JMED

Japan Medical Devices Manufacturers Association

JMED

Chairman's Message

Koji Nakao

Chairman
The Japan Medical Devices
Manufacturers Association (JMED)

As highlighted in the government's "New Growth Strategy", which promotes a policy of "life innovation" as one of high priorities, Japan's healthcare industry is generating major expectations as a growth driver for the country. Furthermore, the market for medical devices on a global scale is enormous, valued at over 20 trillion yen—about 10 times the size of Japan's market. With the aging population around the world along with the economic growth of emerging countries, this market is projected to expand considerably in the future.

As the medical devices industry grows in prominence worldwide, the Japan Medical Devices Manufacturers Association (JMED) celebrated its 10th anniversary in 2010. Our membership presently exceeds 270 companies having an important presence with over 60% of the country's medical devices market.

In 2011, the Japanese government established the Medical Innovation Promotion Office with the aim of helping to develop outstanding healthcare originated in Japan. We also promoted discussions with government agencies and academic institutions on such topics as systemic reforms based on the unique characteristics of medical devices, and the streamlining and acceleration in regulatory approval process of medical devices. Going forward, we will initiate particular actions to realize these proposals and discussions to adopt a new method of evaluating device innovation. While undertaking these tasks, JMED intends to proactively promote internationalization of Japan's medical devices industry, helping to bring Japan's regulations and standards into line with global practices and providing support for member companies to break into markets overseas.

The needs for medical devices such as "medical cost efficiency", "less-invasiveness" and "innovation" will increasingly grow. Therefore, our goal at JMED is to provide the valuable products and services that meet these needs, thereby contributing to healthcare in Japan and development of the country's medical devices industry.

JMED is approaching the next decade on the basic principle of helping the people who receive medical care and the professionals who give it. We will carry out a variety of projects intended to further the development of JMED. In closing, I therefore ask for your continuing support and cooperation as we work together for an even brighter future. Thank you very much.

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History

In 1967, when the market of medical devices was comprised mainly of injection instruments, blood/fluid transfusion kits, blood bags, etc., the “Medical Plastics Conference”, one of the two former organizations of the Japan Medical Devices Manufacturers Association (JMED), was established by 14 manufacturers of plastic medical devices. In 1980, when the market of hollow fiber dialyzers, etc. was gradually expanding with the development and popularization of hemodialysis, the Conference was renamed “Japan Medical Plastics Association”. As members manufacturing non-plastic medical devices such as artificial joints and ceramic bones increased, the Association renamed “Japan Association of Medical and Material Industries (JAMMI)” in 1990. The “Japan Artificial Organ Industry Association (JAOIA)”, the other former organization of JMED, was established in 1979 with the aim of research and development of artificial organs in response to the academic demand of those concerned. Both former organizations had made successful achievements in their respective activity fields, but they joined together on November 17, 2000 to be reborn as JMED and deal with the recent changes in the environment of the medical devices industry. JMED has more than two hundred corporate members whose total revenue is about a trillion yen.

Business

JMED is mainly engaged in the following activities to promote the development and dissemination of medical devices, materials and so on, produced in Japan and overseas, to enhance corporate members’ business activities and capacity and to contribute to the sound development of medical treatment.

1. Concerning medical devices, materials and so on, JMED improves the quality and functions, secures safety, and cooperate for making of standards.

2. Concerning the sound development of medical treatment, JMED clarifies its standpoint and contributes to the development of corporate members.

3. JMED makes proposals and suggestions, provides cooperation and makes communications and adjustments for administrative measures.

4. JMED provides correct information concerning medical devices, materials and similar to users.

5. JMED promotes exchanges of academic, technical and financial information that contributes to the enhancement of the business activities and capacity of corporate members.

6. JMED gathers statistics and documents prepared in Japan and overseas, and conducts surveys and research concerning medical devices, materials and similar.

Activities

To carry out business, JMED has thirteen departments and fourteen committees as the central bodies. The departments examine general standards, Japanese Industrial Standards (JIS), safety and other matters for each type of medical device. Some committees examine legislation such as the Pharmaceutical Affairs Law, the classification of functions of specified national health insurance medical materials and relevant systems such as distribution systems; while others specialize in education and training, public relations and statistics.

Lectures and seminars

JMED provides seminars for the executives of corporate members, seminars on matters related to the Pharmaceutical Affairs Law, etc., for the employees of corporate members, and continuous training for sales business and repair business of medical devices as an organization registered with the Ministry of Health, Labour and Welfare.

Lecture at the 6th JMED Executive Seminar

Continuous training for sales business/repair business

Global activities

JMED attends international conferences to exchange opinions and to gather information as a domestic deliberative body of four ISO technical committees.

- ISO/TC76 (Transfusion, infusion and injection equipment for medical and pharmaceutical use)
- ISO/TC84 (Devices for administration of medicinal products and intravascular catheters)
- ISO/TC150 (Implants for surgery)
- ISO/TC194 (Biological evaluation of medical devices)

ISO/TC meeting

Publications

JMED publishes the “Photograph and Illustration of special treatment materials” which describes the intended use and methods of use, technical fees and refund prices, etc., of special treatment materials and the “Guide to Plastic Medical Devices” describing the plastics and the features for sterilization medical devices.

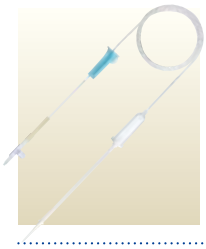
Efforts to maintain the safety of medical devices

JMED publicizes our safety-related efforts by displaying posters at academic meetings. JMED provides information concerning the safety standards of medical devices and information concerning standardization on our website.

Posters at an academic meeting

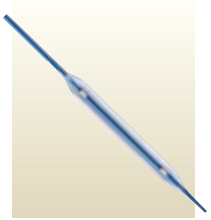
Products covered by JMED

The products that JMED's member companies deal with vary widely, including not only basic medical devices such as those for blood transfusion and fluid infusion but also instruments and materials such as hemodialysis apparatuses, artificial heart-lung apparatuses, blood purifiers, cardiac valve prostheses, vascular catheters, artificial joints and wound covering materials, and home care products for home peritoneal dialysis, home oxygen therapy, etc. Our member companies are also making strenuous efforts to develop artificial organs and new medical materials, applying the results of rapidly advancing researches on advanced medicine and regenerative medicine to them.



Instruments for blood transfusion/fluid infusion

- Instruments for blood transfusion/fluid infusion
- Injection needles and syringes



Vascular catheters

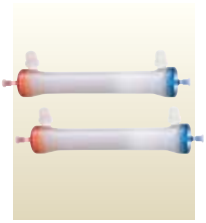
- Catheters for angiography
- Catheters for coronary artery surgery
- Catheters for intravascular surgery
- Thermodilution catheters
- Central venous catheters
- Catheters for anti-arrhythmic treatment
- Other intravascular cathethers

Products for surgery and patient care

- Surgical gloves
- Non-woven products
- Bags
- Stoma-related products

General implants

- Artificial blood vessels
- Stent grafts
- Artificial dura mater
- Hemostasic adhesives
- Non-vascular stents
- Cerebrovascular clips
- Artificial fiber cloths for tissue substitution
- Staplers
- Microfiber collagen
- Artificial esophagus
- Stent

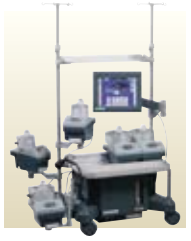


Hemodialysis-related products

- Hemodialysis equipment
- Dialyzers
- Blood circuits

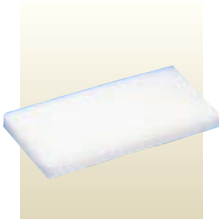
Orthopedic implant-related products

- Artificial joints
- Fixative materials
- Artificial bones
- Bone cement



Cardiovascular-related products

- Artificial heart-lung apparatus
- Artificial lung
- IABP
- Heart-lung circuits
- Cardiac valve prostheses
- Extracorporal circulation cannulas



Wound coverings materials

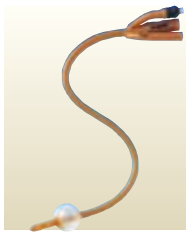
- Grafts for lack of skin
- Various dressings

Plasma exchange-related products

- Blood purifiers
- Membrane plasma separators
- Plasma component adsorbents
- Blood filters

Home care-related products

- Home peritoneal dialysis-related products
- Home enteral tube feeding-related products
- Home oxygen therapy apparatus
- Home pain control-related products



Catheters for general use

- Gastrointestinal catheters
- Renal catheters
- Drain tubes
- Respiratory catheters
- Ventricular drainages

To maintain the effectiveness and safety of medical devices

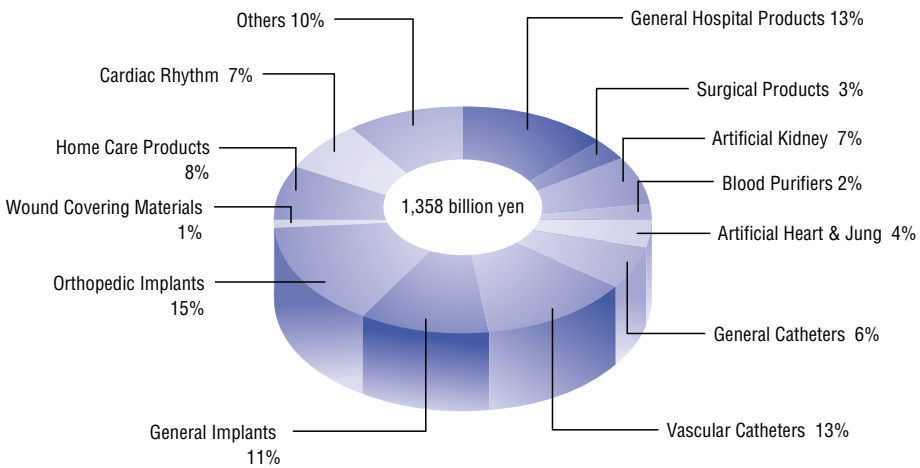
It is vital that medical devices fulfill the expected performance and functions and ensure the safety of patients. From this aspect, the Pharmaceutical Affairs Law regulate various matters concerning medical devices, including research, development, manufacture and post-market surveillance.

