

With medical institutions and others in the medical device industry About Transparency Guidelines

The Japan Federation of Medical Devices Associations (JFMDA) has established the "Transparency Guidelines for the Medical Device Industry with Medical Institutions" (hereinafter referred to as the "Guidelines") to ensure and improve the transparency and reliability of the relationship between member companies and medical institutions.

As companies that play a part in healthcare, member companies of organizations affiliated with the Federation are strongly expected to put patients first and to practice highly transparent corporate activities rooted in a high level of ethics.

For example, in order to meet the needs of diagnosis, treatment and prevention of diseases through medical devices, member companies must not only conduct their own research and development, but also collaborate with universities and other research institutions and medical institutions, etc. Such industry-academia collaboration activities may cause conflicts of interest.

Therefore, in order to gain the public's understanding and trust that the activities of member companies are conducted with a high level of ethics and transparency, it is essential to practice appropriate management of conflicts of interest (COI management) and to increase the transparency of relationships with medical institutions and other parties. Therefore, it is essential to practice appropriate management of conflicts of interest (COI management) and to enhance the transparency of relationships with medical institutions and other parties.

In light of the above, in 2012, the Federation established these guidelines to disclose information on payments of funds to medical institutions and other entities. Since then, the Federation has been working to further ensure and improve transparency and reliability by revising the Guidelines considering revisions to related laws and regulations, changes in the social environment, etc.

In promoting this guideline, we would like to ask for the continued understanding and cooperation of medical institutions and healthcare professionals regarding the purpose of this guideline.

The Japan Federation of Medical Devices Associations

Transparency Guidelines for the Medical Device Industry with Medical Institutions

1. Purpose

The purpose is to ensure the transparency and credibility of the relationship with medical institutions in the activities of member companies, thereby gaining widespread understanding that the medical device industry contributes to the development of life sciences, including medicine and medical engineering, and that corporate activities are conducted with a high level of ethical standards.

Member companies shall formulate their own "transparency guidelines" with reference to these guidelines and make them their own code of conduct.

2. Contents to be disclosed

(1) Method of disclosure

The information will be made public through the company's website and other means.

(2) Release date

To be disclosed within one year after the end of each company's fiscal year.

(3) Subject to public disclosure

Disclose funding and other information for the previous fiscal year in accordance with the following items.

A. Research and development expenses, etc.

Includes costs incurred for research and investigations conducted under public regulations such as the Clinical Research Act and the GCP/GVP/GPSP Ministerial Ordinance based on the Pharmaceuticals and Medical Devices Act, as well as various guidelines.

The funds provided and other information shall be disclosed as follows, along with the annual total amount for each item.

- Specific clinical research expenses (*1)
Name of facility, etc. to be provided (*2): ○○ cases, ○○ yen
- Research expenses based on ethical guidelines (*3)
Name of facility, etc. to be provided (*4): ○○ cases, ○○ yen
- Non-clinical research expenses (*5)
Annual number and total amount of cases, names of facilities, etc. to be served (*4)
- Clinical trial expenses (Clinical trial for marketing authorization)
Name of facility, etc. to be provided (*4): ○○ cases, ○○ yen
- Post-marketing clinical trial expenses
Name of facility, etc. to be provided (*4): ○○ cases, ○○ yen
- Failure/Infectious Case Reporting Fee

Name of facility, etc. to be provided (*4): ○○ cases, ○○ yen

- Post-marketing surveillance expenses

Name of facility, etc. to be provided (*4): ○○ cases, ○○ yen

- Other R&D related expenses

Total annual amount

(*1) "Specific clinical research expenses" means expenses paid under the contract for specific clinical research as defined in the Clinical Research Act.

(*2) "Clinical research identification number," "funding source," "name of the medical institution conducting the research," "name of the principal investigator," etc. will be disclosed.

