

INTERACTION AND RELATIONSHIPS WITH THE PHARMACEUTICAL INDUSTRY

Policy Statement

The Fabry International Network (FIN) recognises the importance of maintaining relationships with the pharmaceutical companies that have FDA or EMA approved therapies or devices or who are developing therapies or devices for individuals with Fabry disease. Ethical relationships with companies are critical to ensuring that FIN provides accurate and unbiased education to individuals and their families affected by Fabry disease about available and future therapies or devices.

The role of the pharmaceutical industry is to provide an educational role to FIN about the benefits and risks of therapies and devices and to provide scientific and educational information. The information received from the pharmaceutical industry must be managed and tempered due to its conflicted nature.

Through interaction between FIN and the pharmaceutical companies, they may gain unique patient perspectives in living with Fabry disease, information about the needs and priorities of FIN members as well as insight into clinical trial designs. This interaction also provides the opportunities for project collaboration including but not limited to disease focus groups, Health Technology Assessment surveys, medical education about diseases and advocacy for product (therapy / device) approval and reimbursement.

Through dialogue and cooperation with the pharmaceutical industry, FIN and national patient associations can promote and support their objectives in working towards achieving the best interest of their members.

The purpose of this policy is to ensure ethical, accountable, and transparent collaboration between FIN, its members and the pharmaceutical industry. FIN suggests to its members association to use this policy. This policy draws upon the existing EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations¹, the World Health Organization's Guidelines on Interaction with Commercial Enterprises to Achieve Health Outcomes, EB107/202 and the Interaction PVO Standards (pertaining to Pharmaceuticals and Medical Resources).

- FIN shall not promote or show favor to a particular prescription-only or non-prescription medicine.
- The pharmaceutical industry shall not request the promotion of a particular prescription-only or nonprescription medication.
- All partnerships between FIN and the pharmaceutical industry shall be based on mutual respect, with
- views and decisions of each partner having equal value.
- The objectives and scope of any partnership shall be transparent. Financial and nonfinancial support
- provided by the pharmaceutical industry shall always be clearly acknowledged.
- FIN shall welcome broad funding from multiple sources

Any collaboration between FIN and a pharmaceutical company must be structured and delivered to ensure and consolidate the integrity, reputation and continued success of the involved parties, and on adding value to patients.

Collaboration between FIN and a pharmaceutical company must comply with:

1. the relevant national laws and regulations, and
2. the pharmaceutical organisation's specific code of practice/internal guidelines.

Collaborations should also have specific aims and meet the following basic criteria:

- a) The relationship should contribute to improving the health and quality of life of Gaucher patients and or their carers;
- b) Terms of all relationships should be recorded by an exchange of clearly written letters or agreements indicating the contribution (financial or otherwise) and expectations that each of the parties brings to the relationship.

Evaluation criteria should be developed and applied to assess arrangements and collaborations with pharmaceutical companies, including: the public image, financial stability and integrity of the company. FIN should develop and maintain written policies and procedures to evaluate potential pharmaceutical donations to ensure that they meet appropriate legal, cultural, and ethical criteria.

Accepting donations/financial support

All donations and financial support should be used in the furtherance of the stated mission, purpose, and program objectives of the patient association, and for the benefit of Gaucher patients without prejudice to race, class, sex, or political or religious affiliation.

Funds should not be sought or accepted from pharmaceutical companies that have a direct commercial interest in the outcome of the project toward which they would be contributing.

Written agreements

When pharmaceutical companies provide financial support, significant indirect support and/or significant nonfinancial support to FIN, for any reason, there must be a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting, projects, etc.). It must also include a description of significant indirect support (e.g. the donation of public relation agency's time and the nature of its involvement) and significant nonfinancial support. FIN should maintain documentation relating to the handling and use of all donations.

Transparency: acknowledgement of donations and sponsorships

FIN must make publicly available a list of pharmaceutical companies that provide financial support and/or significant indirect/non-financial support. This should include a short description of the nature of the support, updated yearly. The basic and most common approach to such recognition is to insert an acknowledgement in documentation relating to the activity concerned and by posting an acknowledgement on the member association website.

Guidance for compensation

There are several situations where industry may propose honoraria to a patient organisation's volunteers or staff members:

- Participation in a meeting or conference organised by the company itself.
- Participation in a meeting or conference organised by a third party.
- Reviewing industry materials, leaflets, protocols etc.
- Consultancy on industry policy, advisory committees etc.

This is current practice for health care professionals. Patient organisations should be considered on an equal basis, and therefore can also receive honoraria for similar circumstances. Payments made to officers or members arising from any such activities should be directed to the FIN rather than to the individual participant or officer of the FIN personally. FIN board members may not receive honoraria directly. A formal agreement should be in place.

Communication

When FIN decides to communicate to the media about Fabry disease or a product it may issue its own press release which is clearly independent of industry. The FIN Board will consider any request by the pharmaceutical industry for FIN to provide a quote taking into consideration current legislation and risk to reputation.

FIN will consider carefully before accepting any invitation to participate in a pharmaceutical company led training opportunity.

FIN will on written request from the pharmaceutical industry be receptive to providing appropriate photographic material that reflects disease course or impact after internal discussion.

FIN will not in any other way contribute to pharmaceutical industry websites except agreeing hyperlinks to the FIN website.

FIN will meet on a regular basis with the pharmaceutical companies, this will be clearly stated in funding agreements with said companies

- Facilitate and coordinate 1/2* individual face to face meeting with the FIN Board* per year - planned to coincide with FIN Expert meeting or congresses and meetings that FIN attends
- Facilitate 1/2* virtual meeting with the FIN Board* per year – to be scheduled in accordance with availability of the FIN Board

*based on partnership

*meetings with FIN Board might not always be with all of the members or the board

FIN invites pharmaceutical companies to attend the annual FIN Expert Meeting.

FIN offers two representatives of the invited pharmaceutical companies attendance free of charge (including registration and meals – excluding accommodation and travel)

FIN welcomes the attendance of one additional colleague but a charge will be incurred for registration and accommodation.

The meeting focus is for patients and patient advocates. Attending pharmaceutical company representatives must be company employees and may attend as observers rather than active participants. Not all planned activities are open to pharmaceutical company attendees.

Policy agreed: December 2020