

CHAPTER 1

ORGANIZATION AND FUNCTION OF THE MINISTRY OF HEALTH, LABOUR AND WELFARE

The Ministry of Health, Labour, and Welfare (MHLW) (Koseirodoshō in Japanese) was established by a merger of the Ministry of Health and Welfare (MHW) and the Ministry of Labour, on January 6, 2001 as part of the government program for reorganizing government ministries. The MHLW, which was originally established in 1938, has been in charge of the improvement and promotion of social welfare, social security and public health, and the new organization has the same tasks.

It consists of the ministry proper, affiliated institutions, councils, local branches, and external organizations. The ministry proper includes the Minister's Secretariat, 11 bureaus, Director-General for Human Resources Development, and the Director-General for Policy Planning and Evaluation.

Councils include the Social Insurance Council, Pharmaceutical Affairs and Food Sanitation Council (PAFSC), and other organizations. Affiliated institutions include the National Institute of Health Sciences and the National Institute of Infectious Diseases. Local branches are regional bureaus of health and welfare and prefectural labor bureaus. The external organization is the Central Labor Relations Commission (**Fig. 1** Organization of Ministry of Health, Labour, and Welfare (Health-related organizations only)).

The MHLW is in charge of pharmaceutical regulatory affairs in Japan (veterinary drugs are under the jurisdiction of the Ministry of Agriculture, Forestry

and Fisheries), and the Pharmaceutical Safety and Environmental Health Bureau (PSEHB) undertakes main duties and functions of the Ministry; it handles clinical studies, approval reviews and post-marketing safety measures, i.e., approvals and licensing. The Health Policy Bureau handles promotion of R&D, production, distribution policies, and drug pricing, i.e., functions related to pharmaceutical companies. The Pharmaceuticals and Medical Devices Evaluation Center (Evaluation Center) in the National Institute of Health Sciences was established to strengthen approval reviews and to introduce a specific system for reviewing tasks for drugs, etc. on July 1, 1997. To confirm the reliability of reviews and application data, the Organization for Pharmaceutical Safety and Research (OPSR) conducted compliance reviews on application data. The OPSR also began offering consultation services on protocols at the clinical trial stage.

This was followed by the integration of the aforementioned Evaluation Center, OPSR, and part of the Medical Devices Center on April 1, 2004 to form a new independent administrative organization, the Pharmaceutical and Medical Devices Agency (PMDA). The role of the PMDA is to provide consultations concerning the clinical trials of new drugs and medical devices, and to conduct approval reviews and surveys of the reliability of application data.

Following this reorganization, the PSEHB and PMDA handle a wide range of activities from clinical studies to approval reviews, reviews throughout post-marketing stage, and pharmaceutical safety measures. (**Fig. 2** Organization of Pharmaceutical Safety and Environmental Health Bureau (PSEHB) and Pharmaceuticals and Medical Devices Agency (PMDA)).

1. PHARMACEUTICAL SAFETY AND ENVIRONMENTAL HEALTH BUREAU (PSEHB)

The Pharmaceutical Safety and Environmental Health Bureau (PSEHB) (except for the Department of Environmental Health and Food Safety) is one of the 11 bureaus of the MHLW. In addition to polices to assure the efficacy and safety of drugs, quasi-drugs, cosmetics, medical devices and cellular and tissue-based products, and policies for safety in medical institutions, the PFSB tackles problems directly related to the lives and health of the general public including policies related to blood supplies and blood products, and narcotics and stimulant drugs. This new bureau consists of a Secretary-General, Councilor in charge of drugs, five divisions, and one office* (Fig. 2 Organization of Pharmaceutical Safety and Environmental Health Bureau (PSEHB) and Pharmaceuticals and Medical Devices Agency (PMDA)). These divisions have the functions described below.

1.1 General Affairs Division

- 1) Overall planning and coordinating activities for the Pharmaceutical Safety and Environmental Health Bureau
- 2) Matters related to pharmacists
- 3) Supervision of the PMDA (excluding areas under the control of the Pharmaceutical Evaluation Division, Medical Device Evaluation Division, Pharmaceutical Safety Division, and Compliance and Narcotics Division)
- 4) Issues related to PSEHB not governed by other divisions

• Office of Drug Induced Damages

- 1) The relief systems operated by the PMDA for damage caused by adverse drug reactions including biological products-induced infection
- 2) Measures for handling health injury caused by

drugs, quasi-drugs, cosmetics, and medical devices (drugs, etc.)

• Office of International Regulatory Affairs

Overall coordinating activities for international affairs under the control of the Pharmaceutical Safety and Environmental Health Bureau.

1.2 Pharmaceutical Evaluation Division

- 1) Technical guidance and supervision concerning the production of drugs, quasi-drugs, cosmetics, and medical devices (drugs, etc.)
- 2) Manufacturing/marketing business licenses and approvals to manufacture and market drugs, etc.
- 3) Reexamination and reevaluation of drugs
- 4) Issues related to the Japanese Pharmacopoeia (JP)
- 5) Standards and specific precautions concerning drugs, etc.
- 6) Designation of orphan drugs
- 7) Work related to the PMDA (limited to approval to manufacture and market drugs, medical devices, etc.)

1.3 Medical Device Evaluation Division

- 1) Technical guidance and supervision concerning the production of medical devices, extracorporeal diagnostic medicines and regenerative medicine products
- 2) Manufacturing business licenses for regenerative medicine products and manufacturing business registrations for medical devices and extracorporeal diagnostic medicines, as well as approvals to manufacture and market medical devices, extracorporeal diagnostic medicines and regenerative medicine products

- 3) Reexamination and reevaluation of regenerative medicine products
- 4) Evaluation of treatment outcomes of medical devices and extracorporeal diagnostic medicines
- 5) Business license and approvals to market, loan, or repair medical devices, or to market regenerative medicine products (excluding areas under the control of Health Policy Bureau [HPB])
- 6) Standards and specific precautions concerning medical devices, extracorporeal diagnostic medicines and regenerative medicine products
- 7) Designation of orphan medical devices and orphan regenerative medicine products
- 8) Work related to PMDA (limited to work related to medical devices, extracorporeal diagnostic medicines and regenerative medicine products)
- 9) Control and dissemination of industrial standards for medical devices, other hygiene products, and regenerative medicine products, and other industrial standards

• **Office of Chemical Safety**

- 1) Enforcement of laws pertaining to poisonous and deleterious substances (excluding areas under the control of the Compliance and Narcotics Division)
- 2) Regulations related to evaluation of chemicals that might cause damage to the health of humans, animals, and plants from the standpoint of environment and public health, as well as regulations related to manufacturing, importing, using, and other handling of such chemicals
- 3) Control of household products containing harmful substances
- 4) Establishment of tolerable daily intake (TDI) of dioxins and related compounds

1.4 Pharmaceutical Safety Division

- 1) Planning and drafting of policies to assure the safety of pharmaceuticals and medical devices, etc.
- 2) Manufacturing/marketing business licenses to manufacture and market pharmaceuticals and medical devices, etc.
- 3) Review of the safety of pharmaceuticals and medical devices, etc. (excluding items handed by the Pharmaceutical Evaluation Division and Medical Device Evaluation Division)
- 4) Guidance and advice concerning preparation and storage of records of biological products and designated medical devices
- 5) Work related to the PMDA (limited to matters related to improve safety of pharmaceuticals and medical devices, etc. and excluding items handed by the Pharmaceutical Evaluation Division and Medical Device Evaluation Division)

1.5 Compliance and Narcotics Division

- 1) Control of poor quality or falsely labeled pharmaceuticals and medical devices, etc
- 2) Guidance and supervision related to advertising of pharmaceuticals and medical devices, etc
- 3) Testing and government certification of pharmaceuticals and medical devices, etc
- 4) Matters related to pharmaceutical inspectors, etc.
- 5) Control of narcotics and stimulants, etc
- 6) Duties of narcotics control officers and staff
- 7) Matters related to international cooperation concerning narcotics and stimulants, etc
- 8) Work related to the PMDA (limited to matters related to on-site inspection, etc. by the PMDA)

1.6 Blood and Blood Products Division

- 1) Regulation of blood collection services
- 2) Promotion of blood donation
- 3) Assurance of proper use of blood products and assurance of stable supply of blood products
- 4) Maintenance of stable supply of blood products
- 5) Promotion, improvement, and coordination concerning production and marketing of biological products (excluding items handed by the Health Service Bureau)

2. HEALTH POLICY BUREAU

With the aging of society, changes in disease structure, and increasing demands from the public for better quality health care, the Health Policy Bureau is drafting policies aimed at achieving a high quality, efficient health care supply system for the 21st century.

The Economic Affairs Division and the Research and Development Division, the two divisions most closely related to the pharmaceutical industry, have the functions described below.

2.1 Economic Affairs Division

- 1) Promotion, improvement and coordination related to production, marketing and consumption of drugs, quasi-drugs, medical devices, sanitary materials, and other hygiene-related products (drugs, etc.) (excluding items handed by PSEHB and the Research and Development Division)
- 2) Advancement, improvement, and coordination of manufacturing of drugs, etc. (excluding items handed by the Research and Development Division)
- 3) Matters related to foreign trade (import and export) of drugs, etc.
- 4) Matters related to outsourcing the work of managers of hospitals, clinics, and maternity

clinics (hospitals, etc.)

- 5) Guidance on enterprises related to the improvement of the management of hospitals, etc. (excluding those governed by the national and local governments)
- 6) Issues related to hygiene inspection offices. This Division includes the Office of Direction for Health-Related Services with the following functions.

• Office of Medical Device Policy

- 1) Promotion, improvement and coordination of manufacturing, marketing and consuming medical devices and other sanitary products (other than those handled by PSEHB and the Research and Development Division)
- 2) Promotion, improvement and coordination of business of manufacturing, manufacturing/marketing, selling, leasing and repairing medical devices and other sanitary products (other than those handled by the Research and Development Division)
- 3) Foreign trades (import and export) of medical devices and other sanitary products
- 4) Installation and use of medical devices (other than medical, dental, and sanitary supplies) (other than those handled by the Guidance of Medical Service Division)

2.2 Research and Development Division

- 1) Matters related to research and development of drugs, etc. (excluding items handed by PSEHB)
- 2) Matters related to the cultivation and production of medicinal plants
- 3) Promotion, improvement, and coordination of manufacturing business of drugs, etc. (limited to items related to research and development)
- 4) Matters related to installation and use of medical devices (excluding medical supplies, dental supplies, and hygiene-related products)

(excluding items handled by the Guidance of Medical Service Division of the HPB)

- 5) Matters related to the improvement of health care information-processing and management system
- 6) Matters related to the evaluation of medical technology (excluding those handled by other bureaus of MHLW)

- **Office of Clinical Trial Promotion**

Promotion of clinical trials specified in Article 2, Paragraph 16 of the Pharmaceutical Affairs Law (Law No. 145 issued in 1960) (other than those handled by PSEHB)

3. NATIONAL INSTITUTE OF HEALTH SCIENCES

In July 1997, the name of the former National Institute of Hygienic Sciences was changed to the National Institute of Health Sciences. In addition to its long-standing work related to testing and research on drugs, quasi-drugs, cosmetics, medical devices, foods, poisonous and deleterious substances, the Institute supervised the Pharmaceuticals and Medical Devices Evaluation Center to undertake the reviews required for approval to manufacture or import drugs, quasi-drugs, cosmetics and medical devices, as well as the reexamination and the reevaluation of drugs, and medical devices. Thereafter, the Evaluation Center was incorporated into the Pharmaceuticals and Medical Devices Agency (PMDA) in April 2004.

4. PHARMACEUTICALS AND MEDICAL DEVICES AGENCY, AN INDEPENDENT ADMINISTRATIVE ORGANIZATION

In accordance with the special corporation rationalization plan passed by the Cabinet in December 2001, and enactment of the Pharmaceuticals and Medical Devices Agency Law in December 2002, the PMDA (KIKO) was established

in April 2004, through the integration of the Pharmaceutical and Medical Devices Evaluation Center in the National Institute of Health Sciences, the OPSR, and part of the Medical Devices Center, and the PMDA started handling all consultation and review work from the preclinical stage to approvals and post-marketing surveillance.

The work of the PMDA can be divided into three main categories: ADR relief work, review work and safety measures.

The PMDA consists of 28 offices, 4 groups, and the Kansai and Hokuriku branches as shown in Fig. 2, and, the duties are indicated below.

The PMDA is currently working to achieve goals under the Fourth Medium Range Plan (FY2019-FY2023), including maintaining the world's fastest review period while improving the quality of the work, seeking appropriate implementation of the SAKIGAKE Designation System and the Conditional Accelerated Approval System and improvement of the Regulatory Science Strategy Consultations and so on, and performing appropriate review and consultation in accordance with domestic and overseas guidelines in the review of new drugs.

1) Drug ADR Relief Work

- Provision of medical benefits to cover healthcare expenses, disability pensions, and survivors pensions for individuals suffering disease or disability due to adverse drug reactions or bioderived infections
- Provision of medical allowances for treatment of myelo-optico-neuropathy (SMON) patients and for HIV carriers and AIDS patients
- Surveys on damage caused by drugs and research on treatment, etc. of adverse drug reactions as health and welfare work
- Provision of medical allowances based on the Special Measures Law for Provision of Medical Allowances for Treatment of

Hepatitis C Patients Infected by Specified Fibrinogen Concentrates or Specified Coagulation Factor XI Concentrates.

2) Review Related Work

- Approval reviews of new drugs and medical devices based on the Pharmaceutical and Medical Device Act
- Guidance and advice related to clinical trials
- Reviews of GLP and GCP compliance of attached data of approval applications and reexamination and reevaluation applications
- Reviews of manufacturing facilities, processes, and quality control based on GMP, QMS, etc.
- Confirmation of reexaminations and reevaluations based on the Pharmaceutical and Medical Device Act

3) Safety Measures

- Collection, analysis, and dissemination of information related to the quality, efficacy, and safety of drugs and medical devices
- Consultations with consumers and other parties concerning drugs and medical devices
- Guidance and advice for manufacturers, etc. to improve the safety of drugs and medical devices

The work of the review and safety offices is detailed below.

4.1 Office of Review Administration

This office handles tasks related to coordination of the matters related to review works, etc., commissioning of the members of expert meetings, and revision of charges, as well as tasks related to the receipt and management of various marketing approval application forms and notifications, etc.

4.2 Office of Review Management

This office handles tasks related to the planning and drafting of review works, etc., management of the protocol and reports of adverse reactions observed in clinical trials, and receipt and processing of clinical trial consultations on new drugs. The office also handles consultation on regulatory science strategy on drugs and medical devices mainly for universities, research institutes, and venture companies.

This office also handles tasks related to the preparation of draft Japanese Pharmacopoeia, standards on drugs, master file systems, and generic names (JAN).

4.3 Office of New Drug I

This office confirms clinical trial notifications and adverse drug reactions and conducts reviews required for approval, reexaminations, and reevaluation of gastrointestinal drugs, dermatologic drugs, hormone preparations, and metabolic disease drugs (e.g., anti-diabetic, osteoporosis, gout, and congenital metabolic disorder drugs)

4.4 Office of New Drug II

This office confirms clinical trial notifications and adverse drug reactions and conducts reviews required for approval, reexaminations and reevaluation of new cardiovascular drugs, drugs to treat Parkinson's disease, drugs to treat Alzheimer's disease, urogenital and anal drugs, combination drugs, radiopharmaceuticals, and contrast media.

4.5 Office of New Drug III

This office confirms clinical trial notifications and adverse drug reactions and conducts reviews required for approval, reexaminations, and reevaluation of new central nervous system drugs, peripheral nervous system drugs, anesthetic agents, sensory organ drugs (other than drugs for inflammatory diseases), and narcotics.

4.6 Office of New Drug IV

This office confirms clinical trial notifications and adverse drug reactions and conducts reviews required for approval, reexaminations, and reevaluation of antibacterial drugs, antiviral agents (except for anti-HIV/AIDS agents), new respiratory tract drugs, anti-allergy drugs, sensory organ drugs (limited to drugs for inflammatory diseases), and anti-HIV/AIDS agents.

4.7 Office of New Drug V

This office confirms clinical trial notifications and adverse drug reactions and conducts reviews required for approval, reexaminations, and reevaluations of antineoplastic drugs.

4.8 Office of Cellular and Tissue-based Products

This office conducts reviews necessary for verification of clinical trial notifications and defects, approval, and reexaminations and reevaluations of regenerative medical products (cellular and tissue-based products and gene therapy products), preliminary reviews for approval or verification based on the Cartagena Protocol, quality review of biological products, and reviews necessary for verification of clinical trial notifications and adverse drug reactions, and approval of biosimilar products.

4.9 Office of Vaccines and Blood Products

This office confirms clinical trial notifications and adverse drug reactions of globulins, blood coagulation-factor products, infection prophylactic vaccines, and antidotes and performs the reviews required for approval, reexamination, or reevaluation.

4.10 Office of OTC/Quasi-drugs

This office conducts reviews required for the approval, export certification, and quality

reevaluations of guidance-mandatory drugs non-prescription drugs, quasi-drugs, and cosmetics.

4.11 Office of Generic Drugs

This office conducts reviews required for the approval, export certification (excluding extracorporeal diagnostic medicines), and quality reevaluations of generic drugs, etc. (ethical drugs excluding new drugs and extracorporeal diagnostic medicines in the reexamination period).

4.12 Office of Non-clinical and Clinical Compliance

This office reviews the documentation included with applications for approval, reexamination, or reevaluation of drugs and regenerative medicine products to assure that the studies on which the data is based comply with GLP, GCP, GPSP, study protocol, etc. both ethically and scientifically to determine if the documents have been prepared appropriately and accurately based on the study results in accordance with the Criteria for Reliability of Application Data (hereinafter "Reliability Criteria") and examined on site and on paper. Compliance of facilities performing GLP-based studies is also examined and certified.

4.13 Office of Medical Devices I

This office conducts reviews required for approval of medical devices intended for use in the fields of robots/information and communication technology (ICT)/others, ophthalmology/otorhinology, and cardiopulmonary circulation.

4.14 Office of Medical Devices II

This office conducts reviews required for approval of medical devices intended for use in the fields of neurology/psychiatry, respiratory/cerebro/vascular systems, gastroenterology, reproductive systems, dentistry/oral cavity, and orthopedics/plastic and

reconstructive surgery.

4.15 Office of Standards and Compliance for Medical Devices

This office conducts works to investigate compliance of the documents related to applications for approval, reexamination, reevaluation, and use results evaluation of medical devices with the source documents, GLP, GCP, and GPSP, and the Criteria for Reliability of Application Data. This office also conducts works to investigate the criteria for certification and approval, etc. of medical devices, works to support acquisition of international standards such as ISO/IEC standards, works to manage the master files for raw materials of medical devices, and works to investigate compliance with the standards necessary for registration of third-party certification bodies.

4.16 Office of In Vitro Diagnostics

This office conducts reviews required for approval of in vitro diagnostics.

4.17 Office of Manufacturing Quality and Vigilance for Medical Devices

This office conducts works related to compliance inspections for QMS, etc., on-site inspection of manufacturing sites of medical devices, etc., and simple consultation on QMS. This office also conducts safety measures for medical devices and in vitro diagnostics.

4.18 Office of Manufacturing Quality for Drugs

This office conducts works related to compliance inspections for GMP and GCTP, etc.

4.19 Office of Informatics and Management for Safety

This office handles tasks related to contributions for safety measures, tasks related to receipt and organization of reports of adverse reactions and publication of the results of organization, and tasks related to provision of information for improvement of the quality, efficacy and safety of drugs and medical devices, etc.

4.20 Office of Pharmacovigilance I

This office conducts safety measures related to drugs in the fields under the jurisdiction of Office of New Drug I, Office of New Drug II, and Office of New Drug III (including generic drugs and OTC drugs), quasi-drugs, and cosmetics.

4.21 Office of Pharmacovigilance II

This office conducts safety measures related to drugs in the fields under the jurisdiction of Office of New Drug IV, Office of New Drug V, and Office of Vaccines and Blood Products (including generic drugs and OTC drugs) and cellular and tissue-based products.

4.22 Office of International Programs

This office makes plans and proposals concerning international activities and undertakes surveys and coordinations associated with this, coordinates the matters related to international conferences, international organizations, and foreign government organizations and groups, and conducts works related to the collection and analysis of overseas information and foreign public relations campaign.

4.23 Office of International Cooperation

This office makes plans and proposals concerning the works conducted by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory

Affairs and undertakes surveys and coordinations associated with this.

4.24 Office of Advanced Evaluation with Electronic Data

This office conducts works related to collection of information on the use of various data related to application, planning, drafting, and investigation and analysis, etc. of the information regarding the quality, efficacy and safety of drugs and medical devices, etc. through the use of various data on planning, drafting, and application. This office also makes plans for education and training regarding access to and analysis of various data related to application.

4.25 Office of Medical Informatics and Epidemiology

This office conducts works related to investigation and analysis of the information regarding the quality, efficacy, and safety of drugs and medical devices, etc. using the technique of pharmacoepidemiology and other scientific techniques, as well as the works related to operation and management, etc. of MID—NET®.

4.26 Kansai Branch

This branch undertakes regulatory science strategy consultations and GMP and QMS inspections in the Kansai area.

4.27 Hokuriku Branch

This branch provides training on GMP inspections at manufacturing sites in Toyama prefecture held by Asia Training Center for Pharmaceuticals and Medical Devices Regulatory Affairs (PMDA-ATC).

5. NATIONAL INSTITUTE OF BIOMEDICAL INNOVATION, HEALTH AND NUTRITION (NIBIOHN)

The National Institute of Biomedical Innovation

was established in April 2005 based on the Law for the National Institute of Biomedical Innovation which was approved by the 159th National Diet Session and promulgated in 2004 to make a major contribution to drug research and development by integrating basic research, research on bioresources, and promotion of research and development.

Research promotion and orphan drug development promotion, which had been conducted by the PMDA, were transferred to the institute.

6. JAPAN AGENCY FOR MEDICAL RESEARCH AND DEVELOPMENT (AMED)

AMED was established on April 1, 2015 to promote integrated research and development in the field of medicine (medical R&D), from basic research to practical application; to ensure smooth application of the R&D outcomes to practices; and to establish and maintain an encouraging environment for medical R&D comprehensively and effectively.

By supporting research activities of universities and research institutions, AMED promotes R&D and furthermore establishes an encouraging environment for R&D.

7. PHARMACEUTICAL AFFAIRS AND FOOD SANITATION COUNCIL (PAFSC)

The Pharmaceutical Affairs and Food Sanitation Council (PAFSC) serves as an advisory body to the MHLW, and reviews and discusses important pharmaceutical and food sanitation-related matters **Fig. 3** Organization of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC). This council was created by merging of the Central Pharmaceutical Affairs Council (CPAC) and the Food Sanitation Investigation Council. It is divided into a Pharmaceutical Affairs Committee and a Food Sanitation Committee. The latter comes under the Food Sanitation Law and the former under other laws.

The Council has as members experts in various

fields¹⁾ including the medical and pharmaceutical sciences.

The frequency of committee meetings differs. For example, the First Committee on New Drugs²⁾ and the Second Committee on New Drugs²⁾, which review new drug applications, each meet approximately eight times a year and the Committee on Guidance-mandatory Drugs/Non-prescription Drugs³⁾ meets as needed.⁴⁾ New drugs are then reviewed or reported and approved by the Pharmaceutical Affairs Committee that meets four times a year.^{5) 6)}

Note 1) Expert areas: Nursing, life sciences, applied biochemistry, mathematics and statistics, law, and economics

Note 2) Categories of drugs for the Second Committee on New Drugs to review: Antiviral drugs, chemotherapeutic agents, anti-malignant tumor agents, blood products, and biological products. Those for the First Committee: Remaining therapeutic categories

Note 3) Categories of drugs for the Committee on Guidance-mandatory/Non-prescription Drugs to review: New guidance-mandatory/non-prescription drugs which are apparently different from existing guidance-mandatory/non-prescription drugs in active ingredient, strength, dosage/administration, indications, etc.

Note 4) The First and Second Committees on New Drugs meet in January, February, April, May, July, August, October, and November in principle.

Note 5) The Pharmaceutical Affairs Committee meets in March, June, September, and December in principle.

Note 6) For recent new drugs, refer to the homepage on drug information.

<http://www.pmda.go.jp/english/review-services/reviews/approved->

[information/drugs/0002.html](http://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0002.html))

8. NATIONAL INSTITUTE OF INFECTIOUS DISEASES

In April 1997, the name of the National Institute of Health was changed to the National Institute of Infectious Diseases. The institute undertakes basic and applied research, reference and surveillance activities, and collection, analysis, and supply of information pertaining to infectious diseases, performs research on the quality control of antibiotics and other biological products, and undertakes national certification/testing and activities related to international cooperation.

- **Infectious Diseases Information Center**

This Center was established in April 1997 to undertake surveys and research, and collect and supply information on infectious diseases, etc.

- **AIDS Research Center**

This Center was established in April 1988 to undertake HIV basic research and to develop methods of prevention and treatment of AIDS.

Pharmaceutical Regulations in Japan:

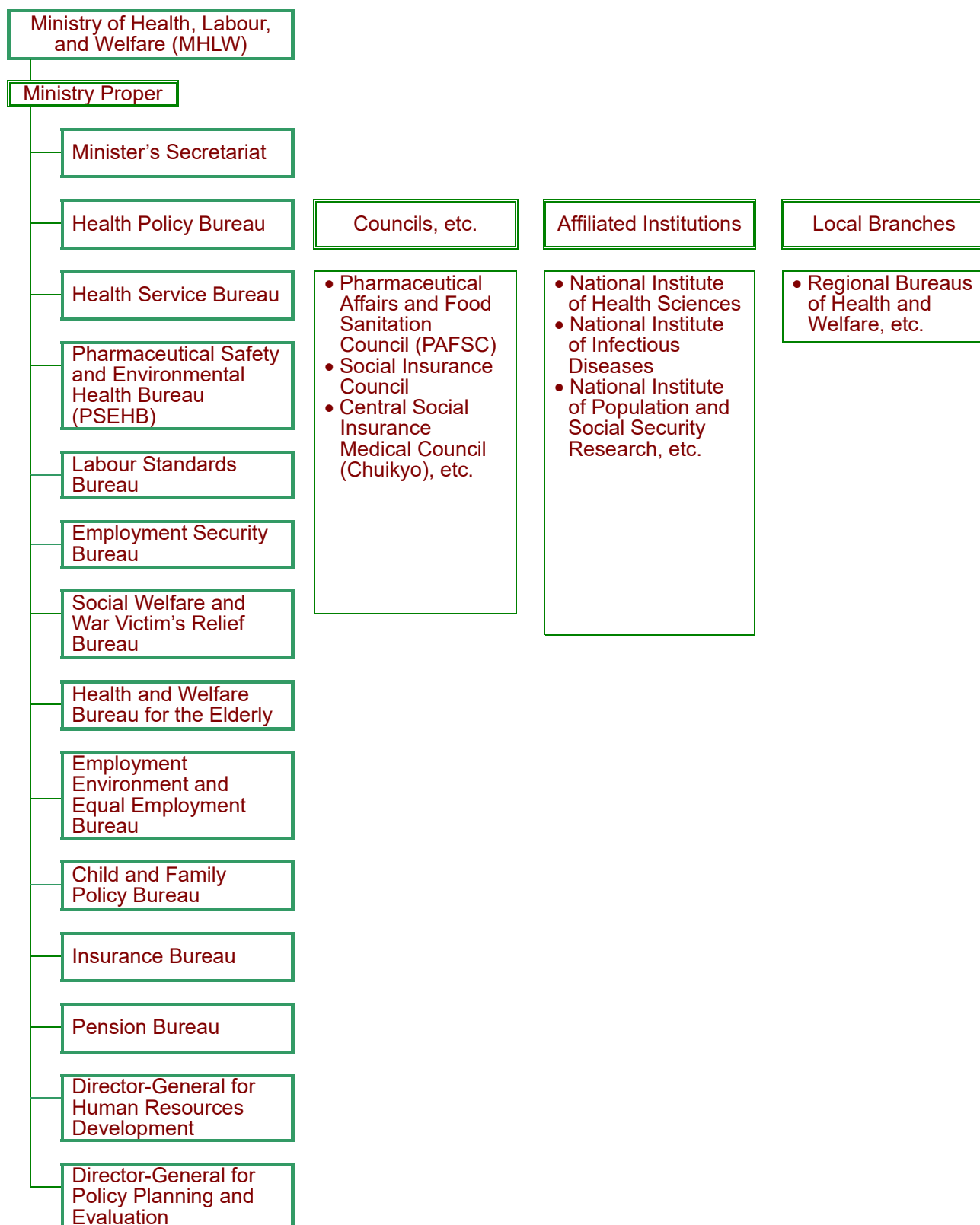
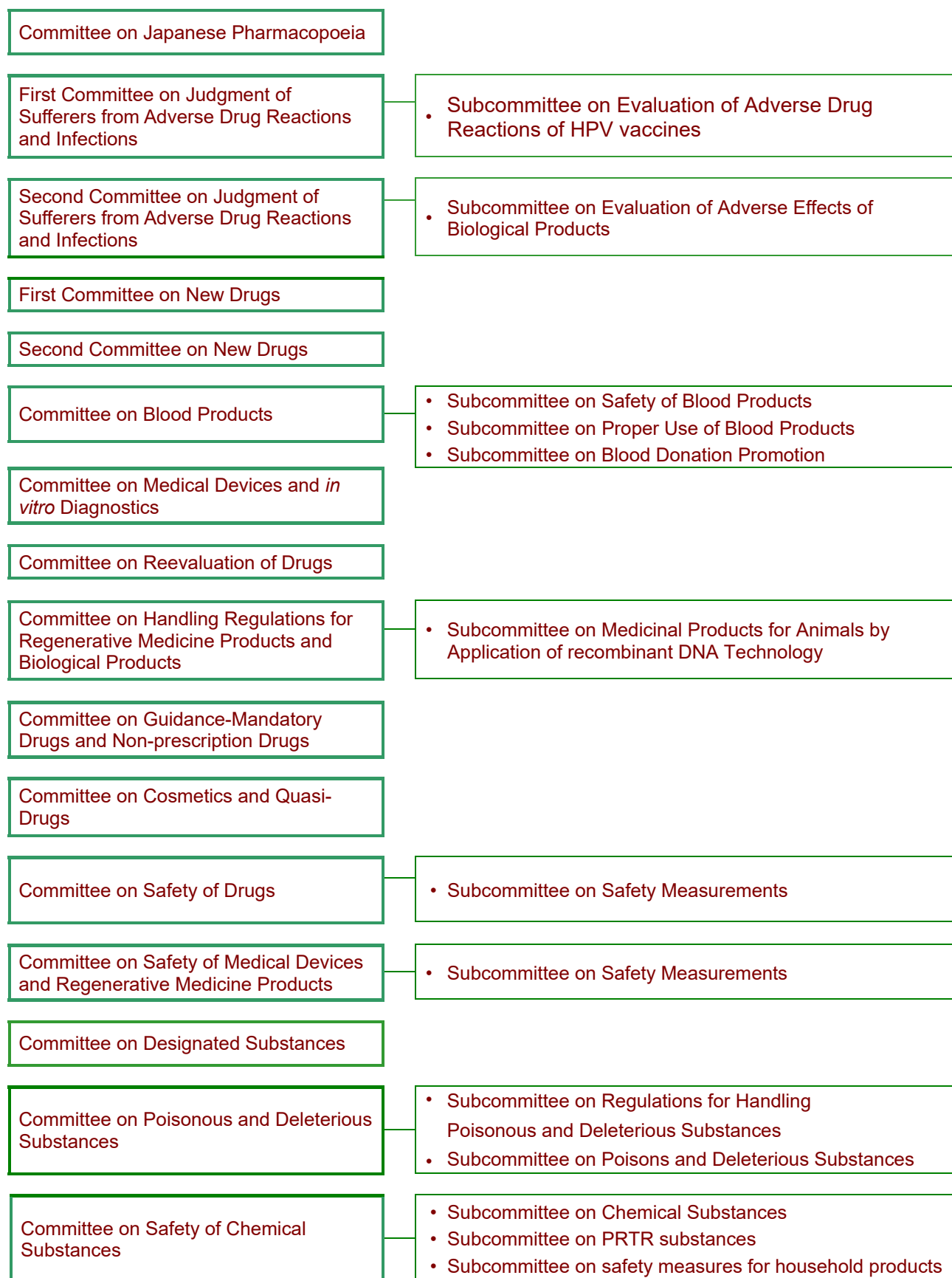


Fig. 1 Organization of Ministry of Health, Labour, and Welfare (Health-related organizations only)



Fig. 2 Organization of Pharmaceutical Safety and Environmental Health Bureau (PSEHB) and Pharmaceuticals and Medical Devices Agency (PMDA)

Pharmaceutical Regulations in Japan:



Pharmaceutical Regulations in Japan:

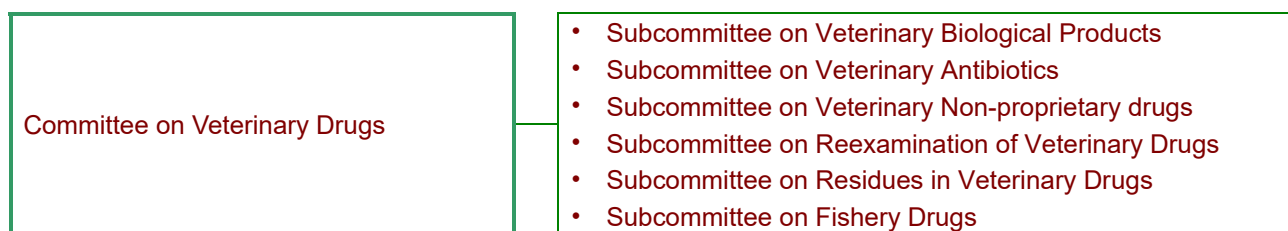


Fig. 3 Organization of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC)
(17 Committees and 19 Subcommittees)