SFEE Code of Practice
on the Relationship between
pharmaceutical companies and patient organizations

Scope

This Code covers the relationship between pharmaceutical companies which are members of SFEE and the patient associations which operate in Greece.

Patient organizations are defined as non-profit organizations representing and/or supporting the needs of people who suffer from medical conditions.

Article 1

Promotion of medicinal products

In the implementation of this Code, the provisions established by national and European legislation prohibiting the advertising of prescription only medicinal products sold to the general public, apply.

Article 2

Written agreement

Any financial support provided by pharmaceutical companies to patient organizations must be covered by a written agreement. The agreement 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. Every pharmaceutical company must implement an approval procedure for this type of agreements.

A template of a written agreement is included in Annex.

Article 3

Use of logos and proprietary material

For a pharmaceutical company to use a patient organization's logo and proprietary material, the Organization's written authorization is required. The pharmaceutical company must clearly mention, in its request to the patient organization, the specific purpose and the way in which the logo and/or the proprietary material shall be used.

Article 4

Control of publications

Pharmaceutical companies financing in any way patient organizations are prohibited from influencing the text concerning the material they are financing in a way favorable to their commercial interests. This does not prevent the companies from correcting any inaccuracies they may detect in the abovementioned text. In

addition, at the request of Patient Organisations, companies may contribute to the drafting of the text from a fair and balanced scientific perspective.

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 description of the nature of the support that is sufficiently complete to enable the average reader to form an understanding of the significance of the support. The description must include the monetary value of financial support and of invoiced costs. For significant non-financial support that cannot be assigned a meaningful monetary value the description must describe clearly the non-monetary benefit that the patient organisation receives. 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.

c) Each company must make publicly available a list of patient organisations that it has engaged to provide significant contracted services. This should include a description of the nature of the services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the arrangement without the necessity to divulge confidential information. Companies must also make public the total amount paid per patient organisation over the reporting period.[2]

ARTICLE 6

Contracted Services

Contracts between companies and patient organisations under which they provide any type of services to companies are only allowed if such services are provided for the purpose of supporting healthcare or research.

It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker 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 contract or agreement is agreed in advance which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;

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1 The requirement to include the monetary value of support must be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of, or ongoing on, 1 January 2012).

2 The requirement to include details of contracted services must be made by companies for the first time by the end of the first quarter of 2013 (covering activities commenced as of or ongoing on 1 January 2012).

b) A legitimate need for the services has been clearly identified and documented in advance of 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 service 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) The contracting company maintains records concerning, and makes appropriate use of, the services;
f) The engaging of Patient Organisations 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 organisations;
h) In their written contracts with Patient Organisations, companies are strongly encouraged to include provisions regarding an obligation of the Patient Organisation to declare that they have provided paid services to the company whenever they write or speak in public about a matter that is the subject of the agreement or any other issue relating to that company;
i) Each company must make publicly available a list of patient organisations that it has engaged to provide paid-for services – *see Article 5.c. above*.

Article 7
Single company funding

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

Article 8

Events and hospitality

All events intended for patient orgnanizations and organized or sponsored by or on behalf of a pharmaceutical company including scientific, business or professional meetings, must be held in an appropriate venue, that is conducive to the main purpose of the event, avoiding venues which are “luxurious” or “well reputed” for their entertainment facilities.

All forms of hospitality provided by a pharmaceutical company to patient organizations and their members shall be reasonable and secondary to the main purpose of the event, whether the event is organized by the patient organization or the pharmaceutical company.

The hospitality extended during the event, is limited to travel expenses, meals, accommodation and registration fees.

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.

All forms of hospitality offered to patient organisations and their representatives shall be “reasonable” in level and strictly limited to the purpose of the event.

Hospitality shall not include sponsoring or organising entertainment (e.g. sporting or leisure events).

A pharmaceutical company is not allowed to organize or sponsor an event held outside the country where it is located unless:

a) the majority of the guests come from abroad in relation to the country where the pharmaceutical country is located and, considering the countries of origin of most guests, it is deemed more reasonable to hold the event in another country; or

b) the specific nature of some facilities (e.g. research labs, production facilities etc) which are part of the objective or the theme of the event are located outside the country and thus it is considered more reasonable to hold the event in another country.

CONTROL PROCEDURE FOR THE ENFORCEMENT OF THE CODE ON THE RELATIONSHIPS BETWEEN PHARMACEUTICAL COMPANIES AND PATIENT ORGANIZATIONS

Article 1

Competent authorities for the control of the enforcement of the Code provisions on the relationships between pharmaceutical companies and patient organizations are the authorities in charge for the observance of the SFFE Code of Practice.

Article 2

Should a SFEE member pharmaceutical company violate the terms of this Code, the procedure for submission of a complaint/report as provided for in articles 2 and 3 of the Control Procedure in the SFEE Code of Practice, is followed.

Article 3

SANCTIONS

A) Matters concerning articles 1 to 6 of this Code

The First Degree Committee for the observance of the SFEE Code of Practice , after considering the submitted report/ complaint and if it judges that there has been a violation of articles 1 to 7 of the Code concerning relationships between pharmaceutical companies and SFEE’s patient organizations, can impose the following sanctions on the member company of SFEE, which has not observed the above mentioned provisions of the present Code:

a. The immediate publication of the First Degree Committee judgment condemning the pharmaceutical company , n the SFEE journal “Theseis” (Θέσεις) .

b. The correction of the promotional material and the obligation of the indicted pharmaceutical company to send the corrected material to the same recipients accompanied by a relevant letter referring to the modifications.

c. The publication of the text of the First Degree Committee judgment, as the case may be, depending on the subject, in scientific journals intended for healthcare professionals.

The above mentioned sanctions (b) and (c) are imposed if the deadline for the referral of the report/complaint to the Second Degree Committee, as provided for in article 2.15 of the SFEE Control Procedure on Implementation of SFEE's Code of Practice, expires and no action has been taken.

The Second Degree Committee may impose on the SFEE member company which has not complied with the judgment of the First Degree Committee the sanctions cited in article 4.1 A of the Control Procedure of SFEE's Code of Practice. The Second Degree Committee may, apart from the above sanctions, impose a fine of 15.000€. The cited fines shall be deposited by the violating pharmaceutical company in a special bank account of SFEE, within a maximum of 30 working days from the date of issuing the judgment.

B) Matters concerning article 8 of this Code

The First Degree Committee for the observance of SFEE Code of Practice, may, after considering the submitted report/ complaint, and if it judges that there has been a violation of article 8 of this Code, impose via its judgment a fine of up to 3.000€ to the SFEE member company.

The cited fines shall be deposited by the indicted pharmaceutical company in a special bank account of SFEE.

After the issuance of the judgement by the First Degree Committee, the opposed parties reserve their right to submit, within 30 working days of notification of the judgment to them by SFEE Secretariat, an application to refer the case to the Second Degree Committee according to article 2.15 of the SFEE Code of Practice Control Procedure. The above-mentioned action suspends the claim for the aforementioned fine.

The Second Degree Committee may impose a fine of up to 15.000€ to the non compliant pharmaceutical SFEE member company.

The cited fines shall be deposited by the violating pharmaceutical company in a special SFEE bank account.

If the fines imposed by the First Degree Committee are not paid and if a report referral has not been submitted to the Second Degree Committee within the deadlines set according to article 2.14 of the SFEE Code of Practice Control Procedure, the Second Degree Committee then decides to impose a fine, ex-officio, to the SFEE member company, to which the First Degree Committee had previously imposed a fine.

Should the SFEE pharmaceutical member company fail to comply with the judgment of the Second Degree Committee again, the latter shall refer the matter to the SFEE Disciplinary Board which may decide to expel the said company from SFEE.

ANNEX **Proposed content of written agreements between pharmaceutical companies and patient organizations**

When pharmaceutical companies offer financial support, considerable indirect support and considerable non-financial support to patient organizations they must sign a written agreement in accordance with article 2 of this Code.

Below follows a template including the key points of a written agreement. The objective of this agreement is to describe clearly, what has been agreed upon, considering the requirements set by the EFPIA Code of Practice concerning the Relationships between pharmaceutical companies and patient organizations.

- Title of the project
- Names of participating parties (pharmaceutical company, patient organization and, where required, third parties involved in the project in order to help.)
- Type of project (i.e. whether the agreement concerns general grants for operational expenses, specific meetings, sponsorships, leaflets, information campaigns, educational programmes, etc.)
- Objectives
- Agreed role of the pharmaceutical company and the patient organization
- Timeframe
- Amount and type of financial support
- Description of the considerable indirect / non-financial support (e.g. donation of a PR agency's time, free of charge training programmes.

All contracting parties are fully aware that the sponsorship must be clearly acknowledged.

Contract Signatories:

Date of agreement: