



European Federation of Pharmaceutical
Industries and Associations

**EFPIA CODE OF PRACTICE ON RELATIONSHIPS
BETWEEN THE PHARMACEUTICAL INDUSTRY AND
PATIENT ORGANISATIONS**

Adopted by EFPIA*

* As adopted by EFPIA Board on 05/10/2007.

Introduction

The European Federation of Pharmaceutical Industries and Associations (EFPIA) is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of thirty countries in Europe and over forty leading pharmaceutical companies. EFPIA's primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in bringing to market medicinal products which improve human health.

The pharmaceutical industry recognises that it has many common interests with patient organisations, which represent and/or support the needs of patients and/or caregivers.

In order to ensure that relationships between the pharmaceutical industry and patient organisations take place in an ethical and transparent manner, EFPIA has adopted the EFPIA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

This Code builds upon the following principles that EFPIA, together with pan-European patient organisations, last updated in September 2006:

1. The independence of patient organisations, in terms of their political judgement, policies and activities, shall be assured.
2. All partnerships between patient organisations and the pharmaceutical industry shall be based on mutual respect, with the views and decisions of each partner having equal value.
3. The pharmaceutical industry shall not request, nor shall patient organisations undertake, the promotion of a particular prescription-only medicine.
4. The objectives and scope of any partnership shall be transparent. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged.
5. The pharmaceutical industry welcomes broad funding of patient organisations from multiple sources.

Scope

This EFPIA Code covers relationships between EFPIA member companies and their subsidiaries/contracted third parties and patient organisations which operate in Europe.

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

Applicability

The EFPIA Code sets out the standards which EFPIA considers must apply. In a manner compatible with their respective national laws and regulations, member associations must adopt provisions in their national codes which are no less rigorous than the provisions contained in the EFPIA Code.

Pharmaceutical companies must comply with the following applicable codes ('Applicable Codes') and any laws and regulations to which they are subject:

1. If the company is located within Europe, the industry code of the country in which the company is located or, if the company is located outside Europe, the EFPIA Code;

AND

2.
 - a) in the case of partnerships and activities taking place in a particular country within Europe, the industry code of the country in which the activity takes place; or
 - b) in the case of cross-border partnerships and activities, the industry code of the country in which the patient organisation has its main European location.

The requirements apply to activities or funding within Europe. 'Europe' as used in this EFPIA Code, includes those countries in which the EFPIA member associations' codes of practice apply.

The Applicable Codes that will apply must be specified in a written agreement between the company and the patient organisation. In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply. For the avoidance of doubt, the term 'company' as used in this EFPIA code, shall mean any legal entity that provides funds or engages in activities with patient organisations covered by an Applicable Code, which takes place within Europe, whether such entity be a parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation. 'Activity' as used above, shall mean any interaction covered by an Applicable Code, including the provision of funding.

Provisions

Article 1

Non-promotion of prescription-only medicines

EU and national legislation and codes of practice, prohibiting the advertising of prescription-only medicines to the general public, apply.

Article 2 **Written agreements**

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency's time and the nature of its involvement) and significant non-financial support. Each pharmaceutical company should have an approval process in place for these agreements.

A template for a written agreement is available in Annex I.

Article 3 **Use of logos and proprietary materials**

The public use of a patient organisation's logo and/or proprietary material by a pharmaceutical company requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Article 4 **Editorial control**

Pharmaceutical companies must not seek to influence the text of patient organisation material they sponsor in a manner favourable to their own commercial interests. This does not preclude companies from correcting factual inaccuracies.

Article 5 **Transparency**

- a) Each company must make publicly available a list of patient organisations to which it provides financial support and/or significant indirect/non-financial support. This should include a short description of the nature of the support. This information may be provided on a national or European level and should be updated at least once a year.¹
- b) Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.

¹ The provision of the information required in article 5a must be made for the first time by member companies no later than the end of the first quarter of 2009 (covering activities commenced as of or ongoing on 1 January 2008)

Article 6
Single company funding

No company may require that it be the sole funder of a patient organisation or any of its major programmes.

Article 7
Events and hospitality

All events sponsored or organised by or on behalf of a company must be held in an appropriate venue that is conducive to the main purpose of the event, avoiding those that are 'renowned' for their entertainment facilities or are 'extravagant'.

All forms of hospitality provided by the pharmaceutical industry to patient organisations and their members shall be reasonable in level and secondary to the main purpose of the event, whether the event is organised by the patient organisation or the pharmaceutical industry.

Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees.

No company may organise or sponsor an event that takes place outside its home country unless:

- a. most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
- b. given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country.

Article 8
Enforcement

Attached to this EFPIA Code as Annex II, are "Implementation and Procedure Rules" which are binding upon member associations and companies and set forth the framework for the implementation of this EFPIA Code, the processing of complaints and the initiation or administration of sanctions by member associations.

Member associations shall provide guidance on the meaning of the terms 'appropriate', 'significant', 'major', 'reasonable', 'renowned' and 'extravagant' as used in this code.

This Code of Practice will be effective from 1 July 2008.

