CODE OF PRACTICE
ON RELATIONSHIPS
BETWEEN PIERRE-FABRE GROUP
AND PATIENT ORGANIZATIONS

- MAY 2017 -

Pierre Fabre

INTRODUCTION

Any Pierre Fabre Group's affiliate that is involved in pharmaceutical products or medical devices development (hereinafter referred to as *Pierre Fabre Affiliates*) may conclude arrangements with patient organizations.

These interactions aim ultimately to help patients and contribute to the optimization of healthcare. Additionally, patients can play a role in helping pharmaceutical development: incorporating their voice contributes in particular to design better clinical study protocols and allows to better define Target Product Profiles.

This code of practice aims at covering relationships between *Pierre Fabre Affiliates* and **patient organizations**. It refers to the different Pierre Fabre laboratories codes[1,2] and complies with the code of practice on relationships between the pharmaceutical industry and patient organizations adopted by the *European Federation of Pharmaceutical Industries and Associations* (EFPIA) and the French Pharmaceutical Companies Association -*Les Entreprises du Médicament* (LEEM)-.

Patient organizations are defined as not-for-profit organizations duly registered (including the umbrella organizations to which they belong), mainly composed of patients and/or caregivers, that represent and/or support the needs of patients and/or caregivers.

This code of practice builds on the following principles that *Pierre Fabre Affiliates* will always be keen to observe in its relations and partnership with patient organizations:

1. **Independence** of patient organizations must be guaranteed, in particular with regards to their policies, activities and political judgment.
2. **Mutual respect** is the basement of partnerships, with the views and decisions of each partner having equal value.
3. **Non-commercial objectives**: the promotion of a Pierre Fabre's drug shall never be the reason or purpose of the partnership.
4. **Transparency**: the objectives, the scope of partnership, financial and non-financial support provided by *Pierre Fabre Affiliates* shall always be clearly acknowledged.
5. **Non-exclusive relationships**: *Pierre Fabre Affiliates* will never require to be the sole funder of a patient organization or any of its major programmes.

APPLICABILITY

This code of practice must apply in a manner compatible with national laws and regulations to which *Pierre Fabre Affiliates* may be subject and/or with applicable pharmaceutical industry codes dealing with relationships between pharmaceutical industry and patient organizations countries in which the activities

[1] *Code of Ethics - Pierre Fabre Laboratories (2015)*
[2] *Pierre Fabre Médicament & santé: Promotion of Drugs & Relationships in the Healthcare Sector - Code of Best Practices (January 2015)*

take place. In the event of a conflict between the provisions of this code and any other applicable codes or laws referred to above, the more restrictive of the conflicting provisions shall apply, as much as they do not violate any law in force.

The code that applies is to be specified in the written agreement between *Pierre Fabre Affiliates* and patient organizations.

Principles and rules describes below apply to all relationships between *Pierre Fabre Affiliates* and patient organizations and must be respected by any Pierre Fabre Affiliates employee dealing in this context.

PROVISIONS

ARTICLE 1

Non-promotion of medicines

Promotion of Pierre Fabre's drug must never be considered within the context of relationships between *Pierre Fabre Affiliates* and patient organizations partnerships.

ARTICLE 2

Nature of Services

Pierre Fabre Affiliates may subcontract to patient organizations different types of services only if such services are aimed at supporting healthcare or research and only if such services are authorized as per the corporate charters of both the patient organizations and the Pierre Fabre affiliate.

Pierre Fabre Affiliates may also engage patient organizations as experts or advisors such as attendance to advisory board meetings and speaker's services. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a. A written agreement is signed in advance (see Article 3);

b. A legitimate need for the services has been clearly identified and documented prior to requesting the services and entering into the arrangements;

c. The criteria for selecting services are directly related to the identified need and the persons responsible for selecting the services have the expertise necessary to evaluate whether the particular experts and advisors meet those criteria;

d. The extent of the service is not greater than is reasonably necessary to achieve the identified need;

e. *Pierre Fabre Affiliates* maintain records concerning, and make appropriate use of, the services;

f. The engaging of patient organizations is not an inducement to recommend a particular medicinal product;

g. The compensation for the services is reasonable and does not exceed the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating patient organizations.

ARTICLE 3

Written agreement

All services subcontracted, partnerships, funding, indirect or non-financial support to patient organizations must be set out in a written agreement. The agreement must specify:

- the purpose of the partnership, funding or support and a clear description of the nature of the involvement of *the parties*;
- the nature of services subcontracted and the basis for payment of those services;
- a description of the assistance or indirect support and of non-financial support;
- the amount of funding, payments etc.. ;
- whether the Pierre Fabre affiliate wish to use the logo of the organization or equipment bearing the organization's name or logo. In that case, the terms of use must be specified;
- information concerning the publication of transfers of value between the Pierre Fabre affiliate and the organization should be included according to applicable regulations and legislation, in terms of the transparency of relationships and personal data protection.
- a provision regarding an obligation of patient organizations to declare, whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to *Pierre Fabre Affiliates*, that they have provided paid services to *Pierre Fabre Affiliates,* or received funding or indirect or non-financial support from *Pierre Fabre Affiliates*.
- the reference to the professional/national code(s) of ethics that is (are) in force in this agreement.

