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, operating under the national health insurance, is closely associated with the lives and health of patients and people, and thus, it is required to secure further transparency and fulfilling further accountability for its activities, compared to other industries. On the other hand, conflicts of interest occur in some cases in industry-academia collaboration between pharmaceutical companies and medical institutions or medical professionals, which are essential to deliver optimal pharmaceutical products to patients.

"Appropriate conflicts of interest management" and "actions to improve transparency of the relation between the pharmaceutical companies and medical institutions or medical professionals" are indispensable to ensure trust from the society, that activities of pharmaceutical companies put patients first and are both ethical and trustworthy.

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 the 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 JPMA member companies in accordance with this Guideline would lead to increased confidence in industry-academia collaboration.

JPMA has striven to improve the transparency/reliability by revising this Guideline referring to opinions from various circles after its formulation. 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.

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

The 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)	Name of the relevant institution, etc. (Note 4)
• 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 Health Research Involving Human Subjects."

(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 for promotion of academic research or research support, etc., and donations to academic societies, etc. and expenses of co-sponsored conferences, etc., as expenses to academic societies, etc. for supporting conferences.

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 Seminar: 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

3. Date of application
This Guideline shall apply to the payments in the new business year that commences on and after October 1, 2018.

Prepared in October 2018