



ASSOCIATION OF THE RESEARCH-BASED
PHARMACEUTICAL MANUFACTURERS IN BULGARIA

**Code of practice on
relationships between the
research-based pharmaceutical
industry and patient
organizations in Bulgaria**

Adopted on 10 July 2008, and shall come into effect as of 31.07.2008,

Introduction

The Association of the Research-based Pharmaceutical Manufacturers in Bulgaria is the representative body of the research-based pharmaceutical industry in Bulgaria. The Association integrates the world manufacturers and marketing authorization holders, operating in the Bulgarian market, investing in the pharmaceutical industry development through synthesis and formulation of medicinal products containing innovative active pharmaceutical substances. The main priority of the Association and its members is to contribute to the protection and provision of health and human life, assuring access for Bulgarian patients to quality, safe and effective medicinal products for prevention, diagnostic testing, and treatment of diseases.

The research-based pharmaceutical industry recognizes 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 in Bulgaria take place in an ethical and transparent manner, the ARPharM member companies have adopted the Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations in Bulgaria.

The present 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 between the pharmaceutical industry and any patient organization(s) shall be transparent and precisely defined. Financial and non-financial support provided by the pharmaceutical industry shall always be clearly acknowledged in a proper way.
5. The pharmaceutical industry welcomes broad funding of patient organisations from multiple sources.

Preamble

The present Code stipulates the principles and the rules which

the pharmaceutical companies are obliged to observe in their relationships with patient organizations functioning in Bulgaria and in Europe.

The adoption and observance of this Code is a mandatory condition for membership to the Association and each member company is obliged to avoid any violation of the regulations and the spirit of this Code. ARPharM member companies shall be obliged to acquaint their contracting partners (third parties) with the present Code in cases where the subject of their contractual relationship concerns deliveries, promotion and advertising or other activities connected with the medicinal products being manufactured by the ARPharM member company or for which the latter holds a marketing authorization.

Any natural person, being a representative of a manufacturing company or marketing authorization holder at ARPharM, shall acknowledge the obligation to observe the present Code by subscribing his/her signature.

Other pharmaceutical manufacturing companies or marketing authorization holders, non-members of ARPharM, could adopt and observe the provisions of the Code.

The application and observance of the Code is an obligation of all companies that have adopted it. The observance of the Code of Ethics is controlled by the Ethical Commission with ARPharM (**the Commission**), established in accordance with provisions of the Code of Ethics of the research-based pharmaceutical industry in Bulgaria. Any complaint related to a probable violation of the Code shall be referred to the Commission. The Commission could deliver decisions in which it could make interpretation of the provisions of the Code any time the Commission has been approached or whenever necessity arises. The interpretative decisions are mandatory by nature regarding the meaning of the provision being interpreted, as of the moment of notification or as of the date specified in them.

The adherence to the provisions of the Code of Ethics shall not relieve ARPharM members and the companies, with respect to which it appears to be mandatory, of their responsibility to conform to the regulations of Bulgarian legislation, the legislation of the European Union and other codes of international organizations and/or companies.

In the case of cross-border partnerships and activities, the company/companies must comply with the respective applicable code of the pharmaceutical industry of the country in which the patient organization has its main European location. The requirements

shall apply with respect to activities or funding within Europe. "Europe" as used in the present 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.

Scope

The Code of practice on relationships between the research-based pharmaceutical industry and patient organizations in Bulgaria regulates any form of partnership between a pharmaceutical company and a patient organization.

"Company" as used in this Code, shall mean any ARPharM member company as well as any manufacturing company or marketing authorization holder which has undertaken the obligation to comply with the present Code.

„Patient organization" as used in this Code, shall mean any non-profit organization (including the umbrella organizations that integrate patient associations), composed of patients and/or caregivers, the main activity and objectives of which are expressed in supporting the needs of patients and/or caregivers.

