



UNITED NATIONS

LAWS AND REGULATIONS

PROMULGATED TO GIVE EFFECT TO THE PROVISIONS OF THE
CONVENTION OF 13 JULY 1931 FOR LIMITING THE MANUFACTURE
AND REGULATING THE DISTRIBUTION OF NARCOTIC DRUGS, AS
AMENDED BY THE PROTOCOL OF 11 DECEMBER 1946

JAPAN

COMMUNICATED BY THE GOVERNMENT OF
JAPAN

NOTE BY THE SECRETARY GENERAL

In accordance with Article 21 of the Convention of 13 July 1931 for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs, as amended by the Protocol of 11 December 1946, the Secretary-General has the honour to communicate the following legislative texts.

New York, 1953

Ministry of Welfare Ordinance No. 38

October 25, 1949

For the enforcement of the Ministry of Welfare Establishment Law (Law No. 151 of 1949) the Regulation governing the Organization of the Ministry of Welfare shall be fixed as follows:

Minister of Welfare

HAYASHI Joji

Regulation governing the Organization of
the Ministry of Welfare

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Supplementary Provisions

Chapter I General Provisions

(Purpose of this Ministerial Ordinance)

Article 1. The purpose of this Ministerial Ordinance is to define the details of the internal organization, the scope of responsibilities and others of the Ministry of Welfare and other necessary matters in order to enforce the Ministry of Welfare Establishment Law (Law No. 151 of 1949).

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Part 3 Medical Affairs Bureau

(Deputy Chief of Bureau)

Article 25. The Deputy Chief of Bureau shall assist the Chief and conduct the affairs of the Bureau.

(Sections in the Medical Affairs Bureau)

Article 26. The Medical Affairs Bureau shall have the following eight sections:

- Medical Affairs Section
- Dental Hygiene Section
- Nursing Section
- Liquidation Section
- Administrative Section
- National Hospital Section
- National Sanatorium Section
- Supply Section

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Part 4 Pharmaceutical and Supply Bureau

(Sections in Pharmaceutical and Supply Bureau)

Article 35. The Pharmaceutical and Supply Bureau shall have the following six sections:

Enterprise Section
Pharmaceutical Affairs Section
Drug Manufacturing Section
Inspection Section
Biologicals Section
Narcotic Section

(Function of the Enterprise Section)

Article 36. The Enterprise Section shall take charge of the following affairs:

- (1) Planning of fundamental policy, coordination and adjustment, and statistical investigation concerning production, trade, etc. of drugs, medical instruments and other sanitary goods;
- (2) Matters regarding financing and improvement concerning enterprises of drugs, medical instruments and other sanitary goods;
- (3) Matters relating to enforcement of the Law concerning Emergency Measures for the Account of Companies (Law No. 7 of 1946), the Enterprise Reconstruction and Reorganization Law (Law No. 40 of 1946) and the Smaller Enterprise, etc. Cooperative Association Law (Law No. 181 of 1949) for enterprises of drugs, medical instruments and other sanitary goods;
- (4) Matters relating to export and import of drugs, medical instruments and other sanitary goods and enforcement of the Law concerning Control of Export Commodities (Law No. 153 of 1948) for them;
- (5) Matters relating to registration of the business of import and sale of drugs, medical instruments and cosmetics;
- (6) Matters relating to distribution of drugs (excluding biological preparations), medical instruments and other sanitary goods;
- (7) Matters relating to economic affairs with regard to drugs, medical instruments and other sanitary goods not in charge of other sections.

(Function of the Pharmaceutical Affairs Section)

Article 37. The Pharmaceutical Affairs Section shall take charge of the following affairs:

- (1) Matters relating to examination, licence and registration of pharmacists;
- (2) Matters relating to the National Committee of Pharmacy;
- (3) Matters relating to enforcement of the Pharmaceutical Affairs Law (Law No. 197 of 1948) (excluding affairs not in charge of the other sections of the Bureau), supervision of poisonous and powerful drugs and other laws and ordinances;

- (4) Technical guidance and supervision with regard to manufacture of the sanitary materials, medical instruments and other sanitary goods (excluding drugs; hereinafter the same);
- (5) To register and license the business of manufacture of the sanitary materials, medical instruments and other sanitary goods;
- (6) Matters relating to standardization of the sanitary materials, medical instruments and other sanitary goods, and materials necessary for production of them;
- (7) Matters relating to registration of manufacturing business of cosmetics;
- (8) Matters relating to the National Hygienic Laboratory;
- (9) Affairs not in charge of other sections of the Bureau.

(Function of the Drug Manufacturing Section)

Article 38. The Drug Manufacturing Section shall take charge of the following affairs:

- (1) Technical guidance and supervision with regard to the production of drugs;
- (2) To register and license the manufacturing business of drugs;
- (3) Matters relating to standardization of drugs and materials necessary for production of them;
- (4) Matters relating to cultivation and production of medical plants.

(Function of the Inspection Section)

Article 39. The Inspection Section shall take charge of the following affairs:

- (1) Matters relating to supervision and inspection of adulterated drugs, devices and cosmetics and misbranded drugs, devices and cosmetics;
- (2) Matters relating to supervision for advertisement of drugs, medical instruments and cosmetics;
- (3) Matters relating to assay of drugs;
- (4) Matters relating to guidance for pharmaceutical inspectors.

