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LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE INTERNATIONAL TREATIES ON NARCOTIC DRUGS AND PSYCHOTROPIC SUBSTANCES

In accordance with the relevant articles of the international treaties on narcotic drugs and psychotropic substances, the Secretary-General has the honour to communicate the following legislative texts.

JAPAN

Communicated by the Government of Japan

NOTE BY THE SECRETARIAT

a) International non-proprietary names in the text have been underlined by the Secretariat.

b) Some editing of texts may be done by the Secretariat in the interest of clarity. In this connection, words in square brackets [ ] have been added or changed by the Secretariat.

c) Only passages directly relevant to the control of narcotic drugs or psychotropic substances have been reproduced in this document. Non-relevant parts of laws and regulations have been deleted by the Secretariat; such deletions are indicated by [...].

INDEX

CANNABIS CONTROL LAW, 1977

(English Edition)
(Law No. 124 of 10 July 1948)
AMENDMENTS:
Law No. 18 of 27 March 1950
Law No. 152 of 28 May 1952
Law No. 15 of 17 March 1953
Law No. 71 of 22 April 1954
Law No. 108 of 21 June 1963
Law No. 111 of 1 June 1970

CONTENTS

* English translation supplied by the Foreign Ministry of Japan.

Chapter I. General Provisions

Article 1. The term "cannabis" in this Law means the cannabis plant (Cannabis Sativa, L.) and the substances manufactured from the cannabis plant, but does not include the mature stalk of the cannabis plant and any other substances produced from such mature stalk (except resin), cultivator and cannabis research worker.

Article 2. The term "cannabis dealer" in this Law means the cannabis cultivator and the cannabis research worker.

2. The term "cannabis cultivator" in this Law means the person licensed by the Metropolitan, Hokkaido or Prefectural Governor to cultivate cannabis plants for the purpose of collecting fiber or seeds.

3. The term "cannabis research worker" in this Law means the person licensed by the Metropolitan, Hokkaido or Prefectural Governor to cultivate cannabis plants or use cannabis for the purpose of research on cannabis.

Article 3. No person other than a cannabis dealer shall possess, cultivate, purchase, transfer cannabis or use cannabis for the purpose of research.

2. A person who may possess cannabis under the provisions of this Law shall not use it for any other purpose than that for which he is permitted to possess it.

Article 4. No one shall commit the following acts. This provision shall not apply to the case where a cannabis research worker imports or exports cannabis under the authorization of the Minister of Health and Welfare.

(1) Import or export cannabis;

(2) Apply for application for or supply medicines manufactured from cannabis;

(3) Undergo the administering of medicines manufactured from cannabis.

Chapter II. License

Article 5. A person who wishes to be a cannabis dealer shall be licensed by the Metropolitan, Hokkaido or Prefectural Governor, according to the provisions of the Ministry of Health and Welfare Ordinance. 1/

2. In either of the following cases, the license of cannabis dealer shall not be granted:

(1) To a person addicted to narcotic drugs, cannabis or opium;

(2) To a person who has been subjected to a penalty more stringent than imprisonment;

(3) To an incompetent person, a quasi-incompetent person or a minor.

Article 6. The Metropolitan, Hokkaido or Prefectural Government shall keep a registration book of cannabis dealers, in which matters concerning the license of cannabis dealer shall be registered.

2. Matters to be registered according to the provisions of the preceding paragraph shall be regulated by the Ministry of Health and Welfare Ordinance.

Article 7. When the Metropolitan, Hokkaido or Prefectural Governor licenses a person as a cannabis dealer, he shall register the said person in the registration book of cannabis dealers and the issuance of the license.

2. The license in the preceding article shall not be transferred or loaned to other persons.

Article 8. The term of validity of the license of cannabis dealer shall be from the day of issue to 31 December of the same year.

Article 9. A person who is to be registered in the registration book of cannabis dealer according to the provisions of article 7, shall pay the registration fee to the Metropolitan, Hokkaido or Prefectural Government, according to the following classification:

Cannabis cultivator	100 yen;
Cannabis research worker	100 yen.

Article 10. When a cannabis dealer wishes to apply for cancellation of the license, he shall make an application to the Metropolitan, Hokkaido or Prefectural Government, according to the provisions of the Ministry of Health and Welfare Ordinance.

2. In case of death or dissolution of a cannabis dealership, the successor (administrator of the estate, when the successor is not known. This shall apply hereinafter) or the liquidator shall give notice of it to the Metropolitan, Hokkaido or Prefectural Government, according to the provisions of the Ministry of Health and Welfare Ordinance.

3. When the Metropolitan, Hokkaido or Prefectural Governor receives the application in paragraph 1 or the report in the preceding paragraph, he shall delete the registration of the said person from the registration book of cannabis dealers.

4. When the license of cannabis dealer is cancelled according to the provisions of article 18 or the license loses its validity, the former cannabis dealer shall return the license to the Metropolitan, Hokkaido or Prefectural Governor.

5. When any change has occurred in the particulars mentioned in the registration book of cannabis dealers, the cannabis dealer shall give notice of it to the Metropolitan, Hokkaido or Prefectural Governor within 15 days after the occurrence of such a change.

6. When the license has been damaged or lost, a cannabis dealer shall apply for its reissue within 15 days with the reasons, and with the license attached in the event of damage to the Metropolitan, Hokkaido or Prefectural Governor.

7. When the lost license has been found after the license was reissued, a cannabis dealer shall return the found license within 15 days to the Metropolitan, Hokkaido or Prefectural Governor.

Article 11. A person who applies for change of registration or reissue of license of cannabis dealer shall pay 50 yen as fee to the Metropolitan, Hokkaido or Prefectural Government.

Chapter III. Cannabis Dealers

Article 12. Deleted.

Article 13. A cannabis cultivator shall not transfer cannabis to a person other than a cannabis dealer.

Article 14. A cannabis cultivator shall not remove cannabis outside of the cultivating area. This provision shall not apply to the case where removals are made by the permission of the Metropolitan, Hokkaido or Prefectural Governor.

Article 15. A cannabis cultivator shall report the following matters to the Metropolitan, Hokkaido or Prefectural Governor, not later than 30 January every year:

(1) Area where cannabis plants were cultivated during the preceding year;

(2) Quantity of cannabis fiber collected during the preceding year.

Article 16. A cannabis research worker shall not transfer cannabis to another person.

Article 17. A cannabis research worker shall submit a report of the following matters to the Metropolitan, Hokkaido or Prefectural Governor, not later than 30 January every year:

(1) Name and quantity of cannabis possessed at the beginning of the preceding year;

(2) Area where cannabis plants were cultivated during the preceding year;

(3) Name and quantity of cannabis collected, purchased during the preceding year;

(4) Name and quantity of cannabis used for the research purpose, and name and quantity of cannabis produced as the result of the research during the preceding year;

(5) Name and quantity of cannabis possessed at the end of the preceding year.

Chapter IV. Supervision

Article 18. When a cannabis dealer has committed a crime or irregularities regarding the business, the Metropolitan, Hokkaido or Prefectural Governor may cancel the license of the cannabis dealer.

Article 19. Deleted.

Article 20. As to the cannabis which has reverted to the State, the Minister of Health and Welfare may make the necessary disposition thereof.

Article 21. The Minister of Health and Welfare or Metropolitan, Hokkaido or Prefectural Governor may, whenever it is especially necessary for cannabis control, make the narcotic control officer, local narcotic control official or other government official enter the cultivating field, warehouse, laboratory or any other places concerned with cannabis to investigate the business situation, documents and other matters or take away cannabis only in such minimum quantity as necessary for examination free of charge.

2. When the narcotic control officer, local narcotic control official or other government official enters the places or takes away cannabis according to the provisions of the preceding paragraph, he shall bear his identification card and present it on demand of the persons concerned.

Chapter V. Miscellaneous Provisions

Article 22. The Metropolitan, Hokkaido or Prefectural Government shall bear the expenses necessary for the responsibilities of licensing and controlling cannabis exercised by the Metropolitan, Hokkaido or Prefectural Governor according to this Law.

Article 23. Except where regulated by this Law, the matters necessary for enforcement of this Law shall be regulated by the Ministry of Health and Welfare Ordinance.

Chapter VI. Penal Provisions

Article 24. A person who comes under any of the following items shall be liable to penal servitude not exceeding 7 years:

(1) A person who, in contravention of the provision of paragraph 2 of article 3, has cultivated cannabis;

(2) A person who, in contravention of the provision of article 4, has imported or exported cannabis.

Article 24-2. A person who comes under any of the following items shall be liable to penal servitude not exceeding 5 years:

(1) A person who, in contravention of the provision of paragraph 1 of article 3, has possessed, purchased, transferred or used cannabis;

(2) A person who has violated the provisions of paragraph 2 of article 3, article 13, article 14 or article 16;

(3) A person who, in contravention of the provision of article 4, has applied or supplied medicines manufactured from cannabis, or undergone the administering thereof.

Article 25. A person who comes under any of the following items shall be liable to penal servitude not exceeding 1 year or a fine not exceeding 30,000 yen:

(1) A person who has violated the provisions of paragraph 2 of article 7;

(2) A person who has failed to submit a report or submitted a false report in the provisions of article 15 or 17.

A person may be liable to both penalties in the preceding paragraph according to the circumstances.

Article 26. A person who comes under any of the following items shall be liable to a fine not exceeding 10,000 yen:

(1) A person who has failed to give notice under the provisions of paragraph 2 of article 10;

(2) A person who has violated the provisions of paragraph 4 or 7 of article 10;

(3) A person who has refused, prevented or evaded the entry inspection or removal in paragraph 1 of article 21.

Article 27. In the case where the representative of a juridical person, or proxy or the other person engaged in the business of a juridical person or of a natural person has violated, in connection with the business of the juridical person or natural person, the provisions of the preceding two articles, not only the violator shall be punished but also the juridical person or natural person concerned shall be liable to the fine regulated in the articles applicable to such violation.

Supplementary Provisions

Article 28. This Law shall come into force as from the date of its promulgation.

(The rest is omitted.)

E/NL.1980/124

PHARMACEUTICAL AFFAIRS LAW, 1979

(Law No. 145 of 10 August 1950)

AMENDMENTS:

Law No. 161 of 15 September 1962
Law No. 135 of 12 July 1963
Law No. 51 of 25 June 1969
Law No. 37 of 13 June 1975
Law No. 56 of 1 October 1979

CONTENTS

Chapter I. General Provisions

Purpose

Article 1. The purpose of this Law is to control and regulate matters relating to drugs, quasi-drugs, cosmetics and medical devices in order to secure their quality, effectiveness and safety.

Definition

Article 2. The term "drug" in this Law means the following articles:

(1) Articles recognized in the Japanese Pharmacopoeia;

(2) Articles (other than quasi-drugs) which are intended for use in the diagnosis, cure or prevention of disease in man or animals, and which are not instruments (including dental materials and medical or sanitary supplies, and referred to as such hereinafter);

(3) Articles (other than quasi-drugs and cosmetics) which are intended to affect the structure or any function of the body of man or animals, and which are not instruments.

2. The term "quasi-drug" in this Law means the following articles:

(1) Articles (other than instruments) whose purpose falls under any of the following and whose action upon the human body is gentle, excluding those intended at the same time for the uses prescribed in item (2) or (3) of the preceding paragraph; (a) Prevention of nausea or other indisposition, or of foul breath or body odor, (b) Prevention of heat rashes, festering and the like, (c) Prevention of loss of hair, or growth or removal of hair, (d) Extermination or elimination of rats, flies, mosquitoes, fleas, etc. for the health of man or animals;

(2) Articles which are designated by the Minister for Health and Welfare as similar to the articles specified in the preceding item.

3. [...]

4. The term "medical device" in this Law means the instruments which are intended for use in the diagnosis, cure or prevention of disease in man or animals, or intended to affect the structure or any function of the body of man or animals, and which are designated by Cabinet Order.

5. The term "pharmacy" in this Law means the place where a pharmacist engages in the practice of preparing drugs for the purpose of sale or giving (including the place necessary for selling drugs in cases where the proprietor concurrently follows the profession of selling drugs), excluding dispensaries in hospitals or clinics, or in medical institutions for domestic animals.

Chapter II. Pharmaceutical Affairs Council

Central Pharmaceutical Affairs Council

Article 3. The Central Pharmaceutical Affairs Council shall be established as one of the auxiliary organs of the Ministry of Health and Welfare to make investigation and deliberation in response to the request of the Minister for Health and Welfare, upon important matters concerning pharmaceutical affairs (including those concerning medical devices, and referred to as such hereinafter), but excluding matters concerning the National Examination for Pharmacists.

2. The organization and management of the Central Pharmaceutical Affairs Council and other necessary matters concerning the Central Pharmaceutical Affairs Council shall be determined by Cabinet Order.

Local Pharmaceutical Affairs Council

Article 4. A Local Pharmaceutical Affairs Council may be established in each prefecture (including To, Do or Fu, and referred to as such hereinafter) in order to make investigation and deliberation in response to the request of the Prefectural Governor, upon important matters concerning the business of pharmaceutical affairs originally appertaining to the prefecture concerned and the business designated by Cabinet Order from among those affairs which belong to the prefecture concerned under the provisions of this Law.

2. The organization and management of the Local Pharmaceutical Affairs Council and other necessary matters concerning the Local Pharmaceutical Affairs Council shall be established by the Regulations of the prefecture concerned.

Chapter III. Pharmacy

License for Establishment

Article 5. No one shall establish a pharmacy without a license from the Governor of the prefecture where the pharmacy is located.

2. The license mentioned in the preceding paragraph shall become invalid unless it is renewed every three years.

Standards for License

Article 6. In either of the following cases, the license under paragraph 1 of the preceding article may not be given:

(1) When the structure or equipment of the pharmacy is not in conformity with the standards laid down by the Ministry of Health and Welfare Ordinance; 1/

(1)-2 When the number of pharmacists engaged in practical business relating to pharmaceutical affairs in the pharmacy does not come up to that laid down by the Ministry of Health and Welfare Ordinance;

(2) When the applicant (including the directors, in the case of a juridical person, and referred to as such in article 13, paragraph 2) comes under any one of the following headings: (a) A person whose license was, less than three years before, cancelled in accordance with the provisions of article 75, paragraph 1; (b) A person who was awarded a court sentence more severe than imprisonment without hard labor and who, less than three years before, completed serving, or was exempted from the execution of, the sentence; (c) Excepting those who fall under (a) or (b), a person who, less than two years before, violated any of the Laws and ordinances relating to pharmaceutical affairs, such as this Law, the Narcotics Control Law (Law No. 14, 1953), 2/ the Law for the Control of Poisonous and Powerful Agents (Law No. 303, 1950), etc., or any of the dispositions made in accordance with these Laws and ordinances; (d) A legally incompetent person, a mental patient, or a person addicted to narcotics, hemp, opium or an arousal drug; (e) A person who, in view of his propensity and conduct, is considered certain to extremely impede the pharmacist administering the pharmacy in the performance of the duty provided for in article 9.

Limitation in Using the Designation of Pharmacy

Article 7. Any place in which drugs are handled and which is not an establishment licensed as a pharmacy under article 5, paragraph 1 (hereinafter referred to as "Pharmacy" in brief), shall refrain from using the designation of pharmacy, except as determined by the Ministry of Health and Welfare Ordinance.

Administration of Pharmacy

Article 8. A person who is licensed in accordance with the provisions of article 5, paragraph 1 (hereinafter referred to as "proprietor of a pharmacy"), shall, if he is a pharmacist in actual practice, administer the pharmacy personally. This regulation shall not apply when the proprietor of a pharmacy designates a pharmacist, from among other pharmacists engaged in practical business relating to pharmaceutical affairs in the pharmacy, as administrator for the practical administration thereof.

2. A proprietor of a pharmacy, if he is not a pharmacist, shall designate a pharmacist, from among the pharmacists engaged in practical business relating to pharmaceutical affairs in the pharmacy, as administrator for the practical administration thereof.

3. An administrator of a pharmacy (including a proprietor of a pharmacy administering the pharmacy in actual practice in accordance with the provisions of paragraph 1) shall not concurrently engage in the administration of any other pharmacy or in any other pharmaceutical practice at any place other than the pharmacy he administers. Exemptions to this rule may be granted under the license of the Governor of the prefecture where the pharmacy is located.

Duty of Administrator

Article 9. In order to prevent breaches of proper sanitary conduct an administrator of a pharmacy shall take good care of the business of the pharmacy, such as supervising pharmacists or other employees working in the pharmacy, and taking charge of the drugs and other articles there and of the structure and equipment of the pharmacy.

Matters to be observed by Proprietor of Pharmacy

Article 9-2. The Minister for Health and Welfare may determine the matters with regard to the business of a pharmacy to be observed by the proprietor of pharmacy in its Ministerial Ordinance, such as the method for test and inspection of drugs in a pharmacy or other items to be considered for an administrator of a pharmacy to perform his duties.

Notification of Abolishment, Suspension, etc.

Article 10. When the proprietor of a pharmacy has closed down his pharmacy, suspended the business, or resumed the business which had been suspended, or when he has appointed a different administrator for his pharmacy or has altered other matters laid down by the Ministry of Health and Welfare Ordinance, he shall give notice of it within thirty days to the Governor of the prefecture where his pharmacy is located.

Mandate to Cabinet Order

Article 11. Regulations which are supplementary to the provisions of this Chapter and which are necessary to the licensing and the establishment of pharmacies, to the renewal of licenses, and to the administration, as well as other necessary matters concerning pharmacies, shall be laid down by Cabinet Order as required.

Chapter IV. Professional Manufacture and Importation of Drugs, etc.

Section 1. Professional Manufacture

License for Professional Manufacture

Article 12. Any person who has not obtained a license for professionally manufacturing drugs, quasi-drugs, cosmetics or medical devices shall not professionally manufacture (including itemization, and referred to as such hereinafter) drugs, quasi-drugs, cosmetics or medical devices.

