

Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations

Japan Pharmaceutical Manufacturers Association (JPMA)

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<In formulating Guidelines>

The mission of R&D-based pharmaceutical companies is to contribute to the improvement of health and medical care for people around the world through the continuous creation and stable supply of innovative new medicines, thereby contributing to the realization of a healthy and comfortable society.

In recent years, the importance of "patient participatory medicine" has been recognized, and efforts to realize this concept have been considered and implemented in various fields. To fulfill the above mission, pharmaceutical companies recognize the needs and concerns of patients and their families at every stage of the relationship between medicines and patients, from the drug discovery stage to the promotion of appropriate use and safety measures for medicines after marketing. Opportunities for active and continuous collaboration with patient organizations have been increasing. In addition, both the government and the medical community are placing a greater emphasis on the "patient voice," and representatives of patient organizations are increasingly participating as members of administrative authority committees and study groups.

As the influence of patient organizations increases in this way, the needs for pharmaceutical companies are increasing to continuously act with integrity and ensure transparency to gain a correct understanding from the public about collaboration with patient organizations. Overseas, in 2007, the European Federation of Pharmaceutical Industries and Associations adopted the "Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations" to ensure that the relationship between pharmaceutical companies and patient organizations is ethical and transparent.

Under these circumstances, Japan Pharmaceutical Manufacturers Association (hereinafter "JPMA") believes that it is important to gain a broad understanding that activities such as financial and other supports provided by the member companies to patient organizations are sincere and ethical, which contribute to the activities and development of patient organizations, by disclosing information and ensuring greater transparency under certain rules. In 2012, JPMA formulated the "Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations." (hereinafter "this guideline")

Later, at the APEC Business Ethics Forum held in Japan (Tokyo) in 2018, patient organizations, government, healthcare professionals, and the pharmaceutical and medical device sectors declared their commitment to promoting transparency and accountability within the "Japanese Consensus Framework for Ethical Collaboration."

JPMA continues to review this guideline to make it easier to understand and in line with the times. The member companies will continue to formulate and faithfully apply their own "Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations" by referring to this guideline.

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This guideline is intended to ensure transparency for the relationship between activities of the member companies and patient organizations and to foster a broader understanding that those activities, ensuring high ethical standards and mutual understanding about the respect for the independence of patient organizations, contribute to activities and development of patient organizations.

1. The member companies shall formulate and act upon their own "Transparency Guideline for Relationships with Patient Organizations" with reference to this guideline.
2. Patient organizations refer to patient organizations and patient support groups that are composed mainly of patients/family members and their advocates, represent the voices of patients, support patients and their families, aim to improve the medical treatment environment, and, in principle, have roles or purposes defined by the articles of incorporation and rules. However, the criteria

for making such decisions shall be left to each of the member companies. In addition, the criteria for selecting organizations to be funded and supported shall be based on the judgment of each of the member companies.

3. It is desirable to state the following in their own "Transparency Guideline for Relationships with Patient Organizations."

Attitude of Member Companies

The member companies shall respect the independence of patient organizations and ensure transparency relationship. To ensure transparency, they shall disclose the fact that they are involved with patient organizations. For funding, they shall make a written contract or agreement, etc. on the purpose, content of activities, etc. with patient organizations before implementation and keep records of such activities and funding. In addition, all activities conducted by the member companies with patient organizations shall comply with the relevant norms such as "JPMA Charter of Corporate Behavior," "JPMA Compliance Program Guidelines," "JPMA Code of Practice," "Transparency Guideline for the Relation between Corporate Activities and Medical Institutions," "Guidelines for Collaboration with Patient Organizations" and the spirit of these norms, as formulated by Japan Pharmaceutical Manufacturers Association (JPMA).

4. Subjects and Contents to be Disclosed

The member companies shall disclose the details of patient organizations to which they have provided direct funding, indirect funding, compensation for requests from the member companies and labor services.

(a) Direct Funding

(Subjects)

Donations, membership/supporting membership fees, sponsorship costs, advertising costs, etc.

(Contents)

The member companies shall list the names of the patient organizations they directly funded and the amount for each expense item. However, the method of setting expense items shall be at the discretion of each of the member companies.

(b) Indirect Funding

(Subjects)

Expenses associated with company-sponsored and co-sponsored lectures, briefings, workshops, etc. for the purpose of supporting

patient organizations

Outsourcing expenses in connection with supporting patient organizations

(Contents)

The member companies shall list the names of the patient organizations they indirectly funded and the total amount of indirect funding. It is not necessary to list each patient organization or expense item separately.

(c) Compensation for requests from the member companies

(Subjects)

Compensation to lecturers, manuscript writing/supervision fees, research fees, commission fees for advisors, etc.

(Contents)

The member companies shall list the names of the patient organizations and the amount of each expense item requested by the member companies. However, the method of setting expense items shall be at the discretion of each of the member companies.

(d) Other

(Subjects)

Providing of Labor Services

(Contents)

The member companies shall list the names of patient organizations they provided labor services to.

5. When to Disclose

The member companies shall disclose the previous physical year's funding and other information through their websites, etc. after announcing their financial results.