Annex I Model template for written agreements between the pharmaceutical industry and patient organisations

Annex II Implementation and Procedure Rules

ANNEX I Model template for written agreements between the pharmaceutical industry and patient organisations

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-financial support to patient organisations, they must have in place a written agreement.

Below is a model template, which may be used in its entirety or adapted as appropriate, setting out key points of a written agreement. It is intended as a straightforward record of what has been agreed, taking into account the requirements of EFPIA' s Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

- Name of the activity
- Names of partnering organisations (pharmaceutical company, patient organisation, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organisation)
- Type of activity (e.g. whether the agreement relates to unrestricted grant, specific meeting, publication, etc.)
- Objectives
- Agreed role of the pharmaceutical company and patient organisation
- Time-frame
- Amount of funding
- Description of significant indirect/non-financial support (e.g. the donation of public relations agency's time, free training courses)

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

Code/s of practice that apply:

Signatories to the agreement:

Date of agreement:

ANNEX II Implementation and Procedure Rules

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the European Federation of Pharmaceutical Industries and Associations (“**EFPIA**”) Code on Relationships between the Pharmaceutical Industry and Patient Organisations (the “**EFPIA Code**”), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. Member Association Implementation.

Each member association is required to:

- (a) establish national procedures and structures to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same including, at a minimum, a national body of the member association that is designated to handle complaints and consists of a non-industry chairman and, besides any industry members, membership from other stakeholders;
- (b) ensure that its national code, together with its administrative procedures and other relevant information, are easily accessible through, at a minimum, publication of its national code on its website; and
- (c) prepare, and provide to the EFPIA Code Committee (defined below), an annual report summarizing the work undertaken by it in connection with the implementation, development and enforcement of its national code during the year.

SECTION 2. EFPIA Code of Practice Committee Implementation and Key Tasks.

- (a) The EFPIA Code of Practice Committee (the “EFPIA Code Committee”) shall assist member associations to comply with their obligations under Section 1 above.
- (b) The EFPIA Code Committee will be composed of all the national code secretaries, and chaired by the EFPIA Director General, assisted by one person from the EFPIA staff.
- (c) As a key part of its role of assisting member associations in their national code compliance activities, the EFPIA Code Committee shall monitor the adoption of compliant national codes. The EFPIA Code Committee will not participate in the adjudication of any individual complaint under any national code.
- (d) EFPIA Code Committee will, at least annually, invite member associations and representatives to participate in a meeting at which the participants will be encouraged to share their respective relevant experiences relating to the EFPIA Code. Any conclusions from the meeting shall be summarised in the annual code report (referred to under (e) of this Section 2 below) and, if appropriate, be presented to the EFPIA Board.

(e) The EFPIA Code Committee shall publish an annual code report, which summarizes the work and operations which have taken place in connection with the implementation, development and enforcement of the various national codes during the applicable year, based on the country reports provided by the member associations pursuant to Section 1(c) above.

(f) On an annual basis, the EFPIA Code Committee shall (i) advise the EFPIA Board of its work and operations and the work and operations of the member associations, as summarized in the member association annual reports and (ii) review with the EFPIA Board any additional recommendations to improve the EFPIA Code with a view towards increasing transparency and openness within the pharmaceutical industry and among member associations and companies.

SECTION 3. Reception of Complaints.

Complaints may be lodged either with a member association or with EFPIA. Adjudication of complaints shall be a matter solely for the national associations.

(a) Complaints received by EFPIA shall be processed as follows:

(i) EFPIA will forward any complaints it receives (without considering their admissibility or commenting upon them) to the relevant member association(s).

(ii) EFPIA will send an acknowledgement of receipt to the complainant, indicating the relevant national association(s) to which the complaint has been sent for processing and decision.

(iii) In addition, upon receipt by EFPIA of multiple external complaints (i.e. several complaints on the same or similar subjects lodged from outside the industry against several subsidiaries of a single company), EFPIA will communicate these complaints to the national association either of the parent company or of the EU subsidiary designated by the parent company.

SECTION 4. Processing of Complaints and Sanctions by Member Associations.

(a) Member associations shall ensure that industry and non-industry complaints are processed in the same manner, without regard to who has made the complaint.

(b) Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to Section 1(a) above. Each member association's national body shall take decisions and pronounce any sanctions on the basis of the national code in force in its country. Sanctions should be proportionate to the nature of the infringement, have a deterrent effect and take account of repeated offences of a similar nature or patterns of different offences.

(c) Where a complaint fails to establish a prima facie case for a violation of an Applicable Code, such complaint shall be dismissed with respect to that national

code. Member associations may also provide that any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

(d) Each member association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at the national level.

(e) National committees shall ensure that any final decision taken in an individual case shall be published in its entirety or, where only selected details are published, in a level of detail that is linked to the seriousness and/or persistence of the breach as follows:

(i) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;

(ii) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

(f) National committees are encouraged to publish summaries in English of cases that have precedential value and are of international interest (keeping in mind that cases resulting in the finding of a breach as well as those where no breach is found to have occurred may each have such value and/or interest).