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 World Medical Association (WMA) announced that “Although the cooperation between physicians and commercial enterprises may lead to significant advances in medicine including the development of new drugs and treatments, it may also result in a conflict of interest between commercial enterprises and physicians that may have adverse effects on patients’ care and the reputation of physicians” in the “WMA Statement Concerning the Relationship Between Physicians and Commercial Enterprises”. In addition, WMA stated that “It is desirable to establish the guideline on the relationship between physicians and commercial enterprises, rather than prohibiting such a relationship. In this guideline, major principles must be established for information disclosure, avoidance of an apparent conflict of interest, and clinical autonomy of physicians to act in the best interests of patients” (cited from the homepage of Japan Medical Association) and provided the guidelines for appropriate cooperation between physicians and commercial enterprises.

In the final proposal in April 2010, “Committee for the inspection of the affair of drug-induced hepatitis and the investigation of the desired state of the pharmaceutical regulatory authority for prevention of recurrence” stated that “It has also been pointed out that the mutual dependence (conflict of interest, etc.) between commercial enterprises and the country, medical institutions, academic society, and medical professionals constituted the background for the affair of drug-induced hepatitis. It is essential to change the way of thinking of the commercial enterprises and the associated personnel”. The interaction among pharmaceutical companies, medical institutions, and medical professionals is essential in order to deliver optimal pharmaceutical products to patients; however, it must be reliable as an ethical and trustworthy relationship that places a priority on the health of the patients. The proposal requests for appropriate management of the conflicts of interest and actions to improve transparency. The latter has been attempted in countries outside Japan. In Japan, efforts have been made to address management of the conflicts of interests in the Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health, Labour and Welfare, and The Japanese Association of Medical Sciences, etc. In various industry-academia collaborative activities conducted by the pharmaceutical companies and medical professionals, specifying the involvement of the commercial enterprises in accordance with this Guideline would contribute to the assurance of reliability for these activities.

This Guideline has been established because the pharmaceutical industry is largely associated with the lives and health of patients and people as life-related industries and more transparency is required for the activities of these industries, compared to other industries, under the national health insurance of the nation of Japan. We continue to strive for more transparent corporate activities, taking this opportunity to carry out this Guideline.

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 wide understanding of the pharmaceutical industry's contribution to life science such as medicine and pharmacy, and that corporate activities are conducted with high ethical standards, by making the relation between member company's 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

It is desirable to declare the member company's stance and include the following items in the in-house "Policy for Transparency".

(1) Disclosure method

The payments, etc. in the previous fiscal year shall be disclosed after financial closing through each company's website, etc.

(2) Timing of disclosure

The payments in each fiscal year shall be disclosed in the following fiscal year. However, for "A. Research and development expenses" included in (3) Targets of disclosure, only the "annual total amount" shall be disclosed in the following fiscal year up to fiscal 2015. From fiscal 2016 and onwards, "annual total amount" and the items specified in (3) Targets of disclosure shall be disclosed from fiscal 2017.

(3) Targets of disclosure

A. Research and development expenses

Research and development expenses include expenses of clinical studies, clinical trials for new drugs and post-marketing clinical studies conducted under public regulations such as the GCP ordinance. Also expenses for adverse drug reactions/infection case reporting and post-marketing surveillance activities that are conducted under public regulations such as GPSP ordinance and GVP ordinance are included.

• Joint research expenses (Clinical) (Note 1)	Name of the relevant institution (Note 3): Number of cases, XX yen
(Others) (Note 2)	Annual number of cases/total amount, name of the relevant institution (Note 3)
• Research commissioning expenses (Clinical) (Note 1)	Name of the relevant institution (Note 3): Number of cases, XX yen
(Others) (Note 2)	Annual number of cases/total amount, name of the relevant institution (Note 3)
• Clinical study expenses (Clinical studies)	Name of the relevant institution (Note 3): Number of cases, XX yen
• Post-marketing clinical study expenses	Name of the relevant institution (Note 3): Number of cases, XX yen
• Adverse drug reaction/infection case reporting expenses	Name of the relevant institution (Note 3): Number of cases, XX yen
• Post-marketing surveillance expenses	Name of the relevant institution (Note 3): Number of cases, XX yen
• Other expenses	Annual total amount

(Note 1) Clinical: Expenses related to clinical research in and after Phase I
(Note 2) Others: Expenses other than those for clinical research in and after Phase I
(Note 3) As the "Name of the relevant institution", "Name of the institution", "Name of the organization within the institution", or "Affiliation/title/name of an individual" shall be published based on the contents of the contract.

B. Academic research support expenses

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

• 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

C. Manuscript/writing fees, etc.

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

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

D. Information provision-related expenses

Expenses of lecture meetings and explanation meetings for providing information, etc. related to the company's pharmaceutical products, medicine and pharmacy to healthcare 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

End

Revised in February 2015