

IGA Code of Practice on Relationships with the Pharmaceutical Industry



Introduction

The International Gaucher Alliance (IGA) is an international umbrella group representing the interest of Gaucher patients and those of non-for-profit Gaucher patient groups as well as rare disease groups throughout the world.

The IGA's vision is 'A world where all Gaucher patients have access to the treatment and care they need and there is a possibility of a cure'.

The IGA's has the mission to be the global voice for Gaucher patients and their families:

- to empower its members'
- to advocate on behalf of Gaucher patients to ensure that the Gaucher research agenda is focused on patients' unmet needs
- to take collective action to address challenges Gaucher patients worldwide face in accessing early diagnosis and optimal treatment and care.

The IGA's Strategic imperatives are:

- Improve Gaucher patients' access to optimal diagnosis, treatment and care
- Provide a strong voice for Gaucher patients worldwide
- Influence the Gaucher research agenda so that it's focused on addressing key unmet needs
- Support member organisations to be more effective and sustainable

IGA recognises that:

- The IGA and Gaucher patient associations, as public charities and not-for-profit entities, may depend on voluntary/pro bono work to run their day-to-day operations and activities, and may be financed by public and/or private funds, i.e. membership fees, donations and corporate sponsorships, including the pharmaceutical industry; and
- Pharmaceutical companies engage in research, development and marketing of products that aim to treat Gaucher disease and manage patients disease and are viewed as a natural collaborative partner.

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

Purpose of the Code

The purpose of this code is to ensure ethical, accountable, and transparent collaboration between IGA, its members and the pharmaceutical industry. The IGA suggests to its members association to use this code. This code draws upon the existing *EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations*¹, the World Health Organization's *Guidelines on Interaction with Commercial Enterprises to Achieve Health Outcomes, EB107/20*², and the *Interaction PVO Standards (pertaining to Pharmaceuticals and Medical Resources)*³.

The IGA, national patient association and pharmaceutical company share an inspiration in ensuring that their individual integrity is maintained when collaborating. Hence, all types of collaboration between the parties are not only to apply to any given rules and guidelines, but also to “good corporate governance”, including this document that defines agreed best practice for collaboration between the parties.

In developing relationships with pharmaceutical companies to further the mission of the IGA and a national Gaucher patient association, consideration should be given as to whether the proposed relationship might involve a real or perceived conflict of interest and IGA/IGA members’ reputation and integrity must be ensured.

The IGA commits itself to adhering to the provisions of this code in all its dealings with industry. It encourages its member organisations to commit to adhering to the provisions of this code when dealing with industry. The IGA expects pharmaceutical companies to adhere to the provisions of this code in all its dealings with the IGA or other national patient groups.

Principles of the Code

- IGA 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 non-prescription medication.
- All partnerships between IGA 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.
- IGA shall welcome broad funding from multiple sources.

The nature and execution of collaboration between IGA and a pharmaceutical company

Any collaboration between IGA 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 IGA 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. IGA 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 non-financial support to IGA, 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. IGA should maintain documentation relating to the handling and use of all donations.

Transparency: acknowledgement of donations and sponsorships

IGA 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 individual 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 IGA rather than to the individual participant or officer of the IGA personally.

This Code of Practice has been adopted by the IGA and will govern its relationship as a separate body with commercial organisations in the field of Gaucher Disease. The IGA will encourage its member organisations to adhere to the provisions of the Code of Practice and express itself to be bound by its terms and express the expectation that commercial organisations will adhere to the principles herein contained in all its dealings with national patient organisations.

References:

1. EFPIA code of practice on relationships between the pharmaceutical industry and patient organizations (5/10/2007). https://www.efpia.eu/media/24310/3c_efpia-code-of-practice-on-relationships-pharmaplust-ops.pdf
2. World Health Organization (EB107/20, November 2000). Guidelines on interaction with commercial enterprises to achieve health outcomes
3. Interaction PVO Standards (November 2009).
4. IFPA Code of Practice on Relationships with the Pharmaceutical Industry <https://ifpa-pso.com/wp-content/uploads/2017/01/IFPA-Code-of-Practice-on-Relationships-with-the-Pharmaceutical-Industry-2017.pdf>

Issue	Description of Change	Approval	Date of Issue
1	Reference to new vision, mission and change of name from EGA to IGA	TCH/Board	24/03/2019