Adopted in 2006.
Present addition is approved by
the General Meeting of AIPM
19.12.2018

CODE OF PRACTICE

of Association of International Pharmaceutical Manufacturers (AIPM)

2019

Having considered the appeal of the Association of International Pharmaceutical Manufacturers (AIPM), the Ministry of Health of the Republic of Belarus reports that it generally approves Provisions of the Code of Marketing Practices developed and approved by the members of the Association.

At the same time, the Ministry of Health of the Republic of Belarus offers all the representative offices and representatives of foreign pharmaceutical companies, business entities licensed to perform medical or pharmaceutical activities to also comply with this Code until a state regulation in this area is developed and approved.

From a letter of the Ministry of Health
of the Republic of Belarus

Contents

The member companies of the Association of International Pharmaceutical Manufacturers (hereinafter – AIPM) understand their high social responsibility to the community. On this basis, they accept and undertake to observe the Code of Practice of AIPM (hereinafter – Code) as well as to adhere to it spirit as well as its letter.

The member companies of AIPM shall follow the rules of fair competition in implementation of their activity and shall not cause damage to the image and economic interests of competitors through misconduct, including misleading advertising and other unfair methods of promotion of medicinal preparations.

The member companies of AIPM expend necessary efforts for promotion of the Code for the purpose of its correct understanding and implementation both among their employees, and among other representatives of pharmaceutical community of the Republic of Belarus.

The member companies of AIPM strive for further development of the Code, which includes making suggestions for its update and amendment of relevant requirements.

If the Code violations are identified, the company whose interests are affected shall be entitled to immediately resort to the procedure for dispute resolution and violation handling established herein (Appendix 1). Herewith AIPM welcomes independent dispute resolution between the companies.

The code is drawn up in Russian and English languages. In case of disputes on interpretation of provisions hereof, Russian text shall prevail.

Where provisions of the Code are inconsistent with the norms of current legislation of the Republic of Belarus, the norms of the current legislation of the Republic of Belarus shall be applied.

When carrying out any programs and events, pharmaceutical companies shall ensure their compliance with the current legislation, including the antitrust law, advertising law and laws on protection of personal data.

The present edition of the Code shall become effective upon approval by the General Meeting of AIPM.

The member companies of AIPM must bring their activities, including advertising and other methods of promotion of medicinal preparations, in line with the new edition of the Code no later than by December 31, 2018.

Complaints concerning the infringements of newly applied or amended requirements shall be accepted after January 1, 2019.

Preamble

The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that HCPs globally have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

The AIPM is a non-profit, non-governmental organization. Member companies of the AIPM include global study-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code.

The AIPM Code includes standards for the ethical promotion of pharmaceutical products to HCPs and helps ensure that member companies' interactions with HCPs and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

It is a requirement of AIPM membership that member companies accept the conditions of the AIPM Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the AIPM Code

1. Purpose and scope

1.1. PURPOSE

The purpose of this Code is to establish the minimal requirements to be followed by the member companies of AIPM when carrying out marketing, research, educational, information and charitable activities in the territory of the Republic of Belarus.

1.2. DEFINITIONS

For the purpose of this Code, the following definitions are used:

medicinal preparation – a substance or a combination of substances of natural, synthetic or biotechnological origin that exhibit pharmacological action and are used in a certain pharmaceutical form for prevention and diagnosis of diseases, treatment and medical rehabilitation of patients or pregnancy prevention through internal or external use (The law of the Republic of Belarus "On Medicinal Preparations"), as mentioned in the text of the Code, a word combination "pharmaceutical product" may be used together with the medicinal product, as its synonym.

promotion – an activity carried out, organized or sponsored by pharmaceutical company in any form with use of various channels of communication (including the Internet) to draw attention, create or maintain the demand and to promote prescription, recommendation, supply, dispensing, administration and/or consumption of medicinal preparations of this company;

healthcare professionals – healthcare providers, medical and pharmaceutical practitioners entitled to prescribe, recommend, purchase, supply and/or administer medicinal preparations in their professional activities.

healthcare organization – a legal entity that mainly performs medical and (or) pharmaceutical activities;

patient organization – a non-profit public organization properly registered in the Republic of Belarus, which primarily represents the interests and needs of patients, their families and caregivers;

expert council – a group of external experts (e.g., healthcare professionals and/or representatives of patient organizations) competent in the respective field of knowledge, whose joint meeting is organized by a pharmaceutical company to discuss and be consulted on the pre-determined matters concerning clinical or scientific aspects, as well as the issues of patients' access to inno-

vative therapies that can't be properly considered using only internal resources of the company;

post-marketing clinical (interventional) study – a study of medicinal preparation conducted in the Republic of Belarus, including with involvement of a contract research organization, for the purpose of further efficacy, safety and the tolerability data collection, which is carried out after the state registration of the respective medicinal preparation and where the pharmaceutical product under study is administrated according to national registration conditions, and specific therapy, diagnostic and monitoring procedures are carried out in strict accordance with the study protocol;

post-marketing observational (non-interventional) study is a post-marketing study of medicinal preparations conducted in the Republic of Belarus, including with involvement of a contract research organization where a pharmaceutical product and/or a specific therapy is administrated to the patient in normal clinical setting according to the national registration conditions for respective medicinal preparation, the decision on prescription of medicinal preparation is separated from the decision on patient enrollment, and no additional diagnostic, medical or monitoring procedures are carried out beyond normal clinical practice of treatment of the respective disease;

epidemiological survey – a study of prevalence, occurrence and severity of various diseases, frequency of prescriptions or health outcomes for identification of the reasons for their development, risk factors and interactions in various populations;

marketing study – a study aimed at collecting, processing and analysis of marketing information for the purpose of studying of current product market to adopt the necessary marketing decisions;

medical representative of a pharmaceutical company – an employee of a pharmaceutical company who has special training and directly interacts with healthcare professionals on the matters concerning clinical use of medicinal preparations;

events – meetings, congresses, conferences, symposiums, and other forms of interaction of marketing, scientific or professional nature (including, but not limited to visiting research and development centers and manufacturing sites, medical representatives visiting healthcare professionals and medical institutions as well as trainings, inception meetings for planning or meetings of researchers concerning clinical and non-interventional studies conduct) organized or financed by pharmaceutical company or on its behalf.

1.3. SCOPE

This Code shall cover:

- medicinal preparation advertising addressed to the general public;
- medicinal preparation advertising addressed to healthcare professionals;
- activities of pharmaceutical companies' medical representatives;
- interaction with healthcare professionals;
- interaction with patient organizations;
- post-marketing clinical (interventional), post-marketing observational (non-interventional) studies and epidemiological surveys;
- marketing studies;
- distribution of scientific information concerning human health or diseases by pharmaceutical companies or organizations representing their interests;
- provision of gratis sponsor support;
- support of continuous medical education;
- handling inquiries from patients and healthcare professionals;
- events for promotion of medicinal preparations to healthcare professionals;
- sponsorship of scientific and professional events involving healthcare professionals;
- use of the Internet and other digital communication channels for promotion of medicinal preparations;
- other methods of promoting medicinal preparations.

The present Code does not include:

- labeling of medicinal preparations, prescribing information and other data given on the product or its packaging;
- claims, representations or references, e.g., in regard to packaging change, warnings about adverse reactions as a part of general measures on safety monitoring;
- cases of price formation or establishing other commercial terms for supply, including trade catalogues and price-lists provided that they contain no specific advertising statements regarding the pharmaceutical product;
- registration clinical studies.

2. General provisions on promotion of medicinal preparations

2.1. BASIC PRINCIPLES OF PROMOTION

Transparency of Promotion

Promotion shall favor proper use of medicinal preparations by fair data representation.

Advertising of medicinal preparation shall be conducted in a manner clearly identifying the product as a medicinal preparation.

Materials sponsored by pharmaceutical company that contain information about pharmaceutical products and their use, regardless of their advertising nature, shall provide a clear reference to advertiser/data source.

Use of “hot lines” for advertising of medicinal preparation issued on prescription is not allowed.

