narcotics Manager (or a Person Licensed to Administer Narcotics at a Medical Facility at Which Narcotics Are Administered without a Narcotics Manager; hereinafter the same applies in this Section and the following Section) must manage the Narcotics that are administered or delivered to persons to administer at the Medical Facility at Which Narcotics Are Administered; and a Narcotics Researcher must manage the Narcotics that the researcher personally uses for research at the Narcotics Research Facility.
- (3) A Person Licensed to Administer Narcotics must not administer a Narcotic or deliver a person a Narcotic to administer at a Medical Facility at Which Narcotics Are Administered if it is other than one of the Narcotics that the Narcotics Manager manages pursuant to the preceding paragraph.

(Custody)

Article 34 (1) Narcotics Handlers must act as custodians of the Narcotics that are under their ownership or under their management, within their Sites of Operations Involving Narcotics.

- (2) Custody as referred to in the preceding paragraph must be implemented through the segregation of Narcotics from non-narcotic pharmaceuticals (other than stimulant drugs) and through their storage under lock and key in an impregnable installation.

(Notification of Incidents and Disposal)

Article 35 (1) If a Narcotic under the ownership or management of a Narcotics Handler is destroyed or stolen, if it becomes unclear where the Narcotic is located, or if any other incident occurs involving the Narcotic, the Narcotics Handler must promptly file a notification giving the product name and quantity of the Narcotic and the necessary information to clarify the circumstances of the incident; if the Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must file this notification with the Minister of Health, Labour and Welfare; and if the Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher it must file this notification with the prefectural governor.

- (2) Having disposed of a Narcotic that has been dispensed based on a Narcotics Prescription pursuant to the proviso to Article 29, a Narcotics Retailer or the operator of a Medical Facility at Which Narcotics Are Administered must file a notification with the prefectural governor within 30 days, giving the product name and quantity of the Narcotic and the information that Order of the Ministry of Health, Labour and Welfare prescribes.
- (3) Having received a notification as referred to in paragraph (1), a prefectural

governor must promptly report this to the Minister of Health, Labour and Welfare.

(Measures for When Licensing Lapses)

Article 36 (1) If the licensing of a Commercial Narcotics Handler lapses, or if a Medical Facility at Which Narcotics Are Administered or Narcotics Research Facility comes to no longer be a Medical Facility at Which Narcotics Are Administered or Narcotics Research Facility (other than if a Commercial Narcotics Handler becomes a Commercial Narcotics Handler, in continuation, after the lapse of its licensing), the Commercial Narcotics Handler, the operator of the Medical Facility at Which Narcotics Are Administered, or the operator of the Narcotics Research Facility must file a notification of the product names and quantities of Narcotics currently under its ownership within 15 days; if the Commercial Narcotics Handler is a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, or Primary Wholesaler of Narcotics, it must file this with the Minister of Health, Labour and Welfare; and if the Commercial Narcotics Handler is a Narcotics Wholesaler, Narcotics Retailer, the operator of a Medical Facility at Which Narcotics Are Administered, or the operator of a Narcotics Research Facility, it must file this with the prefectural governor.

(2) Article 12, paragraph (1); Article 24, paragraph (1); and Article 26, paragraph (3) do not apply to the transfer or acquisition of Narcotics as referred to in the preceding paragraph, but only if the person that must file the notification pursuant to that paragraph transfers those Narcotics to a Commercial Narcotics Handler, the operator of a Medical Facility at Which Narcotics Are Administered or the operator of a Narcotics Research Facility (if the Narcotic referred to in that paragraph is Diacetylmorphine or a Similar Substance, this is limited to a transfer to the operator of a Narcotics Research Facility) within 50 days after the day that the reason to file the notification occurs (if the person is a Narcotics Wholesaler, Narcotics Retailer, the operator of a Medical Facility at Which Narcotics Are Administered, or the operator of a Narcotics Research Facility, this is limited to the person's transfer of those Narcotics to a Commercial Narcotics Handler, operator of a Medical Facility at Which Narcotics Are Administered, or operator of a Narcotics Research Facility that is located within the boundaries of the prefecture containing the locality of the Site of Operations Involving Narcotics for which the person's licensing has lapsed); and Article 12, paragraph (1) and Article 28, paragraph (1) do not apply to that person's possession of Narcotics as referred to in that paragraph, but only during that 50-day period.

(3) A person transferring Narcotics within the period referred to in the preceding

paragraph must file a notification with either the Minister of Health, Labour and Welfare or the prefectural governor, in accordance with the classification provided for in paragraph (1), giving the product name and quantity of the Narcotics, the date of the transfer, and the name and address of the acquirer, within 15 days after the date of the transfer.

(4) Paragraph (1) and the preceding paragraph apply mutatis mutandis to the heir or person administering the estate on behalf of the heir if a Commercial Narcotics Handler, the operator of a Medical Facility at Which Narcotics Are Administered, or the operator of a Narcotics Research Facility dies; and also apply to the liquidator or bankruptcy trustee, or the representative of the corporation that survives or is incorporated in a merger, if a Commercial Narcotics Handler, the operator of a Medical Facility at Which Narcotics Are Administered, or the operator of a Narcotics Research Facility is a corporation and is dissolved; and paragraph (2) applies mutatis mutandis to a transfer and acquisition if the heir, person administering the estate, liquidator, bankruptcy trustee, or representative transfers Narcotics, as well as to the relevant person's possession of Narcotics.

#### **Section 4 Business Records and Notifications**

(Books)

Article 37 (1) A Commercial Narcotics Handler (other than a Narcotics Retailer) must keep books at its Sites of Operations Involving Narcotics and enter the following information in them:

(i) the product names and quantities of the Narcotics imported, exported, manufactured, formulated into pharmaceutical preparations, packaged, transferred, and accepted; of the Narcotics used to manufacture Narcotics and Exempt Narcotics and to formulate pharmaceutical preparations of Narcotics; and of the Narcotics disposed of, as well as the dates of these actions;

(ii) the names and addresses of the other parties to its imports, exports, transfers, and acquisitions;

(iii) the product names and quantities of Narcotics about which it has filed notifications pursuant to Article 35, paragraph (1).

(2) A Commercial Narcotics Handler (other than a Narcotics Retailer) must keep the books referred to in the preceding paragraph on file for two years after the date of the last entry (if it is a Narcotics Manufacturer, this includes entries under Article 39, paragraph (1) of the Opium Control Act).

Article 38 (1) A Narcotics Retailer must keep books at its Sites of Operations Involving Narcotics and must enter the following information in them:

- (i) the product names and quantities of the Narcotics accepted, as well as the dates of their acquisition;
  - (ii) the product names and quantities of Narcotics transferred (other than codeine, dihydrocodeine, ethylmorphine, and their salts), as well as the dates of their transfer;
  - (iii) the product names and quantities of the Narcotics about which it has filed notifications pursuant to Article 35, paragraph (1);
  - (iv) the product names and quantities of the Narcotics it has disposed of, as well as the dates of their disposal.
- (2) A Narcotics Retailer must keep the books referred to in the preceding paragraph on file for two years after the date of the last entry.

Article 39 (1) A Narcotics Manager must keep books at the Medical Facility at Which Narcotics Are Administered and must enter the following information in them:

- (i) the product names and quantities of Narcotics accepted and disposed of by the operator of the Medical Facility at Which Narcotics Are Administered, as well as the dates of these actions;
  - (ii) the product names and quantities of Narcotics transferred by the operator of the Medical Facility at Which Narcotics Are Administered (other than codeine, dihydrocodeine, ethylmorphine, and their salts, when these are delivered to a person to administer), as well as the dates of their transfer;
  - (iii) the product names and quantities of Narcotics administered at the Medical Facility at Which Narcotics Are Administered (other than codeine, dihydrocodeine, ethylmorphine, and their salts), as well as the dates on which they are administered;
  - (iv) the product names and quantities of Narcotics about which it has filed notifications pursuant to Article 35, paragraph (1).
- (2) Having closed the books referred to in the preceding paragraph, a Narcotics Manager must promptly deliver them to the operator of the Medical Facility at Which Narcotics Are Administered.
- (3) Having been delivered books pursuant to the preceding paragraph, the operator of a Medical Facility at Which Narcotics Are Administered must keep them on file for two years after the last entry.

Article 40 (1) A Narcotics Researcher must keep books at the Narcotics Research Facility and enter the following information in them:

- (i) the product names and quantities of Narcotics newly coming under or leaving the management of the researcher, as well as the dates of these occurrences;
- (ii) the product names and quantities of Narcotics manufactured, formulated

into pharmaceutical preparations, and used for research purposes, as well as the dates of these actions:

- (iii) the product names and quantities of Narcotics about which the researcher has filed notifications pursuant to Article 35, paragraph (1).
- (2) Having closed the books referred to in the preceding paragraph, a Narcotics Researcher must promptly deliver them to the operator of the Narcotics Research Facility.
- (3) Having been delivered books pursuant to the preceding paragraph, the operator of a Narcotics Research Facility must keep them on file for two years after the last entry (this includes entries under Article 39, paragraph (2) of the Opium Control Act).

(Record of Narcotics Administered)

Article 41 Having administered a Narcotic or delivered a person a Narcotic to administer, a Person Licensed to Administer Narcotics must enter the name and address of the patient (or, if the patient is an animal, the type of animal and the name of its owner or handler), the name of the illness, its primary symptoms, the product name, and the quantity of Narcotics administered or delivered to a person to administer, as well as the date it was administered or delivered to that person, in a medical record as provided in Article 24 of the Medical Practitioners' Act or Article 23 of the Dental Practitioners' Act (Act No. 202 of 1948) or in a medical report as provided in Article 21 the Veterinarians Act (Act No. 186 of 1949).

(Notifications by Narcotics Importers)

Article 42 Within 15 days after the end of each Semiannual Period, a Narcotics Importer must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product names and quantities of Narcotics under its ownership at the beginning of the period, the amount of Narcotics in a single container (hereinafter referred to as the "Amount Per Container"), and the number of containers;
- (ii) the product names and quantities of the Narcotics it has imported during the period, the Amount Per Container, the number of containers, and the import dates;
- (iii) the product names and quantities of the Narcotics it has transferred during the period, the Amount Per Container, the number of containers, and the transfer dates;
- (iv) the product name and quantities of the Narcotics under its ownership at the end of the period, the Amount Per Container, and the number of containers.



(Notifications by Narcotics Exporters)

Article 43 Within 15 days after the end of each Semiannual Period, a Narcotics Exporter must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product names and quantities of the Narcotics under its ownership at the beginning of the period, the Amount Per Container, and the number of containers;
- (ii) the product names and quantities of the Narcotics it has exported during the period, the Amount Per Container, the number of containers, and the export dates;
- (iii) the product names and quantities of the Narcotics it has accepted during the period, the Amount Per Container, the number of containers, and the date of acquisition;
- (iv) the product names and quantities of the Narcotics under its ownership at the end of the period, the Amount Per Container, and the number of containers.

(Notifications by Narcotics Manufacturers, Formulators of Narcotic Pharmaceuticals, and Manufacturers of Exempt Narcotics)

Article 44 Within 15 days after the end of each Semiannual Period, a Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, or Manufacturer of Exempt Narcotics must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product names and quantities of the Narcotics under its ownership at the beginning of the period, the Amount Per Container, and the number of containers;
- (ii) the product names and quantities of the Narcotics it has used to manufacture or formulate pharmaceutical preparations of Narcotics or to manufacture Exempt Narcotics during the period;
- (iii) the product names and quantities of the Narcotics it has manufactured, formulated into pharmaceutical preparations, or packaged or of the Exempt Narcotics it has manufactured during the period; and the Amount Per Container and number of containers of the Narcotics it has manufactured, formulated into pharmaceutical preparations, or packaged during the period;
- (iv) the product names and quantities of the Narcotics it has transferred and accepted during the period, the Amount Per Container, the number of containers, and the dates of transfer and acquisition;
- (v) the product names and quantities of the Narcotics under its ownership at the end of the period, the Amount Per Container, and the number of containers;

(vi) the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(Notifications by Primary Wholesalers of Narcotics)

Article 45 Within 15 days after the end of each Semiannual Period, a Primary Wholesaler of Narcotics must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product names and quantities of the Narcotics under its ownership at the beginning of the period, the Amount Per Container, and the number of containers;
- (ii) the product names and quantities of the Narcotics it has transferred or accepted during the period, the Amount Per Container, and the number of containers;
- (iii) the product names and quantities of the Narcotics under its ownership at the end of the period, the Amount Per Container, and the number of containers.

(Notifications by Narcotics Wholesalers)

- Article 46 (1) Within 15 days after the end of each Semiannual Period, a Narcotics Wholesaler must file a notification with the prefectural governor giving the information set forth in the items of the preceding Article.
- (2) A prefectural governor must compile the notifications referred to in the preceding paragraph and file a report with the Minister of Health, Labour and Welfare within 50 days after the end of that period.

(Notifications by Narcotics Retailers)

- Article 47 A Narcotics Retailer must file a notification with the prefectural governor giving the following information no later than November 30 of each year:
- (i) the product names and quantities of the Narcotics under its ownership as of October 1 of the previous year;
  - (ii) the product names and quantities of the Narcotics it has transferred or accepted during the period from October 1 of the previous year to September 30 of the year in question;
  - (iii) the product names and quantities of the Narcotics under its ownership as of September 30 of the year in question.

(Notifications by Narcotics Managers)

Article 48 A Narcotics Manager must file a notification with the prefectural governor giving the following information no later than November 30 of each year:

- (i) the product names and quantities of the Narcotics under the ownership of the operator of the Medical Facility at Which Narcotics Are Administered as of October 1 of the previous year;
- (ii) the product names and quantities of the Narcotics that the operator of the Medical Facility at Which Narcotics Are Administered has accepted during the period from October 1 of the previous year to September 30 of the year in question, and the Narcotics administered or delivered to persons to administer at that facility during that period;
- (iii) the product names and quantities of the Narcotics under the ownership of the operator of the Medical Facility at Which Narcotics Are Administered as of September 30 of the year in question.

(Notifications by Narcotics Researchers)

Article 49 A Narcotics Researcher must file a notification with the prefectural governor giving the following information no later than November 30 of each year:

- (i) the product names and quantities of the Narcotics under the researcher's management as of October 1 of the previous year;
- (ii) the product names and quantities of the Narcotics newly coming under the researcher's management during the period from October 1 of the previous year to September 30 of the year in question and of the Narcotics that the researcher has manufactured, formulated into pharmaceutical preparations, or used for research purposes during that period;
- (iii) the product names and quantities of the Narcotics under the researcher's management as of September 30 of the year in question.

### **Chapter III Control of Psychotropics**

#### **Section 1 Licensing and Registration**

(Licensing)

Article 50 (1) For each Commercial Establishment at Which Psychotropics Are Handled, the Minister of Health, Labour and Welfare handles the licensing of Psychotropics Importers, Psychotropics Exporters, Psychotropics Manufacturers, Formulators of Psychotropic Pharmaceuticals, and Psychotropics Processors; and prefectural governors handle the licensing of Psychotropics Wholesalers and Psychotropics Retailers.

- (2) It is permissible not to grant licensing to a person if:
- (i) the structure or equipment of the facility where business would be conducted does not conform to the standards that Order of the Ministry of Health, Labour and Welfare prescribes;
  - (ii) the would-be licensee falls under one of the following items (a) through (g):

- (a) a person whose licensing has been rescinded pursuant to Article 51, paragraph (2), if three years have not passed since the day of the rescission;
- (b) a person that has been sentenced to imprisonment or a heavier punishment, if three years have not passed since the day on which the person completed the sentence or ceased to be subject to its enforcement;
- (c) a person not otherwise falling under item (a) or (b) that has violated this Act, the Cannabis Control Act, the Opium Control Act, the Pharmacists Act, the Act on Pharmaceuticals and Medical Devices, other laws and regulations on pharmaceuticals, or a disposition based on any of these, if two years have not passed since the date of the violation;
- (d) an adult ward;
- (e) a person that Order of the Ministry of Health, Labour and Welfare prescribes as one that is incapable of appropriately engaging in the business operations of a Commercial Psychotropics Handler due to a physical or mental disorder;
- (f) a Narcotics Addict or a stimulants addict;
- (g) a corporation or organization that has a person falling under one of items (a) through (f) among the officers engaged in its business operations.

(Licensing Validity)

Article 50-2 The licensing of a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor is valid for five years after the licensing date, and the licensing of a Psychotropics Wholesaler or Psychotropics Retailer is valid for six years after the licensing date.

(Lapse of Licensing)

Article 50-3 The licensing of a Commercial Psychotropics Handler lapses at the end of its validity, if it is rescinded pursuant to Article 51, paragraph (2), or if it files the notification referred to in Article 7, paragraph (1) as applied mutandis pursuant to the following Article.

(Mutatis Mutandis Application)

Article 50-4 The provisions of Article 4; Article 7, paragraphs (1) and (3); and Articles 8 through 10 apply mutatis mutandis to a Commercial Psychotropics Handler. In that case, the phrase "15 days" in Article 7, paragraph (1) and (3) and in Articles 8 through 10 is deemed to be replaced with "30 days", and Cabinet Order provides for any other necessary technical replacement of terms in these provisions.

(Registration)

- Article 50-5 (1) The Minister of Health, Labour and Welfare handles the registration of Operators of Facilities Conducting Experiments or Research Involving Psychotropics for each Facility Conducting Experiments or Research Involving Psychotropics that is operated by the national government; and the prefectural governor handles the registration of Operators of Facilities Conducting Experiments or Research Involving Psychotropics for each other Facility Conducting Experiments or Research Involving Psychotropics.
- (2) It is permissible for the Minister of Health, Labour and Welfare or the prefectural governor not to register a person whose registration has been rescinded pursuant to Article 51, paragraph (3), if three years have not passed since the date of the rescission.

(Lapse of Registration)

- Article 50-6 The registration of the Operator of a Facility Conducting Experiments or Research Involving Psychotropics lapses if rescinded pursuant to Article 51, paragraph (3), or if it files the notification referred to in Article 7, paragraph (1) as applied mutandis pursuant to the following Article.

(Mutatis Mutandis Application)

- Article 50-7 The provisions of Article 4; Article 7, paragraph (1) and (3); and Articles 8 through 10 apply mutatis mutandis to the Operator of a Facility Conducting Experiments or Research Involving Psychotropics. In that case, the phrase "15 days" in Article 7, paragraph (1) and (3) and in Articles 8 through 10 is deemed to be replaced with "30 days", and Cabinet Order provides for any other necessary technical replacement of the terms in these provisions.

## **Section 2 Prohibitions and Restrictions**

(Import)

- Article 50-8 It is prohibited for a person other than as follows to import a Psychotropic:
- (i) a Psychotropics Importer;
  - (ii) persons entering Japan who import a Psychotropic by bringing it with them as treatment for an illness from which they suffer, as provided by Order of the Ministry of Health, Labour and Welfare;
  - (iii) the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that imports a Psychotropic for academic research purposes or experimentation and testing;
  - (iv) a person that Order of the Ministry of Health, Labour and Welfare prescribes.

(Permission for Import)

Article 50-9 (1) On each occasion that a Psychotropics Importer seeks to import a Psychotropic that Cabinet Order prescribes (hereinafter referred to as a "Type I Psychotropic"), it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(2) On each occasion that a person set forth in item (iii) or (iv) of the preceding Article seeks to import a Psychotropic, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(3) The provisions of Article 14, paragraphs (2), (3), (5), and (6) and Articles 15 and 16 apply mutatis mutandis to a person seeking to import a Type I Psychotropic with the permission referred to in the preceding two paragraphs. In that case, in Article 14, paragraph (2), the phrase "the preceding paragraph" is deemed to be replaced with "Article 50-9, paragraph (1) or (2)" and the term "Narcotic" is deemed to be replaced with "Type I Psychotropic"; in Article 14, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (1) or (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of paragraph (2) of Article 14 as applied mutandis pursuant to Article 50-9, paragraph (3)"; in Article 14, paragraph (5), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (1) or (2)" and the phrase "paragraph (2)" is deemed to be replaced with "Article 14, paragraph (2) as applied mutandis pursuant to Article 50-9, paragraph (3)"; in Article 14, paragraph (6), the phrase "paragraph (3)" is deemed to be replaced with "Article 14, paragraph (3) as applied mutandis pursuant to Article 50-9, paragraph (3)"; and in Articles 15 and 16, the term "Narcotics Importer" is deemed to be replaced with "Psychotropics Importer or a person set forth in item (iii) or (iv) of Article 50-8" and the term "Narcotic" is deemed to be replaced with "Type I Psychotropic".

(4) The provisions of Article 14, paragraphs (2), (3), (5), and (6) and Articles 15 and 16 apply mutatis mutandis to a person seeking to import a Psychotropic that Cabinet Order prescribes, with the permission referred to in paragraph (2) (hereinafter referred to as a "Type II Psychotropic"). In that case, in Article 14, paragraph (2), the phrase "the preceding paragraph" is deemed to be replaced with "Article 50-9, paragraph (2)" and the term "Narcotic" is deemed to be replaced with "Type II Psychotropic"; in Article 14, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of paragraph (2) of Article 14 as applied mutandis pursuant to Article 50-9, paragraph (4)"; in Article 14, paragraph (5), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (2)", the phrase "paragraph (2)" is deemed to be replaced with "Article 14, paragraph (2)

as applied mutandis pursuant to Article 50-9, paragraph (4)", and the phrase "import permit and certificate of permission for import" is deemed to be replaced with "import permit"; in Article 14, paragraph (6), the phrase "paragraph (3)" is deemed to be replaced with "Article 14, paragraph (3) as applied mutandis pursuant to Article 50-9, paragraph (4)" and the phrase "import permit and certificate of permission for import" is deemed to be replaced with "import permit"; in Article 15, the term "Narcotics Importer" is deemed to be replaced with "person set forth in item (iii) or (iv) of Article 50-8", the term "Narcotic" is deemed to be replaced with "Type II Psychotropic", the phrase "certificate of permission for export issued by the country of export" is deemed to be replaced with "export notification prepared by the exporter (or a certificate of permission for export, if the country of export issues the certificate; the same applies hereinafter in this Article)", and the phrase "or received the certificate of permission for export" is deemed to be replaced with "or received the export notification"; and in Article 16, the term "Narcotics Importer" is deemed to be replaced with "person set forth in item (iii) or (iv) of Article 50-8" and the term "Narcotic" is deemed to be replaced with "Type II Psychotropic".

- (5) The provisions of Article 14, paragraphs (2), (3), (5), and (6) and Article 16 apply mutatis mutandis to a person seeking to import a Psychotropic other than a Type I Psychotropic or Type II Psychotropic, with the permission referred to in paragraph (2) (hereinafter referred to as a "Type III Psychotropic"). In that case, in Article 14, paragraph (2), the phrase "the preceding paragraph" is deemed to be replaced with "Article 50-9, paragraph (2)" and the term "Narcotic" is deemed to be replaced with "Type III Psychotropic"; in Article 14, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of paragraph (2) of Article 14 as applied mutandis pursuant to Article 50-9, paragraph (5)"; in Article 14, paragraph (5), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-9, paragraph (2)", the phrase "paragraph (2)" is deemed to be replaced with "Article 14, paragraph (2) as applied mutandis pursuant to Article 50-9, paragraph (5)", and the phrase "import permit and certificate of permission for import" is deemed to be replaced with "import permit"; in Article 14, paragraph (6), the phrase "paragraph (3)" is deemed to be replaced with "Article 14, paragraph (3) as applied mutandis pursuant to Article 50-9, paragraph (5)" and the phrase "import permit and certificate of permission for import" is deemed to be replaced with "import permit"; and in Article 16, the term "Narcotics Importer" is deemed to be replaced with "person set forth in item (iii) or (iv) of Article 50-8" and the term "Narcotic" is deemed to be replaced with "Type III

Psychotropic".

(Submitting Export Notifications)

Article 50-10 Having imported a Type II Psychotropic, a Psychotropics Importer must submit the export notification prepared by the exporter (or a certificate of permission for export, if the country of export issues the certificate; the same applies hereinafter in this Article) to the Minister of Health, Labour and Welfare, within 10 days after the date of the import of the Psychotropic or receipt of the export notification.

(Export)

Article 50-11 It is prohibited for a person other than as follows to export a Psychotropic:

- (i) a Psychotropics Exporter;
- (ii) persons departing from Japan who export a Psychotropic by bringing it with them as treatment for an illness from which they suffer, as provided by Order of the Ministry of Health, Labour and Welfare;
- (iii) the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that exports a Psychotropic to a person using Psychotropics for academic research purposes or experimentation and testing;
- (iv) a person that Order of the Ministry of Health, Labour and Welfare prescribes.

(Permission for Export)

Article 50-12 (1) On each occasion that a Psychotropics Exporter seeks to export a Type I Psychotropic, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(2) On each occasion that a person set forth in item (iii) or (iv) of the preceding Article seeks to export a Psychotropic, it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(3) The provisions of Article 18, paragraphs (2) through (6) and Article 19 apply mutatis mutandis to a person seeking to export Type I Psychotropics with the permission referred to in the preceding two paragraphs. In that case, in Article 18, paragraph (2), the phrase "preceding paragraph" is deemed to be replaced with "Article 50-12, paragraph (1) or (2)", the word "information" is deemed to be replaced with "information and the destination", and the term "Narcotic" is deemed to be replaced with "Type I Psychotropic"; in Article 18, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-12, paragraph (1) or (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (3)"; in Article 18, paragraph



(4), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-12, paragraph (1) or (2)" and the phrase "the items of paragraph (2)" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (3)"; in Article 18, paragraph (5), the phrase "paragraph (3)" is deemed to be replaced with "Article 18, paragraph (3) as applied mutandis pursuant to Article 50-12, paragraph (3)"; and in Article 14, paragraph (6) and Article 19, the term "Narcotics Exporter" is deemed to be replaced with "Psychotropics Exporter or a person set forth in item (iii) or (iv) of Article 50-11" and the term "Narcotic" is deemed to be replaced with "Type I Psychotropic".

(4) The provisions of Article 18, paragraphs (2) through (6) and Article 19 apply mutatis mutandis to persons seeking to export Type II Psychotropics with the permission referred to in paragraph (2). In that case, in Article 18, paragraph (2), the phrase "preceding paragraph" is deemed to be replaced with "Article 50-12, paragraph (2)" the word "information" is deemed to be replaced with "information and the destination", the phrase "accompanied by a certificate of permission for import issued by the country of import" is deemed to be deleted, and the term "Narcotic" is deemed to be replaced with "Type II Psychotropic"; in Article 18, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-12, paragraph (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (4)"; in Article 18, paragraph (4), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-12, paragraph (2)" and the phrase "the items of paragraph (2)" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (4)"; in Article 18, paragraph (5), the phrase "paragraph (3)" is deemed to be replaced with "Article 18, paragraph (3) as applied mutandis pursuant to Article 50-12, paragraph (4)"; and in Article 14, paragraph (6) and Article 19, the term "Narcotics Exporter" is deemed to be replaced with "a person set forth in item (iii) or (iv) of Article 50-11" and the term "Narcotic" is deemed to be replaced with "Type II Psychotropic".

(5) The provisions of Article 18, paragraphs (2) through (5) and Article 19 apply mutatis mutandis to a person seeking to export Type III Psychotropics with the permission referred to in paragraph (2). In that case, in Article 18, paragraph (2), the phrase "preceding paragraph" is deemed to be replaced with "Article 50-12, paragraph (2)" the word "information" is deemed to be replaced with "information and the destination", the phrase "accompanied by a certificate of permission for import issued by the country of import" is deemed to be deleted, and the term "Narcotic" is deemed to be replaced with "Type III Psychotropic"; in Article 18, paragraph (3), the phrase "paragraph (1)" is deemed to be

replaced with "Article 50-12, paragraph (2)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (5)"; in Article 18, paragraph (4), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-12, paragraph (2)" the phrase "the items of paragraph (2)" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-12, paragraph (5)" and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit"; in Article 18, paragraph (5), the phrase "paragraph (3)" is deemed to be replaced with "Article 18, paragraph (3) as applied mutandis pursuant to Article 50-12, paragraph (5)" and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit"; and in Article 19, the term "Narcotics Exporter" is deemed to be replaced with "a person set forth in item (iii) or (iv) of Article 50-11", the term "Narcotic" is deemed to be replaced with "Type III Psychotropic", and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit".

(Special Considerations for Exports to Specified Regions)

Article 50-13 (1) On each occasion that a Psychotropics Exporter seeks to export a Psychotropic that Cabinet Order prescribes (hereinafter referred to as a "specified psychotropic" in this Article and the following Article) and that constitutes a Type II Psychotropic (referred to as a "specified type II psychotropic" in the following paragraph) or to export a specified psychotropic that constitutes a Type III Psychotropic (referred to as "specified type III psychotropic" in paragraph (3)), to a destination in a region that Cabinet Order prescribes (hereinafter referred to as a "specified region" in this Article and the following Article), it must obtain the permission of the Minister of Health, Labour and Welfare to do so.

