

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

The objective of these guidelines is to gain a wider understanding that by ensuring transparency and credibility in the business activities of member companies with medical institutions and other organizations, 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.

## **1. The member companies shall use these guidelines to establish their own transparency guidelines as standards for behavior. The companies will implement the following procedures as preparation.**

- ( 1 ) Draw up procedures to obtain approval for information disclosure from the medical institutions and other organizations (procedures for trust agreement as prerequisite for information disclosure, etc.)
- ( 2 ) Establish a system for the early compilation and release of payment information

## **2. It is desirable that the company include the following items in its transparency guidelines.**

### **( 1 ) Basic policies as a member company**

Member companies in all their activities shall follow 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 JFMDA 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. Member companies shall also set forth their corporate policies for transparency in their dealings with medical institutions and other organizations.

### **( 2 ) Disclosure methods**

Member companies shall disclose compensation provided during the previous fiscal year through their websites or other method after the settlement of accounts.

### **( 3 ) Timing of disclosure**

Payments made during fiscal year 2013 shall be disclosed in fiscal year 2014.

## **( 4 ) Scope of disclosure**

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

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

- Joint research expenses  
Total annual amount
- Contract research expenses  
Total annual amount
- Clinical trial expenses  
Total annual amount
- Post-marketing clinical study expenses  
Total annual amount
- nonconformity and infection case reporting expenses  
Total annual amount
- Post-marketing surveillance expenses  
Total annual amount

### **B. Academic research support expenses**

This includes expenses for scholarships, general and academic conference donations, as well as academic conference co-sponsoring expenses.

- Scholarship donations  
Department, university, number of cases, amount
- General donations  
University/foundation, number of cases, amount
- Academic conference donations  
Conference number, 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, and seminars to provide healthcare professionals with information regarding appropriate and safe use of medical devices.

- 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**

Expenses for receptions and social courtesy

- Reception expenses  
Total annual amount