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(Function of the Narcotic Section)

Article 41. The Narcotic Section shall take charge of the following affairs:

- (1) Matters relating to licence and registration of dealers in narcotics and Cannabis Sativa L;
- (2) Matters relating to supervision of narcotics and Cannabis Sativa L;

- (3) Matters relating to statistic investigation into narcotic and Cannabis Sativa L;
- (4) Matters relating to direction and supervision of narcotic agents;
- (5) In addition to the affairs listed in each of the preceding items, matters relating to narcotics.

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E/NL.1953/5

I hereby promulgate the Ministry of Welfare Establishment Law.

Signed: HIROHITO, Seal of the Emperor

This thirty-first day of the month of the twenty-fourth year of Showa
(May 31, 1949)

Prime Minister
YOSHIDA Shigeru

Law No. 151

The Ministry of Welfare Establishment Law

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Supplementary Provisions

Chapter I General Provisions

(Purpose of this Law)

Article 1. The purpose of this Law is to define clearly the scope of responsibilities and the powers of the Ministry of Welfare and to provide an organization fit for the efficient conduct of the administrative affairs and enterprises under the jurisdiction of the Ministry.
(Definitions)

Article 3. The Ministry of Welfare is hereby established under the provision of Article 3, paragraph 2 of the National Government Organization Law (Law No. 120 of 1948).

2. The Ministry of Welfare shall be headed by the Minister of Welfare.
(Mission of the Ministry of Welfare)

Article 4. The Ministry of Welfare shall be the administrative organ responsible for the integrated administration of the following administrative affairs and enterprises of the National Government, aiming at the elevation and promotion of social welfare, social security and public health as its mission:

(2) Pharmaceutical affairs and control of narcotics and Cannabis Sativa L;

Article 5. For the purpose of carrying out the responsibilities provided for in this Law of the Ministry shall have the powers as listed below. Such powers shall, however, be exercised in accordance with laws (including order issued thereunder):

- (44) To execute the registration of the manufacturers, importers and sellers of medical drugs, devices or cosmetics and to order the cancellation of registration or the suspension of professional practices;
- (45) To prepare and issue official compendium according to the recommendation submitted by the National committee of Pharmacy;
- (46) To permit production item by item, when manufacturers of medical drugs intend to manufacture medical drugs which are not included in official compendium or when manufacturers of devices intend to manufacture devices;
- (47) To make allocation of medical drugs, medical devices, other sanitary articles and their raw materials;
- (48) To direct pharmaceutical inspectors to enter and examine as required and direct them, in case of necessity, to take away articles for examination;
- (49) To license and register dealers in narcotics and Cannabis Sativa L, to

cancel their licence and delete their registration and to designate, supervise and direct narcotic agents;

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(63) In addition to those listed in the preceding items, such powers as are placed under the Ministry of Welfare by laws (including orders issued thereunder).

Chapter II The Ministry Proper

Section I Internal Subdivisions

(Internal Subdivisions)

Article 6. The Ministry Proper shall have the Minister's Secretariat and the following six Bureaux:

- Public Sanitation Bureau
- Medical Affairs Bureau
- Pharmaceutical and Supply Bureau
- Social Affairs Bureau
- Children's Bureau
- Insurance Bureau

Article 11. The Pharmaceutical and Supply Bureau shall take charge of the following affairs:

- (1) Guidance, encouragement, supervision and coordination of business in regard to production, distribution, sale, etc. of medical drugs, medical devices and other sanitary goods;
- (2) Guidance and supervision over the status and professional practices of pharmacists;
- (3) Matters concerning manufacturers, importers and sellers of medical drugs, devices or cosmetics;
- (4) Control over false or misbranded medical drugs, devices and cosmetics stipulated in the Pharmaceutical Affairs Law (Law No. 197 of 1948);
- (5) Guidance in examination, assay and research of medical drugs, devices and cosmetics;
- (6) Matters concerning products, anti-biotic preparations and specified medical drugs;
- (7) Control of poisonous and powerful drugs;
- (8) Control and supervision over all activities concerning narcotics and Cannabis Sativa L and disposition of such articles;
- (9) In addition to the affairs listed in the preceding items, enforcement of laws concerning pharmaceutical affairs, and control of narcotics and Cannabis Sativa L.

Article 29. The organs entered in the left column of the following table shall be those established as auxiliary organs of the Ministry proper, the purpose of their establishment being given in the right column.

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The Research Council on Medical
and Pharmaceutical Systems

To make research and deliberation, in response to the request of the Minister of Welfare, on important matters for improvement of medical and pharmaceutical systems.

The National Committee of Pharmacy

To submit an original draft to the Minister of Welfare concerning revision of official compendiums or their supplements, to conduct national examination for pharmacists, to make recommendation to the Minister of Welfare concerning new medical drugs and other pharmaceutical affairs and to conduct reexamination for cancellation of license or registration, or suspension of professional practices.

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2. The following Imperial Ordinances shall be abolished. However unless otherwise provided for by laws (including orders issued thereunder), the organs existing heretofore and personnel thereof shall become the corresponding organs and personnel under this Law and shall retain respective identities:

Regulations Governing the Organization of Ministry of Welfare

(Imperial Ordinance No. 7 of 1938)

Minister of Welfare

HAYASHI Joji

Prime Minister

YOSHIDA Shigeru