2. The license specified in the preceding paragraph shall be issued by the Minister for Health and Welfare for each manufacturing establishment.

3. The license in paragraph 1 shall become invalid unless it is renewed every three years.

Standards for License

Article 13. If the product which the applicant for the license mentioned in paragraph 1 of the preceding article intends to manufacture is a drug, or a quasi-drug mentioned in paragraph 1 of the next article, or one of the cosmetics or medical devices which are specified in the said paragraph and is a product for which the applicant has not obtained the approval of the Minister for Health and Welfare as provided for in the next article (including cases where it applies mutatis mutandis under article 23), then, with respect to such a product, the license specified in paragraph 1 of the preceding article shall not be granted.

2. In either of the following two cases the license specified in paragraph 1 of the preceding article may not be granted:

(1) When the structure or equipment of the factory is not in conformity with the standards fixed by the Ministry of Health and Welfare Ordinance;

(2) When the applicant comes under one of the Headings of article 6, item (2).

Approval for Manufacturing Drugs, etc.

Article 14. When an application has been made, in regard to a drug (excluding drugs listed in the Japanese Pharmacopoeia and designated by the Minister for Health and Welfare), a quasi-drug, a cosmetic containing the ingredients designated by the Minister for Health and Welfare or a medical device (excluding those

designated by the Minister for Health and Welfare), by a person intending to manufacture it, then the Minister for Health and Welfare shall, for every item, give his approval for its manufacture.

2. The approval mentioned in the preceding paragraph shall be granted after examining the name, ingredients, quantity, usage and dosage, effect, efficacy, efficiency, side effect, etc. of the drug, quasi-drug, cosmetic or medical device for which the application has been made and shall not be granted in the following respective cases:

(1) Where it has been found that the drug, quasi-drug or medical device for which application has been made has no effect, efficacy or efficiency which has been indicated in the application.

(2) Where it has been found that the drug, quasi-drug or medical device for which the application has been made is not useful as the drug, quasi-drug or medical device respectively since it has remarkably dangerous properties as compared with its effect, efficacy or efficiency.

(3) Besides those mentioned in the preceding two items, where the drug, quasi-drug or medical device has come under the case designated by the Ministry of Health and Welfare Ordinance as the improper drug, quasi-drug or medical device.

3. Any person who intends to obtain approval under paragraph 1 shall submit the application, together with data of test results or any other materials, in accordance with provisions of the Ministry of Health and Welfare Ordinance.

4. When a person who has obtained the approval mentioned in paragraph 1 plans to alter a part of the matters approved, he may ask for approval of the alteration.

The provisions of the preceding two paragraphs shall apply mutatis mutandis to this case.

Re-examination of New Drug, etc.

Article 14-2. Any person who has obtained the approval for manufacturing the drug enumerated in the following respective case shall apply for the re-examination of such drug with the Minister for Health and Welfare within the period fixed in the following respective items.

(1) The drug indicated by the Minister for Health and Welfare in approving the manufacture of such drug, as the drug different in ingredients, quantities, usage and dosage, effect, efficacy, etc. from the drug which was already approved for its manufacture (hereinafter referred to as the New Drug) within three months calculated from the date after six years (or a period not more than six years which is designated by the Ministry of Health and Welfare in case of the drug designated by the Ministry of Health and Welfare after the hearing from the Central Pharmaceutical

Affairs Council, same as above in the next item) elapse from the date of approval for manufacturing the New Drug.

(2) The drug indicated by the Minister for Health and Welfare in approving the manufacture of such drug, as the drug whose ingredients, quantities, usage and dosage, effect, efficacy, etc. are the same as those of the New Drug (excluding those which have passed six years after the approval for manufacture or import being granted) the period fixed by the Minister for Health and Welfare so as to expire on the same date of the period fixed in the preceding item.

2. The re-examination by the Minister for Health and Welfare shall be conducted in such a way as to confirm that the drug enumerated in the respective items of the preceding paragraph does not fall under any item of paragraph 2 of the preceding article based upon knowledges and experiences available in conducting the re-examination.

3. When the application mentioned in paragraph 1 is made, the date of test results or any other materials determined by the Ministry of Health and Welfare Ordinance shall be attached to the written application.

4. Any person who has obtained the approval for manufacturing the drug enumerated in the respective items of paragraph 1 under the preceding article shall conduct the investigation on the result of use of such drug and inform the Minister for Health and Welfare of the result of such investigation in accordance with provisions of the Ministry of Health and Welfare Ordinance.

Re-evaluation of Drug

Article 14-3. When the Minister for Health and Welfare, hearing the opinion of the Central Pharmaceutical Affairs Council, has made it public that drugs in the range designated by the Minister shall be re-evaluated, any person who has obtained the approval for manufacturing the drug shall cause the designated drug to be re-evaluated by the Minister for Health and Welfare.

2. The re-evaluation by the Minister for Health and Welfare shall be conducted in such a way as to confirm that the drug designated in the preceding paragraph does not fall under the respective items of paragraph 2 of article 14 based on the public knowledge at the time of re-evaluation.

3. The public notice mentioned in paragraph 1 shall show the materials which the person who shall cause the drug to be re-evaluated shall submit and its submission period.

Supervision of the Manufacture of Drugs

Article 15. A manufacturer of drugs, unless he is a pharmacist in actual practice, and supervises the manufacture personally, shall keep a pharmacist in every factory

to supervise the actual manufacture; however, when manufacturing drugs for which it is not necessary to have a pharmacist, he may, with the approval of the Minister for Health and Welfare, substitute a technician other than a pharmacist.

2. Notwithstanding the provisions of the preceding paragraph, a manufacturer of biological preparations or other drugs designated by the Minister for Health and Welfare, except when supervising his own factory personally and in actual practice with the approval of the Minister for Health and Welfare, shall, with the approval of the Minister for Health and Welfare, employ a doctor, a person having knowledge of bacteriology, or any other technician, for each factory in order to supervise the manufacture in actual practice.

3. The provisions of article 8, paragraph 3 and article 9 shall be applied mutatis mutandis to a person who supervises the manufacture of drugs under the provisions of the preceding two paragraphs (hereinafter referred to as "supervisor of drug making"). In this case, in article 8, paragraph 3, "the Governor of the prefecture where the pharmacy is located" shall read "The Minister for Health and Welfare".

Application Mutatis Mutandis

Article 16. Article 9-2 shall apply with necessary modifications to the manufacturer of drugs.

Responsible Technician in Manufacturing Quasi-drugs, Cosmetics or Medical Devices

Article 17. A manufacturer of quasi-drugs, cosmetics or medical devices shall, in accordance with the provisions of the Ministry of Health and Welfare Ordinance, employ a responsible technician for each factory for the practical supervision of the manufacture of quasi-drugs, cosmetics or medical devices.

2. The provisions of article 9 shall be applicable with necessary modifications to the responsible technician under the preceding paragraph.

License for Modification, etc., of Manufacturing Items

Article 18. When a manufacturer of drugs, quasi-drugs, cosmetics or medical devices wants to modify or add to the items to be manufactured in his factory, he shall obtain a license from the Minister for Health and Welfare.

2. The provisions of article 13 shall be applied mutatis mutandis to the above-mentioned license.

Notification of Abolishment, Suspension, etc.

Article 19. When a manufacturer has closed down his factory, suspended operations in his factory, or resumed the operations he had previously suspended, or when he has appointed a different supervisor of drug making or responsible technician in

his factory for quasi-drugs, cosmetics or medical devices, or modified other matters regulated by the Ministry of Health and Welfare Ordinance, he shall give notice of it to the Minister for Health and Welfare within thirty days.

Application or Notification through Prefectural Governor

Article 20. The application for a license, for the renewal of a license, or for approval (excluding approval under the provisions of article 14) and also the notification, which are prescribed in this Section, shall be made through the Governor of the prefecture where the factory is located.

2. The application for approval provided for in article 14, for re-examination under article 14-2 or for re-evaluation under article 14-3 shall be made through the Governor of the prefecture in which the applicant's residence (signifying the main office, in the case of a juridical person, and referred to as such hereinafter) is located. However, the application may be made through the Governor of the prefecture where the factory in which the concerned items of drugs are planned to be manufactured or are being manufactured is located.

Mandate to Ministerial Ordinance

Article 21. Matters not covered by the provisions of this section, in so far as they relate to licensing for professional manufacture, renewal of licenses, approval of items for manufacture, re-examination, re-evaluation, and administration of factories, as well as other necessary matters concerning the manufacturing of drugs, quasi-drugs, cosmetics or medical devices, shall be regulated by the Ministry of Health and Welfare Ordinance.

Section 2. Professional Importation

License for Professional Importation

Article 22. No person who has not obtained the license for professionally importing drugs, quasi-drugs, cosmetics or medical devices shall professionally import drugs, quasi-drugs, cosmetics or medical devices.

2. The license specified in the preceding paragraph shall be granted by the Minister for Health and Welfare to each business office.

