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

Introduction

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, AIFP has adopted the AIFP Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

This Code builds upon the following principles:

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 AIFP Code covers relationships between AIFP 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 AIFP Code sets out the standards which AIFP members must comply with:

1. AIFP Code of Practice on relationships between the pharmaceutical industry and patient organizations

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 AIFP 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 EFPIA and AIFP 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 member 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 member 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 member 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

Member 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 members from correcting factual inaccuracies.

Article 5
Transparency

a) Each member 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) Member 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].

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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).

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;
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 member 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 sponsored or organised by or on behalf of a member including scientific, business or professional meetings,must be held in an appropriate locations and venues that are 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.

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).

No member 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.

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

When members 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 AIFP 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 member 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: