

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” (hereinafter “this Guideline”) and makes efforts to secure and improve the transparency and credibility of the relationship with member companies and medical institutions and other organizations.

- ◆ Member companies in the associations joining in JFMDA are strongly required to put patients first as well as to practice transparent business activities rooted in a high level of ethics as a company to take on part of the responsibility for health care.
- ◆ For example, in order for medical devices to meet the needs of diagnosis, treatment and prevention of diseases, not only independent research and development by member companies but collaboration with academic and other research facilities and medical institutions is indispensable. However, for such industry-academia collaboration activities, conflicts of interest may arise in some cases.
- ◆ Therefore, it is important to practice appropriate conflicts of interest management (COI Management) and to secure the transparency of relationships with medical institutions and other organizations to gain a wider understanding and trust from society that a high level of ethics and transparency is guaranteed in business activities of member companies.
- ◆ Considering the above, JFMDA prepared this Guideline in 2012 and has publicly disclosed information pertaining to funds, etc. paid to medical institutions and other organizations. JFMDA has also striven to improve the transparency/reliability by reviewing this Guideline. As part thereof, we revised this Guideline based upon full understanding of the purpose and objective of the Clinical Trials Act which was enforced in April 2018.

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

The Japan Federation of Medical Devices Associations

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

1. Purpose

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 Contents of publication

(1) Disclosure Methods

The payments, etc. shall be disclosed through each company's own website.

(2) Timing of Disclosure

The payments, etc. shall be disclosed within one (1) year after conclusion of each fiscal year of each company.

(3) Targets of Disclosure

The payments, etc. in the previous fiscal year shall be disclosed in accordance with each item below.

A. Research and development expenses, etc.

Research and development expenses, etc. include expenses required for research/surveillance, etc. conducted under public regulations and various policies such as the Clinical Trials Act and GCP/GVP/GPSP ordinances under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices. Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

- Specified clinical trial expenses (*1)
Name of receiving facilities (*2): number of cases, amount
- Research expenses based on ethical guidelines (*3)
Name of receiving facilities (*4): number of cases, amount
- Research expenses other than clinical trials (*5)
Total annual number of cases and amount, name of receiving facilities: number of cases, amount
- Clinical trials expenses (clinical study expenses)
Name of receiving facilities (*4): number of cases, amount
- Post-marketing clinical trials expenses
Name of receiving facilities (*4): number of cases, amount
- Device deficiency and/or infection disease reports expenses
Name of receiving facilities (*4): number of cases, amount
- Post-marketing surveillance expenses
Name of receiving facilities (*4): number of cases, amount
- Other research and development related expenses
Total annual amount

- (*1) “Specified clinical trial expenses” refer to expenses paid pursuant to a contract for a specified clinical trial as defined in the Clinical Trials Act.
- (*2) “Clinical trial identification number”, “facilities to which funds are provided”, “name of medical institution conducting the trial” and “name of principal investigator”, etc. shall be disclosed.
- (*3) “Ethical guidelines” as used for the “research expenses based on ethical guidelines” shall mean the “Ethical Guidelines for Medical and Health Research Involving Human Subjects.”
- (*4) 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.
- (*5) “Research expenses other than clinical trials” refer to expenses required for research other than a specified clinical trial, research based on ethical guidelines, clinical trials, or post-marketing surveillance, etc., such as the so-called “basic research”.

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 promotion for learning or research support, etc.

Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

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

(*This paragraph includes information obliged to be disclosed under the Clinical Trials Act.)

C. Manuscript writing fees, etc.

This includes expenses, paid as consideration for lectures, writing or supervision of the manuscript and the consignment of services including other consulting, etc. to provide information regarding the appropriate use of medical devices.

Funds, etc. provided shall be disclosed as follows together with the annual total amount of each item.

- 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

(*This paragraph includes information obliged to be disclosed under the Clinical Trials Act.)

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 April 2019

- Japan Electronics and Information Technology Industries Association
- Japan Medical Industry Association
- Medical Technology Association of Japan
- Association of Japan Medical Devices Network
- Japan Hygiene Products Industry Association
- Japan Ophthalmic Instruments Association
- Japan Condoms Industrial Association
- Japan Dental Trade Association
- The Japan Home-health Apparatus Industrial Association
- Japan Hearing Instruments Dispensers Association
- Japan Association of Clinical Reagents Industries
- Japan Medical-Optical Equipment Industrial Association
- Japan Association of Medical Devices Industries
- Japan Association of Health Industry Distributors
- Japanese Association of Surgical Sutures
- Japan Medical Imaging and Radiological Systems Industries Association
- Japan Contact Lens Association
- Japan Home Health Care Association
- Japan Analytical Instruments Manufacturers' Association
- Japan Hearing Instruments Manufacturers Association
- Japan Industries Association of Physical Therapy Devices

(Japanese alphabetical order)

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