3. The license in paragraph 1 shall become invalid unless it is renewed every three years.

Application Mutatis Mutandis

Article 23. To professional importers of drugs, quasi-drugs, cosmetics or medical devices, the provisions of articles 13 to 21 inclusive shall apply, with necessary modifications.

Chapter V. Professional Selling of Drugs and Medical Devices

License for Professionally Selling Drugs

Article 24. No person, unless he is either a proprietor of a pharmacy or has obtained a license for professionally selling drugs, shall professionally sell or give drugs, or store or exhibit (including periodical door-to-door distribution, and referred to as such hereinafter) drugs for the purpose of sale or giving. The provisions shall not apply to a manufacturer or importer of drugs who intends to sell or give drugs, which the manufacturer or importer himself has manufactured or imported, to a proprietor of a pharmacy or another drug manufacturer or importer, or intends to store or exhibit such drugs for the purpose of sale or giving to such persons.

2. The license under the preceding paragraph shall become invalid unless it is renewed every three years.

Kinds of License for Selling Drugs

Article 25. The license for professionally selling drugs shall be divided into the following four kinds:

(1) The first-class license for professionally selling drugs;

(2) The second-class license for professionally selling drugs;

(3) The license for professionally selling drugs by distribution;

(4) The third-class license for professionally selling drugs.

First-class License for Professionally Selling Drugs

Article 26. The first-class license for professionally selling drugs shall be granted to every shop by the Governor of the prefecture where the shop is located.

2. To the license in the preceding paragraph, the provisions of article 6 shall apply, with necessary modifications; provided that, to the first-class license for a seller who professionally sells or gives drugs only to a proprietor of a pharmacy, a manufacturer, importer or seller of drugs, or a proprietor of a hospital, clinic or institution for domestic animals, the provision of item (1)-2 of the same article shall not apply.

3. No person who has obtained the first-class license for professionally selling drugs under the provided provision of the preceding paragraph (hereinafter referred to as the "First-class wholesale professional") shall, with respect to the shop concerned, professionally sell or give drugs to those other than a proprietor of a pharmacy, a manufacturer, importer or seller of drugs, or a proprietor of a hospital, clinic or institution for domestic animals; provided that this shall not apply in the case where he has been licensed by the Prefectural Governor.

4. To the license under the provided provision of the preceding paragraph, the provision of article 6, item (1)-2 shall apply.

Application Mutatis Mutandis

Article 27. To businesses holding first-class licenses for professionally selling drugs the provisions of articles 8 to 9-2 shall apply, with necessary modifications.

Second-Class License for Professionally Selling Drugs

Article 28. The second-class license for professionally selling drugs shall be granted to every shop by the Governor of the prefecture where the shop is located.

2. The above-mentioned license shall not be given unless the applicant (including the directors and the quasi-director fixed by Cabinet Order, in the case of a juridical person, and referred to as such in the next paragraph and article 30, paragraph 2) has passed the examinations establishing that he has the necessary knowledge and experience for carrying on the business of his profession, or unless the applicant meets the standards laid down by Cabinet Order for those who have the necessary knowledge and experience to deal with drugs other than those specified in the next article.

3. In either of the following two cases, the license in paragraph 1 may not be given:

(1) When the structure or equipment of the shop is not in conformity with the standards laid down by the Ministry of Health and Welfare Ordinance;

(2) When the applicant falls under any of Headings (a) to (d) inclusive under article 6, item (2).

Prohibition of Selling Designated Drugs

Article 29. No person who has obtained a second-class license for professionally selling drugs (hereinafter referred to as "second-class seller") shall sell or give, or store or exhibit for the purpose of sale or giving, certain drugs as designated by the Minister for Health and Welfare.

License of Professionally Selling Drugs by Distribution

Article 30. The license for professionally selling drugs by distribution shall be granted, for every prefecture containing the whole or a part of the business area, by the Governor of the prefecture concerned. In this case the Governor shall specify the items of drugs according to the standards fixed by the Minister for Health and Welfare.

2. In either of the following two cases, the license in the preceding paragraph may not be granted:

(1) When the applicant falls under any one of Headings (a) to (d) inclusive under article 6, item (2).

(2) When the applicant lacks the necessary knowledge and experience for carrying on the business of the profession.

3. The necessary matters in regard to determining whether or not the applicant comes under item (2) of the preceding paragraph, shall be established by Cabinet Order.

Limitation of Items of Drugs

Article 31. No person who has a license for professionally selling drugs by distribution (hereinafter referred to as "periodical household distributor") shall sell or give, or store or exhibit for the purpose of sale or giving, drugs other than those designated by the Prefectural Governor under the provisions of paragraph 1 of the preceding article.

Notification of Engaging in Distribution

Article 32. When any periodical household distributor or any of his employees intends to engage in selling drugs by means of distribution, he shall give prior notice of his name, his business area, and other matters laid down by the Ministry of Health and Welfare Ordinance, to the Governor of the prefecture containing the business area.

Identification Card for Person Engaging in Distribution

Article 33. No periodical household distributor nor any of his employees shall engage in selling drugs by means of distribution, unless he carries with him the identification card issued by the Governor of the prefecture where his residence is located.

2. The necessary matters concerning the identification card of the preceding paragraph shall be laid down by the Ministry of Health and Welfare Ordinance.

Direction and Superintendence of Employees

Article 34. A periodical household distributor shall, in order to ensure proper sanitary conduct, direct and superintend, with respect to the business of selling drugs by distribution, his employees engaging in the distribution.

Third-Class License for Professionally Selling Drugs

Article 35. The third-class license for professionally selling drugs shall be granted to every shop by the Governor of the prefecture where the shop is located, but only in cases of special need; special need arises, for example, when insufficient facilities for selling drugs are available in the vicinity of the shop. In this case the Governor shall specify the drugs.

Limitation of Items of Drugs

Article 36. No person who has obtained the third-class license for professionally selling drugs (hereinafter referred to as "exceptional seller") shall sell or give, or store or exhibit for the purpose of sale or giving, drugs other than those specified by the Prefectural Governor in accordance with the provisions of the preceding article.

Limitation of Means of Selling, etc.

Article 37. No proprietor of a pharmacy and no person who has obtained the first-class license for professionally selling drugs (hereinafter referred to as "first-class seller") and no second-class seller and no exceptional seller, by means other than sale or giving on the basis of a shop; no periodical household distributor, by means other than distribution; shall sell or give drugs, or store or exhibit drugs for the purpose of sale or giving.

2. No periodical household distributor and no exceptional seller shall open the immediate container or wrapper (not including the package inner, and referred to as such hereinafter except in article 54 and article 57, paragraph 1) of a drug and sell it in lots.

Application Mutatis Mutandis

Article 38. To the profession of selling drugs, the provisions of articles 10 and 11 shall apply, with necessary modifications.

Profession of Selling Medical Devices

Article 39. [...]

Chapter VI. Standards and Tests for Drugs, etc.

Japanese Pharmacopoeia

Article 41. For the purpose of regulating the properties and qualities of drugs, the Minister for Health and Welfare shall establish and publish the Japanese Pharmacopoeia, after hearing the opinion of the Central Pharmaceutical Affairs Council.

2. The Japanese Pharmacopoeia shall consist of the First Part and the Second Part. In the First Part, popular crude drugs and fundamental preparations shall chiefly be contained, and in the Second, mixed preparations and their crude drugs.

3. In order that the Central Pharmaceutical Affairs Council may make investigations into the whole of the Japanese Pharmacopoeia at least every ten years, the Minister for Health and Welfare shall consult the Central Pharmaceutical Affairs Council on the revision of the Japanese Pharmacopoeia.

Standards of Drugs, etc.

Article 42. The Minister for Health and Welfare may lay down the necessary standards, after hearing the opinion of the Central Pharmaceutical Affairs Council, relating to the process, properties, quality, storing method, etc. of those drugs to which special attention shall be paid for public health and sanitation, such as biological or antibiotic preparations.

2. The Minister for Health and Welfare may, when it is indispensable for the prevention of hazards to the public health and sanitation, fix the necessary standards relating to the properties, quality, efficiency, etc., of quasi-drugs, cosmetics and medical devices, after hearing the opinion of the Central Pharmaceutical Affairs Council.

Test

Article 43. The drugs or medical devices designated by the Minister for Health and Welfare shall not be sold or given, or stored or exhibited for the purpose of sale or giving, unless they have passed the test made by the person whom the Minister for Health and Welfare has designated; provided that reasonable variations shall be permitted by regulation laid down by the Ministry of Health and Welfare Ordinance.

2. Necessary matters concerning the tests under the preceding paragraph shall be provided for by Cabinet Order.

3. With respect to the results of the test provided for in paragraph 1, no appeal can be made under the Administrative Appeal Law (Law No. 160, 1962).

Chapter VII. Handling of Drugs, etc.

Section 1. Handling of Poisonous and Powerful Drugs

Indication

Article 44. On the immediate container or wrapper of any drug designated as noxious by the Minister for Health and Welfare (hereinafter referred to as "poisonous drug"), its name and the letters "Poison" shall be exhibited in white on a black ground framed in white.