If during the event employees of pharmaceutical company make a presentation for healthcare professionals or they are authors of publication, they shall be clearly identified as employees of the relevant pharmaceutical company.

2.2. MARKETING AUTHORIZATION STATUS

In the territory of the Republic of Belarus, only authorized medicinal preparations are subject to promotion within their registered therapeutic indications as specified in the prescribing information and/or clinical protocols and other regulations approved by the Ministry of Health of the Republic of Belarus.

This provision is not intended to restrict disclosure of information regarding any medicinal preparation to stakeholders as required by legislation. It also does not intend violate the right of scientific community for exchange of scientific information concerning unauthorized pharmaceutical products provided that disclosing such information does not serve to promote the medicinal preparation.

2.3. STANDARDS OF PROMOTIONAL INFORMATION

Promotion of medicinal preparation shall comply with applicable Belarusian legislation on promotion and competition.

Promotion of medicinal preparation shall contain the true, reliable, full and up-to-date information based on properly approved product information, i.e.

prescribing information, clinical protocols and labeling, as well as applicable regulations of the Ministry of Health of the Republic of Belarus.

Manufacturers shall seek to fully reflect product safety data in promotion of medicinal preparation.

Promotional information shall be clear, accurate, balanced, true, objective and sufficient. It shall be based on up-to-date evaluation of all relevant evidence and its accurate reflection as to enable the recipient to form an objective opinion on the therapeutic value of the medicinal preparation promoted.

Promotional information shall not mislead by distortion, exaggeration or omission of significant information. Ambiguity should be avoided.

Statements on therapeutic effect shall not exaggerate the data shown in prescribing information of the medicinal preparation.

Promotional information concerning medicinal preparation should be supported by relevant scientific evidence. Such evidence should be made available to stakeholders upon inquiry. The companies shall handle such inquiries in good faith and provide the true data according to the inquiry.

Comparative information on medicinal preparations may only be provided on the basis of the studies and materials prepared by a third independent party.

The requirements established in articles 3.2 and 4.2 hereof shall be applied to the printed promotional materials. The current Belarusian legislation on promotion shall be applied to audiovisual materials.

2.4. USE OF EXPERT OPINIONS, REFERENCES TO STUDY RESULTS AND QUOTATIONS

When using expert opinions and references to study/observational data in promotional materials, a source of such data and date of its receipt should be specified.

When using quotations from medical or scientific literature or someone's speeches in promotional materials for healthcare professionals, a source a quotation/name of the author, date and place of publication/speech should be specified.

2.5. PROMOTION ON THE INTERNET

Promotion of medicinal preparations on the Internet, including through banners, active links, information on websites, in blogs, social networks, forums, conferences and other electronic resources, shall comply with general requirements for advertising and special requirements for advertising of medicinal preparations established by the legislation of the Republic of Belarus.

More specifically, when using the web-sites related to medicinal preparations, it should be clear which pharmaceutical company provides the information and to whom it is addressed, and its contents should comply with the audience addressed.

Advertising of prescription medicines on the Internet is forbidden.

Information on prescription medicines may be provided at online events (webinars) for healthcare professionals as well as in restricted sections of Internet resources open for healthcare professionals only.

Engaging advertising agencies as well as other persons for promotion of medicinal preparations on the Internet shall not indemnify the pharmaceutical company against liability for violation of provisions hereof.

This Code shall apply to promotion of medicinal preparations in the territory of the Republic of Belarus on any websites, regardless of the hosting and domain as well as location and domestic policies of pharmaceutical company that promotes medicinal preparations.

2.6. INFORMATION RELATING TO HUMAN HEALTH AND DISEASES

Pharmaceutical companies shall be entitled to provide to general public the information on diseases, their prevention and treatment when observing the following rules:

- such activity shall not be the subject of the licensed medical activity;
- the information provided shall be reliable, conscientious, ethical, full, and it shall not substitute medical consultation or encourage self-treatment;
- such information shall include a reference to the pharmaceutical company providing the same;
- such information shall not contain names of prescription medicines as well as images of packaging of such pharmaceutical products or its details or to otherwise promote prescription medicines;
- such information shall contain the advise medical supervision.