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 agreement

Any financial support or other forms of significant non-financial support from a Company to a patient organization shall be provided basing on written agreement. The agreement must specify the amount of funding/non-financial support as well as its purpose (e.g. unrestricted grant, specific meeting or publication, etc.). In cases when direct or indirect non-financial support is provided, the agreement must include a detailed description of the nature of the support (e.g. the donation of public relations agency's time and the nature of its involvement). Each Company should have an approval process in place for these agreements.

Article 3
Use of logos and proprietary materials

The public use of patient organization's logo and/or its proprietary materials by a Company requires written permission from the patient organization. The provision of such permission shall be based on a written inquiry made by the Company, clearly stating the specific purpose and the way the logo and/or the proprietary materials will be used.

Article 4
Editorial control

Companies must not influence the text of materials made by a patient organization they sponsor in a manner favourable to their own commercial interests. This prohibition does not preclude companies from correcting factual inaccuracies in materials.

Article 5 **Transparency**

- a) Each company must appropriately make available to the public a list of patient organizations to which it provides financial support and/or significant direct or indirect non-financial support. The list must 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 year¹.
- b) Companies must ensure that the support provided is always acknowledged and apparent from the outset.

Article 6 **Single company funding**

The provision of a support may not require that the Company be the sole sponsor of the respective patient organization or any of its major programmes.

Article 7 **Events and hospitality**

7.1 All events sponsored or organized by 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".

7.2 In cases of sponsorship of an event organized by a third party (company or organization, which is not a member of the Association and has not undertaken the obligation to observe the Code), the members of the Association may not lay down conditions to those third parties organizing the event that other companies' sponsorship should not be accepted, if the other companies are willing to provide it.

¹ The companies should provide the information required by art.5, (a) for the first time no later than the end of the first quarter of 2009 (including activities, started or continuing on 1st of January 2008)

7.3. No company may organize or sponsor an event that takes place outside Bulgaria, ("**international event**") unless:

- a. Most of the invitees are from other countries and it makes a greater logistical sense to hold the event in another country; or
- б. Given the location of the relevant resource or expertise that is the subject matter of the event, it makes greater logistical sense to hold the event in another country.

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

7.5. All forms of hospitality provided to patient organizations and their members shall be reasonable in level and be strictly limited to the main purpose of the event. The arrival of participants, patient organizations' members, to the venue of the event should not be earlier than a twenty-four hour period prior to its beginning, and the departure shall be not be later than a twenty-four hour period after its ending. If the participant/participants wish to arrive earlier or to leave later, all expenses connected with their extra stay, may not be paid or reimbursed by the sponsoring company.

7.6. Organizing an event by a company:

a) Companies organize/sponsor events for patient organizations and their members in compliance with the provisions this Code.

b) Events, organized in the territory of Republic of Bulgaria, should have a duration not exceeding three twenty-four hour periods. Each full day of the event shall involve working/scientific program duration of no less than six hours.

c) International events organized by a Company should not continue more than four twenty-four hour periods. Each full day of the event shall involve a working/scientific program duration of no less than six hours. This provision shall not be applied to events organized by the main office of the Company.

7.7. Covering of expenses of participants related to the event organized or sponsored by the Company shall be made by bank transfers, by checks or postal orders, basing on primary supporting documents concerning the expenses made. If the participants are given daily allowances, this shall be arranged in accordance with the Bulgarian legislation.

7.8. The maximum permissible limits of hospitality are:

a) flight tickets (for Bulgaria and international ones) – economy (tourist) class. Business class is allowed only on the exception of a non-stop flight of over six hours duration.

b) stay in a hotel – hospitality is limited to the value of an accommodation and breakfast package. All additional expenses shall be on the account of the participant.

7.9. Hospitality may not impose conditions obliging patient organizations or their members to advertise or promote particular medicinal products.

7.10. The provisions of this section shall apply also in cases when the event has been organized by a third party but completely or partially financed by a Company.