(2) The provisions of Article 18, paragraphs (2) through (6) and Article 19 apply mutatis mutandis to a person seeking to export a specified type II psychotropic to a destination in a specified region, with the permission referred to in the preceding paragraph. In that case, in Article 18, paragraph (2), the phrase "preceding paragraph" is deemed to be replaced with "Article 50-13, paragraph (1)" the word "information" is deemed to be replaced with "information and the destination", the phrase "accompanied by a certificate of permission for import issued by the country of import" is deemed to be deleted, and the term "Narcotic" is deemed to be replaced with "specified type II psychotropic"; in Article 18, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-13, paragraph (1)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of Article 18, paragraph

- (2) as applied mutandis pursuant to Article 50-13, paragraph (2)"; in Article 18, paragraph (4), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-13, paragraph (1)" and the phrase "the items of paragraph (2)" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-13, paragraph (2)"; in Article 18, paragraph (5), the phrase "paragraph (3)" is deemed to be replaced with "Article 18, paragraph (3) as applied mutandis pursuant to Article 50-13, paragraph (2)"; and in Article 14, paragraph (6) and Article 19, the term "Narcotics Exporter" is deemed to be replaced with "Psychotropics Exporter" and the term "Narcotic" is deemed to be replaced with "specific type II psychotropic".
- (3) The provisions of Article 18, paragraphs (2) through (5) and Article 19 apply mutatis mutandis to a person seeking to export a specified type III psychotropic to a destination in a specified region, with permission under paragraph (1). In that case, in Article 18, paragraph (2), the phrase "the preceding paragraph" is deemed to be replaced with "Article 50-13, paragraph (1)", the word "information" is deemed to be replaced with "information and the destination", the phrase "accompanied by a certificate of permission for import issued by the country of import" is deemed to be deleted, and the term "Narcotic" is deemed to be replaced with "specified type III psychotropic"; in Article 18, paragraph (3), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-13, paragraph (1)" and the phrase "the items of the preceding paragraph" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-13, paragraph (3)"; in Article 18, paragraph (4), the phrase "paragraph (1)" is deemed to be replaced with "Article 50-13, paragraph (1)", the phrase "the items of paragraph (2)" is deemed to be replaced with "the items of Article 18, paragraph (2) as applied mutandis pursuant to Article 50-13, paragraph (3)", and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit"; in Article 18, paragraph (5), the phrase "paragraph (3)" is deemed to be replaced with "Article 18, paragraph (3) as applied mutandis pursuant to Article 50-13, paragraph (3)" and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit"; and in Article 19, the term "Narcotics Exporter" is deemed to be replaced with "Psychotropics Exporter", the term "Narcotic" is deemed to be replaced with "specific type III psychotropic", and the phrase "export permit and certificate of permission for export" is deemed to be replaced with "export permit".
- (4) It is permissible for the Minister of Health, Labour and Welfare not to grant the intended permission referred to paragraph (1) or Article 50-12, paragraph (1) or (2) for the export of a specified psychotropic to a destination in a specified region, if the minister does not receive a special import permit

prepared by the country of import.

- (5) Having granted the permission referred to in paragraph (1) or Article 50-12, paragraph (1) or (2) for the export of a specified psychotropic to a destination in a specified region, in addition to issuing the documents provided for in Article 18, paragraph (4) as applied mutandis pursuant to paragraph (2) or (3) of this Article or pursuant to Article 50-12, paragraphs (3) through (5), the Minister of Health, Labour and Welfare delivers the special import permit prepared by the country of import.
- (6) When exporting a specified psychotropic to a destination in a specified region, in addition to sending the documents provided for in Article 18, paragraph (6) as applied mutandis pursuant to paragraph (2) of this Article or to Article 50-12, paragraph (3) or (4), a Psychotropics Exporter or a person set forth in Article 50-11, item (iii) or (iv) must send the special import permit prepared by the country of import along with that psychotropic.
- (7) If a person as provided in the preceding paragraph does not export the specified psychotropic within the permitted period referred to in paragraph (1) or Article 50-12, paragraph (1) or (2) for exporting the specified psychotropic to a destination in a specified region, in addition to returning the documents provided in Article 19 as applied mutandis pursuant to paragraph (2) or (3) of this Article or paragraphs (3) through (5) of Article 50-12, it must return the special import permit prepared by the country of import to the Minister of Health, Labour and Welfare within 10 days after the end of that period.

#### (Notification of Export)

Article 50-14 (1) Before exporting a Type II Psychotropic (other than a specified psychotropic for export to a specified region), a Psychotropics Exporter must submit an export notification to the Minister of Health, Labour and Welfare giving the product name of the Type II Psychotropic it seeks to export and the information that Order of the Ministry of Health, Labour and Welfare prescribes (simply referred to as an "export notification" in the following paragraph).

- (2) When exporting a Type II Psychotropic (other than a specified psychotropic exported to a destination in a specified region), a Psychotropics Exporter must send an export notification along with the psychotropic.

#### (Manufacturing)

Article 50-15 (1) It is prohibited for a person that is not a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals to manufacture, formulate a pharmaceutical preparation of, or package a Psychotropic; provided, however, that this does not apply:

- (i) if a person engaged in academic research or experimentation and testing at

a Facility Conducting Experiments or Research Involving Psychotropics (but only a facility whose operator has been registered as referred to in Article 50-5, paragraph (1); the same applies in the following paragraph) manufactures, formulates pharmaceutical preparations of, or packages Psychotropics for academic research purposes or experimentation and testing;

(ii) in a case that Order of the Ministry of Health, Labour and Welfare prescribes.

(2) It is prohibited for a person that is not a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals or Psychotropics Processor to turn a Psychotropic into a substance other than a Psychotropic by subjecting it to a chemical transformation; provided, however, that this does not apply if a person engaged in academic research or experimentation and testing at a Facility Conducting Experiments or Research Involving Psychotropics implements that process for the purpose of academic research or experimentation and testing.

(Transfer)

Article 50-16 (1) It is prohibited for a person that is not a Commercial Psychotropics Handler (except a Psychotropics Processor) to transfer a Psychotropic or to have a Psychotropic in its possession with the objective of transferring it; provided, however, that this does not apply:

(i) if the operator of a Hospital or Similar Facility transfers, or has in its possession so that it can transfer, a Psychotropic that will be delivered to a person to administer;

(ii) if the Operator of a Facility Conducting Experiments or Research Involving Psychotropics transfers, or has in its possession so that it can transfer, a Psychotropic to another Operator of a Facility Conducting Experiments or Research Involving Psychotropics;

(iii) in a case that Order of the Ministry of Health, Labour and Welfare prescribes.

(2) It is prohibited for a Psychotropics Importer, a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or a Psychotropics Wholesaler to transfer a Psychotropic to a person other than a Commercial Psychotropics Handler (except a Psychotropics Importer), the operator of a Hospital or Similar Facility, or the Operator of a Facility Conducting Experiments or Research Involving Psychotropics; provided, however, that this does not apply if a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals or a Psychotropics Wholesaler is returning a Psychotropic accepted from a Psychotropics Importer, nor does it apply in a case provided for by Order of the Ministry of Health, Labour and Welfare.

(3) A Psychotropics Exporter must not transfer Psychotropics except when

exporting them; provided, however, that this does not apply if it is returning a Psychotropic it has accepted from a Commercial Psychotropics Handler, nor does it apply in a case provided for by Order of the Ministry of Health, Labour and Welfare.

- (4) A Psychotropics Retailer must not transfer a Psychotropic other than to a person in possession of a Psychotropics Prescription; provided, however, that this does not apply if it is returning a Psychotropic accepted from a Commercial Psychotropics Handler, nor does it apply in a case provided for by Order of the Ministry of Health, Labour and Welfare.

(Transfer by Psychotropics Retailers)

Article 50-17 When transferring a Psychotropic to a person in possession of a Psychotropics Prescription, a Psychotropics Retailer must not transfer a Psychotropic other than the one dispensed based on that prescription.

(Mutatis Mutandis Application)

Article 50-18 Article 19-2 applies mutatis mutandis to a Psychotropics Exporter, and Article 29-2 applies mutatis mutandis to advertisements for Psychotropics. In that case, the term "Narcotic" in Article 19-2 is deemed to be replaced with "Psychotropic".

### **Section 3 Handling**

(Labeling of Containers and Packaging)

Article 50-19 A Commercial Psychotropics Handler (other than a Psychotropics Retailer) must not transfer a Psychotropic other than one bearing the mark "((向))" (an abbreviation of the word "psychotropic", which is pronounced "kou") and the following information on its container and the packaging directly surrounding that container (hereinafter referred to as the "packaging label" in this Article); provided, however, that this does not apply if the surface area of the container is too small to clearly display the packaging label or in a case provided for by Order of the Ministry of Health, Labour and Welfare, if the handler transfers a Psychotropic bearing a simplified packaging label on its container or the packaging directly surrounding that container pursuant to Order of the Ministry of Health, Labour and Welfare:

- (i) the product name of the ingredient Psychotropic, as well as its quantity or content;
- (ii) the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(Person In Charge of Psychotropics Handling)

- Article 50-20 (1) A Commercial Psychotropics Handler must engage a person in charge of psychotropics handling for each Commercial Establishment at Which Psychotropics Are Handled; provided, however, that this does not apply to a Commercial Establishment at Which Psychotropics Are Handled where the Commercial Psychotropics Handler personally manages the handling of Psychotropics as the person in charge of psychotropics handling.
- (2) A person in charge of psychotropics handling must supervise persons engaged in operations involving the Psychotropics under the management thereof at the relevant Commercial Establishment at Which Psychotropics Are Handled, so as to prevent violations of this Act and violations of dispositions of the Minister of Health, Labour and Welfare or the prefectural governor based on this Act.
- (3) A person that is not a pharmacist or a person that Cabinet Order prescribes as having the necessary knowledge and experience to handle Psychotropics may not be appointed as a person in charge of psychotropics handling.
- (4) Having engaged a person to be in charge of psychotropics handling or having personally become the person in charge of psychotropics handling, a Commercial Psychotropics Handler must file a notification giving the name of the person in charge of psychotropics handling or indicating that it has personally become the person in charge of psychotropics handling, and giving the information that Order of the Ministry of Health, Labour and Welfare prescribes within 30 days; if the Commercial Psychotropics Handler is a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor, it must file this notification with the Minister of Health, Labour and Welfare; and if the Commercial Psychotropics Handler is a Psychotropics Wholesaler or Psychotropics Retailer, it must file this information with the prefectural governor.

(Custody)

Article 50-21 Psychotropics Handlers must act as custodians of the Psychotropics that are under their ownership or dispose of them, or take other necessary measures to prevent Psychotropic abuse, pursuant to Order of the Ministry of Health, Labour and Welfare.

(Notification of Incidents)

Article 50-22 (1) If a Psychotropic under the ownership of a Psychotropics Handler is destroyed or stolen, if it becomes unclear where the Psychotropic is located, or if any other incident occurs involving the Psychotropic, the Psychotropics Handler, pursuant to Order of the Ministry of Health, Labour and Welfare, must promptly file a notification giving the product name and quantity of the Psychotropic and the necessary information to clarify the

circumstances of the incident; if the Psychotropics Handler is a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor, or if it is the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that the Minister of Health, Labour and Welfare has registered, it must file this with the Minister of Health, Labour and Welfare; and if the Psychotropics Handler is a Psychotropics Wholesaler, Psychotropics Retailer, or operator of a Hospital or Similar Facility, or if it is the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that the prefectural governor has registered, it must file this with the prefectural governor.

- (2) Having received a notification as referred to in the preceding paragraph, a prefectural governor must promptly report this to the Minister of Health, Labour and Welfare.

#### **Section 4 Business Records and Notifications**

(Records)

Article 50-23 (1) A Commercial Psychotropics Handler (other than a Psychotropics Retailer) must keep records of the following information:

- (i) the product names and quantities of the Psychotropics imported, exported, manufactured, formulated into pharmaceutical preparations, and packaged; of the Psychotropics used to manufacture and formulate pharmaceutical preparations of Psychotropics; and of the Psychotropics used as a raw material in substances resulting from the chemical transformation of a psychotropic (meaning substances other than a Psychotropic into which a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals or a Psychotropics Processor turns a Psychotropic by subjecting it to a chemical transformation; the same applies in the following item and the following Article), as well as the dates of these actions;
- (ii) the product names, quantities, and intended purposes of substances resulting from the chemical transformation of psychotropics;
- (iii) the product names and quantities of Psychotropics (other than Type III Psychotropics; the same applies in the following item) transferred, accepted, or disposed of, as well as the dates of these actions;
- (iv) the names and addresses of the other parties to its imports, exports, transfers, and acquisitions of Psychotropics.

(2) A Psychotropics Retailer or the operator of a Hospital or Similar Facility must keep records of the following information:

- (i) the product names and quantities of the Psychotropics (other than Type III Psychotropics, Psychotropics transferred to a person in possession of a



- Psychotropics Prescription, or any other Psychotropics provided for by Order of the Ministry of Health, Labour and Welfare; the same applies in the following items) transferred, accepted, or disposed of, as well as the dates of these actions;
- (ii) the names and addresses of the other parties to its transfers and acquisitions of Psychotropics.
- (3) The Operator of a Facility Conducting Experiments or Research Involving Psychotropics must keep records of the following information:
- (i) the product names and quantities of the Psychotropics imported, exported, and manufactured, as well as the dates of these actions;
  - (ii) the product names and quantities of the Psychotropics (other than Type III Psychotropics; the same applies in the following item) transferred, accepted, or disposed of, as well as the dates of these actions;
  - (iii) the names and addresses of the other parties to its imports, exports, transfers, and acquisitions of Psychotropics.
- (4) A Psychotropics Handler must keep the records under the preceding three paragraphs on file at its Commercial Establishment at Which Psychotropics Are Handled, Hospital or Similar Facility, or Facility Conducting Experiments or Research Involving Psychotropics for two years after the date that the record is made.

(Notifications)

- Article 50-24 (1) A Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor must file a notification with the Minister of Health, Labour and Welfare giving the following information no later than the last day of February of each year:
- (i) the product names and quantities of Psychotropics imported, exported, manufactured, formulated into pharmaceutical preparations, or packaged; of the Psychotropics used to manufacture or formulate pharmaceutical preparations of Psychotropics; and of the Psychotropics used as a raw material in substances resulting from the chemical transformation of a psychotropic, in the previous year;
  - (ii) the product names and quantities of Type I Psychotropics under its ownership at the beginning of the previous year, and the product names and quantities of Type I Psychotropics under its ownership at the end of the previous year;
  - (iii) the information that Order of the Ministry of Health, Labour and Welfare prescribes.
- (2) The Operator of a Facility Conducting Experiments or Research Involving Psychotropics must file a notification no later than the last day of February of

each year giving the following information; it must file this with the Minister of Health, Labour and Welfare if it is the Operator of a Facility Conducting Experiments or Research Involving Psychotropics registered thereby; or with the prefectural governor if it is the Operator of a Facility Conducting Experiments or Research Involving Psychotropics registered thereby:

- (i) the product names and quantities of the Psychotropics imported, exported, and manufactured in the previous year;
- (ii) the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(3) A prefectural governor must compile the notifications referred to in the preceding paragraph and file a report with the Minister of Health, Labour and Welfare no later than April 30 of that year.

### **Section 5 Miscellaneous Provisions**

(Exclusions from Application of This Act)

Article 50-25 It is permissible to employ Cabinet Order to establish a partial exclusion from the application of this Act and prescribe the necessary special measures for a Psychotropic set forth in item (xii) of Appended Table III which poses no risk of abuse and is prescribed by Order of the Ministry of Health, Labour and Welfare as having no harmful effects.

(Special Considerations for Operators of Pharmacies)

Article 50-26 (1) In applying this Act (other than Article 50-4 and Article 50-20, paragraph (4)), a person that has obtained permission (or a renewal of permission) to operate a pharmacy pursuant to the Act on Pharmaceuticals and Medical Devices (hereinafter referred to as the "operator of a pharmacy" in this Article) is deemed to have been licensed as a Psychotropics Wholesaler and Psychotropics Retailer pursuant to Article 50, paragraph (1); and a person that has obtained permission for pharmaceutical wholesales (other than that involving pharmaceuticals provided in Article 83, paragraph (1) of the Act on Pharmaceuticals and Medical Devices; the same applies in this Article) is deemed to have been licensed as a Psychotropics Wholesaler pursuant to Article 50, paragraph (1); provided, however, that this does not apply if the operator of a pharmacy or person that has obtained permission for pharmaceutical wholesales has filed a request to be treated otherwise with the prefectural governor pursuant to Order of the Ministry of Health, Labour and Welfare.

(2) In addition to lapsing pursuant to Article 50-3, the licensing of a person that is deemed to have been licensed as a Psychotropics Wholesaler or Psychotropics Retailer pursuant to the preceding paragraph lapses if:

- (i) permission as referred to in Article 4, paragraph (1) or Article 34, paragraph (1) of the Act on Pharmaceuticals and Medical Devices lapses pursuant to Article 4, paragraph (4) or Article 24, paragraph (2) of that Act;
  - (ii) a notification under Article 10, paragraph (1) of the Act on Pharmaceuticals and Medical Devices (including as applied mutatis mutandis pursuant to Article 38, paragraph (2) of that Act) is filed (but only if the notification is about the discontinuation of business operations);
  - (iii) the permission referred to in Article 4, paragraph (1) or Article 34, paragraph (1) of the Act on Pharmaceuticals and Medical Devices is rescinded pursuant to Article 75, paragraph (1) of that Act.
- (3) In a case as referred to in the main clause of paragraph (1), the pharmacy administrator, as prescribed in Article 7, paragraph (3) of the Act on Pharmaceuticals and Medical Devices, that is affiliated with the pharmacy of the relevant operator; or the administrator of the business establishment, as prescribed in Article 35, paragraph (2) of that Act, that is affiliated with the person that has obtained permission for pharmaceutical wholesales, is deemed to be the person in charge of psychotropics handling referred to in Article 50-20, paragraph (1).
- (4) The prefectural governor issues a public notice upon having received a request as referred to in the proviso to paragraph (1), or if the licensing of a person that is deemed to have been licensed as a Psychotropics Wholesaler or Psychotropics Retailer pursuant to that paragraph is rescinded pursuant to Article 51, paragraph (2) (but only if the business operations of the pharmacy or pharmaceutical wholesales continue).

### **Chapter III-2 Notifications Concerning Narcotic and Psychotropic Raw Materials**

(Business Notifications)

Article 50-27 A person seeking to become an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials must first file a notification giving its name and address, as well as the information that Order of the Ministry of Health, Labour and Welfare prescribes, for each Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled (but only for each Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled where the person will conduct business, if the person seeks to become a Manufacturer of Specified Narcotic or Psychotropic Raw Materials or Retailer of Specified Narcotic or Psychotropic Raw Materials; the same applies in Article 50-28, paragraph (1) and Article 50-

34, paragraph (2)); a person seeking to become an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, or Manufacturer of Specified Narcotic or Psychotropic Raw Materials must file these notifications with the Minister of Health, Labour and Welfare; and a person seeking to become a Retailer of Specified Narcotic or Psychotropic Raw Materials must file these notifications with the prefectural governor. The same applies if an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials seeks to change a piece of information about which it has already filed a notification.

(Notification of Discontinuation of Business Operations)

Article 50-28 (1) Having discontinued business operations involving Narcotic or Psychotropic Raw Materials (or involving Specified Narcotic and Psychotropic Raw Materials, in the case of a Manufacturer of Specified Narcotic or Psychotropic Raw Materials or a Retailer of Specified Narcotic or Psychotropic Raw Materials; the same applies in Article 50-34, paragraph (1)) at a Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled that is subject to a notification under the preceding Article, an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials must file a notification of this within 30 days; if it is an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, or Manufacturer of Specified Narcotic or Psychotropic Raw Materials, it must file this with the Minister of Health, Labour and Welfare; and if it is a Retailer of Specified Narcotic or Psychotropic Raw Materials, it must file this with the prefectural governor.

(2) If an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials dies, the heir or the person administering the estate on behalf of the heir must file a notification of this within 30 days; and if an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials that is a corporation is dissolved, its liquidator or bankruptcy trustee, or the representative of a corporation that survives or is incorporated in a merger, must do the same; if the person that dies or is dissolved is an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic

Raw Materials, or Manufacturer of Specified Narcotic or Psychotropic Raw Materials, this notification must be filed with the Minister of Health, Labour and Welfare; and if the person that dies or is dissolved is a Retailer of Specified Narcotic or Psychotropic Raw Materials, this notification must be filed with the prefectural governor.

(Notification of Imports by Importers of Narcotic and Psychotropic Raw Materials)

Article 50-29 On each occasion that an Importer of Narcotic or Psychotropic Raw Materials seeks to import a Narcotic or Psychotropic Raw Material that Cabinet Order prescribes, it must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product name and quantity of the Narcotic or Psychotropic Raw Material that Cabinet Order prescribes which it seeks to import;
- (ii) the name and address of the exporter;
- (iii) the import period.

(Notification of Exports by Exporters of Narcotic and Psychotropic Raw Materials)

Article 50-30 (1) On each occasion that an Exporter of Narcotic or Psychotropic Raw Materials seeks to export a Narcotic or Psychotropic Raw Material that Cabinet Order prescribes, it must file a notification with the Minister of Health, Labour and Welfare giving the following information:

- (i) the product name and quantity of the Narcotic or Psychotropic Raw Material that Cabinet Order prescribes which it seeks to export;
- (ii) the name and address of the importer;
- (iii) the export period;
- (iv) the destination.

(2) On each occasion that an Exporter of Narcotic or Psychotropic Raw Materials seeks to export a Narcotic or Psychotropic Raw Material that Cabinet Order prescribes to a destination in a region that Cabinet Order prescribes, it must file a notification with the Minister of Health, Labour and Welfare, giving the following information:

- (i) the product name and quantity of the Narcotic or Psychotropic Raw Material that Cabinet Order prescribes which it seeks to export;
- (ii) the name and address of the importer;
- (iii) the export period;
- (iv) the destination.

(Notification of Imports by Persons Other Than Importers of Narcotic and Psychotropic Raw Materials)

Article 50-31 On each occasion that a person other than an Importer of Narcotic or Psychotropic Raw Materials seeks to import a Narcotic or Psychotropic Raw Material, it must file a notification with the Minister of Health, Labour and Welfare giving the following information; provided, however, that this does not apply if the quantity of the Narcotic or Psychotropic Raw Material is equal to or lower than the quantity that Order of the Ministry of Health, Labour and Welfare prescribes:

- (i) the product name and quantity of the Narcotic or Psychotropic Raw Material that Cabinet Order prescribes which it seeks to import;
- (ii) the name and address of the exporter;
- (iii) the import period.

(Notification of Exports by Persons Other Than Exporter of Narcotic or Psychotropic Raw Materials)

Article 50-32 On each occasion that a person other than an Exporter of Narcotic or Psychotropic Raw Materials seeks to export a Narcotic or Psychotropic Raw Material, it must file a notification with the Minister of Health, Labour and Welfare giving the following information; provided, however, that this does not apply if the quantity of the Narcotic or Psychotropic Raw Material is equal to or lower than the quantity that Order of the Ministry of Health, Labour and Welfare prescribes:

- (i) the product name and quantity of the Narcotic or Psychotropic Raw Material that Cabinet Order prescribes which it seeks to export;
- (ii) the name and address of the importer;
- (iii) the export period;
- (iv) the destination.

(Notification of Incidents)

Article 50-33 (1) If a Narcotic or Psychotropic Raw Material under the ownership of a Commercial Handler of Narcotic or Psychotropic Raw Materials is stolen, if it becomes unclear where the material is located, or if any other incident occurs involving the material, the Commercial Handler of Narcotic or Psychotropic Raw Materials, pursuant to Order of the Ministry of Health, Labour and Welfare, must promptly file a notification giving the product name and quantity of the Narcotic or Psychotropic Raw Material and the necessary information to clarify the circumstances of the incident; if the Commercial Handler of Narcotic or Psychotropic Raw Materials is an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, or Manufacturer of Narcotic or Psychotropic Raw Materials, it must file this with the Minister of Health, Labour and Welfare; and if the Commercial Handler of Narcotic or Psychotropic Raw Materials is a Retailer of

Narcotic or Psychotropic Raw Materials, it must file this with the prefectural governor.

- (2) If a Commercial Handler of Narcotic or Psychotropic Raw Materials' import, export, manufacture, packaging, or transfer of a Narcotic or Psychotropic Raw Material is found to fall under circumstances that Order of the Ministry of Health, Labour and Welfare prescribes as raising the suspicion of an involvement in the manufacture of a Narcotic or Psychotropic that is prohibited pursuant to Article 12, paragraph (1); Article 20, paragraph (1); or Article 50-15, paragraph (1), the handler must promptly file a notification of this, giving the information that Order of the Ministry of Health, Labour and Welfare prescribes; if it is an Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, or Manufacturer of Narcotic or Psychotropic Raw Materials, it must file this with the Minister of Health, Labour and Welfare; and if it is a Retailer of Narcotic or Psychotropic Raw Materials, it must file this with the prefectural governor.
- (3) Having received a notification as referred to in one of the preceding two paragraphs, the prefectural governor must promptly report this to the Minister of Health, Labour and Welfare.

(Records)

- Article 50-34 (1) An Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials must keep records of the following information:
- (i) the product names and quantities of the Narcotic and Psychotropic Raw Materials imported, exported, manufactured, packaged, transferred, and accepted, as well as the dates of these actions;
  - (ii) the names and addresses of the other parties to its imports, exports, transfers, and acquisitions of Narcotic and Psychotropic Raw Materials.
- (2) An Importer of Narcotic or Psychotropic Raw Materials, Exporter of Narcotic or Psychotropic Raw Materials, Manufacturer of Specified Narcotic or Psychotropic Raw Materials, or Retailer of Specified Narcotic or Psychotropic Raw Materials must keep the records referred to in the preceding paragraph on file at the Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled for two years after the date that the record is made.

(Mutatis Mutandis Application)

- Article 50-35 The provisions of Article 19-2 apply mutatis mutandis to an Exporter of Narcotic or Psychotropic Raw Materials. In that case, the term "Narcotic" in that Article is deemed to be replaced with "Narcotic or Psychotropic Raw Material".

(Exclusions from Application of This Act)

Article 50-36 It is permissible to employ Cabinet Order to establish an exclusion from the application of this Act and prescribe the necessary special measures for a Narcotic or Psychotropic Raw Material that Order of the Ministry of Health, Labour and Welfare prescribes as being extremely difficult to use to manufacture Narcotics and Psychotropics, considering things such as its composition and its properties.

(Notifying the Relevant Ministers)

Article 50-37 On finding that it is necessary to do so, the Minister of Health, Labour and Welfare is to notify the relevant ministers of the information received in a notification pursuant to Article 50-27 and Article 50-28 so as to seek their assistance.

#### **Chapter IV Supervision**

(Collection of Reports)

Article 50-38 (1) On finding it to be necessary to do so as a part of the control of Narcotics or Psychotropics, the Minister of Health, Labour and Welfare or the prefectural governor may collect the necessary reports from a Narcotics Handler, Psychotropics Handler, or other related person; may have a ministry narcotics agent, prefectural narcotics agent, or other official enter the premises of a Site of Operations Involving Narcotics, Commercial Establishment at Which Psychotropics Are Handled, Hospital or Similar Facility, Facility Conducting Experiments or Research Involving Psychotropics, or other place connected with Narcotics or Psychotropics to inspect books and other articles; to ask questions of the relevant persons; or to take samples of Narcotics, Exempt Narcotics, Psychotropics, or anything suspected of being these, in the smallest quantities necessary for testing.

(2) The Minister of Health, Labour and Welfare or the prefectural governor may ask a Commercial Handler of Narcotic or Psychotropic Raw Materials or any other related person to file the necessary reports, and may have a ministry narcotics agent, prefectural narcotics agent, or other official inspect the books and other articles at a Commercial Establishment at Which Narcotic or Psychotropic Raw Materials Are Handled or other place connected with Narcotic or Psychotropic Raw Materials, as long as it is necessary to do so in order to investigate the actual circumstances of the import, export, manufacture, packaging, transfer, or acquisition of a Narcotic or Psychotropic Raw Material.

(3) Officials as referred to in the preceding two paragraphs must carry



identification cards with them and present these at the request of the relevant persons.

(4) The authority prescribed in paragraph (1) or (2) must not be construed as having been granted for the purpose of a criminal investigation.

(Order for Measures)

Article 50-39 If the Minister of Health, Labour and Welfare finds a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor, or the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that the minister has registered to have violated Article 50-21; or if the prefectural governor finds a Psychotropics Wholesaler, Psychotropics Retailer, or operator of a Hospital or Similar Facility, or the Operator of a Facility Conducting Experiments or Research Involving Psychotropics that the governor has registered to have violated those provisions, the minister or prefectural governor may order that person to change its method of storing or disposing of Psychotropics or to take any other necessary measures within a fixed timeframe.