2. On the immediate container or wrapper of any drugs designated as powerful by the Minister for Health and Welfare (hereinafter referred to as "powerful drug"), its name and the letters "Powerful" shall be exhibited in red on a white ground framed in red.

3. No poisonous or powerful drugs conflicting with the provisions of the preceding two paragraphs shall be sold or given, or stored or exhibited for the purpose of sale or giving.

Limitation of Sale, etc., with Flying Seal

Article 45. No sellers of drugs other than first-class sellers shall sell or give, or store or exhibit for the purpose of sale or giving, poisonous or powerful drugs when the seal applied under the provisions of article 58 has been removed.

Transfer Procedure

Article 46. No proprietor of a pharmacy, and no manufacturer, importer or seller of drugs shall sell or give a poisonous or powerful drug to a person unless he receives from the assignee a document with the subscription or seal of the assignee in which are entered the name of the poisonous or powerful drug, the amount, the purpose of use, the date of transfer, and the name, address, and occupation of the assignee.

2. When a poisonous or powerful drug is sold or given to a pharmacist, a proprietor of a pharmacy, a manufacturer or seller of drugs, a doctor, dentist or veterinary surgeon, or a proprietor of a hospital, clinic or medical institution for domestic animals, the provisions of the preceding paragraph shall not apply, provided that the assignee presents an identification card issued by the official agency, or has permanent business relations with the assignor.

3. The assignor shall keep the document in paragraph 1 for two years from the date of the transfer.

Limitation of Delivery

Article 47. Poisonous or powerful drugs shall not be delivered to a person who is under fourteen years of age or who is considered likely to handle such a drug without due care.

Storage and Exhibition

Article 48. A person who handles poisonous or powerful drugs in the conduct of his business shall store or exhibit them separately from other goods.

2. In the case mentioned in the preceding paragraph, the warehouse or showcase for poisonous drugs shall be locked.

Section 2. Handling of Drugs

Sale of Drugs Requiring Direction

Article 49. No proprietor of a pharmacy and no seller of drugs shall sell or give drugs so designated by the Minister for Health and Welfare to persons other than those who have received a prescription or direction from a doctor, dentist or veterinary surgeon. This rule shall not apply when such drugs are sold or given to

a pharmacist, a proprietor of a pharmacy, a manufacturer or seller of drugs, a doctor, dentist or veterinary surgeon, a proprietor of a hospital, clinic or institution for domestic animals.

2. A proprietor of a pharmacy or a seller of drugs shall keep a book in his pharmacy or shop, and when he has sold or given the drugs prescribed in the preceding paragraph to those who have received a prescription or instructions from a doctor, dentist or veterinary surgeon, he shall, according to the provisions of the Ministry of Health and Welfare Ordinance, enter in the book the matters concerning the sale or giving of such drugs.

3. A proprietor of a pharmacy or a seller of drugs shall maintain the above-mentioned book for two years from the date of the last entry.

Matters to be Indicated on Immediate Container, etc.

Article 50. On the immediate container or wrapper of a drug, the matters prescribed in the following items shall be indicated; provided that reasonable variations may be permitted by regulations laid down by the Ministry of Health and Welfare Ordinance:

(1) The name and address of the manufacturer or importer;

(2) The name (for a drug recognized by the Japanese Pharmacopoeia, the name recognized in it; for any of the other drugs, the common or usual name, if such there be);

(3) The number or sign of the manufacture;

(4) The quantity of the contents in terms of weight, measure, numerical count, etc.;

(5) For a drug recognized by the Japanese Pharmacopoeia, the wording "Japanese Pharmacopoeia" and the matters specified by the Japanese Pharmacopoeia to be indicated on the immediate container or wrapper;

(6) For a drug of which the standards have been laid down under the provisions of article 42, paragraph 1, the matters specified by the standards to be indicated on the immediate container or wrapper;

(7) For a drug not recognized by the Japanese Pharmacopoeia, the name (common or usual name, if such there be) and quantity of each ingredient (for a drug with unknown active ingredients, its essence and the gist of its process);

(8) For a drug designated as habit-forming by the Minister for Health and Welfare, the letters "Warning - Habit-forming";

(9) For a drug designated by the Minister for Health and Welfare under the provisions of paragraph 1 of the preceding article, the letters "Warning - Use only pursuant to the prescription or direction of a doctor, etc.";

(10) For a drug designated by the Minister for Health and Welfare, the period for its use;

(11) Any matters laid down by the Ministry of Health and Welfare Ordinance supplementary to those provided for in the preceding items.

Article 51. If the immediate container or wrapper of a drug is packaged for retail sale, and if the matters indicated thereon which are prescribed in article 44, paragraph 1 or 2, or in the passages of the preceding article, are not easily legible through the outside container or wrapper, the same matters shall also be indicated on the outside one.

Matters to be Indicated on Package Leaflet, etc.

Article 52. On the leaflet enclosed with a drug, or on the container or wrapper of a drug, the matters prescribed in the following passages shall be indicated, provided that exemptions may be established by regulations prescribed by the Ministry of Health and Welfare Ordinance:

(1) Mode of use, dosage, or other necessary suggestions for use and handling;

(2) For a drug recognized in the Japanese Pharmacopoeia, the matters specified by the Japanese Pharmacopoeia to be indicated on the leaflet, container, or wrapper;

(3) For a drug of which the standards have been established under article 42, paragraph 1, the matters required by the standards to be indicated on the leaflet, container, or wrapper;

(4) In addition to matters provided for in the preceding items, matters laid down by the Ministry of Health and Welfare Ordinance.

Article 53. The matters provided for in article 44, paragraph 1 or 2, or in the preceding three articles shall be exhibited more prominently than other texts, statements, diagrams, or designs, and these matters shall be accurately indicated, pursuant to the provisions provided for by the Ministry of Health and Welfare Ordinance, in such terms as to render them easily read and understood by the ordinary purchaser or user of the drug concerned.

Impermissible Claims

Article 54. On the leaflet, container, or wrapper (including the package inner) of a drug, or on the drug itself, none of the following matters shall appear: false or misleading claims concerning the drug; effect or efficacy not approved pursuant to the provisions of article 14 (including cases where it applies mutatis mutandis under article 23); and such uses, dosage, or duration of treatment as is dangerous to health.

Prohibition of Sale, Giving, etc.

Article 55. Drugs which fail to comply with the provisions of the preceding five articles shall not be sold or given, or stored or exhibited for the purpose of sale or giving.

2. No drug which is an imitation of another drug, or is manufactured or imported contrary to the provisions of article 12, paragraph 1, article 18, paragraph 1 (including cases where it applies mutatis mutandis under article 23), or article 22, paragraph 1 shall be sold or given, or stored or exhibited for the purpose of sale or giving.

Prohibition of Sale, Manufacture, etc.

Article 56. No drug which comes under any of the following items shall be sold or given, or manufactured, imported, stored, or exhibited for the purpose of sale or giving:

(1) A drug which is recognized in the Japanese Pharmacopoeia and of which the quality or properties are not in conformity with the standards established by the Japanese Pharmacopoeia;

(2) A drug which is approved according to the provisions of article 14 (including cases where it applies mutatis mutandis under article 23) and of which the ingredients or quantity (for a drug with unknown ingredients its essence or the gist of its process) are not as approved;

(3) A drug of which the standards are laid down under the provisions of article 42, paragraph 1 and which is not in conformity with the standards (excluding the standards provided for in article 50, item (6) and article 52, item (3));

(4) A drug of which the whole or a part consists of any filthy, putrid or decomposed substance;

(5) A drug in or on which any foreign matter is found;

(6) A drug which is tainted, or is likely to be tainted by pathogenic microorganisms;

(7) A drug which bears or contains, for the purpose of coloring only, any coal-tar color other than those established by the Ministry of Health and Welfare Ordinance.

Article 57. No drug shall be packed with any article, or in any container or wrapper (including the package inner), which is composed, wholly or partly, of any poisonous or deleterious substance which may render the contents injurious to health; and the container or wrapper of a drug shall not be of such a nature that it leads to the possibility of misuse of the drug.

2. No drug which fails to comply with the provisions of the preceding paragraph shall be sold or given, or manufactured, imported, stored, or exhibited for the purpose of sale or giving.

Seal

Article 58. When a manufacturer or an importer of drugs sells or gives a drug that he himself has manufactured or imported, he shall, according to the regulations prescribed by the Ministry of Health and Welfare Ordinance, seal the container or wrapper of the drug; provided that the same shall not apply in the case of a drug sold or given to a manufacturer of drugs.

Section 3. Handling of Quasi-Drugs

Matters to be Indicated on Immediate Container, etc.

Article 59. On the immediate container or wrapper of a quasi-drug, the matters prescribed in the following items shall be indicated; provided that reasonable variations may be permitted by regulations laid down by the Ministry of Health and Welfare Ordinance:

(1) The name and address of the manufacturer or importer;
(2) The designation "quasi-drug";
(3) The name (common or usual name, if such there be);
(4) The number or sign of the manufacture;
(5) The quantity of the contents in terms of weight, measure, numerical count, etc.;
(6) For a quasi-drug containing the ingredient designated by the Minister for Health and Welfare, the name of such ingredient;
(7) For a quasi-drug designated by the Minister for Health and Welfare, the period for its use;
(8) Any matters laid down by the Ministry of Health and Welfare Ordinance supplementary to those provided for in the preceding items.