(*3) "Ethical guidelines" in "research expenses based on ethical guidelines" refers to the " Ethical Guidelines for Medical and Biological Research Involving Human Subjects

(*4) "Names of facilities, etc. to be provided" will be disclosed based on the contents of the contract, including "name of facility," "name of organization within the facility," and "affiliation, title, and name of individual.

(*5) "Non-clinical research expenses" means expenses spent for research other than specific clinical research, research based on ethical guidelines, clinical trials (clinical studies), and post-marketing surveillance, etc., such as so-called "basic research.

B. Academic research grants

Donations include scholarship and general donations for the purpose of academic promotion and research grants, as well as donations for academic societies and other organizations to support the holding of academic meetings, academic co-sponsorship fees, etc. The "academic co-sponsoring fees, etc." includes expenses for co-sponsoring seminars and other events associated with the holding of academic societies, advertising fees, exhibition fees, etc.

The funds provided and other information shall be disclosed as follows, along with the annual total amount for each item.

- Scholarship endowment

○○ University, ○○ Department: ○○ cases, ○○ yen

- General Donations

○○ University (○○ Foundation): ○○ cases, ○○ yen

- Contributions from academic societies, etc.

The ○○th ○○ academic conference (○○ regional meeting, ○○ research meeting): ○○ yen

- Expenses for co-sponsoring academic conferences, etc.

The ○○th ○○ academic society (○○ regional meeting, ○○ research

meeting) : ○○ yen

(*This section also includes information required to be disclosed under the Clinical Research Act.)

C. Manuscript writing fees, etc.

Includes fees paid for outsourcing services such as lectures, manuscript writing and supervision, and other consulting services to provide information on the proper use of the company's medical devices.

The funds provided and other information shall be disclosed as follows, along with the annual total amount for each item.

- Lecturer gratuities
○○ University (○○ Hospital), ○○ Department, ○○ Professor (Head of Department): ○○ cases, ○○ yen
- Manuscript writing and supervision fees
○○ University (○○ Hospital), ○○ Department, ○○ Professor (Head of Department): ○○ cases, ○○ yen
- Consulting and other outsourcing expenses
○○ University (○○ Hospital), ○○ Department, ○○ Professor (Head of Department): ○○ cases, ○○ yen

(*This section also includes information required to be disclosed under the Clinical Research Act.)

D. Information provision-related expenses

Includes the cost of lectures, mock practical training, and briefing sessions necessary for the proper and safe use of the company's medical devices for medical professionals.

- Lecture and other meeting expenses
Number of cases and total amount per year
- Briefing fee
Number of cases and total amount per year
- Medical and medical engineering literature provision expenses
Total annual amount

E. Other expenses

This includes the cost of hospitality and other expenses as a social ritual.

- Hospitality Expenses
Total annual amount

3. Revision History

Established in April 2012

Revised March 2017

Revised April 2019

Revised October 2022

The Japan Federation of Medical Devices Associations

20 member organizations (approx. 4,300 member companies)

As of 10/2022

Japan Medical Optical Instruments Manufacturers Association
Japan Electronics and Information Technology Industries Association
Commerce and Industry Association Japan
Medical Devices Association (JMDA)
Japan Medical Device Technology Association
Japan Medical Device Network Association
Japan Medical Devices Distributors Association
Japan Medical Suture Association
Japan Hygienic Materials Industries Association(JHIA)
Japan Imaging and Medical Systems Industries Association (JIIMA)
Japan Ophthalmic & Medical Instruments Association (JODA)
Japan Contact Lens Association (JCLA)
Japan Condom Industry Association
Japan Dental Industry and Commerce Association
Japan Analytical Instrument Manufacturers Association, Inc.
The Japan Home-Health Apparatus Industrial Association
Japan Hearing Aid Manufactures Association, Inc.
Japan Hearing Aid Dealers Association
Japan Physiotherapy Equipment Manufacturers Association
Japan Association of Laboratory Medicine