SYMPOSIUM ON DRUG EVALUATION AND LICENCING

EM/SYM.DRG.EVL.LIC./9 JAPAN

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Country Statement of Japan

by

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1. PHARMACEUTICAL LEGISLATION

1) Historical Background

The regulations on handling of drugs in Japan date back to the 19th century. The first regulation was the Medical Service Order (promulgated in 1874) which was not applicable to those drugs produced on the industrial basis but aimed at clarifying the principle of dispensing. The second was the Medicine Order (1889), which kept pace with the first order. The third was the Pharmacists Law (1925). This law was developed into the old Pharmaceutical Affairs Law (1943) which was further revised in 1948 to include new provisions related to cosmetics and medical devices. In 1960, the present Pharmaceutical Affairs Law was established.

2) Present Legislation

The Pharmaceutical Affairs Law (the Law) is a health legislation with the purpose of controlling and regulating matters relating to drugs, quasi-drugs, cosmetics and medical devices. Drugs and medical devices controlled and regulated by the Law are those intended for use mainly in man or other animals, and quasi-drugs and cosmetics intended for use mainly in man.

In the Law, there are major provisions on: Pharmaceutical Affairs Council; pharmacy; manufacture (importation) of drugs, quasi-drugs, cosmetics and medical devices; sellers of drugs and medical devices; the Japanese Pharmacopoeia; quality standards of drugs etc.; national assay of drugs; distribution of drugs; labeling of drugs, quasi-drugs, cosmetics and medical devices; advertising of drugs.

The Law is enforced in accordance with the detailed rules in Government or Ministerial Ordinance or notification.

The above products intended for use in man are controlled by MHW and those for use in animals by the Ministry of Agriculture and Forestry, in cooperation with the prefectural governments.

2. ORGANIZATION AND FUNCTION OF THE PHARMACEUTICAL AFFAIRS BUREAU

1) Pharmaceutical Administration by MHW

In order to improve and promote its three major services - social welfare, social security and public health - the Ministry of Health and Welfare (MHW) maintains far-ranging activities which are broadly divided into the following lines: (1) preservation of health of the people; (2) control of drugs, narcotics, cannabis (marihuana) and other related products; (3) social services, relief of disasters, and protection and guidance in the life of the people; (4) promotion of welfare of mothers and children; (5) services for social insurance program; (6) services for national pension schemes; (7) population problems. MHW also continues services for the management of the problems resulting from World War II, such as repatriates relief.

The administrative organization of MHW consists of intra- and extra-ministerial offices. The former comprises Minister's Secretariat and nine Bureaus, and the latter, the Social Insurance Agency, affiliated institutions, national hospitals and local branch offices (Chart 1).

Some 55,000 full-time personnel were registered in the above organization of MHW as of March 31, 1976, including 2,170 working at the intraministerial offices. The Pharmaceutical Affairs Bureau (PAB), which is in charge of the pharmaceutical administration, has seven Divisions staffed with a total of 155 officials consisting

of two M.D.'s, 56 pharmacists and 97 administrative officers (Chart 2).

PAB is headed by Director-General who wi . background of jurisprudence has senior administrative power. He is assisted by Deputy Director-General (Councillor) who is required to have a scientific background (incumbent Deputy Director-General holds a Ph. D. degree). The man at the post of Deputy Director-General is responsible for the important technical matters regarding research and drug control laboratories as well as technological development, in addition to any other PAB-dealt technical matter. Brief description of the seven PAB Divisions.

Chart 1. Organization of the Ministry of Health and Welfare (MHW)

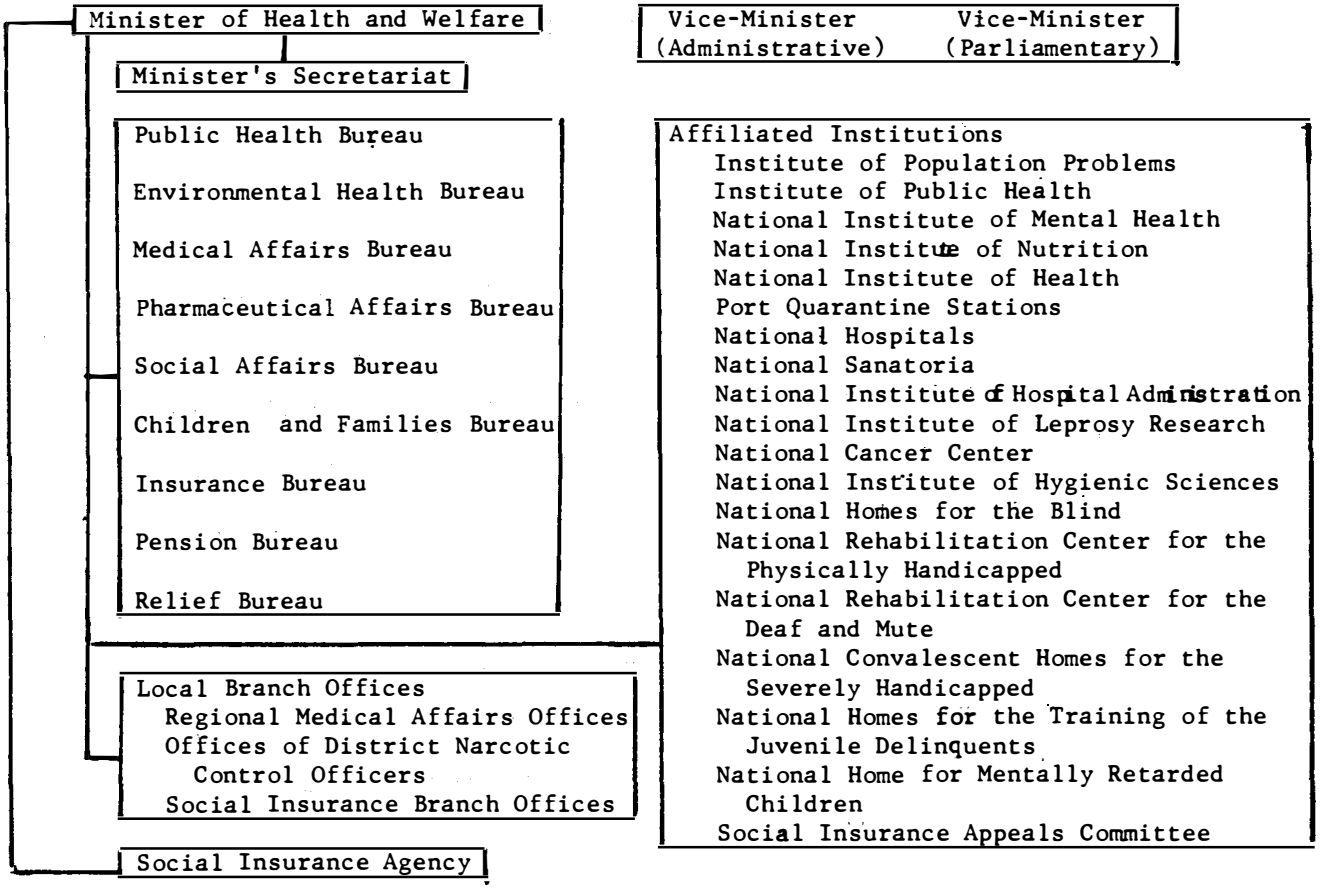
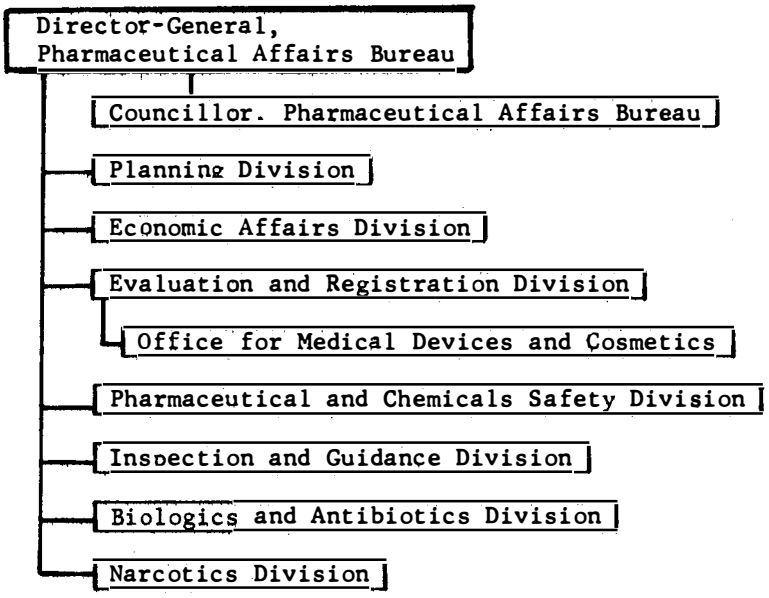


Chart 2. Seven Divisions of the Pharmaceutical Affairs Bureau (PAB)



2) Planning Division

The Planning Division of PAB is headed by Director who is a senior legal and administrative officer. The division is to make overall planning and coordination on all matters of pharmaceutical administration under the PAB jurisdiction, and to execute the matters regarding the National Institute of Hygienic Sciences and the Central Pharmaceutical Affairs Council which has the advisory capacity to the Minister for Health and Welfare.

The division also executes the work necessary for the implementation of the Pharmaceutical Affairs Law which controls drugs, quasi-drugs, cosmetics and medical devices, and for the Pharmacists Law which rules the responsibility and function of pharmacists' license. The scope of the activity of the division was extended recently

to a new function for the establishment of a relief system for sufferers from adverse drug reactions.

3) Economic Affairs Division

The Economic Affairs Division is headed by Director who is a senior legal and administrative officer. The division is in the position to make planning, survey and adjustment of production and trade of drugs, quasi-drugs, medical devices and sanitary goods; and to extend financial aid to certain small manufacturers and traders of the above products. It also gives proper guidance on the promotion and development of smaller drug enterprises, and makes proper adjustment and coordination of foreign enterprises which come into Japan to gain footing taking advantage of the full liberalization of capital transaction effective from May 1, 1975. Further, the division is responsible for ensuring stable supply and distribution of drugs as well as for proper adjustment of drug pricing particularly for those to be used for health insurance scheme.

4) Evaluation and Registration Division

The Evaluation and Registration Division is led by a senior pharmaceutical officer called Director who is a pharmacist. The division is responsible for giving technical guidance and supervision over the manufacture of drugs (excluding biological and antibiotic preparations), quasi-drugs, cosmetics and medical devices. It also manages licensing and permission of manufacture, importation or sale of the above products. Giving guidance on the cultivation and production of medicinal plants is another activity of the division. Licensing or permission of the cosmetics and medical devices is handled at the Office for Medical Devices and Cosmetics which has been created in

the division.

5) Pharmaceuticals and Chemicals Safety Division

The Pharmaceuticals and Chemicals Safety Division is headed by a senior pharmaceutical officer called Director who is a pharmacist. The division is responsible for establishing the Japanese Pharmacopoeia which defines and fixes the standards of drugs for frequent use, and prepare the standards of drugs (excluding those of biological and antibiotic preparations), quasi-drugs, cosmetics and medical devices. It investigates the indications, effectiveness, quality and safety of these drugs. It is engaged in the control not only of poisonous and deleterious substances from the viewpoint of health in accordance with the poisonous and Deleterious Substances Control Law (1950), but of harmful chemical substances with subtle properties from the viewpoint of prevention of environmental pollution. It promotes domestic and international drug monitoring for ensuring safety of drugs.

To work out the program for drug efficacy review for ensuring safety and effectiveness of drugs is a function of this division.

6) Inspection and Guidance Division

The Inspection and Guidance Division is headed by Director who is a senior legal and administrative officer. The division is responsible for carrying out proper guidance and control over the misbranded or adulterated drugs, quasi-drugs, cosmetics and medical devices, and their exaggerated advertising. It also directs testing of drugs and national assay of drugs, and makes inspection of drugs and poisonous and deleterious substances. Another task of the division which has been newly added is to supervise drug manufacturers in accordance with Good Manufacturing Practices

enforced in April 1976 for ensuring good quality of drugs.

7) Biologics and Antibiotics Division

The Biologics and Antibiotics Division is headed by Director who is a medical officer having an M.D. degree.

The division is responsible for giving a technical guidance and supervision over the production of biologic and antibiotic preparations, while it handles licensing and permission of manufacture, importation or sale of these products. It manages service for the testing and assay of the above products as well as for establishing their minimum requirements and standards. Ensuring stable supply of those products, particularly preventive vaccines, is also the important function of the division. In addition, the division maintains services under the Bleeding and Blood Donor Supply Service Control Law (1956) for the prevention of risks due to bleeding as well as for the protection of the health of the blood donors in the scheme for blood collection and supply.

8) Narcotics Division

The Narcotics Division is headed by Director who is a senior pharmaceutical officer. Its activity is to regulate and control import, manufacture, transfer, possession, etc. of narcotics, cannabis (marihuana) and opium in conformity with Narcotic Control Law (1953), Cannabis Control Law (1953), and Opium Law (1954). The division also makes statistical investigation of these products. In order to regulate import, export and possession of stimulants (amphetamines) for the prevention of health risks due to their abuse, the division undertakes services required by Stimulants Control Law (1951).