(Improvement Order)

Article 50-40 Having found that the structure or facilities of a Commercial Establishment at Which Psychotropics Are Handled by a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor no longer comply with the standards prescribed by Order of the Ministry of Health, Labour and Welfare which are referred to in Article 50, paragraph (2), item (i), the Minister of Health, Labour and Welfare may order the structure or facilities to be improved or prohibit the use of all or part of the Commercial Establishment at Which Psychotropics Are Handled until the completion of improvements; having found the same with regard to the structure or facilities of a Commercial Establishment at Which Psychotropics Are Handled by a Psychotropics Wholesaler or Psychotropics Retailer, the prefectural governor may also order the improvements or prohibit the use.

(Order to Change the Person in Charge of Psychotropics Handling)

Article 50-41 If a person in charge of psychotropics handling at a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Formulator of Psychotropic Pharmaceuticals violates this Act, other laws and regulations on pharmaceuticals, or a disposition based on any of these, or is found to be inappropriate as the person in charge of psychotropics handling, the Minister

of Health, Labour and Welfare may order the Commercial Psychotropics Handler to change the person in charge of psychotropics handling; and if a person in charge of psychotropics handling at a Psychotropics Wholesaler or Psychotropics Retailer commits a relevant violation or is found to be inappropriate as the person in charge of psychotropics handling, the prefectural governor may order the Commercial Psychotropics Handler to change the person in charge of psychotropics handling.

(Rescission of Licensing)

- Article 51 (1) If a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, or Manufacturer of Exempt Narcotics violates this Act, a disposition of the Minister of Health, Labour and Welfare based on this Act, or a condition attached to its licensing or permission, if it or comes to fall under Article 3, paragraph (3), item (ii) through (vii), the Minister of Health, Labour and Welfare may revoke its licensing or may order the suspension of its business operations during a fixed timeframe; and if a Narcotics Wholesaler, Narcotics Retailer, Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher violates this Act, a disposition of the prefectural governor based on this Act, or a condition attached to its licensing or permission, or if it comes to fall under Article 3, paragraph (3), item (ii) through (vii), the prefectural governor may revoke its licensing or may order the suspension of its business operations or research during a fixed timeframe.
- (2) If a Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor violates this Act, a disposition of the Minister of Health, Labour and Welfare based on this Act, or a condition attached to its licensing or permission, or if it comes to fall under Article 50, paragraph (2), item (ii), clause (b) through (g), the Minister of Health, Labour and Welfare may revoke its licensing or may order the suspension of its business operations during a fixed timeframe; and if a Psychotropics Wholesaler or Psychotropics Retailer violates this Act, a disposition of the prefectural governor based on this Act, or a condition attached to its licensing or permission, or if it comes to fall under Article 50, paragraph (2), item (ii), clause (b) through (g), the prefectural governor may revoke its licensing or may order the suspension of its business operations during a fixed timeframe.
- (3) If the Operator of a Facility Conducting Experiments or Research Involving Psychotropics registered by the Minister of Health, Labour and Welfare violates this Act or a disposition of the minister based on this Act, the minister may rescind its registration; and if the Operator of a Facility Conducting Experiments or Research Involving Psychotropics registered by the prefectural

governor violates this Act or a disposition of the governor based on this Act, the prefectural governor may rescind its registration.

(Special Considerations for the Way Hearings Are Conducted)

- Article 52 (1) Notice as referred to in Article 15, paragraph (1) or Article 30 of the Administrative Procedure Act (Act No. 88 of 1993) in connection with a disposition under the preceding two Articles must be given no later than one week before the hearing date or the deadline for submitting a written explanation (or no later than one week before the date for oral explanations, if the person in question is granted the opportunity to give an oral explanation).
- (2) Having issued an order to replace a person in charge of psychotropics handling under Article 50-41, having rescinded licensing under paragraph (1) or (2) of the preceding Article, or having notified the relevant person as referred to in Article 15, paragraph (1) of the Administrative Procedure Act in connection with the rescission of a registration under paragraph (3) of that Article (the action is referred to as an "order for replacement or a recession" in the following paragraph), the Minister of Health, Labour and Welfare or the prefectural governor must issue public notice of the date and place of the hearing.
- (3) The proceedings on the hearing date in connection with an order for replacement or a recession must be open to the public.

Article 53 (Deleted)

(Ministry Narcotics Agents and Prefectural Narcotics Agents)

- Article 54 (1) Ministry narcotics agents are assigned to the Ministry of Health, Labour and Welfare, and are appointed by the Minister of Health, Labour and Welfare from among the officials of the Ministry of Health, Labour and Welfare.
- (2) A prefectural governor appoints prefectural narcotics agents from among the officials of the prefectural government, in consultation with the Chief Prosecutor of the District Public Prosecutors Office for the District Court which has jurisdiction in the locality of the agent's principal place of operations.
- (3) Cabinet Order provides for a fixed number of ministry narcotics agents.
- (4) Cabinet Order provides for the necessary particulars regarding the qualifications of ministry narcotics agents.
- (5) Ministry narcotics agents perform their duties under the direction and supervision of the Minister of Health, Labour and Welfare, and prefectural narcotics agents perform their duties under the direction and supervision of the prefectural governor, as judicial police officers under the Code of Criminal Procedure (Act No. 131 of 1948) in connection with criminal violations of this Act, the Cannabis Control Act, the Opium Control Act, the Stimulants Control

Act (Act No. 252 of 1951), and the Act on Special Measures under the Narcotics and Psychotropics Control Act for Preventing Activities in Furtherance of Illicit Conduct Involving Controlled Substances through International Cooperation (Article No. 94 of 1991); criminal violations of the Act on Pharmaceuticals and Medical Devices (limited to the crimes under Article 83-9, Article 84, item (xxv) (but only the part with which Article 76-7, paragraphs (1) and (2) of the Act on Pharmaceuticals and Medical Devices are concerned) and item (xxvi); Article 85, items (vi), (ix), and (x); Article 86, paragraph (1), items (xxiii) and (xxiv); Article 87, item (xiii) (but only the part with which Article 76-8, paragraph (1) of the Act on Pharmaceuticals and Medical Devices is concerned) and item (xv) (hereinafter referred to as "Article 83-9 and related provisions" in this paragraph), and Article 90 (but only the part with which Article 83-9 and related provisions are concerned)); crimes prescribed in Part II, Chapter XIV of the Penal Code (Act No. 45 of 1907); and crimes that a person commits while addicted to Narcotics, Opium, or stimulants.

- (6) Judicial police officers as under the preceding paragraph and other judicial police officers must cooperate with each other in performing their duties.
- (7) Ministry narcotics agents and prefectural narcotics agents may carry a small weapon with them when performing their duties as judicial police officers.
- (8) Article 7 of the Police Duties Execution Act (Act No. 136 of 1948) applies *mutatis mutandis* to the use of a weapon as referred to in the preceding paragraph by ministry narcotics agents and prefectural narcotics agents.

(Places Where Ministry Narcotics Agents Perform Their Duties)

Article 55 (1) Ministry narcotics agents belong to the Regional Bureaus of Health and Welfare established pursuant to other laws and regulations, and perform their duties within the jurisdictional districts of those Regional Bureaus of Health and Welfare.

- (2) Ministry narcotics agents may perform their duties even outside the jurisdictional districts of the Regional Bureaus of Health and Welfare to which they belong if it is necessary for an investigation.

(Cooperation between Ministry Narcotics Agents and Prefectural Narcotics Agents)

Article 56 (1) On finding it to be particularly necessary for the investigation of a specific case, the Minister of Health, Labour and Welfare may ask the prefectural governor to have prefectural narcotics agents cooperate with ministry narcotics agents. In that case, the prefectural narcotics agents in question are subject to the direction and supervision of the Minister of Health, Labour and Welfare, within the scope necessary for the investigation.

- (2) On finding it to be particularly necessary for the investigation of a specific

case, the prefectural governor may file an application with the Minister of Health, Labour and Welfare for the cooperation of ministry narcotics agents belonging to the Regional Bureau of Health and Welfare with jurisdiction in the relevant prefectural area. In that case, the Minister of Health, Labour and Welfare is to have ministry narcotics agents cooperate, on finding this to be appropriate.

(Prefectural Narcotics Agents and Prefectural Boundaries)

Article 57 Beyond as provided for in the preceding Article, prefectural narcotics agents may perform their duties even outside the boundaries of their prefectures if permitted by the Minister of Health, Labour and Welfare, as necessary for an investigation.

(Acquisition of Narcotics by Ministry Narcotics Agents and Prefectural Narcotics Agents)

Article 58 Notwithstanding what is prescribed in this Act, with the permission of the Minister of Health, Labour and Welfare, a ministry narcotics agent or prefectural narcotics agent may accept a Narcotic from any person in order to investigate a crime involving Narcotics.

## **Chapter V Measures for Narcotics Addicts**

(Notifications by Physicians)

Article 58-2 (1) On diagnosing a person that has undergone a medical examination to be a Narcotics Addict as a result of that medical examination, a physician must promptly file a notification with the governor of the prefecture where the person examined resides (or with the governor of the prefecture where the person is located at the time, if the person has no place of residence or if the person's place of residence is unknown; hereinafter the same applies in this Chapter) giving the person's name, address, age, and sex, and the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(2) Having received a notification as referred to in the preceding paragraph, the prefectural governor must promptly report to the Minister of Health, Labour and Welfare.

(Reporting by Ministry Narcotics Agents)

Article 58-3 On encountering a Narcotics Addict or a person suspected of being a Narcotics Addict, a ministry narcotics agent, prefectural narcotics agent, police officer, or officer of the coast guard must promptly report the person's name, address, age, and sex, as well as the reason for determining or suspecting the

person to be a Narcotics Addict, to the governor of the prefecture where the person resides.

(Reporting by Public Prosecutors)

Article 58-4 On deciding not to prosecute a Narcotics Addict or a person suspected of being a Narcotics Addict, or once a judicial decision (other than a judicial decision sentencing the accused to imprisonment with or without work, a judicial decision not stipulating a full suspension of the execution of the sentence, or a judicial decision sentencing the accused to penal detention) with regard to a Narcotics Addict or a person suspected of being a Narcotics Addict becomes final and binding, the public prosecutor must promptly report the person's name, address, age, and sex, as well as the reason for determining or suspecting the person to be a Narcotics Addict, to the governor of the prefecture where the person resides.

(Reporting by Heads of Correctional Institutions)

Article 58-5 Before releasing a Narcotics Addict or an inmate suspected of being a Narcotics Addict, the head of a correctional institution (meaning a penal institution, juvenile training school, juvenile detention home, or women's guidance home) must first report the inmate's name, place of residence after release, age, sex, and date of release; the name and address of the person taking the inmate in; and the reason for determining or suspecting the inmate to be a Narcotics Addict, to the prefectural governor of the place where the inmate will reside after release (or to the prefectural governor for the locality of the correctional institution, if the inmate has no place to reside after release or if it is unclear where the inmate will reside after release).

(Medical Examination of Narcotics Addicts)

Article 58-6 (1) On finding it to be necessary, a prefectural governor may have a designated mental health doctor conduct a medical examination on a Narcotics Addict or a person suspected of being a Narcotics Addict.

(2) In a case as referred to in the preceding paragraph, the mental health doctor must evaluate, based on the methods and criteria that Cabinet Order prescribes, the presence or absence of a Narcotics Addiction and whether the person being examined needs to be hospitalized as under Article 58-8, and on finding that the person needs to be hospitalized as under that Article, the doctor must fix a period not to exceed thirty days as a period during which the Narcotics Addict will be hospitalized until a decision is reached on the period during which the Narcotics Addict will be hospitalized as under paragraph (6) of that Article.

(3) If it is necessary to do so in order for the mental health doctor to conduct a

medical examination pursuant to paragraph (1), the doctor may ask the person that will be examined to come to the place where the doctor seeks to conduct the examination or may ask the person being examined to remain at the place where the examination is being conducted as long as is necessary.

- (4) When having a medical examination conducted pursuant to paragraph (1), the prefectural governor must have a prefectural official present at the examination.
- (5) A mental health doctor and the relevant prefectural official may enter the residence of a person being examined, as long as it is necessary for them to do so in order to perform the duties referred to in paragraph (1) and the preceding paragraph.
- (6) The provisions of Article 50-38, paragraphs (3) and (4) apply mutatis mutandis to the entry referred to in the preceding paragraph.
- (7) When conducting a medical examination under paragraph (1), a mental health doctor must be careful not to damage the reputation of the person being examined, and must afford the person an opportunity to present an opinion as to the matters prescribed in paragraph (2).
- (8) If a person that undergoes a medical examination under paragraph (1) is diagnosed as a Narcotics Addict as a result of the examination, the prefectural governor must promptly report to the Minister of Health, Labour and Welfare.

#### (Duties of Mental Health Doctors)

Article 58-7 In addition to performing the duties prescribed in Article 19-4 of the Act on Mental Health and the Welfare of Persons with Mental Disorders and Intellectual Disabilities (Act No. 123 of 1950), mental health doctors perform the duties prescribed in the preceding Article that the prefectural governor designates, in the capacity of government employees.

#### (Hospitalization)

Article 58-8 (1) Having found, as the result of a medical examination by a mental health doctor under Article 58-6, paragraph (1), that the person that has been examined is a Narcotics Addict and that there is a significant risk, in light of the person's symptoms, character and conduct, as well as environment, that, because of the Narcotics Addiction, the person will continue to self-administer Narcotics, cannabis, or Opium if not hospitalized, the prefectural governor may have the person hospitalized in a hospital that Order of the Ministry of Health, Labour and Welfare prescribes (hereinafter referred to as "Medical Facility for Treating Narcotics Addicts") so as to provide the person with the necessary medical treatment.

- (2) On finding that a person hospitalized in a Medical Facility for Treating Narcotics Addicts pursuant to the preceding paragraph (hereinafter referred to

as an "Inpatient") needs to remain hospitalized in excess of the period designated by the mental health doctor pursuant to Article 58-6, paragraph (2), the administrator of that facility must inform the prefectural governor of the reason for this and of the period of hospitalization that the administrator finds to be necessary.

- (3) On being notified as under the preceding paragraph and finding that the Inpatient needs to remain hospitalized, the prefectural governor must notify the narcotics addiction review board of the reason for this and of the period of hospitalization that is found to be necessary, and ask for a review as to whether continued hospitalization is appropriate.
- (4) On being asked to conduct a review pursuant to the preceding paragraph, the narcotics addiction review board must promptly review whether the matter at issue is appropriate and notify the prefectural governor of the results of its review. In that case, if the narcotics addiction review board finds it to be appropriate to discharge the Inpatient from the facility before the end of the period fixed by the mental health doctor pursuant to Article 58-6, paragraph (2), it must notify the prefectural governor of the date on which the Inpatient should be discharged.
- (5) In conducting a review as referred to in the preceding paragraph, the narcotics addiction review board must seek opinions from the Inpatient and from physicians in charge of the Inpatient's treatment at the Medical Facility for Treating Narcotics Addicts.
- (6) Acting in accordance with the narcotics addiction review board's decision, of which the prefectural governor has been notified pursuant to paragraph (4), the governor must have the Inpatient discharged or fix a period of hospitalization for the Inpatient and notify the administrator of the Medical Facility for Treating Narcotics Addicts and the Inpatient of that period.
- (7) If there is no notice as referred to in the preceding paragraph regarding an Inpatient within the period designated by the mental health doctor pursuant to Article 58-6, paragraph (2), the administrator of the Medical Facility for Treating Narcotics Addicts must discharge the Inpatient from the facility.
- (8) The period of hospitalization under paragraph (6) must not continue beyond three months after the date that the Inpatient is first hospitalized.

(Extension of Periods of Hospitalization)

- Article 58-9 (1) The period of hospitalization under paragraph (6) of the preceding Article may be extended by up to two months at a time, for up to six months after the date that the Inpatient is first hospitalized.
- (2) The provisions of paragraphs (2) to (7) of the preceding Article apply mutatis mutandis to the extension of the period of hospitalization as referred to in the preceding paragraph.



(Restriction of Activities)

Article 58-10 The administrator of a Medical Facility for Treating Narcotics Addicts may impose the necessary restrictions on an Inpatient's activities, as long as this is essential for the Inpatient's medical treatment.

(Custody of Personal Belongings)

Article 58-11 If an Inpatient has an object among the personal belongings thereof that would interfere with medical treatment, the prefectural governor may have a prefectural official act as custodian of the object while the Inpatient is hospitalized.

(Discharge)

Article 58-12 (1) On finding that an Inpatient no longer needs to be hospitalized, the prefectural governor must promptly have the Inpatient discharged from the facility. Before doing so, the prefectural governor is to first seek the opinion of the administrator of the Medical Facility for Treating Narcotics Addicts.

(2) On finding that continued hospitalization is no longer necessary in light of the Inpatient's symptoms and other factors, the administrator of a Medical Facility for Treating Narcotics Addicts must promptly notify the prefectural governor.

(Narcotics Addiction Review Boards)

Article 58-13 (1) A narcotics addiction review board is established for each prefecture, for the purpose of conducting reviews as under Article 58-8, paragraph (4) (including as applied mutatis mutandis pursuant to Article 58-9, paragraph (2)).

(2) Notwithstanding the preceding paragraph, a prefecture may provide, by prefectural ordinance, that a narcotics addiction review board is to be established in the event that the prefectural governor finds continued hospitalization to be necessary for an Inpatient pursuant to Article 58-8, paragraph (3). In that case, the narcotics addiction review board is disbanded upon the Inpatient's discharge from the facility.

(3) Members of a narcotics addiction review board are appointed by the prefectural governor from among persons with academic knowledge or experience in the field of law or in the medical treatment of Narcotics Addicts.

(4) Beyond what is provided in the preceding three paragraphs, Cabinet Order provides for the necessary particulars of narcotics addiction review boards.

(Treatment Policies for When Addicts Are Hospitalized; Expenses That Medical Care Requires)

Article 58-14 (1) The treatment policies for the medical care that a Medical Facility for Treating Narcotics Addicts provides to Inpatients and the way of calculating the expenses that the medical care requires are governed by the treatment policies under health insurance and the way of calculating required medical expenses under health insurance.

(2) If the treatment policies and way of calculating the expenses that medical care requires which are prescribed in the preceding paragraph cannot be applied, or if it is considered inappropriate to apply them, the treatment policies and way of calculating the expenses that medical care requires are as provided by the Minister of Health, Labour and Welfare.

(Entrustment of the Social Insurance Medical Fee Payment Fund with Administrative Processes)

Article 58-15 A prefecture may entrust the Social Insurance Medical Fee Payment Fund with reviewing whether the medical care that a Medical Facility for Treating Narcotics Addicts has provided to an Inpatient complies with the treatment policies prescribed in the preceding Article; with calculating the expenses that the medical care requires; and with the administrative processes involved in paying medical fees to the operator of a Medical Facility for Treating Narcotics Addicts.

(Reporting)

Article 58-16 (1) On finding that it is necessary to do so in order to investigate whether the medical fees requested by a Medical Facility for Treating Narcotics Addicts are appropriate, the Minister of Health, Labour and Welfare or the prefectural governor may ask the administrator of the facility to make the needed reports, and may have the relevant officials inspect medical records and other books and documents (or electronic or magnetic records (meaning a record used in computerized data processing which is created in electronic form, magnetic form, or any other form that cannot be perceived with the human senses), if these are prepared or kept on file in lieu of paper documents) with the consent of the administrator.

(2) If, without a legitimate reason for doing so, the administrator of a Medical Facility for Treating Narcotics Addicts fails to comply with the request to make a report as referred to in the preceding paragraph, makes a false report, or refuses to give the consent referred to in that paragraph, the Minister of Health, Labour and Welfare or the prefectural governor may cause a temporary suspension of the prefecture's payment of medical fees to the Medical Facility for Treating Narcotics Addicts, or may stop paying those fees.

(Expenses Borne by Prefectures)

Article 58-17 (1) The expenses needed for hospitalizing Narcotics Addicts that the prefectural governor causes to be hospitalized pursuant to Article 58-8, paragraph (1) are borne by the prefecture.

(2) Article 30-2 of the Act on Mental Health and the Welfare of Persons with Mental Disorders and Intellectual Disabilities applies mutatis mutandis to the prefecture's bearing of expenses under the preceding paragraph.

(Officers for Narcotics Addicts to Consult)

Article 58-18 (1) A prefecture may appoint an officer for Narcotics Addicts and persons abusing Psychotropics to consult.

(2) An officer as referred to in the preceding paragraph is available for consultations by current and former Narcotics Addicts and persons currently or formerly abusing Psychotropics, gives them the necessary guidance, and provides them with associated services.

(3) The officer under paragraph (1) works on a part-time basis, and is appointed by a prefectural governor from among persons with favorable reputations and the necessary enthusiasm and knowledge to perform the duties prescribed in the preceding paragraph.

(Confidentiality)

Article 58-19 It is prohibited for a mental health doctor, the worker of a Medical Facility for Treating Narcotics Addicts, the member of a narcotics addiction review board, or an officer as referred to in paragraph (1) of the preceding Article to divulge any confidential information about a person learned in the course of duty based on this Act. The same applies even after these persons leave those jobs.

## **Chapter VI Miscellaneous Provisions**

(Payment of Expenses by Prefectures)

Article 59 The following expenses are borne by the prefecture:

(i) the expenses needed for prefectural narcotics agents that are appointed pursuant to Article 54, paragraph (2), and the expenses directly needed for them to perform their duties outside the area of the prefecture pursuant to Article 56, paragraph (1);

(ii) the expenses needed for having a mental health doctor carry out a medical examination pursuant to Article 58-6, paragraph (1);

(iii) the expenses that the prefecture bears pursuant to Article 58-17, paragraph (1);

(iv) the expenses needed for the narcotics addiction review board that is established pursuant to Article 58-13, paragraph (1) or (2);

(v) the expenses needed for an officer appointed pursuant to Article 58-18, paragraph (1).

(Expenses Borne by the National Government)

Article 59-2 The national government bears three-quarters of the expenses that the prefecture pays pursuant to item (iii) of the preceding Article, pursuant to Cabinet Order.

(State Subsidies)

Article 59-3 The national government may provide a subsidy of up to half of the expenses needed to operate a Medical Facility for Treating Narcotics Addicts operated by a prefecture, municipality, or not-for-profit corporation, pursuant to Cabinet Order and within the limit of the budget.

(Measures to Collect Expenses)

Article 59-4 A prefectural governor may take measures to collect all or part of the expenses referred to in Article 59, item (iii) from the Inpatient, from the spouse of the Inpatient, or from a person with a duty to support the Inpatient as provided in Article 877, paragraph (1) of the Civil Code (Act No. 89 of 1896), commensurate with the relevant person's ability to pay.

(Fees)

Article 59-5 The following persons must pay the amount of fees that Cabinet Order prescribes in consideration of actual costs:

- (i) an applicant for licensing as a Narcotics Importer;
- (ii) an applicant for licensing as a Narcotics Exporter;
- (iii) an applicant for licensing as a Narcotics Manufacturer;
- (iv) an applicant for licensing as a Formulator of Narcotic Pharmaceuticals;
- (v) an applicant for licensing as a Manufacturer of Exempt Narcotics;
- (vi) an applicant for licensing as a Primary Wholesaler of Narcotics;
- (vii) an applicant for licensing as a Psychotropics Importer;
- (viii) an applicant licensing as a Psychotropics Exporter;
- (ix) an applicant for licensing as a Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals;
- (x) an applicant for licensing as a Psychotropics Processor;
- (xi) an applicant for registration as the Operator of a Facility Conducting Experiments or Research Involving Psychotropics (but only an applicant for registration by the Minister of Health, Labour and Welfare);
- (xii) an applicant for the reissuance of its license as a Narcotics Importer, Narcotics Exporter, Narcotics Manufacturer, Formulator of Narcotic Pharmaceuticals, Manufacturer of Exempt Narcotics, Primary Wholesaler of

Narcotics, Psychotropics Importer, Psychotropics Exporter, Psychotropics Manufacturer or Formulator of Psychotropic Pharmaceuticals, or Psychotropics Processor, or of its certificate of registration as the Operator of a Facility Conducting Experiments or Research Involving Psychotropics (but only the certificate of a registration by the Minister of Health, Labour and Welfare).

(Conditions for Licensing and Permission)

Article 59-6 (1) Conditions may be attached to licensing or permission as prescribed in this Act, and those conditions may be modified.

(2) The conditions referred to in the preceding paragraph must be limited to the minimum necessary conditions for preventing health and sanitation hazards from arising due to the abuse of Narcotics or Psychotropics, and must not unduly obligate the person being licensed or receiving the permission.

(Measures for Narcotics and Psychotropics Belonging to the National Treasury)

Article 60 The Minister of Health, Labour and Welfare may take the necessary measures for Narcotics and Psychotropics belonging to the national treasury, pursuant to laws and regulations.

(Narcotics Used in Forensic Investigations Excluded from Application of This Act)

Article 60-2 (1) Notwithstanding what is prescribed in this Act, the Minister of Health, Labour and Welfare may import, manufacture, and accept Narcotics and Psychotropics for use in forensic investigations involving Narcotics and Psychotropics.

(2) The Minister of Health, Labour and Welfare is to deliver the Narcotics and Psychotropics imported, manufactured, and accepted pursuant to the preceding paragraph to national and prefectural institutions engaged in forensic investigations involving Narcotics and Psychotropics.

(3) An official working for an institution as referred to in the preceding paragraph may make use of or be in possession of the Narcotics received by the institution from the Minister of Health, Labour and Welfare pursuant to that paragraph for forensic investigations involving Narcotics.

(4) The head of an institution that has received Narcotics or Psychotropics from the Minister of Health, Labour and Welfare pursuant to paragraph (2) must keep books, and must enter in them the product names and quantities of Narcotics and Psychotropics used for forensic investigations involving Narcotics and Psychotropics, as well as the dates of their use and the information that Order of the Ministry of Health, Labour and Welfare prescribes.

(5) Notwithstanding what is prescribed in this Act, at the request of a foreign government indicating that it wants to import Narcotics or Psychotropics made available for forensic investigations involving Narcotics or Psychotropics, the Minister of Health, Labour and Welfare, pursuant to laws and regulations, may export Narcotics or Psychotropics that have been imported, manufactured, or accepted pursuant to paragraph (1) or Narcotics or Psychotropics that belong to the national treasury to that foreign government.

(Prices of Certification Stickers)

Article 61 If a Narcotics Importer, Narcotics Manufacturer, or Formulator of Narcotic Pharmaceuticals applies to be delivered a certification sticker as prescribed in Article 30, paragraph (1), it must pay to the national treasury the price that Order of the Ministry of Health, Labour and Welfare prescribes in consideration of actual costs.

(Handling for When a Single Person Has Multiple Credentials)

Article 62 (1) In order to apply the provisions of this Act that concern the transfer and acquisition of Narcotics if a single person has multiple Commercial Narcotics Handlers licenses or if a Commercial Narcotics Handler is also the operator of a Medical Facility at Which Narcotics Are Administered or the operator of a Narcotics Research Facility, that single person is deemed to be a different person for each credential. The same applies if a single person operates multiple Medical Facilities at Which Narcotics Are Administered or multiple Narcotics Research Facilities, or if the operator of a Medical Facility at Which Narcotics Are Administered also operates a Narcotics Research Facility.

(2) In order to apply the provisions of this Act that concern the transfer and acquisition of Narcotics if a single person has multiple Commercial Psychotropics Handlers licenses or if a Commercial Psychotropics Handler is also the operator of a Hospital or Similar Facility or the Operator of a Facility Conducting Experiments or Research Involving Psychotropics, that single person is deemed to be a different person for each credential. The same applies if a single person operates multiple Hospitals or Similar Facilities or multiple Facilities Conducting Experiments or Research Involving Psychotropics, or if the operator of a Hospital or Similar Facility also operates a Facility Conducting Experiments or Research Involving Psychotropics.

(Categories of Administrative Processes)

Article 62-2 Administrative processes that it is decided will be handled by a prefecture pursuant to Article 24, paragraph (12) (but only the part that item (i) concerns); Article 29; Article 35; Article 36, paragraphs (1) and (3)

(including as applied mutandis pursuant to paragraph (4) of that Article); Articles 46 through 49; Article 50-22; Article 50-24, paragraphs (2) and (3); Article 50-33; Article 50-38, paragraphs (1) and (2); Article 50-39; Articles 58-2 through 58-5; Article 58-6, paragraphs (1), (4), (5), and (8); Article 58-8, paragraph (1); paragraphs (2) through (6) of that Article (including as applied mutandis pursuant to Article 58-9, paragraph (2)); Article 58-11; Article 58-12; and Article 58-16 are treated as Item I statutorily entrusted functions as prescribed in Article 2, paragraph (9), item (i) of the Local Autonomy Act (Act No. 67 of 1947).

(Delegation of Authority)

Article 62-3 (1) The authority of the Minister of Health, Labour and Welfare as prescribed in this Act may be delegated to the head of a Regional Bureau of Health and Welfare, pursuant to 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 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 Order of the Ministry of Health, Labour and Welfare.

(Transitional Measures)

Article 62-4 If Cabinet Order or Order of the Ministry of Health, Labour and Welfare is enacted, revised, or repealed based on this Act, each of these may provide for the necessary transitional measures (including transitional measures for penal provisions), to the extent that is judged to be reasonably necessary for its enactment, revision, or repeal.

(Order for Implementation)

Article 63 Beyond what this Act delegates to Cabinet Order, Order of the Ministry of Health, Labour and Welfare prescribes the necessary processes for implementing this Act and provides for the necessary detailed regulations to enforce this Act.

## **Chapter VII Penal Provisions**

Article 64 (1) A person importing Diacetylmorphine or a Similar Substance to Japan or a foreign country, exporting it from Japan or a foreign country, or manufacturing it, without due cause, is subject to imprisonment for a definite term not less than one year.

(2) A person committing one of the offenses referred to in the preceding

paragraph with the objective of profiting from it is subject to life imprisonment or imprisonment for a term not less than three years, or, depending on the circumstances of the offense, to a sentence that combines either life imprisonment or imprisonment for a term not less than three years with a fine not exceeding 10,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 64-2 (1) A person formulating pharmaceutical preparations, packaging, transferring, accepting, delivering, or having possession of Diacetylmorphine or a Similar Substance without due cause is subject to imprisonment for a term of not more than ten years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a definite term of not less than one year, or, depending on the circumstances of the offense, to a combined sentence of imprisonment for a definite term of not less than one year and a fine not exceeding 5,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 64-3 (1) A person administering, disposing of, or being administered Diacetylmorphine or a Similar Substance in violation of Article 12, paragraph (1) or (4) is subject to imprisonment for a term of not more than ten years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a definite term of not less than one year, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a definite term of not less than one year with a fine of not more than 5,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 65 (1) A person falling under one of the following items is subject to imprisonment for a term of not less than one year but not more than ten years:

- (i) a person importing a Narcotic other than Diacetylmorphine or a Similar Substance to Japan or a foreign country, exporting it from Japan or a foreign country, or manufacturing it, without due cause (other than a person falling under Article 69, items (i) through (iii));
- (ii) a person cultivating a Plant Containing a Narcotic Raw Material without due cause.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for



a definite term of not less than one year, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a definite term of not less than one year with a fine not exceeding 5,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 66 (1) A person formulating pharmaceutical preparations of a Narcotic other than Diacetylmorphine or a Similar Substance; packaging, transferring, or accepting the Narcotic; or having possession of the Narcotic without due cause (other than a person falling under Article 69, item (iv) or (v) or Article 70, item (v)) is subject to imprisonment for a term of not more than seven years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a term of not less than one year but not more than ten years, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a term of not less than one year but not more than ten years with a fine of not more than 3,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 66-2 (1) A person violating Article 27, paragraph (1) or paragraphs (3) through (5) is subject to imprisonment for a term of not more than seven years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a term of not less than one year but no more than ten years, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a term of not less than one year but not more than ten years with a fine of not more than 3,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 66-3 (1) A person importing a Psychotropic to Japan or a foreign country, exporting it from Japan or a foreign country, manufacturing it, formulating pharmaceutical preparations of it, or packaging it, without due cause (other than a person falling under Article 70, item (xv) or (xvi)) is subject to imprisonment for a term of not more than five years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a term of not more than seven years, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a term of not more than seven years with a fine of not more than 2,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 66-4 (1) A person transferring a Narcotic or having it in its possession for the purpose of transferring it, without due cause (other than a person falling under Article 70, item (xvii) or Article 72, item (vi)) is subject to imprisonment for a term of not more than three years.

(2) A person committing one of the offenses referred to in the preceding paragraph with the objective of profiting from it is subject to imprisonment for a term of not more than five years, or, depending on the circumstances of the offense, to a sentence that combines imprisonment for a term of not more than five years and a fine of not more than 1,000,000 yen.

(3) Any attempt to commit one of the offenses referred to in the preceding two paragraphs is also punishable.

Article 67 A person making preparations to commit one of the offenses referred to in Article 64, paragraph (1) or (2) or Article 65, paragraph (1) or (2) is subject to imprisonment for a definite term of not more than five years.

Article 68 A person knowingly providing or conveying the funds, land, building, vessel, aircraft, vehicle, equipment, machine, device, or raw material (including the seeds of a Plant Containing a Narcotic Raw Material) needed for any act constituting an offense as referred to in Article 64, paragraph (1) or (2) or Article 65, paragraph (1) or (2) (referred to as "funds or other instrumentality" in Article 69-4), is subject to imprisonment for a term of not more than five years.

Article 68-2 A person acting as an intermediary in a transfer or acceptance of Narcotics constituting an offense as referred to in Article 64-2, paragraph (1) or (2) or Article 66, paragraph (1) or (2) is subject to imprisonment for a term of not more than three years.

Article 69 A person falling under one of the following items is subject to imprisonment for a term of not more than three years, a fine of not more than 500,000 yen, or both:

(i) a person importing a Narcotic without permission, in violation of Article 14, paragraph (1);

(ii) a person exporting a Narcotic without permission, in violation of Article 18, paragraph (1);

(iii) a person manufacturing a Narcotic or Exempt Narcotic without permission, in violation of Article 20, paragraph (1);

- (iv) a person formulating pharmaceutical preparations of or packaging a Narcotic without permission, in violation of Article 23, paragraph (1);
- (v) a person violating Article 25;
- (vi) a person violating Article 29-2;
- (vii) a person violating an order suspending business operations or research as under Article 51, paragraph (1).

Article 69-2 A person making preparations to commit one of the offenses referred to in Article 66-3, paragraph (1) or (2) is subject to imprisonment for a term of not more than two years.

Article 69-3 (1) A Narcotic or Psychotropic connected with an offense as referred to in Articles 64 through 67 or Article 69-2 which under the ownership or in the possession of the offender is confiscated; provided, however, that it is permissible not to confiscate the Narcotic or Psychotropic if it is owned by a person other than the offender.

(2) A vessel, aircraft, or vehicle used to convey a Narcotic or Psychotropic in connection with one of the offenses prescribed in the preceding paragraph (other than an offense as referred to in Article 64-3 or Article 66-2) may be confiscated.

Article 69-4 A person knowingly providing or conveying the funds or other instrumentality needed for an act constituting an offense as referred to in Article 66-3, paragraph (1) or (2) is subject to imprisonment for a term of not more than two years.

Article 69-5 A person acting as an intermediary in a transfer or acceptance of Psychotropics constituting an offense as referred to in Article 66-4, paragraph (1) or (2), is subject to imprisonment for a term of not more than one year.

Article 69-6 The offenses referred to in Article 64; Article 64-2; Article 65; Article 66; Article 66-3 through Article 68-2; Article 69-2; Article 69-4; and Article 69-5 are governed by Article 2 of the Penal Code.

Article 70 A person falling under one of the following items is subject to imprisonment for a term of not more than one year, a fine of not more than 200,000 yen, or both:

- (i) a person violating Article 4, paragraph (3);
- (ii) a person violating Article 19-2;
- (iii) a person including false information when writing a prescription under Article 27, paragraph (6);

- (iv) a person disposing of a Narcotic in violation of Article 29;
- (v) a person violating Article 30, paragraphs (1) through (3) or Article 31;
- (vi) a person delivering a Narcotic without having been delivered proof of acquisition under Article 32, paragraph (1), or without exchanging the Narcotic for the proof of acquisition;
- (vii) a person delivering a Narcotic without giving a proof of transfer under Article 32, paragraph (1);
- (viii) a person including false information on a proof of acquisition or proof of transfer as prescribed in Article 32, paragraph (1), or recording false information in an electronic or magnetic record under paragraph (3) of that Article;
- (ix) a person violating Article 32, paragraph (3), Article 33 or Article 34;
- (x) a person falsely making a notification under Article 35, paragraph (1) or (2) or Article 36, paragraph (1) (including as applied mutatis mutandis pursuant to paragraph (4) of that Article) or paragraph (3) (including as applied mutatis mutandis pursuant to paragraph (4) of that Article);
- (xi) a person failing to keep books, in violation of Article 37, paragraph (1); Article 38, paragraph (1); Article 39, paragraph (1); or Article 40, paragraph (1); or a person failing to include a piece of information in its books or including false information in its books;
- (xii) a person failing to keep the books, in violation of Article 37, paragraph (2); Article 38, paragraph (2); Article 39, paragraph (3); or Article 40, paragraph (3);
- (xiii) a person including false information in a medical record or medical report under Article 41;
- (xiv) a person forging or altering a Narcotics Prescription;
- (xv) a person importing Psychotropics without permission, in violation of Article 50-9, paragraph (1) or (2);
- (xvi) a person exporting Psychotropics without permission, in violation of Article 50-12, paragraph (1) or (2) or Article 50-13, paragraph (1);
- (xvii) a person violating Article 50-17;
- (xviii) a person violating Article 29-2 as applied mutandis pursuant to Article 50-18;
- (xix) a person violating an order under Articles 50-39 to 50-41;
- (xx) a person violating an order suspending business operations under Article 51, paragraph (2);
- (xxi) a person violating Article 58-19.

Article 71 A person violating Article 35, paragraph (1) or (2); Article 36, paragraph (1) (including as applied mutatis mutandis pursuant to paragraph (4) of that Article) or paragraph (3) (including as applied mutatis mutandis

pursuant to paragraph (4) of that Article); Article 39, paragraph (2); Article 40, paragraph (2); Article 41; Article 50-15, paragraph (2); or Article 58-2, paragraph (1) is subject to imprisonment for a term of not more than six months, a fine of not more than 200,000 yen, or both.

Article 72 A person falling under one of the following items is subject to a fine of not more than 200,000 yen:

- (i) a person violating Article 7, paragraph (1) (including as applied mutatis mutandis pursuant to paragraph (2) of that Article) or paragraph (3); Article 15; or Article 18, paragraph (6);
- (ii) a person failing to file a notification, in violation of Article 42 through 45; Article 46, paragraph (1); or Article 47 through 49; or a person filing a false notification;
- (iii) a person violating Article 4, paragraph (3) as applied mutandis pursuant to Article 50-4 or Article 50-7;
- (iv) a person forging or altering a Psychotropics Prescription;
- (v) a person violating Article 19-2 as applied mutandis pursuant to Article 50-18;
- (vi) a person violating Article 50-19;
- (vii) a person failing to file a notification, in violation of Articles 50-22, paragraph (1), or a person filing a false notification;
- (viii) a person failing to prepare records, in violation of Article 50-23, paragraphs (1) through (3), or a person including false information in a record;
- (ix) a person failing to keep records on file, in violation of Article 50-23, paragraph (4);
- (x) a person failing to file a notification under Article 50-27, or a person filing a false a notification;
- (xi) a person failing to report or reporting falsely; or a person refusing, obstructing, or evading an entry, inspection, or sampling as under Article 50-38, paragraph (1).

Article 73 A person falling under one of the following items is subject to a fine of not more than 200,000 yen:

- (i) a person refusing, obstructing, or evading a medical examination by a mental health doctor as under Article 58-6, paragraph (1);
- (ii) a person refusing to come to a place when asked to do so pursuant to Article 58-6, paragraph (3), or refusing to remain in a place when requested to do so pursuant to that paragraph;
- (iii) a person refusing or obstructing an entry under Article 58-6, paragraph (5).

Article 73-2 A person falling under one of the following items is subject to a fine of not more than 100,000 yen:

- (i) a person violating Article 7, paragraph (1) or (3) as applied mutandis pursuant to Article 50-4 or Article 50-7; Article 15 as applied mutandis pursuant to Article 50-9, paragraph (3) or (4); Article 18, paragraph (6) as applied mutandis pursuant to Article 50-12, paragraph (3) or (4); or Article 50-13, paragraph (2); Article 50-10; Article 50-13, paragraph (6); or Article 50-14;
- (ii) a person failing to file a notification, in violation of Article 50-24, paragraph (1) or (2), or a person filing a false notification;
- (iii) a person violating Article 50-28;
- (iv) a person failing to file a notification, in violation of Article 50-29 through Article 50-32 or Article 50-33, paragraph (1), or a person filing a false notification;
- (v) a person failing to prepare records, in violation of Article 50-34, paragraph (1), or a person including false information in a record;
- (vi) a person failing to keep records on file, in violation of Article 50-34, paragraph (2);
- (vii) a person violating Article 19-2, as applied mutandis pursuant to Article 50-35;
- (viii) a person failing to report or falsely reporting; or a person refusing, obstructing, or evading an inspection under Article 50-38, paragraph (2).

Article 74 If the representative of a corporation or the agent, employee, or other worker of a corporation or individual commits an offense as referred to in Article 64, paragraph (2) or (3); Article 64-2, paragraph (2) or (3); Article 65, paragraph (2) or (3); Article 66, paragraph (2) or (3); Article 66-3, paragraph (2) or (3); or Article 66-4, paragraph (2) or (3), or commits a violation as referred to in Article 64-3, paragraph (2) or (3); Article 66-2, paragraph (2) or (3); Article 69; Articles 70 through 72; or Article 73 in connection with the business of the corporation or individual, in addition to the offender or the violator being subject to punishment, the corporation or individual is subject to the fine that the relevant Article prescribes.

Article 75 A person violating Article 8 (including as applied mutandis pursuant to Article 50-4 or Article 50-7) or Article 10 (including as applied mutandis pursuant to Article 50-4 or Article 50-7) is subject to a fine of not more than 100,000 yen.

Article 76 To apply this Chapter to a Narcotic if it is not possible to learn whether it is Diacetylmorphine or a Similar Substance, a Narcotic as

prescribed in Article 12, paragraph (2), or some other Narcotic, the Narcotic is deemed to be a Narcotic other than either Diacetylmorphine or a Similar Substance or a Narcotic as prescribed in paragraph (2) of that Article.

### **Supplementary Provisions [Extract]**

(Effective Date)

(1) This Act comes into effect from April 1, 1953.

(Repeal of Narcotics Control Act)

(2) The Narcotics Control Act (Act No. 123 of 1948; hereinafter referred to as "the Former Act") is repealed.

(Transitional Measures)

(3) Licensing, permission, or any other action taken by the Ministry of Health and Welfare based on the Former Act for which corresponding provisions exist in this Act is deemed to be an action taken by the Ministry of Health and Welfare or prefectural governor based on this Act.

(4) The license of a Narcotics Handler delivered based on the Former Act is deemed to have been delivered based on this Act.

(5) Certification stickers issued pursuant to Article 29, paragraph (1) of the Former Act and seals affixed pursuant to that paragraph are deemed to have been issued and affixed pursuant to Article 30, paragraph (1) of this Act.

