

# **Regarding Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations**

The Japan Federation of Medical Devices Associations (JFMDA) formulates “Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations” and makes efforts to secure and improve the transparency and credibility of the relationship with medical institutions and other organizations in the business activities.

- ◆ Member companies in the associations joining in JFMDA are required to take its role to contribute to the development and improvement of health care, by extension, the public health, welfare and the realization of quality of life through the development, manufacture, import and sale, etc. of medical devices, as well as to be deeply aware of that they must practice business activities rooted in a high level of ethics as a company to take on part of the responsibility for health care.
- ◆ In order for medical devices to meet the needs of diagnosis, treatment and prevention of diseases, not only independent research and development by companies but comprehensive research through collaboration with academic and other research facilities and medical institutions (industry-academia collaboration) is indispensable and this industry-academia collaboration will give birth to new effective and safe medical devices.
- ◆ On the other hand, the industry-academia collaboration may be performed based on contracts and other agreement with medical institutions and healthcare professionals and so on and there have been cases where financial compensation are made in regard to those activities, and therefore, it is incontrovertible that the chances arise for medical institutions and related healthcare professionals to become deeply involved in a specific company or product and there is concern over the possibility that this can affect fair judgment, so called, conflict of interest may arise.
- ◆ Therefore, for such industry-academia collaboration activities, companies are strongly required to secure the transparency of relationships with medical institutions and other organizations. Furthermore, it is important to gain a wider understanding and trust from society, by disclosing information regarding funds, etc. paid to medical institutions and other organizations, that the medical device industry are contributing to the development of medicine, medical technology and all life sciences as well as guarantee a high level of ethics in business activities.
- ◆ Recently, also in Japan, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, the Japanese Association of Medical Sciences have promoted efforts for managing conflict of interest, as well as that the Japan Pharmaceutical Manufacturers Association (JPMA) published its Guidelines for Transparency of Relationships between Corporate Activities and Medical Institutions and, in light of these trends, JFMDA has formulated these guidelines.

For promoting these guidelines, we hope that all of medical institutions and related healthcare professionals will understand the aim of these guidelines and cooperate with us.

Japan Federation of Medical Devices Associations

# Transparency Guidelines for the Medical Device Industry and its Relationships with Medical Institutions and Other Organizations

1. The purpose is to gain a wider understanding, by securing transparency and credibility of the relationship with medical institutions and other organizations in the business activities of member companies, that the medical device industry can contribute to the development of medicine, medical technology and all life sciences as well as guarantee a high level of ethics in business activities.

Member companies shall use these guidelines to establish their own transparency guidelines as standards for behavior.

2. Member Companies shall take account of the following points and aim for the transparency of the relationship with medical institutions and other organizations.

## **(1) Stance of Member Companies**

Member companies shall set forth their corporate policies for transparency of the relationship with medical institutions and other organizations, following in both word and spirit the “Code of Ethics”, the “Charter of Business Behavior” and the “Promotion Code of the Medical Device Industry” which were established by the Japan Federation of Medical Devices Associations as well as the “Fair Competition Code of the Medical Device Industry” which was established by the Japan Fair Trade Council of the Medical Device Industry.

## **(2) Disclosure Methods**

Member companies shall disclose funds and so on provided to medical institutions and other organizations during the previous fiscal year through their websites or other method after the settlement of accounts of each company.

## **(3) Timing of Disclosure**

Payments made during each fiscal year shall be disclosed in the next fiscal year. Provided, however, that, with regard to A. Research and development expenses of (4) Scope of Disclosure, only total annual amount is disclosed for those before and on fiscal year 2017, and total annual amount and the details listed in (4) Scope of Disclosure are disclosed for those on fiscal year 2018 onward.

## **(4) Scope of Disclosure**

### **A Research and development expenses**

This includes expenses for trials, reports, and surveillance studies conducted under public regulations (clinical trials, post-marketing clinical studies, nonconformity and infection case reports, post-marketing surveillance studies, etc.) and those for independent investigations.

- Joint research expenses  
(clinical) Name of receiving facilities (\*1): number of cases, amount  
(other than clinical) Total annual number of cases and amount, name of receiving facilities (\*1)
- Contract research expenses  
(clinical) Name of receiving facilities (\*1): number of cases, amount  
(other than clinical) Total annual number of cases and amount, name of receiving facilities (\*1)
- Clinical trial expenses  
Name of receiving facilities (\*1): number of cases, amount

- Post-marketing clinical study expenses  
Name of receiving facilities (\*1): number of cases, amount
- Nonconformity and infection case reporting expenses  
Name of receiving facilities (\*1): number of cases, amount
- Post-marketing surveillance expenses  
Name of receiving facilities (\*1): number of cases, amount
- Other research and development related expenses  
Total annual amount  
(\*1) For “Name of receiving facilities”, “name of facility”, “name of organization in the facility” and “department, role and name of an individual” will be disclosed based on the contract.

**B Academic research support expenses**

This includes expenses for scholarships, general and academic conference donations as well as academic conference co-sponsoring expenses to support for holding meetings such as academic conferences conducted for the purpose of the promotion of learning or research support for medical technology.

- Scholarship donations  
Department, university : number of cases, amount
- General donations  
University (foundation): number of cases, amount
- Academic conference donations  
Conference number (area conference, research council): amount
- Academic co-sponsoring expenses  
Conference number, seminar: amount

**C Manuscript writing fees, etc.**

This includes expenses for lectures, manuscript writing and the consignment of services including consulting to provide information regarding the appropriate use of medical devices.

- Lecturers fees  
Professor (director), department, university (hospital): number of cases, amount
- Manuscript writing/supervising fees  
Professor (director), department, university (hospital): number of cases, amount
- Expenses for the consignment of services, including consulting  
Professor (director), department, university (hospital): number of cases, amount

**D Expenses related to information provision**

This includes expenses for lectures, workshops, seminars and so on necessary for appropriate and safe use of medical devices given to healthcare professionals.

- Lecture expenses  
Total annual number of cases and amount
- Seminar expenses  
Total annual number of cases and amount
- Expenses for the provision of medical/medical engineering-related literature, etc.  
Total annual amount

**E Other expenses**

This includes expenses for receptions and social courtesy.

- Reception expenses  
Total annual amount

## 21 Member Associations (about 4,300 companies)

As of March 2017

Japan Electronics and Information  
Technology Industries Association

Japan Medical-Optical Equipment Industrial  
Association

Japan Medical Industry Association

Japan Association of Medical Devices Industries

Medical Technology Association of Japan

Japan Association of Health Industry Distributors

Association of Japan Medical Devices  
Network

Japanese Association of Surgical Sutures

Japan Hygiene Products Industry  
Association

Japan Medical Imaging and Radiological Systems  
Industries Association

Japan Ophthalmic Instruments Association

Japan Contact Lens Association

Japan Condoms Industrial Association

Japan Home Health Care Association

Japan Dental Trade Association

Japan Analytical Instruments Manufacturers'  
Association

The Japan Home-health Apparatus Industrial  
Association

Japan Hearing Instruments Manufacturers  
Association

Japan Hearing Instruments Dispensers  
Association

Japan Industries Association of Physical Therapy  
Devices

Japan Association of Clinical Reagents  
Industries

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