All parties should be fully aware that sponsorship must be clearly acknowledged and apparent from the outset.

ARTICLE 4

Editorial control

Pierre Fabre Affiliates must not seek to influence or select the text on the organization’s material or equipment in order to favor its own interest. Correction for factual errors may still be proposed.

The purpose of the partnership must not be to promote the Pierre Fabre’s drugs, and national and international laws in force prohibiting the advertising of prescription drugs to the general public apply.

ARTICLE 5

Transparency

According to legislation and national association's codes that are locally applicable, *Pierre Fabre Affiliates* must be able, as much as this does not violate any law in force, to:

- provide a list of patient organizations to which it provides direct or indirect financial or non-financial support, including a brief description of the nature of this support
- record and trace all financial relationships or transfers of value from the company to patient organizations (costs for accommodation, meals, travel, registration fees, established fees, including for R&D activity agreements, etc.), with the aim of potential disclosure, in accordance with applicable local regulations or professional association codes.

ARTICLE 6

Events

All events sponsored or organized by or on behalf of *Pierre Fabre Affiliates* (including congresses, convention booth rental, professional or scientific meetings, boards of experts, production or research site tours, investigator meetings, sponsoring associations or learned societies for the organization of these events, etc.) must aim to contribute to the body of scientific or educational information for patients organizations.

They must be held in "appropriate" venues that correspond to the purposes of the event. *Pierre Fabre Affiliates* must not organize or fund events in places that are "renowned" for their entertainment facilities or are "extravagant".

No event may be organized or sponsored outside the country of origin of the patient organizations involved, unless this is relevant and justified from a logistical or security point of view[3]. Events welcoming participants from several countries are allowed.

The choice to participate, to sponsor an event or finance the participation of a patient organization in an event must comply with the following criteria:

- **Geographical location**

o Depending on the facilities and accommodations available and potentially the safety conditions: for example, the choice of a city or a location near a city known for its science infrastructures and its business center, as well as easy access for the various participants, and not for its tourism and leisure

[3] *e.g. if a significant number of attendees come from countries other than that of the patient organization or the Pierre Fabre affiliate, or if the place where relevant expertise for the event is located outside the patient organization or the Pierre Fabre affiliate's country of residence and it makes greater logistical sense to hold the event in another country.*

infrastructures. The location must not be considered as the main attraction, or implied or perceived as such.

- The event date must not coincide with the date of a cultural or sporting event in the same place, or take place just before or just after such an event.

Capitals and major cities considered as business and economic hubs are appropriate for the organization of such events.

A particular location that is not in accordance with the above rules can only be selected when the aim of the meeting, the scientific or medical program and the availability of the necessary and appropriate expertise warrants this.

- **Venue:**

- It must be in line with the scientific or medical objective of the event, and provide the technical infrastructure for holding meetings, conferences and exhibitions, and not cultural, sports and leisure infrastructures.
- If possible, it should be located away from well-known tourist spots.
- The following should be avoided: golf courses, spas, beach, lake or riverside resorts, ski resorts, casinos, etc. (non-exhaustive list).
- The safety of participants must be guaranteed.

- **Scientific or medical program:**

- This program must be available in advance to allow participants to choose to participate or to sponsor the event, or not, according to its presumed scientific and educational quality.
- It must not include free time for entertainment to be organized, between scientific/medical sessions.
- It must be adapted to the scientific/medical objective of the event: scientific and educational value, nature and quality of the speakers, participants, etc.
- Meals must not be organized in connection with cultural or leisure events.

To ensure compliance with laws in all relevant jurisdictions, which vary from one country to another, the program must refer to the codes of relevant national associations[4] when organizing international events. All Pierre Fabre partners likely to make recommendations at local level must be informed of these codes.

ARTICLE 7

Hospitality

As part of organized or sponsored events, hospitality may be offered to participating patient organization's members.

Only costs related to travel, meals, accommodation and registration fees may be covered. They must be reasonable in level and must be limited to the main purpose of the event, whether the event is organized

[4] e.g. such as the EFPIA *"Code of Practice on Relationships between the pharmaceutical industry and patients organizations"* in the EU *(http://www.efpia-e4ethics.eu)*, or the LEEM *"Dispositions déontologiques professionnelles" (http://www.leem.org/article/dispositions-deontologiques-professionnelles).*

by the Pierre Fabre affiliate or the patient organization. Generally, costs incurred must not exceed what the participants would themselves be willing to spend for an event of this type.

The amounts for meals must not exceed the maximum defined by local laws/regulations where appropriate.

The costs covered must not be extended to participants companions if they are not qualified to fully participate in the event. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases, in case of clear health needs (e.g. disability), the travel meals, accommodation and registration fees cost of an accompanying person considered to be a carer can be taken.

No entertainment, recreational or social activities or other events of a festive nature may be covered or sponsored.

According to local regulations, a portion of the costs of the event will remain the responsibility of the patient organizations and their representatives.

The duration of this hospitality must be strictly limited to that of the event.