3. Features of interaction with healthcare professionals as well as other methods of promoting medicinal preparations

3.1. GENERAL PRINCIPLES OF INTERACTION WITH HEALTHCARE PROFESSIONALS

Interaction of pharmaceutical companies with healthcare professionals shall be aimed to benefit the patients and improve the medical practice. This interaction shall provide healthcare professionals with data on medicinal preparations, scientific and educational information.

Interaction of pharmaceutical and medical equipment companies with healthcare professionals intends Continued Professional Development (CPD). CPD is a continuing learning process, outside formal undergraduate and postgraduate training, which enables doctors to maintain and improve their performance across all areas of their practice through the development of knowledge, skills, attitudes and behaviours. It covers all learning activities, both formal and informal, by which doctors keep up to date.

Quality Improvement (QI) relevant to ME. QI relevant to ME consists of systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups.

Independent medical education (IME/CME), which could be funded by industry but its scientific programme and content are always decided independently from the industry. The audience is identified and invited by the organizer and not the pharmaceutical company. Cooperation of pharmaceutical companies with healthcare professionals should not lead to a conflict of interests, in particular, between professional duties of healthcare professionals and their personal interest. Among other things, such conflict should not arise upon prescription of medicinal preparations by a medical practitioner as well as in case of recommendation and sale of medicinal preparations by pharmaceutical practitioners.

Healthcare professionals should not be offered, promised, provided or given remuneration in any form for prescription or recommendation of a certain medicinal preparation to patients as well as enter agreements regarding prescription or recommendation of any medicinal preparation to patients (except for contracts on clinical studies of medicinal preparations).

Personal information of healthcare professionals may be entered in databases only upon their proper consent and in compliance with the legislation on protection of personal data.

3.2. MEDICAL EDUCATION APPROACHES

ME must keep pace with changes in medicine and ensure that healthcare professionals stay up to date and develop their skills to ensure high quality patient care. Pharmaceutical companies have a significant role to play in the provision of ME. Their involvement with ME must meet the relevant requirements of local codes and national laws, and must never have the primary aim of increasing prescriptions or sales.

Pharmaceutical companies may assist with the provision of ME in a variety of ways. It may be CME-accredited by one or more independent bodies.

1. Independent medical education (IME/CME), which could be funded by a pharmaceutical company but its scientific programme, speakers and content are always decided independently from the pharmaceutical company. The audience is identified and invited by the organizer and not the pharmaceutical company. The role of the pharmaceutical company must be declared as required by the Code.

2. Medical Education through collaboration / Partnership, which is provided by one or more pharmaceutical company and other key stakeholders, working together towards mutually established ME goals in a collaborative setting. Such arrangements should be formalized by a written agreement, and effective collaborations and partnerships should have the following characteristics:

Clear intent and objectives of the ME programme, defined at the beginning and agreed by the parties;

Clearly defined areas of responsibility and deliverables for each party;

Transparency and disclosure of financial support.

3. Pharmaceutical Industry Led Medical Education activities which may address specific disease-related topics and/or product-specific topics. Although these activities are initiated and provided by the pharmaceutical industry, disease-related educational activities might also involve scientific organizations or professional associations.

Quality and Ethics in Medical Education: Both quality and an ethical approach to ME must be the key priorities for all continuing medical education providers.

ME providers should consider the following criteria as a minimum:

Programme should have clear educational objectives to support high-quality patient care.

Content should be balanced, fair, ethical, and up-to-date.

Roles and responsibilities of the parties should be agreed, documented, and clearly communicated.

Ongoing evaluation should be an integral component of the programme.

The ability of the intended audience to access programmes.

Funding by pharmaceutical companies should be reasonable and appropriate (fair-market value) and disclosed according to transparency principles and requirements.