Article 8 **Ethics Commission**

The Ethics Commission has been established in compliance with the **Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria**.

Article 9 **Procedure of lodging and processing complaints**

1. The procedure, laid down in the **Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria**, shall apply.
2. Each complaint and the documents connected with it shall be submitted to the following address:

ARPharM Ethics Commission

**Sofia 1113, Iztok residential area,
19, Frederic Joliot-Curie street, bl. 1, floor 14, ap. 26**

3. The claimant shall pay a charge of 600 levs for the review of each complaint lodged. In Commission's judgement, when the claimant is a patient, patient organization, healthcare professional, as well as in other cases, he/she might be relieved from payment of charges for reviewing complaints.
4. The decisions of the Commission in its regular composition are subject to appeal before its extended composition, in compliance with the provisions of the **Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria**.

Article 9 **Sanctions**

1. In case of violation of the present Code ascertained, the Commission shall impose sanctions to an amount, and according to the stipulations, as determined in the **Code of Ethics of the Research-based Pharmaceutical Industry in Bulgaria**.

General provisions

1. The Commission shall perform monitoring on observance of the present Code and shall issue annual reports about its implementation which shall be sent to EFPIA.
2. The annual reports shall be sent to all member companies and the Commission may recommend to the Managing Board of the Association that the report be published in an appropriate manner.
3. The contents of the annual report:
 - a. Respondents on complaints with respect to which there are decisions in place stating violations of this Code.
 - b. Promotion and advertising activities and materials violating the provisions of this Code.
 - c. Provisions of the Code that have been breached.
 - d. Sanctions imposed.
 - e. Number of complaints lodged and processed.
 - f. Total number of the violations of this Code.
 - g. Short summary in English of any cases that have precedential value and are of international interest (keeping in mind 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 be of international interest).
 - h. In cases of a minor breach, or in cases where there is no breach, publication of the details of the case may exclude the name (names) of the company.
4. Ethics Commission administrative expenses related to the procedure of complaints review, as well as the charges paid for reviewing claims are:
 - a. Chargeable to the respondent – when a violation of the Code has been found, and in the cases when the respondent has admitted the claimed violation.

- b. Chargeable to the claimant – when Ethics Commission fails to establish a violation or when the complaint is inadmissible.
 - c. Chargeable to association's budget - when Ethics Commission fails to establish a violation, or when the claimant is a person different from a Company, as used in this Code.
5. The Commission shall terminate proceedings with respect to a complaint on the subject matter of which legal or administrative proceedings have been initiated by the respective competent authorities, until final completion of the proceedings of those authorities. On resumption of those proceedings, the Commission shall take into account the decision of the respective authority.

Transitional and conclusive provisions

1. The present Code was adopted by ARPharM members on 10 July 2008, and shall come into effect as of 31.07.2008, and shall apply to violations performed after its coming into effect.
2. Non-member companies may adopt the present Code and for them the Code shall come into effect as of the date on which it has been signed by the respective company, and shall apply to violations performed after that date.
3. ARPharM shall not bear any responsibility for damages that have occurred as a result of Ethics Commission's decisions concerning the implementation and the interpretation of the provisions of this Code.

ANNEX I Template for a written agreement between the pharmaceutical industry and patient organizations

Compulsory key data:

- Sponsored activity description
- Name of partnering organizations (pharmaceutical company, patient organization, and where applicable, third parties that will be brought in to help, as agreed by both the pharmaceutical company and the patient organization)

- Type of activity (e.g. whether the agreement relates to unrestricted grant, specific event, publication, etc.)
- Objectives
- Rights and obligations of the pharmaceutical company and the patient organization
- Time-frame
- Amount of funding
- Description of significant indirect/non-financial support (e.g. the donation of public relations agency, free training courses)

The parties shall unambiguously specify and apparently acknowledge sponsorship as of the commencement of the corresponding partnership.

Applicable codes:

Signatories:

Date of agreement: