FPMAJ

The Federation of Pharmaceutical Manufacturers' Association of Japan

Guidance

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Summary

1.Name

The Federation of Pharmaceutical Manufacturers' Association of Japan (also known as the FPMAJ)

2.Establishment

October 16, 1948

3.Purpose

The Federation investigates and studies necessary matters for the development of the pharmaceutical industry, and collects, compiles, and implements impartial suggestions provided by the industry. Additionally, the Federation strives to maintain the relationships, communications and developments among our members, and to promote the collective best interests of our affiliated members. Moreover, the Federation acts as the coordinator to assist in the healthy development of the pharmaceutical industry and strives to improve the overall quality of life of all citizens.

4.Business

In order to achieve the goals disclosed in Article 3, general business conducted by the Federation is described as follows:

I. Collect and provide relevant information to affiliated members.

II. Establish mechanisms such as committees, meetings, and roundtables to investigate common matters of the industry, and work to innovation in company operations as well as the development of pharmaceutical technology.

III. Compile and consider impartial suggestions from the industry and submit proposal to government or other agencies if necessary.

IV. Work to improve the quality, of pharmaceutical products and their materials, raise standards and increase efficiency in production and distribution.

V. Organize meetings, seminars and roundtables as well as provide visiting opportunities in addition to publishing the journal of the Federation.

VI. Facilitate communication and close interaction among organizations.

VII. Investigate current status of overseas pharmaceutical industries through communication with relevant overseas agencies, information exchange or sending an observation team.

VIII. Other necessary tasks required for fulfilling the goals of the Federation.

5.Organization

FPMAJ is .an organization whose members are composed of pharmaceutical manufactures organized by region (16 members located in Tokyo, Osaka and other prefectures) and industry (15 members with membership classified based on industry, such as prescription or nonprescription).

6.President/Vice President

President:	Mr. Isao Teshirogi, Shionogi & Co.,Ltd.
Vice President:	Mr. George Nakayama, Daiichi Sankyo Co.,Ltd.
	Mr. Tatsuo Higuchi, Otsuka Pharmaceutical Co.,Ltd.
	Mr. Shigenobu Maekawa, Nippon shinyaku Co.,Ltd.
Director General:	Mr. Toshihiko Miyajima
Managing Director:	Mr. Yasuyuki Kurokawa

7.Executive Organization

Board of Directors: The board consists of directors who are elected by the council members, and is responsible for reviewing tasks assigned by the committee and other emergency matters.
Board of Trustees: The council members are chosen based on the principles established by individual organizations, and are responsible for reviewing important business operations matters related to the Federation.

8.Committees

The executive member meeting of the board is held regularly for investigating and planning strategies in professional fields.

Member Associations

The Federation of Pharmaceutical Manufacturers' Association of Japan

- 15 Industrial Organizations
  - Japan Pharmaceutical Manufacturers Association (JPMA)
  - Japan Generic Pharmaceutical Association
  - Japan Self-Medication Industry
  - Japan Direct-Selling Pharmaceutical Manufacturers Association (JDSPA)
  - Japan Ophthalmic Pharmaceutical Manufacturers Association (JOPMA)
  - Japan Kampo Medicines Manufacturers Association (JKMA)
  - Home Medicine Association of Japan
  - External Pharmaceutical Association
  - Japan Association of Vaccine Industries
  - The Intravenous Solutions Society
  - Japan Blood Products Association
  - Japan Household Medicine Association
  - Japan Association of Clinical Reagents Industries (JACRI)
  - Pharmaceutical Contract Manufacturers Association
  - Forum for Innovative Regenerative Medicine (FIRM)
- 16 Regional Organizations
  - Pharmaceutical Manufacturers'Association of Tokyo
  - Kansai Pharmaceutical Industries Association
  - Aichi Pharmaceutical Manufacturers Association
  - Toyama Pharmaceutical Association
  - Hyōgo Pharmaceutical Manufacturers Association
  - Tokushima Pharmaceutical Manufacturers Association
  - Saga Pharmaceutical Manufacturers Association
  - Kanagawa Pharmaceutical Manufacturers Association
  - Nara Pharmaceutical Manufacturers Association
  - Shiga Pharmaceutical Manufacturers Association
  - Nagano Pharmaceutical Manufacturers Association
  - Gifu Pharmaceutical Manufacturers Association
  - Saitama Pharmaceutical Manufacturers Association
  - Chiba Pharmaceutical Manufacturers Association
  - Ishikawa Pharmaceutical Manufacturers Association
  - Niigata Pharmaceutical Manufacturers Association

Organization Chart

The Federation of Pharmaceutical Manufacturers' Association of Japan

- Director General
  Managing Director
  Secretariat
- President
- Board of Trustees
- Board of Directors
  - Policy Research Committee
  - Relief System Committee
  - Personal Information Protection Committee
  - Quality Committee
  - Pharmacopoeieial Committee
  - Reevaluation Committee
  - Safety Committee
  - Environment Committee
- Vice President
- Auditor Secretary

Pharmaceutical PL Center

- PL Meeting of Council Members
- Review Department Meeting

- Personal Information Protection Center
- General Affairs Committee
- Corporate Ethics Committee
- Pharmaceutical PL Center Operations Committee
- Regulatory Affairs Committee
- NHI Pricing Committee
- Distribution Issue Association
- Washington Convention Relationship Association
- SME Strategies Roundtables
- International Affairs Committee

Committee Business ()=No. of Committee Member

Policy Research Committee (8)	(1)Review the necessity of the revisions to the organizations or agencies (2)Research the operations of the FPMAJ (3)Research and investigate the activities conducted by each committee
Corporate Ethics Committee (17)	(1)Takes action regarding social responsibilities (2)Takes action regarding social ethics-related issues
Relief System Committee (14)	(1)Takes action regarding side effects caused by pharmaceutical products under the victim relief system (2)Takes action regarding infections caused by biological products under the victim relief system
Personal Information Protection Committee (12)	(1)Takes action regarding the Personal Information Protection Act (2)Takes necessary action regarding industrial and corporate protection of personal information
Pharmaceutical PL Center Operations Committee (16)	Verify the validity and international integration of pharmaceutical jurisprudence and review the efficiency as well as the rationales of the system
Regulatory Affairs Committee (33)	(1)Verifies the validity and international integration of pharmaceutical jurisprudence and discusses how to create a more efficient and rational system (2)Reviews the relevant loosening of regulations, as specified in the Pharmaceutical Affairs Act. (3)Takes action regarding the sales of general pharmaceutical products (4)Relevant amendments and updates to the basis of licensing general pharmaceutical products (5)Continuous management of the identification bar codes of pharmaceutical products such as tablets, and assists in registration procedures for examination (6)Organizes a variety of seminars and workshops for managers involved in manufacturing and sales of pharmaceutical products
Quality Committee (48)	(1)Reviews matters relevant to pharmaceutical Good Quality Practice (GQP) and Good Manufacturing Practice (GMP) (2)Integrates GQP/GMP-related suggestions provided by relevant organizations and finds compromises between the organizations and administrative authorities (3)Conducts GQP/GMP-related meetings and training
Pharmacopoeial Committee (13)	(1)Serves as the comprehensive institutional liaison for processing relevant regulations, notifications, and Q&A for countries and organizations, as specified in the Japanese Pharmacopoeia (2)Proposes or submits written requests to the countries or organizations relating to the Japanese Pharmacopoeia regarding policies or systems (3)Coordinates the opinions provided by member organizations of the Japanese Pharmacopoeia and obtains cooperation from pharmaceutical manufacturers (4)Recommends committee members to organizing committees or research classes in relevant countries or organizations relating to the Japanese Pharmacopoeia
Reevaluation Committee (18)	(1)Manages and responds to issues concerning secondary assessment (2)Secondary assessment of the operations of collaboration (3)Delivery of information related to the announced secondary assessment results

General Affairs Committee (80)	(1)Relevant responses to applications for general donations (2)Matters related to donation amounts
NHI Pricing Committee (215)	(1)All necessary responses to the release of new drugs for treatments not included in its indications (2)Reviews major issues such as developing drug prices for new drugs, the methods of changing the prices of essential drugs for healthcare insurance, secondary price calculations for market expansion, special price reductions for brand name drugs, and the principles of determination of drug prices for brand name drugs and generic drugs, etc. (3)Reviews issues relevant to the healthcare insurance system (4)Assists in delivery of information on drug prices (5)Investigates the health care insurance systems and drug price systems in European countries and the U.S.
Distribution Issue Association (26)	(1)Assists in the operation processes, including the completion of unfinished improvements to pharmaceutical logistics (emergency motion) as well as improvements to pre-payment collections and total price contracts (2)Reviews matters related to correct usage and the assurance of a stable supply of pharmaceutical products (3)Promotes efficiency as well as transparency in the distribution process (4)Reviews the principles of providing accurate information (5)Promotes appropriate ways of selling general pharmaceutical products (6)Promotes new identification barcodes for pharmaceutical products specifically for medical use
SME Strategies Roundtables (15)	(1)Reviews taxation of SMEs (2)Exchange of information and its corresponding responses
Safety Committee (35)	(1)Assists in formulating agreements on issues related to pharmaceutical safety (2)Controls safety-related information and informs relevant parties accordingly (3)Manages the issues of safety precautions of drugs for treatment (4)Responds to collaborations
Washington Convention Relationship Association (11)	(1)Relevant responses to revisions of the Washington Convention (2)Collects information on and responds to issues related to the animals and plants listed in the Washington Convention (3)Assists in the import of bears for gall farming and establishes the distribution system of bear gall produced domestically (4)Keep informed of the domestic distributions of bear gall, rhinoceros, and musk (5)Exchanges opinions with international monitoring organizations on the issues of farming wild animals and corresponding responses
Environment Committee (11)	(1)Implements the environmental strategies of all pharmaceutical manufacturers and performs continued tracking of the strategies developed for environmental issues and executed by government or economic organizations (2)Provides information to affiliated organizations and facilitates coordination as well as communications among member organizations (3)Sends council members to participate in meetings held by associations and organizations in various countries
International Affairs Committee (13)	(1)International related information sharing among member associations (2)Support international activity of each member association (3)Cooperate & support growing strategy of pharmaceutical industry which government forwarding