

Code of Practice on Relationships with the Commercial Organisations

Introduction

1. The object of the EWGGD is to promote research into Gaucher disease and to improve the lives of patients with Gaucher disease and to do anything that is in keeping with this object or may be conducive to it.
2. The EWGGD seeks to achieve this object by bringing together researchers, scientists and patients in order to discuss freely all aspects of Gaucher disease, to promote the presentation and publication of scientific data and research and periodically to organize workshops.
3. The EWGGD is a not for profit organisation.

1. It is recognised that:

- 1.1. The EWGGD and its member groups, as not-for-profit entities, may depend on voluntary/pro bono contributions to run its operations and activities, and may be financed by public and private funds, including membership fees, private donations and corporate sponsorship, including donations and sponsorship from the Commercial Organisations; and
- 1.2. Commercial Organisations including pharmaceutical companies engage in research, development and marketing of products that aim to treat Gaucher disease and manage patient's disease and are viewed as a natural collaborative partner of the EWGGD.
- 1.3. Through dialogue and cooperation with the Commercial Organisations, the EWGGD and its member groups can promote and support their objectives in working towards achieving the best interest of Patients.

2. Purpose of the Code

- 2.1. The purpose of this code is to ensure ethical, accountable, and transparent collaboration between EWGGD, its members and the Commercial Organisations.
- 2.2. This code draws upon the *EFPIA (European Federation of Pharmaceutical Industries and Associations) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organizations*, 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) and the code of practice adopted by the International Gaucher Alliance (IGA).
- 2.3. It is recognised that the EWGGD, and Commercial Organisations share an aspiration to ensure that their integrity is maintained when collaborating. Accordingly collaboration between the parties is not only to be governed by European and National rules and guidelines, but also by principals of "good corporate governance", and this code defines agreed best practice for collaboration.
- 2.4. In developing relationships with Commercial Organisations to further the objects of the EWGGD, consideration should be given as to whether the proposed relationship might involve a real or perceived conflict of interest and not damage the reputation and integrity of the EWGGD which must be ensured.
- 2.5. The EWGGD, commits itself to adhering to the provisions of this code in all its dealings with the Commercial Organisations. It encourages its member organisations to commit to adhering to the provisions of this code when dealing with the Commercial Organisations. The EWGGD expects Commercial Organisations to adhere to the provisions of this code in all its dealings with the EWGGD and its member organisations.

3. Principles of the Code

- 3.1. The EWGGD, shall not promote or show favour to a particular prescription-only or non-prescription medicine.
- 3.2. A Commercial Organisation shall not request the promotion of a particular prescription-only or non-prescription medication.
- 3.3. All partnerships between EWGGD, and members of the Commercial Organisations shall be based on mutual respect, with views and decisions of each having equal value.
- 3.4. The objectives and scope of any partnership shall be transparent. Financial and nonfinancial support provided by the Commercial Organisations shall always be clearly acknowledged.

- 3.5. The EWGGD welcomes and invites funding from multiple industry sources on the basis of this code.
- 3.6. Clinical data shall belong to the patient but subject to the patient giving express consent and the data being anonymised so that no individual patient may be identified such data may be disseminated to advance the interest of patients generally and such dissemination may not be restricted due to sponsorship by a Commercial Organisation

4. The nature and execution of collaboration between EWGGD and a pharmaceutical company

- 4.1. Any collaboration between EWGGD, and a Commercial Organisation 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.
- 4.2. Collaboration between EWGGD, and a Commercial Organisation must comply with:
 - 4.2.1. the relevant National and European laws and regulations, and
 - 4.2.2. the Commercial Organisation's internal code of practice and/or policy guidelines.
 - 4.2.3. all regulations related to GDPR
- 4.3. All collaborations should also have specific aims and meet the following criteria:
 - 4.3.1. The relationship should contribute to improving scientific understanding of Gaucher disease, education of Gaucher specialists and the improvement in the health and quality of life of Gaucher patients and or their carers.
- 4.4. Evaluation criteria should be developed and applied to assess arrangements and collaborations with Commercial Organisations, including the impact on the public image, the financial impact, and outcomes of the collaboration and integrity of the parties.
- 4.5. The EWGGD, should develop and maintain written policies and procedures to consider potential donations from Commercial Organisations to ensure that they meet appropriate legal, cultural, and ethical criteria and comply with this Code.

5. Accepting donations/financial support

- 5.1. All donations and financial support must be used in the furtherance of the stated mission, purpose, and program objectives of the EWGGD, and for the benefit of Gaucher patients without prejudice to race, class, gender, sexual orientation, political or religious affiliation.
- 5.2. Funds should not be sought or accepted from Commercial Organisations for the promotion of an event or project that may result in a direct financial benefit from the outcome of the event or project toward which they would be contributing.

