

CODE OF PRACTICE ON RELATIONSHIPS BETWEEN THE PHARMACEUTICAL INDUSTRY AND PATIENT ASSOCIATIONS

Adopted by EFPIA and Forum of International R&D Pharmaceutical Companies*

* As adopted by EFPIA Statutory General Assembly on 14.6.2011.

* As adopted by General Assembly of Forum on 20.1.2012 and 7.12.2018.

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 countries in Europe (i.e. member associations) and leading pharmaceutical companies (i.e. corporate members)¹. EFPIA membership also includes two specialised groups: the “European Biopharmaceutical Enterprises” (EBE) and the “European Vaccines Manufacturers” (EVM).

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 (The EFPIA Patient Organisation (PO) Code)

This Code builds upon the following principles that EFPIA, together with pan-European patient organisations, subscribed to:

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 Patient Organisation Code covers relationships between EFPIA corporate members including their subsidiaries and contracted third parties (e.g. agencies) and patient organisations which operate in Europe.

¹ The complete list of EFPIA membership is available on www.efpia.eu

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 Patient Organisation 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 Patient Organisation 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 Patient Organisation 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 Patient Organisation 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 Patient Organisation 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. 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.

- 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 during a calendar year by end of June of the next calendar year.

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 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 sponsored or organised by or on behalf of a company including scientific, business or professional meetings, must be held in 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 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 9 **Enforcement**

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

Forum Members shall within 3 months from adoption of this code adopt guidelines on the meaning of the terms ‘appropriate’, ‘significant’, ‘major’, ‘reasonable’, ‘renowned’ and ‘extravagant’ as used in this code.

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.

Arrangements for making transparent the details of the activities subject to the agreement

Code/s of practice that apply: *to be completed*

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 PO Code**”), the processing of complaints and the initiation or administration of sanctions by member associations.

SECTION 1. Member Associations’ 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 Codes 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 Codes Committee Implementation and Key Tasks

- a) The EFPIA Codes Committee shall assist member associations to comply with their obligations under Section 1 above.
- b) The EFPIA Codes 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 Codes Committee shall monitor the adoption of compliant national codes. The EFPIA Codes Committee will not participate in the adjudication of any individual complaint under any national code.
- d) EFPIA Codes 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 PO Code. Any conclusions from the meeting shall be summarised in the annual

codes report (referred to under (e) of this Section 2 below) and be presented to the EFPIA Executive Committee, and to the EFPIA Board, if appropriate.

- e) EFPIA shall publish an annual codes 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 Codes Committee shall (i) advise the EFPIA Executive Committee, and the EFPIA Board, if appropriate, 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 Executive Committee, and the EFPIA Board, if appropriate, any additional recommendations to improve the EFPIA PO 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.

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. Complaints will be processed at the national level through the procedures and structures established by the member associations pursuant to Section 1(a) above.
- b) 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).

Addendum

*(Guidelines on meaning of the terms)**

* As adopted by General Assembly of Forum on March 7th, 2012.

Pursuant to Article 9(2) of the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations (“Code”) the Members of Forum of International R&D Pharmaceutical Companies adopted the guidelines of the following terms used in the Code:

- “**APPROPRIATE**” location or venue under Article 8 shall mean any location or venue which is usually used for organisation of similar events with exception of RENOWNED or EXTRAVAGANT venues as defined below.
- “**SIGNIFICANT**” support (Art. 2, Art. 5(a)) or contacted service (Art. 5(c)) shall mean any support or service with financial value, which can be attributed to it, not exceeding 150,00 EUR per transaction and 600,00 EUR per year.
- “**MAJOR**” programme in sense of Article 7 means a programme to which a patient association devotes more than 25% of its annual resources.
- “**REASONABLE**” hospitality under Article 8 shall mean hospitality within the boundaries of what members of patient associations would normally be prepared to pay for themselves and shall be understood to exclude the events with predominantly entertainment purpose. Entertainment events with other purpose than hospitality (e.g. fundraising or disease awareness) are allowed.
- “**REOWNED**” location or venue in the meaning of Article 8 shall mean any location which is predominantly known to offer specific entertainment (rather than typical congress activity), such as casino, golf or spa (with exception of those spa resorts which carry out medical services as part of the public healthcare financed by the Health Insurance Fund of Slovenia).
- “**EXTRAVAGANT**” venue in the meaning of Article 8 shall mean a hotel or similar facility of high or luxurious category which is predominantly used for leisure or entertainment and rarely for scientific, business or professional meetings.