

Guideline for Collaboration with Patient Organizations

Japan Pharmaceutical Manufacturers Association (JPMA)

(Formulated on January 16, 2013, implemented on April 1, 2013)

(Revised February 22, 2017, implemented April 1, 2017)

(Revised September 25, 2017, implemented April 1, 2018)

(Revised May 25, 2022, implemented May 25, 2022)

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. Pharmaceutical companies have increasing opportunities to collaborate with patient organizations actively and continuously.

Under these circumstances, in 2013, the member companies formulated the "Guideline for Collaboration with Patient Organizations (hereinafter, "this guideline")" endeavoring to ensure that they act with high ethical standards and sincerity in all collaborations with patient organizations, respect the independence of patient organizations, and understand each other well with patient organizations about the purpose and content of collaboration.

Later, at the APEC Business Ethics Forum held in Japan (Tokyo) in 2018, patient organizations, government, healthcare professionals, the pharmaceutical and the medical device sectors declared the establishment of the "Japanese Consensus Framework for Ethical Collaboration" with the principles of "put patients first," "support ethical research and innovation," "ensure independence and ethical conduct" and "promote transparency and accountability."

JPMA continues to review this guideline to make it easier to understand and in line with the times. The member companies that collaborate with patient organizations will continue to formulate and faithfully apply their own "Guideline for Collaboration with Patient Organizations" by referring to this guideline.

1. Mutual Understanding

The member companies shall collaborate with patient organizations based on mutual understanding, respecting their views and decisions.

2. Building Relationships of Trust

The member companies shall build the relationship of trust with patient organizations on an equal footing and play their respective roles in realizing common objectives.

3. Respect for the Independence of Patient Organizations

The member companies shall respect the autonomy and independence of patient organizations concerning their policies and operations.

4. Ensuring Transparency

The member companies shall disclose appropriate information regarding financial and other support they provide to patient organizations in accordance with the "Transparency Guidelines for the Relationship between Corporate Activities and Patient Organizations."

5. Written Agreements, etc.

The member companies shall make a written contract or agreement, etc. on the purpose and content of activities and funding for collaboration with patient organizations before implementation and keep records of such activities and funding.

6. Providing Appropriate Information

The member companies shall provide information to patient organizations in accordance with relevant laws and regulations.

7. Prohibition of Advertising and Promotion of Products

The member companies shall not advertise or promote ethical drugs to patient organizations.

8. Prohibition of Exercising of Influence

The member companies shall not exercise any influence over patient organizations for the company's benefit regarding the contents of materials, publications, websites, social networking sites, or statements made by patient organizations.

9. Recommending Diversity of Funding Sources

The member companies shall not provide support on the condition that they become an exclusive funder. Patient organizations shall be encouraged to seek funding for their activities from multiple sources.

10. Appropriate Support

The member companies shall provide support to patient organizations only to an appropriate level and scope. The member companies shall provide appropriate support for meetings, etc. held by patient organizations after confirming that they are suitable for the purposes.

11. Management and Protection of Personal Information

In collaboration with patient organizations, the member companies shall respect the privacy of patients and patient advocates, comply with relevant laws and regulations such as the Act on the Protection of Personal Information, and properly manage and protect personal information obtained through collaborative activities.

Glossary

Patient Organizations

In this guideline, 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, it does not matter whether or not there is a legal personality and which form it is founded in.

Collaboration with Patient Organizations

Collaboration with patient organizations means that pharmaceutical companies and patient organizations work together on an equal footing. Activities range from interactions with and support for patient organizations to activities aimed at solving shared issues.

Financial support, etc.

These refer to direct funding such as donations, indirect funding associated with lectures and other events, compensation such as lecturer's fees, and the provision of labor services to patient organizations. Please refer to "Transparency Guideline for the Relationship between Corporate Activities and Patient Organizations."