(6) A proof of acquisition or proof of transfer delivered pursuant to Article 13, paragraph (1) of the Former Act is deemed to have been delivered pursuant to Article 32, paragraph (1) of this Act.

(7) Article 33, paragraph (1) does not apply for three months after this Act comes into effect to the operator of a veterinary facility at which two or more Persons Licensed to Administer Narcotics are actually engaged in medical care at the time this Act comes into effect.

(8) A Person Licensed to Administer Narcotics that is engaged in medical care at a veterinary facility as referred to in the preceding paragraph must manage the Narcotics that the person administers or delivers to persons to administer at that facility, and must not administer a Narcotic other than one of the Narcotics that person manages or delivers a person this to administer, until the operator referred to in the preceding paragraph itself becomes a Narcotics Manager or appoints a Narcotics Manager.

(9) A person violating the preceding paragraph is subject to imprisonment for a term of not more than one year, a fine of not more than 30,000 yen, or both.

(10) Books being kept on file pursuant to Article 14, paragraph (3) of the Former Act at the time this Act comes into effect are deemed to be books as referred to

in Article 37, paragraph (1); Article 38, paragraph (1); Article 39, paragraph (1); or Article 40, paragraph (1).

- (11) A Person Licensed to Administer Narcotics, Narcotics Manager, or Narcotics Researcher that is keeping the books referred to in the preceding paragraph on file at the time this Act comes into effect must promptly deliver them to the operator of the Medical Facility at Which Narcotics Are Administered or the operator of the Narcotics Research Facility.
- (12) A person violating the preceding paragraph is subject to imprisonment for a term of not more than six months, a fine of not more than 10,000 yen, or both.
- (13) The books having been handed over pursuant to paragraph (11), the operator of a Medical Facility at Which Narcotics Are Administered or the operator of a Narcotics Research Facility must keep them on file for two years after the date of the last entry.
- (14) A person violating the preceding paragraph is subject to imprisonment for a term of not more than one year, a fine of not more than 30,000 yen, or both.
- (15) The provisions of Article 74 apply mutatis mutandis to a violation as referred to in the preceding paragraph.
- (16) Prior law continues to govern the applicability of penal provisions to a violation committed before this Act comes into effect (other than a violation involving something that constitutes a Narcotic under the Former Act but that is not categorized as a Narcotic or Exempt Narcotic under this Act; and other than a violation involving something that constitutes an Exempt Narcotic under the Former Act).
- (17) Unless Article 10 of the Supplementary Provisions of the Act Partially Revising the Public Officers Pension Act (Act No. 77 of 1947) applies, if a ministry narcotics agent who is assigned to work for a prefecture pursuant to Article 52-2 of the Former Act at the time this Act comes into effect becomes a narcotics agent for the prefecture in continuation, that paragraph applies mutatis mutandis, but only for the period that the agent continues to engage in administrative processes involving narcotics control.
- (18) Notwithstanding Article 3 of the Act on Free Loans and Gifts of State-Owned Articles (Act No. 229 of 1947), movables owned by the national government that are put to use in the administrative processes of a ministry narcotics agent who is assigned to work for a prefecture at the time this Act comes into effect may be gifted to the prefecture. In that case, Article 5, paragraph (2) of that Act apply mutatis mutandis.

(Special Considerations for Fiscal Years 1985 through 1988)

- (20) To apply Article 59-2 to each of the fiscal years from 1985 through 1988, the phrase "eight-tenths" in item (ii) of that Article is deemed to be replaced with "seven-tenths".



Appended Table I (relating to Article 2)

- (i) 3-acetoxy-6-dimethylamino-4,4-diphenylheptane (also called acethylmetadol) and its salts
- (ii)  $\alpha$ -3-acetoxy-6-dimethylamino-4,4-diphenylheptane (also called  $\alpha$ -acethylmetadol) and its salts
- (iii)  $\beta$ -3-acetoxy-6-dimethylamino-4,4-diphenylheptane (also called  $\beta$ -acethylmetadol) and its salts
- (iv)  $\alpha$ -3-acetoxy-6-methylamino-4,4-diphenylheptane (also called noracymethadole) and its salts
- (v) 1-[2-(4-aminophenyl)ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called anileridine) and its salts
- (vi) N-allylnormorphine (also called nalorphine), its ester and their salts
- (vii) 3-allyl-1-methyl-4-phenyl-4-(propionyloxy) piperidine (also called allylprodine) and its salts
- (viii) ecgonine and its salts
- (ix) 3-(N-ethyl-N-methylamino)-1,1-di-(2-thienyl)-1-buten (also called ethylmethylthiambutene) and its salts
- (x)  $\alpha$ -3-ethyl-1-methyl-4-phenyl-4-(propionyloxy) piperidine (also called alphameprodine) and its salts
- (xi)  $\beta$ -3-ethyl-1-methyl-4-phenyl-4-(propionyloxy) piperidine (also called betameprodine) and its salts
- (xii) 2-(4-chlorobenzyl)-1-(diethylamino) ethyl-5-nitrobenzimidazole (also called clonitazene) and its salts
- (xiii) cocaine and other ecgonine ester and its salts
- (xiv) coca leaf
- (xv) codeine, ethylmorphine, other morphine ether, and its salts
- (xvi) diacetylmorphine (also known as heroin), other morphine ester, and its salts
- (xvii) 1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called diphenoxylate) and its salts
- (xviii) 4-cyano-2-dimethylamino-4,4-diphenylbutane (also called methadone intermediate) and its salts
- (xix) 4-cyano-1-methyl-4-phenylpiperidine (also called pethidine intermediate A) and its salts
- (xx) 1-(diethylamino)ethyl-2-(4-etoxybenzyl)-5-nitrobenzimidazole (also called etonitazene) and its salts
- (xxi) 3-diethylamino-1,1-di-(2-thienyl)-1-butene (also called diethylthienebutene) and its salts
- (xxii) dihydrocodeinone (also called hydrocodone), its ester, and their salts
- (xxiii) dihydrocodeine, its ester, and their salts

- (xxiv) dihydrodeoxy-morphine (also called desomorphine), its ester, and their salts
- (xxv) dihydrohydroxy-codeinone (also called oxycodone), its ester, and their salts
- (xxvi) dihydrohydroxy-morphinone (also called oxyxmorphine) and its salts
- (xxvii) dihydromorphine, its ester, and their salts
- (xxviii) dihydromorphinone (also called hydromorphone), its ester, and their salts
- (xxix) 4,4-diphenyl-6-piperidiny-3-heptanone (also called dipipanone) and its salts
- (xxx) (2-dimethylamino)ethyl-1-ethoxy-1,1-diphenylacetate (also called dimenoxadol) and its salts
- (xxxix) 3-dimethylamino-1,1-di-(2-thienyl)-1-butene (also called dimethylthiambutene) and its salts
- (xxxix) 6-dimethylamino-4,4-diphenyl-3-hexanone (also called normesadone) and its salts
- (xxxix) 6-dimethylamino-4,4-diphenyl-3-heptanol (also called dimepheptanol) and its salts
- (xxxix)  $\alpha$ -6-dimethylamino-4,4-diphenyl-3-heptanol (also called  $\alpha$ -methadol) and its salts
- (xxxix)  $\beta$ -6-dimethylamino-4,4-diphenyl-3-heptanol (also called  $\beta$ -methadol) and its salts
- (xxxix) 6-dimethylamino-4,4-diphenyl-3-heptanone (also called methodone) and its salts
- (xxxix) 4-dimethylamino-3-methyl-1,2-diphenyl-2-(propionyloxy) butane (also called propoxyphine) and its salts
- (xxxix) 6-dimethylamino-5-methyl-4,4-diphenyl-3-hexanone (also called isomethadone) and its salts
- (xxxix) 1,3-dimethyl-4-phenyl-4-(propionyloxy)azacycloheptane (also called proheptazine) and its salts
- (xl)  $\alpha$ -1,3-dimethyl-4-phenyl-4-(propionyloxy) piperidine (also called  $\alpha$ -prodine) and its salts
- (xli)  $\beta$ -1,3-dimethyl-4-phenyl-4-(propionyloxy) piperidine (also called  $\beta$ -prodine) and its salts
- (xlii) thebaine and its salts
- (xliii) 1,2,5-trimethyl-4-phenyl-4-(propionyloxy) piperidine (also called trimeperidine) and its salts
- (xliv) 6-nicotinylcodein (also called nicocodine) and its salts
- (xlv) normorphine (also called demethylmorphine), its ether, and their salts
- (xlvi) 1-[2-(2-hydroxyetoxy)ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called etoxyeridine) and its salts

- (xlvii) 14-hydroxydihydromorphine (also called hydromorphanol) and its salts
- (xlviii) 3-hydroxy-N-phenacetylmorphinan (other than dextrorotatory one) and its salts
- (xlix) 1-(3-hydroxy-3-phenylpropyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called phenoperidine) and its salts
- (l) 4-(3-hydroxyphenyl)-1-methyl-4-piperidineethylketone (also called ketobemidone) and its salts
- (li) 4-(3-hydroxyphenyl)-1-methylpiperidine-4-carboxylic acid ethyl ester (also called hydroxypethidine) and its salts
- (lii) 3-hydroxy-N-phenethylmorphinan (also called phenomorphan) and its salts
- (liii) 3-hydroxy-N-methylmorphinan (other than dextrorotatory one) and its salts
- (liv) 3-hydroxymorphinan (other than dextrorotatory one) and its salts
- (lv) 4-phenyl-1-[2-(tetrahydrofurfuryloxy)ethyl]piperidine-4-carboxylic acid ethyl ester (also called furethidine) and its salts
- (lvi) 4-phenylpiperidine-4-carboxylic acid ethyl ester (also called pethidine intermediate B) and its salts
- (lvii) 4-phenyl-1-(3-pheminoaminopropyl)piperidine-4-carboxylic acid ethyl ester (also called piminodine) and its salts
- (lviii) 1,2,3,4,5,6-hexahydro-8-hydroxy-6,11-dimethyl-3-phenethyl-2,6-methano-3-benzazocine (also called phenazocine) and its salts
- (lix) 1,2,3,4,5,6-hexahydro-8-hydroxy-3,6,11-trimethyl-2,6-methano-3-penzazocine (also called metazocine) and its salts
- (lx) 1-[2-(benzyloxy)ethyl]-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called benzethidine) and its salts
- (lxi) 6-methyldihydromorphine (also called methyldihydromorphine) and its salts
- (lxii) methyldihydromorphinone (also called metopon), its ester, and their salts
- (lxiii) 6-methyl- $\Delta$ 6-dioxymorphine (also called metyldesorphine) and its salts
- (lxiv) N-(1-methyl-2-piperidinoethyl)propyonanilide (also called phenanpromid) and its salts
- (lxv) 1-methyl-4-phenylpiperidine-4-carboxylic acid ester and its salts
- (lxvi) N-[2-(methylphenethylamino)propyl]propyonanilide (also called diampromide) and its salts
- (lxvii) [(3-methyl-4-morpholino-2,2-diphenyl)putyryl]piperidine and its salts
- (lxviii) 3-methyl-4-morpholino-2,2-diphenyl butyrate (also called moramido intermediate) and its salts
- (lxix) 3-methoxy-N-methylmorphinan (other than dextrorotatory one) and its salts
- (lxx) morphine and its salts
- (lxxi) morphine-N-oxydo, other pentavalent nitrogen morphine, and its

derivatives

- (lxxii) 1-(2-morpholinoethyl)-4-phenylpiperidine-4-carboxylic acid ethyl ester (also called morphlidine) and its salts
- (lxxiii) 6-morpholino-4,4-diphenyl-3-heptanone (also called phenadoxone) and its salts
- (lxxiv) 4-morpholino-2,2-diphenyl buturate ethyl ester (also called dioxaphetyl putyrate) and its salts
- (lxxv) substances that Cabinet Order prescribes which pose a risk of the same type of abuse and harmful effect as the substances set forth in the preceding items
- (lxxvi) substances containing any of the substances set forth in the preceding items, other than Opium; provided, however, that the following items are excluded:
  - (a) substances containing 10/1000 or less of codeine, dihydrocodeine, or their salts, and, other than these, not containing any substance specified in the preceding items;
  - (b) plants (including plant parts) other than Plants Containing a Narcotic Raw Material.

Appended Table II (relating to Article 2)

- (i) erythroxyton coca rum (referred to in Japanese as koka)
- (ii) erythroxyton novogranatense hieron
- (iii) papaver bracteatum lindl (referred to in Japanese as hakamaonigeshi)
- (iv) plants that Cabinet Order prescribes

Appended Table III (relating to Article 2)

- (i) 5-ethyl-5-phenylbarbitic acid (also called phenobarbital) and its salts
- (ii) 5-ethyl-5-(1-methyl butyl) barbituric acid (also called pentobarbital) and its salts
- (iii) 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepine-2-on (also called diazepam) and its salts
- (iv) 10-chloro-2,3,7,10-tetrahydro-2-methyl-10-b-phenyloxazolo[3,2-d][1,4]benzodiazepin-6(5H)-on (also called oxazolam) and its salts
- (v) 5-(2-chlorophenyl)-7-ethyl-1,3-dihydro-1-methyl-2H-thieno-[2,3,-e]-1,4-diazepin-2-on (also called clotiazepam) and its salts
- (vi) 7-chloro-2-methylamino-5-phenyl-3H-1,4-benzodiazepin-4-oxido (also called chlorodiazepoxydo) and its salts
- (vii) 5,5-diethylbarbituric acid (also called barbital) and its salts
- (viii) 1,3-dihydro-7-nitro-5-phenyl-2H-1,4-benzodiazepin-2-on (also called nitrazepam) and its salts
- (ix) 2-phenyl-2-(2-piperidyl) acetic acid methyl ester (also called

- methylphenidate) and its salts
- (x) 1,2,3,4,5,6-hexahydro-6,11,-dimethyl-3-(3-methyl-2-butenyl)-2,6-methano-3-benzazocine-8-ol (also called pentazocine) and its salts
  - (xi) substances that Cabinet Order prescribes which pose a risk of the same type of abuse and harmful effect as the substances set forth in the preceding items
  - (xii) substances containing any of the substances set forth in the preceding items

Appended Table IV (relating to Article 2)

- (i) acetone
- (ii) anthranilic acid and its salts
- (iii) ethyl ether
- (iv) ergotamines and its salts
- (v) ergometrin and its salts
- (vi) piperidine and its salts
- (vii) acetic anhydride
- (viii) lysergic acid and its salts
- (ix) substances that Cabinet Order prescribes which can be used as the raw materials for Narcotics or Psychotropics, beyond what is provided for in the preceding items
- (x) substances containing any of the substances set forth in the preceding items