

Translation from Croatian language

Pursuant to Article 16 of the Statute, General Assembly of the **Innovative Pharmaceutical Initiative** on its session held on **30 June 2014** in Zagreb adopted the following

**CODE OF CONDUCT
OF INNOVATIVE PHARMACEUTICAL COMPANIES
IN RELATIONSHIPS WITH PATIENT ORGANISATIONS**

Introduction

Pharmaceutical companies being members of the association Innovative Pharmaceutical Initiative (hereinafter: **the Association**) is the representative body of research-oriented manufacturers of medicinal products that are duly organised and act in the Republic of Croatia in line with applicable legislation, recognise the fact of existence of common interests between pharmaceutical industry and patient organisations in the area of health and social care.

By adoption of this Code the Association wishes to ensure that cooperation between patient organisations in the area of health and social care takes place in an ethical and transparent manner with full commitments to 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 promotion of a particular prescription-only medicine shall not be requested or undertaken.
- 4) the objective 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.

Applicability

This code applies to relationships between members of the Association and patient organisations duly organised and existing on the territory of the Republic of Croatia. The following codes and applicable laws shall apply (hereinafter: **Applicable Codes**) in following cases:

- a) if the pharmaceutical company has a company seat within Europe – the industry code of the country in which the pharmaceutical company has a company seat;
- b) if the pharmaceutical company has a company seat outside Europe – the EFPIA Code of practice on relationships between the pharmaceutical industry and patient organisations;
- c) 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
- d) in the case of cross-border partnerships and activities – the industry code of the country in which the patient organisation has its main European 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.

Definitions

In this Code the following terms shall have the following meanings:

Patient Organisation means association or other form of organising of patients providing health services and social care in the Republic of Croatia on non-profit basis which has been funded and acts with the goal of achievement and protection of the interests of its members including associations (domestic and international) whose members or associates are associations;

Europe the term which in the context of provision of applicability of this Code, in line with the definition of EFPIA, includes those country members of EFPIA

with their own codes of practice;

Pharmaceutical Company

members of Association, their branch offices and all affiliated companies in the sense of Croatian Company Law that in any way provides funds or supports the activities of the Patient Organisations. For the purpose of this definition, the term „activities“ shall mean any interaction covered with any Applicable Code, including the provision of funding.

Article 1: Non-Promotion of Prescription-Only Medicines

Valid provisions of legislation prohibiting advertising of prescription-only medicines to the general public shall apply to this Code.

Article 2: Written Agreements

1. A Pharmaceutical Company and a Patient Organisation must have in place a written agreement always where Pharmaceutical Company provides financial support, significant indirect support and/or significant non-financial support to the Patient Organisation. Written agreements must state:

- the amount of funding,
- the purpose (e.g. unrestricted grant, specific meeting or publication etc.),
- description of significant indirect support (e.g. donation of public relations donation agencies, time and nature of their involvement) and significant non-financial support,
- the statement on the Applicable Code within the meaning of the provision on applicability of this Code.

2. All agreements must pass the internal approval process of each Pharmaceutical Company, in line with the internal procedures on approval of legal documents (if any).

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, 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 interest. 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 Pharmaceutical 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 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 nonfinancial 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 the European level and should be updated at least once a year.

- b) Pharmaceutical Companies must ensure that their sponsorship is always clearly acknowledged and apparent from the outset.
- c) Each Pharmaceutical 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. Pharmaceutical Companies must also make public the total amount paid per patient organisation over the reporting period

Article 6: Contracted services

It is permitted to engage Patient Organisations as experts and advisors for services such as participation at advisory board meetings and speaker services at Events. The arrangements that cover consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all criteria provided in Art. 16.1. of the Code of conduct in promotion of prescription-only medicinal products of innovative Pharmaceutical Companies to healthcare professionals in the Republic of Croatia and interactions with Healthcare Professionals (hereinafter: **HCP Code**).

Article 7: Single Company Funding

No Pharmaceutical Company may require that it be the sole founder of a Patient Organisation or any of its major programmes.

Article 8: Events and Hospitality

Provisions of Article 11 of the HCP Code shall apply accordingly.

Article 9: Enforcement

Provisions of Title VI, "Enforcement", Art. 24 – 39 of the HCP Code shall apply accordingly.

Article 10: Final Provisions

1. This Code is adopted by the General Meeting of the Association at its session held on 30 June 2014 in line with Article 16 of the Statute of the Association.

2. This Code shall **enter into force on 01 July 2014** and shall be binding for all members of the Association from that date.

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President of the Association:

Karolina Matic