Flow of medical devices from research and development to after-sales

JMED in medical industry

It is said that domestic shipments of medical devices exceed ¥2 trillion, more than 60% of which by JMED members. JMED members supply a lot of medical devices which are special treatment materials.

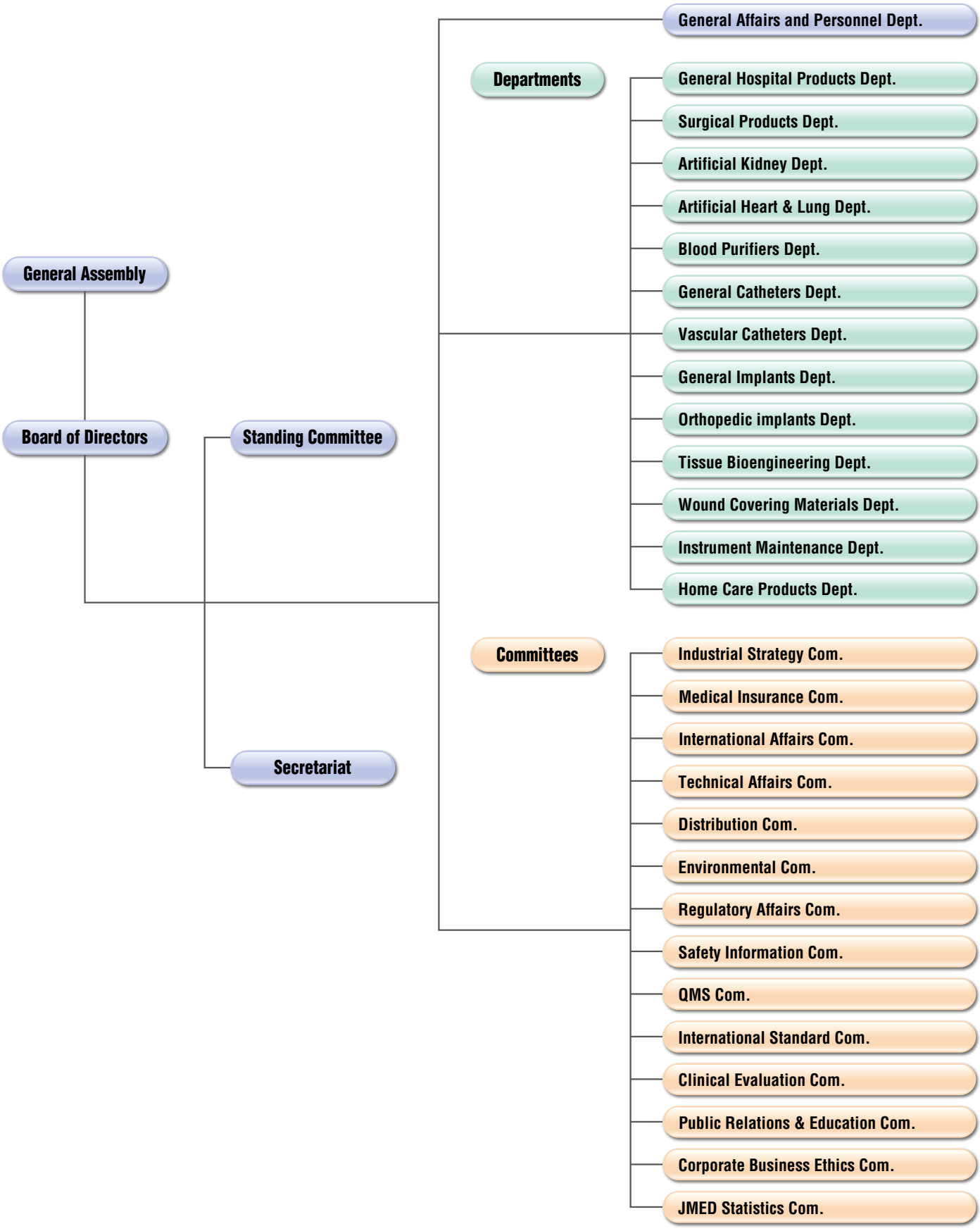
Composition of Domestic Shipment for JMED products※



※2011 JMED Data

Organization

As of June, 2012



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