Application Mutatis Mutandis

Article 60. To quasi-drugs, the provisions of articles 51 to 57 inclusive shall apply, with necessary modifications. In this case, "in article 44, paragraph 1 or 2, or in the items of the preceding article" in article 51 shall read "in the passages of article 59"; "article 42, paragraph 1" in article 52, paragraph 3 shall read "article 42, paragraph 2"; "in article 44, paragraph 1 or 2, or in the preceding three articles" in article 53 shall read "in article 59 or in article 51 which is applicable mutatis mutandis under article 60,"; "the preceding five

articles" in article 55, paragraph 1 shall read "article 59, or article 51 through 54 which is applicable mutatis mutandis under article 60,"; and "article 42, paragraph 1" in article 56, item (3) shall read "article 42, paragraph 2".

Section 4. Handling of Cosmetics

[...]

Section 5. Handling of Medical Devices

[...]

Chapter VIII. Advertising of Drugs, etc.

Exaggerated Advertisement

Article 66. No person shall, explicitly or implicitly, advertise, describe or circulate false or exaggerated statements regarding the name, process, effect, efficacy or efficiency of drugs, quasi-drugs, cosmetics or medical devices.

2. It shall be construed as falling under the preceding paragraph to advertise, describe or circulate such statements as lead to the false impression that a doctor or other person has certified the effect, efficacy or efficiency of drugs, quasi-drugs, cosmetics or medical devices.

3. Statements or diagrams suggesting abortion, or any obscene statements or diagrams, shall not be used in connection with drugs, quasi-drugs, cosmetics or medical devices.

Restriction of Advertising of Drugs for Specific Diseases

Article 67. With regard to the advertisement of the drugs designated by Cabinet Order which are intended for use in the cure of cancer or other specific diseases laid down by Cabinet Order and of which use that is not under the direction of doctors or dentists is most likely to be dangerous, necessary measures for maintaining the appropriate use of such drugs may be provided for by Cabinet Order, such as to restrict the means of advertising to the ordinary people other than the persons concerned with medical and pharmaceutical affairs.

2. The Minister for Health and Welfare shall, in advance, hear the opinion of the Central Pharmaceutical Affairs Council, when he intends to ask for a Cabinet Conference relating to the establishment, alteration or abolition of the regulations of Cabinet Order laying down the specific diseases under the preceding paragraph.

Prohibition of Advertisement of Drugs, etc. before their Approval

Article 68. No person shall advertise the name, process, effect, efficacy or efficiency of those which are either drugs or medical devices provided for in article 14, paragraph 1, and which have not yet been approved in accordance with the provisions of the same paragraph (including cases where it applies mutatis mutandis under article 23).

Chapter IX. Supervision

Spot Inspection, etc.

Article 69. The Minister of Health and Welfare or the Prefectural Governor may, when he deems it essential demand necessary reports in accordance with provisions of the Ministry of Health and Welfare Ordinance from a proprietor of a pharmacy, an establisher of a hospital, clinic or medical institution for domestic animals, a manufacturer, importer or seller of drugs, quasi-drugs, cosmetics or medical devices, or other persons who handle drugs, quasi-drugs, cosmetics or medical devices in the course of business, or cause the competent official to enter a pharmacy, hospital, clinic, medical institution for domestic animals, factory, shop, office or other places where drugs, quasi-drugs, cosmetics or medical devices are handled in the course of business, and to inspect its structure or equipment, or books or other articles, to question the employees or other persons concerned, or to take materials which are suspected of falling under the matters specified in article 70, paragraph 1, only in such minimum quantity as is necessary for examination.

2. The qualified official shall bear the certificate showing his status and present it on demand of the persons concerned, in cases where he enters the places and inspects, questions, or takes away materials in accordance with the provisions of the preceding paragraph.

3. The powers under the preceding paragraph shall not be construed as having been authorized for detection of crime.

Urgent Order

Article 69-2. The Minister for Health and Welfare may, when he considers essential to prevent occurrence or extension of damage to be caused by drugs, quasi-drugs, cosmetics or medical devices, order a manufacturer, seller by importation or seller of drugs, quasi-drugs, cosmetics or medical devices or a proprietor of a pharmacy to suspend its sales of drugs, quasi-drugs, cosmetics or medical devices, or to take other urgent measures so as to prevent occurrence or extension of the damage.

Disposing of Drugs, etc.

Article 70. With regard to the drugs or medical devices which are stored or exhibited contrary to the provisions of article 43, paragraph 1; to the drugs or medical devices which have been sold or given contrary to the provisions of the same paragraph; to the drugs, quasi-drugs, cosmetics or medical devices which are stipulated under article 44, paragraph 3, article 55 (including cases where it applies mutatis mutandis under articles 60, 62 and 64), article 56 (including cases where it applies mutatis mutandis under articles 60 and 62), article 57, paragraph 2 (including cases where it applies mutatis mutandis under articles 60 and 62) or article 65; the drugs, quasi-drugs, cosmetics or medical devices with regard to which the approval for manufacturer or importation was cancelled under article 74-2, paragraph 1; or, to adulterated raw and processed materials, the Minister for Health and Welfare or the Prefectural Governor may order the persons who handle drugs, quasi-drugs, cosmetics or medical devices in the course of business to take steps which suffice to prevent hazards to the public health and sanitation, such as destroying or collecting them, etc.

2. The Minister for Health and Welfare or the Prefectural Governor may, when a person who has received an order in accordance with the provisions of the preceding paragraph, has not obeyed it, or in an urgent necessity, cause the competent official to dispose of, or collect, the materials provided for in the same paragraph or to take other necessary action.

3. In cases where the competent official takes the action pursuant to the preceding paragraph, the provisions of article 69, paragraph 2 shall be applied with necessary modifications.

Order of Test

Article 71. The Minister for Health and Welfare or the Prefectural Governor may, when he deems it necessary, issue to a manufacturer or importer of drugs, quasi-drugs, cosmetics or medical devices, an order that the drugs, quasi-drugs, cosmetics or medical devices, which the manufacturer or importer himself has manufactured or imported, shall be tested by the person designated by the Minister for Health and Welfare or the Prefectural Governor.

Order of Improvement, etc.

Article 72. If the structure or equipment of a pharmacy, factory, business office or shop is not in conformity with the standards laid down by the Ministry of Health and Welfare Ordinance according to the provisions of article 6, paragraph 1, item (1) (including cases where it applies mutatis mutandis under article 26, paragraph 2), article 13, paragraph 2, item (1) (including cases where it applies mutatis mutandis under article 23), article 28, paragraph 3, item (1) or

article 39, paragraph 2, or, if it is likely to cause drugs, quasi-drugs, cosmetics or medical devices to fall under the drugs, etc., which are prescribed under article 56 (including cases where it applies mutatis mutandis under articles 60 and 62) or article 65, the Minister for Health and Welfare or the Prefectural Governor may order the proprietor of the pharmacy, the manufacturer or importer of drugs, quasi-drugs, cosmetics or medical devices, or the seller of drugs or the medical devices specified in accordance with the provisions of article 39, paragraph 1, to improve the structure or equipment, or may prohibit him from using a part or the whole of the facilities concerned until the completion of the improvement.

Article 72-2. The Prefectural Governor may, when the number of pharmacists engaged in practical business relating to pharmaceutical affairs in a pharmacy or a first-class seller's shop has come to be smaller than that laid down by the Ministry of Health and Welfare Ordinance under the provisions of article 6, paragraph 1, item (1)-2 (including cases where it applies mutatis mutandis under article 26, paragraph 2), order the proprietor or the first-class seller to increase the pharmacists up to the required number.

Order of Replacement of the Supervisor, etc.

Article 73. The Minister for Health and Welfare, with respect to the supervisors or responsible technicians in the professional manufacture or import of drugs, quasi-drugs, cosmetics or medical devices; the Prefectural Governor, with respect to the administrators of pharmacies or first-class sellers' shops; may order the manufacturers, importers, proprietors or sellers to replace them, when they have violated this Law or any of the other Laws and ordinances relating to pharmaceutical affairs, or any of the dispositions made in accordance with these Laws and ordinances, or when they are considered unfit for their post.

Administration of the Business of Professionally Selling Drugs by Distribution

Article 74. When an employee of a periodical household distributor has, in connection with the business of distribution, violated this Law, any of the ordinances under this Law or any of the dispositions made in accordance with these, the Prefectural Governor may order the periodical household distributor to keep the employee from the business of distribution for a specified period. In this case, the Governor may, if necessary, also order the employer to suspend his business for a specified period.

Cancellation of License, etc.

Article 74-2. When the Minister for Health and Welfare has considered that the drug, quasi-drug, cosmetic or medical device for which the license for manufacture

or importation has been previously given fell under the following respective items of article 14, paragraph 2, he shall cancel the license.