3.3. PRINTED PROMOTIONAL MATERIALS

Printed promotional materials, except for those described in the subparagraph 4.2.2., shall contain the following minimal information:

- Name of a medicinal preparation (usually trade name);
- common names of active substances (where the medicinal preparation contains no more than three active substances);
- name and address of pharmaceutical manufacturing companies as well as their representative in the territory of the Republic of Belarus;
- date of advertisement production;
- "abbreviated prescribing information" including approved indications together with the dosage and method of administration, summary of contraindications, precautions and side-effects.
- indication of target audience, for which this promotional material is intended.

3.4. EVENTS

The aim of all the events, including meeting of medical representatives with healthcare professionals and visits to medical institutions, shall be collection of data on side effects, provision of information to healthcare professionals on medicinal preparations and/or scientific or educational information in healthcare or pharmaceutics.

Companies shall not organize events that take place outside of the healthcare professionals' country of residence unless it is justified by logistics and safety. International scientific congresses and symposiums that gather participants from many countries are therefore justified and permitted.

Information distributed among the participants of international scientific congresses or symposiums may concern the medicinal preparations that are not authorized in the country where the event is held or registered under other conditions provided that the following requirements are met:

- distribution of such information is permitted by the current legislation of the host country;

- the event should be truly an international scientific event with a large number of healthcare professionals from other countries (as speakers or attendees);
- materials on medicinal preparation that is not authorized in the host country shall be accompanied by a suitable statement that such product is not authorized in this country;
- materials that refer to prescribing information (indications, warnings, etc.) approved in other country/countries where this medicinal preparation is authorized should be accompanied by a statement that registration conditions differ internationally.

The event shall be held in an appropriate venue and under conditions promoting achievement of scientific and educational purposes of this event. Companies must avoid using renowned or extravagant venues.

No venues generally associated with entertainment, luxury or exclusivity should be used, irrespective of their class.

It is recommended to organize events at business centers, educational institutions, hotels and other venues intended for business and educational events.

The event may only be held at a public venue if the room is isolated or public access is restricted during the event.

No leisure and sports events should be used to attract healthcare professionals to promotional and scientific events.

Stationery (pens, notebooks, pencils) of minimal value may be provided to HCPs at the events for taking notes; they should not bear the name of any medicinal preparations but may bear the name of the company providing them.

Refreshments, tea/coffee, snacks and/or hot dishes may be providedif it is justified by the event duration, it is clearly secondary to the main purpose of the event, and they are reasonable and provided exclusively to participants of the event, but not the accompanying individuals. As a general rule, the hospitality provided must not exceed what participants would normally be prepared to pay for themselves.

No entertainment or other leisure or social activities should be provided or paid for by member companies.

3.5. GUESTS

Companies must not pay any costs associated with individuals accompanying invited HCPs, except in cases of medical necessity.

3.6. SPOSORSHIP

Member companies may sponsor HCPs to attend events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code;
- Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCPs for time spent in attending the event unless inviting of HCPs for delivery of scientific information;
- Any sponsorship provided to individual HCPs must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

3.7. ENGAGING OF HEALTHCARE PROFESSIONALS FOR RENDERING SERVICES

Pharmaceutical companies shall be entitled to engage healthcare professionals for rendering scientific and information services, creation of objects of copyright and also for clinical trials of medicinal preparations and to pay them remuneration for rendering these services.

While engaging healthcare professionals for rendering services the following requirements shall be observed:

- a written contract. A written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- remuneration for the rendered services must be reasonable and reflect the market value; it may include reimbursement of reasonable expenses including travel, meals and accommodation;
- a reasonable need for services;
- the criteria for selecting consultants must be directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- the number of healthcare professionals involved must match the number reasonably necessary to achieve the goal;
- the conclusion of service contract shall not, directly or indirectly, put healthcare professional under obligation to recommend and prescribe medicinal preparations.

Payment or reimbursement for healthcare professionals directly related to rendered services, including the travel, catering and accommodation cost, is permitted.

Payment or reimbursement provided in execution of contracts should meet the following requirements:

- ino hotels or venues publicly associated with luxury or exclusivity should be used, irrespective of their class;
- reasonable meals shall be permitted;
- in case of daytime travel that does not exceed four hours, economy class tickets are recommended;
- no reimbursement of any costs of accompanying individuals shall be permitted.

3.8. GIFTS

The possibility of and procedure for granting gifts to healthcare professionals (including medical and educational items) shall be established according to the Belarusian legislation.

3.8.1 GIFTS AND PROMOTIONAL AIDS

3.8.1.1 PROHIBITION OF GIFTS

Gifts including for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP.

3.8.1.2 PROMOTIONAL AIDS

Promotional aids of minimal value and quantity may be provided or offered to HCPs if relevant to the practice of the HCP. A promotional aid is a non-monetary item given for a promotional purpose. Providing or offering them to HCPs in relation to the promotion of prescription-only medicines is prohibited.

Promotional aids of minimal value and quantity may be provided or offered to healthcare organizations solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP.

3.8.2 INFORMATIONAL OR EDUCATIONAL ITEMS THAT ENHANCE PATIENT CARE

Informational or educational items provided to healthcare organizations for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

Informational and educational items provided to healthcare organizations for patient use may include the name of a company but they must have no indication of a trade mark if the name of a product, which is identical to the trade mark, is of no relevance for the correct use of a product by the patient.

The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

3.8.3 GUIDANCE ON VALUES

Member companies correlate guidance using local currency, on acceptable monetary amounts for the following:

- "minimal value" for promotional aid items;
- "modest value" for items of medical utility and informational & educational items.
- "reasonable value" for scientific books & journal subscriptions.

3.9. BASIC RULES AND STANDARDS OF MEDICAL REPRESENTATIVES' ACTIVITIES

The purpose of activities of medical representatives of pharmaceutical companies shall be to Increase the professional level of healthcare professionals and to implement the obligation of the pharmaceutical company to monitor safety of medicinal preparations.

Medical representatives shall be entitled to participate in congresses, symposiums, conferences, presentations, meetings and other events for healthcare professionals in medical organizations, including visits, in the manner established by the said medical organization.

During these events, medical representatives shall be entitled to provide healthcare professionals with printed promotional materials and informational materials, such as partial reprints of certain chapters and sections of specialized publications, scientific monographs and reference books, scientific articles, reports and other printed materials to increase of professional level of healthcare professionals.

The above information may be provided on CDs and memory cards which are not intended for personal use is allowed. However any materials, including promotional materials, should raise the professional level of healthcare professionals and avoid pursuing exclusively advertising goals.

Medical representatives of pharmaceutical companies shall have appropriate training and knowledge to provide healthcare professionals with full, true, reliable and up-to-date information about pharmaceutical products.

Pharmaceutical company shall be responsible for contents and form of information provided by medical representatives to healthcare professionals.

Upon the healthcare professional's request, medical representatives must provide the prescribing information for each medicinal preparation which he informs about as well as prescription status (i.e. over-the-counter or prescription only medicine, subsidized medicine) of the medicinal preparation and its availability in pharmacies.

Medical representative must observe professional ethics in interactions with consumers, healthcare professionals and the company whose interests he (she) represents as well as with representatives of the competing companies.

Medical representatives must inform the head of the relevant division of the company about the practical use of the company's medicinal preparations, including adverse reactions, as reported by healthcare professionals.

3.10. SAMPLES

Pharmaceutical companies shall not be entitled to supply samples of medicinal preparations directly healthcare professionals both for subsequent transfer to patients, and for personal use (including samples for demonstration (demo packs) and empty secondary and primary packing).

3.11. EXPERT COUNCIL

The objective of Expert Council is to discuss and providing external advice regarding the pre-determined scientific issue where the company lacks expertise or experience to resolve it and the issue cannot be resolved otherwise.

Expert Councils cannot be used as a means for distribution of information or promotion of medicinal preparations while the information obtained by the Expert Council may be used for resolution of marketing issues (e.g., information to be included in marketing plans or advertising meetings).

Pharmaceutical companies shall be entitled to pay the experts (healthcare professionals) a remuneration for their work at Expert Council (including compensation of expenses related to participation in Expert Council) only provided

that activity of such experts within Expert Council has scientific character. While reimbursement the requirements of the article 3.4 of the present Code shall be observed.