6. Written agreements

- 6.1. When Commercial Organisations provide financial support, significant indirect support and/or significant non-financial support to the EWGGD, there must be a written agreement.
- 6.2. Such Agreement must detail the amount of funding (or other support) and also the mode of support (e.g. unrestricted grant, specific meeting support, project support,).
- 6.3. The Agreement must also include a description of any significant indirect support (e.g. the donation of public relation agency's time and the nature of its involvement) and any significant nonfinancial support.
- 6.4. The EWGGD must maintain documentation records relating to the handling and use of all support.

7. Specific Regulations for sponsors of the EWGGD Scientific Workshop

The main purpose of the workshop is to facilitate the primary goal of the EWGGD, which is to promote clinical and basic research into Gaucher disease for the ultimate purpose of improving the lives of patients with this disease. It brings together clinicians, scientists and patients in an open forum for discussion on all aspects of the condition. The opportunity for presenting unpublished scientific data as well as free discussion is a central premise of the Group.

Although a limited number of representatives from commercial parties are invited to attend the workshop, the Working Group seeks to ensure that at all times it remains an independent organisation with a not for profit purpose. Fundraising to support the workshops from commercial parties is allowed, according to the following rules:

- 7.1. Commercial Organisations may not participate in the work of the international or local scientific or planning committees – the latter convened to assist with the programme development for individual workshops.
- 7.2. Financial support from Commercial Organisations should always come from more than one company

- 7.3. The total amount of financial support from Commercial Organisations is primarily used to support the workshop, but can in addition be used by EWGGD for the purpose of providing travel grants, scholarships or costs for maintenance of the EWGGD,
- 7.4. the EWGGD will disclose details of all financial support received in the annual financial report.
- 7.5. Financial support from Commercial Organisations should always be unrestricted. Funds will only be accepted on the basis that no commercial party can make specific demands, such as asking for benefits not accorded to other donors.
- 7.6. Commercial Organisations cannot sponsor the attendance of specific attendees to a workshop directly or indirectly. Participants can apply for a travel grant from Commercial Organisations as per their local regulations or through the EWGGD website.
- 7.7. The number of delegates from the Commercial Organisation allowed to attend the workshop depends on the financial support provided by the company. For each 10.000 € donation a company is entitled to register one corporate delegate.
- 7.8. At the discretion of the local Organising committee Commercial Organisations giving sponsorship above a level determined from time to time by the organising committee are entitled to have a stand in an area designated by the local organising committee. The people servicing the stand (not more than two per stand are permitted) need not be delegates at the Workshop, but if not delegates they may not attend the scientific sessions or social functions.
- 7.9. Commercial Organisations delegates may not promote their product(s) directly to patient delegates
- 7.10. Commercial Organisations may hold meetings before or after the Workshop i.e. of a whole or half day's duration. This is welcomed as it helps to prevent proliferation of meetings and is an efficient use of members' time. Satellite meetings, including separate closed or private meetings/dinners taking place during the duration of the Workshop from its opening until its official closing, are not permitted.

8. Transparency: acknowledgement of donations and sponsorships

- 8.1. The EWGGD, will publish a list of Commercial Organisations 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. This will include an acknowledgement in documentation relating to the activity concerned and by posting an acknowledgement of such support on its website.
- 8.2. The EWGGD will disclose sponsorship in publications
- 8.3. Member organisations are specifically encouraged to adopt the same approach to ensure transparency
- 8.4. The EWGGD will retain all intellectual property, for the benefit of patients, arising from all activities resulting from industry donations or sponsorship.

9. Guidance for individual compensation

Individuals receiving personal compensation or institutional support from Commercial organisations are expected to comply with the relevant national or European laws and regulations, and the Commercial Organisations specific code of practice/internal guidelines and to make disclosure of all support in presentations and in publications.

10. This Code of Practice has been adopted by the EWGGD.

- 10.1. This Code is designed to govern its relationship as a separate body with pharmaceutical companies in the field of Gaucher Disease.
- 10.2. The EWGGD encourages its member organisations to adhere to the provisions of this Code of Practice to express itself be bound by its terms and to express the expectation that pharmaceutical companies will adhere to the principles herein contained in all its dealings with member organisations of the EWGGD.

References:

1. EFPIA code of practice on relationships between theand patient organizations (5/10/2007). https://www.efpia.eu/media/24310/3c_efpia-code-of-practice-on-relationships-pharmapluspt-orgs.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 <https://ifpa-pso.com/wp-content/uploads/2017/01/IFPA-Code-of-Practice-on-Relationships-with-the-Pharmaceutical-Industry-2017.pdf>