2. The Minister for Health and Welfare may, when he considers necessary from the viewpoint of health and sanitation, order an alteration of part of the materials which were licensed for manufacture or import for drugs, quasi-drugs, cosmetics or medical devices.

3. Besides those provided for in the preceding two paragraphs, when the person who has obtained the license for manufacturing or importing drugs, quasi-drugs, cosmetics or medical devices comes under the following respective items, the Minister for Health and Welfare may cancel the license or order an alteration of a part of the matters approved:

(1) Where the person, in case the re-examination or re-evaluation shall be made under article 14-2, paragraph 1 or article 14-3, paragraph 1, has not submitted a part or the whole of the necessary materials within the fixed period or has submitted false materials;

(2) Where the person has not manufactured or imported, without any justifiable reason, the drug, quasi-drug, cosmetic or medical device for which the approval for importation was granted, for three years.

4. When the license for manufacture or importation which was given to the manufacturer or seller for importation of drugs, quasi-drugs, cosmetics or medical devices, has been cancelled in accordance with the provisions of paragraph 1 or the preceding paragraph, the license for manufacturing or importing the items concerned shall be deemed to be cancelled.

Cancellation of Licence, etc.

Article 75. The Minister for Health and Welfare, with respect to the manufacturers or the importers of drugs, quasi-drugs, cosmetics or medical devices; the Prefectural Governor, with respect to the proprietors of a pharmacy or the sellers of drugs or the medical devices under article 39, paragraph 1; may cancel their licence or order suspension of the whole or a part of their business for a specified period, when they have violated this Law, any of the other Laws and ordinances relating to pharmaceutical affairs or any of the dispositions made in accordance with these Laws and ordinances, or when they (including the directors, when they are juridical persons, and including further persons who shall be laid down by Cabinet Order pursuant to the provisions of article 28, paragraph 2, when the juridical persons are second-class sellers of drugs or periodical household distributors) come to fall under the provisions of article 6, paragraph 1, item (2) (including cases where it applies mutatis mutandis under article 26, paragraph 2, article 13, paragraph 2, item (2) (including cases where it applies mutatis

mutandis under article 23), article 28, paragraph 3, item (2) or article 30, paragraph 2, item (1)).

2. When the Prefectural Governor has recognized the necessity to apply the legislation provided for in the preceding paragraph with respect to the manufacturer or importer of drugs, quasi-drugs, cosmetics or medical devices, he shall report the result to the Minister for Health and Welfare.

Hearing

Article 76. The Minister for Health and Welfare or the Prefectural Governor shall, when he intends to take action under article 73, article 74-2, paragraph 3 or paragraph 1 of the preceding article, or when he intends to reject the renewal of the license under article 5, paragraph 2, article 12, paragraph 3, article 22, paragraph 3 or article 24, paragraph 2, notify the reason for such disposition in advance to the person against whom the proceedings are to be made (to the supervisor, responsible technician or administrator under article 73, in addition, when the action is to be taken in accordance with the provisions of the same article) and afford him an opportunity to make an explanation on his behalf and to submit evidence in his favor.

Pharmaceutical Affairs Inspectors

Article 77. There shall be Pharmaceutical Affairs Inspectors in the state and prefectures charged with the functions of the competent officials provided for in article 69, paragraph 1 and article 70, paragraph 2.

2. Pharmaceutical Affairs Inspectors shall be appointed from among government to public officials by the Minister for Health and Welfare or the Prefectural Governor.

3. Regulations which are supplementary to the provisions of the preceding two paragraphs and which are necessary to Pharmaceutical Affairs Inspectors shall be laid down by Cabinet Order as required.

Information Supply, etc.

Article 77-2. The manufacturer or importer of drugs or medical devices, or the person who has obtained the license for first-class wholesale professional shall try to provide a proprietor of a pharmacy, establisher of a hospital, clinic or institution for domestic animals, seller of drugs or medical devices, doctor, dentist, pharmacist, veterinary surgeon, or any other person engaged in the medical or pharmaceutical business with any information on efficiency and safety of drugs or medical devices or any other necessary information for a proper use of drugs or medical devices.

2. The proprietor of a pharmacy, establisher of a hospital, clinic or institution for domestic animals, seller of drugs or medical devices, doctor, dentist, pharmacist, veterinary surgeon, or any other person engaged in the medical or

pharmaceutical business shall try to co-operate with a manufacturer, importer of drugs or medical devices or the person who has obtained the license for first-class wholesale professional in collecting information necessary for a proper use of drugs or medical devices.

Chapter X. Miscellaneous Provisions

Fees

Article 78. A person who meets the following items shall pay a fee of the amount fixed by Cabinet Order being considered the actual expense for the examination of the application mentioned in the respective items:

(1) Any person who applies for the license mentioned in article 12, paragraph 1 or article 22, paragraph 1;

(2) Any person who applies for renewal of the license mentioned in article 12, paragraph 3 or article 22, paragraph 3;

(3) Any person who applies for the approval mentioned in article 14 (including cases where it applies mutatis mutandis in article 23);

(4) Any person who applies for the re-examination mentioned in article 14-2 (including cases where it applies mutatis mutandis in article 23).

Terms of License

Article 79. Terms may be added to the license or approval prescribed in this Law.

2. The above-mentioned terms shall be confined to the minimum necessary for the prevention of hazards to the public health and sanitation and shall never be those imposing undue obligations upon the person who receives the license.

Drugs, etc., for Export

Article 80. As to the drugs, quasi-drugs, cosmetics or medical devices for the purpose of exportation, such necessary exceptions, as exemption from application of part of this Law, may be laid down by Cabinet Order.

Clinical Trial

Article 80-2. Any person who intends to ask for carrying out clinical trials (hereinafter referred to as the "clinical trials") for the purpose of collecting data of test of clinical trials out of materials to be submitted under article 14, paragraph 3 (including cases where it applies mutatis mutandis in paragraph 4 of the same article and article 23) shall ask for clinical trials in conformity with the standard prescribed in the Ministry of Health and Welfare Ordinance.

2. Any person who intends to ask for clinical trials shall submit in advance the plan for clinical trials to the Minister for Health and Welfare in accordance with provisions of the Ministry of Health and Welfare Ordinance.

3. The Minister for Health and Welfare may, when he considers necessary for preventing the occurrence or extension of a hazard due to the use of drugs or devices and apparatuses (hereinafter referred to as the "Clinical Trial Drug, etc."), may order the person who intends to ask for clinical trials or has asked for clinical trials to cancel or modify such clinical trials or to take any other necessary step.

Delegation of Power

Article 81. Part of the competence of the Minister for Health and Welfare prescribed in this Law may be delegated to the Prefectural Governor.

Interim Measures

Article 82. When a Cabinet Order or the Ministry of Health and Welfare Ordinance is enacted, altered or abolished in accordance with the provisions of this Law, interim provisions (including those for penalties) necessary for the enactment or the change may, within reasonable limits, be established respectively by Cabinet Order or the Ministry of Health and Welfare Ordinance. This shall also apply when the Minister for Health and Welfare specifies or changes the scope of poisonous or powerful drugs and other matters.

Article 83. [...]

Article 83-2. [...]

Chapter XI. Penal Provisions

Article 84. Any person who comes under any of the following definitions shall be liable to penal servitude not exceeding three years or a fine not exceeding 500,000 yen, or both:

(1) A person who has violated the provisions of article 5, paragraph 1;

(2) A person who has violated the provisions of article 12, paragraph 1;

(3) A person who has violated the provisions of article 18, paragraph 1 (including cases where it applies mutatis mutandis under article 23);

(4) A person who has violated the provisions of article 22, paragraph 1;

(5) A person who has violated the provisions of article 24, paragraph 1;

(6) A person who has violated the provisions of article 29;

(7) A person who has violated the provisions of article 31;

(8) A person who has violated the provisions of article 36;

(9) A person who has violated the provisions of article 43, paragraph 1;

(10) A person who has violated the provisions of article 44, paragraph 3;

(11) A person who has violated the provisions of article 49, paragraph 1;

(12) A person who has violated the provisions of article 55, paragraph 2 (including cases where it applies mutatis mutandis under articles 60, 62 and 64);

(13) A person who has violated the provisions of article 56 (including cases where it applies mutatis mutandis under articles 60 and 62);

(14) A person who has violated the provisions of article 57, paragraph 2 (including cases where it applies mutatis mutandis under articles 60 and 62);

(15) A person who has violated the provisions of article 65.

Article 85. Any person who comes under any of the following definitions shall be liable to penal servitude not exceeding two years or a fine not exceeding 300,000 yen, or both:

(1) A person who has violated the provisions of article 37, paragraph 1;

(2) A person who has violated the provisions of article 47;

(3) A person who has violated the provisions of article 55, paragraph 1 (including cases where it applies mutatis mutandis under articles 60, 62 and 64);

(4) A person who has violated the provisions of article 66, paragraph 1 or 3;

(5) A person who has violated the provisions of article 68;

(6) A person who has violated the order to suspend business, issued in accordance with the provisions of article 75, paragraph 1.

