Regarding the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions

The members of The Japan Pharmaceutical Manufacturers Association are making efforts to improve the transparency/reliability of the relation between corporate activities and medical institutions with cooperation from medical institutions and medical professionals.

The pharmaceutical industry is closely associated with the lives and health of patients and people, and thus, securing transparency and fulfilling accountability are required more for the activities of these industries, compared to other industries, under the national health insurance of the nation of Japan. On the other hand, conflicts of interest occur in some cases in industry-academia collaboration between the pharmaceutical companies and medical institutions or medical professionals, which are essential for delivering optimal pharmaceutical products to patients.
“Appropriate management of the conflicts of interest” and “actions to improve transparency for the relation between the pharmaceutical companies and medical institutions or medical professionals” will be indispensable to make activities of the pharmaceutical companies reliable ethically and in a trustworthy manner, placing a priority on the health of the patients.

Considering the above, The Japan Pharmaceutical Manufacturers Association (hereinafter “JPMA”) prepared in 2011 the “the Transparency Guideline for the Relation between Corporate Activities and Medical Institutions” (hereinafter this “Guideline”) and has publicly disclosed the funds, etc. pertaining to industry-academia collaborative activities with understanding and cooperation from medial institutions and medical professionals.

We believe that efforts which have been promoted by the government agencies concerned and each organization for management of the conflicts of interest and the publication of funds, etc. by member companies of JPMA in accordance with this Guideline would lead to increased confidence in industry-academia collaboration.

JPMA will continue to review this Guideline based on feedback from various sources to further improve transparency and reliability.

We hope that the medical institutions and medical professionals will kindly understand the purpose of this Guideline and provide their cooperation.

Japan Pharmaceutical Manufacturers Association

1. Purpose

The purpose of this Guideline is to gain a wide understanding of the pharmaceutical industry's contribution to life sciences, such as medicine and pharmacy, and for corporate activities to be conducted with high ethical standards, by making the relation between member companies' activities and medical institutions, etc. transparent.

Each member company shall prepare its own in-house "Policy for Transparency" as a code of practice, referring to this Guideline.

2. Contents of publication

(1) Disclosure method

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 Pharmaceutical and Medical Device Act.

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

• Specified clinical trial expenses (Note 1)	Name, etc. of the relevant institution, etc. (Note 2): Number of cases, XX yen
• Research expenses based on ethical guidelines (Note 3)	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
• Research expenses other than clinical trials (Note 5)	Annual number of cases/total amount, name of the relevant institution, etc.
• Clinical trial expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
• Post-marketing clinical study expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
• Adverse drug reaction/infection case reporting expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
• Post-marketing surveillance expenses	Name of the relevant institution, etc. (Note 4): Number of cases, XX yen
• Other expenses	Annual total amount

(Note 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.

(Note 2) "Clinical trial identification number", "institution, etc. to which funds are provided", "name of medical institution conducting the research" and "name of principal investigator", etc. shall be disclosed.

(Note 3) "Ethical guidelines" as used for the "research expenses based on ethical guidelines" shall mean the "Ethical Guidelines for Medical and Biological Research Involving Human Subjects" (life/medical and health guidelines).

(Note 4) For "name of the relevant institution, etc.", "name of the institution", "name of in-house

organization" and "department/title/name of the individual" shall be disclosed based on the contents of the contract.

(Note 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" and "pharmaceutical research."

B. Academic research support expenses

Scholarship donations and general donations made for the purpose of promoting academic research and subsidizing research, etc., as well as donations to academic societies, etc. to support the costs of holding meetings of academic societies, etc. and expenses for co-sponsoring conferences of academic societies, etc.

The "expenses for co-sponsoring conferences of academic societies, etc.", include co-sponsorship expenses for seminars, etc., advertising fees, exhibition fees, etc. incidental to the holding of the meeting.

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

• Scholarship donation	XX Department of XX University: Number of donations, XX yen
• General donation	XX University (XX Foundation): Number of donations, XX yen
• Donation to academic society, etc.	XXth XX Academic Society Meeting (XX Regional Meeting, XX Study Group Meeting): XX yen
• Expenses of co-sponsored conference, etc.	XXth XX Academic Society Meeting (XX Regional Meeting, XX Study Group Meeting): XX yen

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

C. Manuscript/writing fees, etc.

Fees, etc. for provision of scientific information, etc. on the company's pharmaceutical products, medicine, and pharmacy or fees, etc. paid as consideration for lectures and writing or supervision of the manuscript that are related to research and development, or commissioning of services including consulting contracts, etc.

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

• Lecture fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen
• Manuscript writing fee/supervision fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen
• Consulting, etc. commissioning fees	Professor (Director) XX, XX Department of XX University (XX Hospital): Number of services, XX yen

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

D. Information provision-related expenses
Expenses of lecture meetings and explanation meetings, etc. for providing information, etc. related to the company's pharmaceutical products, medicine and pharmacy to medical professionals.

- Expenses for meetings including lectures, etc. — Annual number of meetings and total amount
- Explanation meeting expenses — Annual number of meetings and total amount
- Medical/pharmaceutical literature, etc. supply expenses — Annual total amount

E. Other expenses
Expenses for hospitality, etc. as social courtesy

- Expenses for hospitality, etc. — Annual total amount

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