

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

Japan Federation of Medical Devices Associations

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