Article 86. Any person who comes under any of the following definitions shall be liable to penal servitude not exceeding one year or a fine not exceeding 260,000 yen, or both:

(1) A person who has violated the provisions of article 8, paragraph 1 or 2 (including cases where it applies mutatis mutandis under article 27);

(2) A person who has violated the provisions of article 15, paragraph 1 or 2 (including cases where it applies mutatis mutandis under article 23);

(3) A person who has violated the provisions of article 17, paragraph 1 (including cases where it applies mutatis mutandis under article 23);

(4) A person who has violated the provisions of article 45;

(5) A person who has violated the provisions of article 46, paragraph 1 or 3;

(6) A person who has violated the provisions of article 48, paragraph 1 or 2;

(7) A person who, contrary to the provisions of article 49, paragraph 2, has not described the matters prescribed in the same paragraph or has described them falsely, or who has violated the provisions of paragraph 3 of the same article;

(8) A person who has violated the provisions of article 58 in regard to poisonous or powerful drugs;

(9) A person who has violated the limitations or other action fixed by Cabinet Order enacted under the provisions of article 67;

(10) A person who has violated the stipulation under the provisions of article 72 to prohibit him from using his facilities;

(11) A person who has violated the order under the provisions of article 73;

(12) A person who has violated the order under the provisions of article 74;

(13) Any person who violated the provision of article 83-2, paragraph 2.

2. Any person who has used to his own advantage, or revealed without reason to persons other than the competent officials, business matters acquired under authority of this Law, shall be liable to penal servitude not exceeding one year or a fine not exceeding 200,000 yen.

Article 87. Any person who comes under any of the following definitions shall be liable to a fine not exceeding 100,000 yen:

(1) A person who has violated the provisions of article 10 (including cases where it applies mutatis mutandis under articles 38 and 40);

(2) A person who has violated the provisions of article 19 (including cases where it applies mutatis mutandis under article 23);

(3) A person who has violated the provisions of article 33, paragraph 1;

(4) A person who has violated the provisions of article 39, paragraph 1;

(5) A person who has neglected to report or made false reports contrary for reporting prescribed in article 69, paragraph 1, or who has refused, hindered or evaded the inspection or the acquisition of samples provided for in the same paragraph, or who has neglected to report without reason or made false reports on the questions provided for in the same paragraph;

(6) A person who violated the order under article 69, paragraph 2;

(7) A person who has violated the order issued in accordance with the provisions of article 70, paragraph 1, or who has refused, hindered or evaded the stipulation of abandonment, etc., under the provisions of paragraph 2 of the same article;

(8) A person who has violated the order under the provisions of article 71;

(9) A person who violated the provision of article 80-2 of paragraph 2.

Article 88. Any person who comes under any of the following definitions shall be liable to a fine not exceeding 50,000 yen:

(1) A person who has violated the provisions of article 7;

(2) A person who has violated the provisions of article 32.

Article 89. If any representative of a juridical person, or any agent, employee or other worker of a juridical person or an individual has perpetrated, in connection with the business of the juridical person or the individual a violation under

article 84, article 85, article 86, paragraph 1 of the preceding two articles, not only the perpetrator shall be punished, but also the juridical person or the individual shall be subject to a fine under the respective articles.

Pharmaceutical Affairs Law
1 October 1979
Supplementary Provisions

Enforcement Date

Article 1. This Law shall come into force as from the date to be laid by Cabinet Order so long as the period between the date of the promulgation and the date of the enforcement does not exceed one year.

Transitional Measures

Article 2. The person who manufactures or imports, at the time of the enforcement of the Law, drugs which were approved under article 12, paragraph 1 or article 22, paragraph 1 and which are recognized in the Japanese Pharmacopoeia (excluding drugs to be designated by the Minister for Health and Welfare under article 14, paragraph 1 of the revised Law) shall apply for the approval under the provision of the above article (including the application mutatis mutandis of article 23) within one year reckoning from the date of the enforcement of this Law.

2. With regard to the renewal of the approval under article 12, paragraph 1 or article 22, paragraph 1 relating to the application performed in accordance with the preceding paragraph by the person in the preceding paragraph, the provision of article 13, paragraph 1 (including its application mutatis mutandis to the revised Law) shall not be applied to until the approval or the non-approval on the concerned application is determined.

3. With regard to the drugs stipulated in paragraph 1 of this article and for which approval sought under the said paragraph, article 68 of the revised Law shall not be applied until the approval or non-approval on the concerned application is determined.

4. If the application for approval under paragraph 1 of this article is not performed within one year reckoning from the date of enforcement of this Law, or if the non-approval on the application has been determined within the said period in case of having performed the application, the previous approval on the manufacture or importation of the concerned drugs shall be deemed to have been withdrawn.

Article 3. With regard to the drugs, quasi-drugs, cosmetics and medical devices which exist at the time of the enforcement of this Law and which have the statement on their package and container that meets the provision of the former Pharmaceutical Affairs Law (hereinafter referred to as the Old Law), such drugs,

quasi-drugs, cosmetics and medical devices shall be deemed to have the statement that meets the provision of the revised Pharmaceutical Affairs Law (hereinafter referred to as the New Law) during two years reckoning from the enforcement of this Law and as far as those have the expression that meets the provision of Old Law.

Article 4. If a package and/or a container to be used for drugs, quasi-drugs, cosmetics and medical devices and/or papers to be attached to those, which have the expression to meet the provision of the Old Law at the time of the enforcement of this Law, are used as the package and/or container for drugs, quasi-drugs, cosmetics and medical devices and/or the papers to be attached to those within the one year period reckoning from the date of the enforcement of this Law, such expression on the package, container and/or papers shall be deemed as to meet the provision under the New Law during two years reckoning from the enforcement of this Law and as far as those packages, containers and/or papers have the expression that meet the provision under Old Law.

Article 5. The disposal or the procedure determined under the provision of the Old Law shall be deemed as the disposal or the procedure performed under the provision of the New Law.

Application of Penal Provisions to former Act

Article 6. The application of the penal provisions to an act enacted before the enforcement of this Law shall be in accordance with the previous provisions.

E/NL.1980/125

CABINET ORDER NO. 210

for Partial Amendment to the Cabinet Order for Designating Narcotic Drugs
8 August 1980

In accordance with the provisions of paragraph 53 under the heading Synthetic Narcotic Drugs in the Annexed List of the Narcotic Control Law (Law No. 14 of 1953), [1] the Cabinet enacts the present Cabinet Order.

The Cabinet Order for Designating Narcotic Drugs (Cabinet Order No. 327 of 1963) [3] shall be partially amended as follows:

Next to item No. 10 of article 2, the following items shall be added:

"11. N-(4-(methoxymethyl)-1-(2-(2-thienyl)ethyl)-4-piperidyl) propionanilide and its salts.

12. trans-2-(dimethylamino)-1-phenyl-3-cyclohexene-1-carboxylic acid ethyl ester and its salts."

Supplementary Provision

The present Cabinet Order shall come into force as from the day when thirty days have elapsed reckoning from the day of its promulgation.

E/NL.1980/126

CABINET ORDER NO. 8

for Partial Amendment to the Cabinet Order
for Designating Narcotic Drugs
16 February 1970

In accordance with the provisions of paragraph 53 under the heading Synthetic Narcotic Drugs in the Annexed List of the Narcotic Control Law (Law No. 14 of 1953), 1/ the Cabinet enacts the present Cabinet Order.

The Cabinet Order for Designating Narcotic Drugs (Cabinet Order No. 327 of 1963) 3/ shall be partially amended as follows:

Next to the item No. 6 of article 2, the following item shall be added:

"7. lysergic acid diethylamide and its salts.".

Supplementary Provision

The present Cabinet Order shall come into force as from the day when ten days have elapsed reckoning from the day of its promulgation.

E/NL.1980/127

CABINET ORDER NO. 130

for Partial Amendment to the Cabinet Order
for Designating Narcotic Drugs
23 May 1970

In accordance with the provisions of paragraph 20 under the heading Narcotic Drugs of Opium-Alkaloid Group in the Annexed List of the Narcotic Control Law (Law No. 14 of 1953), 1/ the Cabinet enacts the present Cabinet Order.

The Cabinet Order for Designating Narcotic Drugs (Cabinet Order No. 327 of 1963) 3/ shall be partially amended as follows:

In article 1, "the following substances" shall be substituted for "dihydrocodeinone-6-carboxymethyloxime and its salts" and "narcotic drugs", for "a narcotic drug" and next to that, the following items shall be added:

"1. dihydrocodeinone-6-carboxymethyloxime and its salts,

2. 14-hydroxydihydro-6β-thebainol 4-methyl ether and its salts."

Supplementary Provision

The present Cabinet Order shall come into force as from the day when thirty days have elapsed reckoning from the day of its promulgation.

Notes

1/ E/NL.1953/4-5.

2/ E/NL.1949/56, E/NL.1950/108, E/NL.1952/16, E/NL.1954/145, E/NL.1964/73, E/NL.1979/16.

3/ E/NL.1964/75.