Organization of Expert Council is possible only with reasonable scientific need and shall not be aimed at financing of actions of professional communities.

The choice of members of Expert Council shall be based only on their professional competence and qualification and shall not be somehow connected with last, current or possible future appointments or recommendations of medicinal preparations of the company. Workers of the sales departments shall not have influence on a choice of experts and work of Expert Council.

The number of healthcare professionals involved shall correspond to the quantity which is really needed for achievement of the goal.

The total number of employees of the company visiting the meeting of Expert Council shall not exceed one quarter of number of the independent third-party experts participating in meeting. However employees have no right to use participation in work of Expert Council for promotion of medicinal preparations of the company.

3.12. HANDLING MEDICAL INQUIRIES

Medical inquiries may be received from healthcare professionals and patients. The company shall show consideration for each request. Each request shall be registered in the manner established by the legislation on the appeals from citizens and legal entities, and the response shall be provided.

The information provided to healthcare professionals upon the inquiry shall comply with the Belarusian legislation and provisions hereof with due consideration of the approved prescribing information.

A response to the request of healthcare professional shall not serve the promotion of a medicinal preparation. It shall be limited to answering the question itself.

Product information of other companies must be unbiased.

The response shall be given in legible and ethical format.

The pharmaceutical company's personnel shall not be entitled to initiate discussion with healthcare professionals and other third parties regarding unauthorized medicinal preparations and/or unauthorized indications.

Information regarding unauthorized medicinal preparations and/or unauthorized indications shall only be provided to healthcare professionals exclusively upon the inquiry sent to the pharmaceutical company.

Responses to all inquiries from healthcare professionals shall be provided by the medical information service or any other authorized personnel of a Medical/Regulatory Affairs Department to ensure the appropriate quality and unbiased nature of information.

All phone calls shall be received and registered by the personnel with the inquiry data being further sent to the Medical/Regulatory Affairs Department.

Sales and marketing employees may only answer the questions asked in interactions with healthcare professionals within the approved prescribing information. Sales and marketing employees have to redirect the questions beyond the scope of the properly approved prescribing information to Medical/Regulatory Affairs Department.

The response to a healthcare professional shall provide comprehensive scientifically evidenced information regarding the inquiry.

All statements and facts In written responses must be supported by suitable references indicating the name of the author, the full name of the article or monograph, the publication place (traditional abbreviations are allowed), year of the publication, the number of volume, issue and page.

Personal information of healthcare professionals and other individuals that is not otherwise provided in open access may be entered into databases of pharmaceutical companies upon the consent in a proper legal form and in compliance with other legislation on protection of personal data.

4. Features of advertizing and other methods of promotion of medicinal preparations to population

4.1. GENERAL REQUIREMENTS

Public advertising of prescription only medicines shall not be permitted.

The advertised medicinal preparation being intended for certain categories of population, subsidized or refunded by the state shall no be mentioned in public advertising.

It is recommended to avoid in public advertising of medicinal preparations special medical terms which can be misunderstood by or mislead consumers of advertising.

4.2. PRINTED PROMOTIONAL MATERIALS

4.2.1. ALL PRINTED PROMOTIONAL MATERIALS

All printed promotional materials, other than those covered below in subparagraph 4.2.2., must include:

- the name of the product (usually trade name), as well as international non-proprietary name, of the product contains only one active agent;
- the active ingredients, using approved names where they exist;
- date of production of the advertisement;
- "abbreviated prescribing information" which should include approved indications together with the dosage and method of administration, where necessary; and a succinct statement of the contraindications, precautions, and side-effects;
- the name and the address of pharmaceutical company or its representative in the territory of the Republic of Belarus.

4.2.2. REMINDER ADVERTISEMENTS

A "reminder" advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For "reminder" advertisements, "abbreviated prescribing information" referred to in subparagraph 4.2.1. above may be omitted.

Minimal reminder advertisement shall include:

- name of the product;

- warning about contraindications for use;
- need to refer to prescribing information or professional advice.

4.2.3. ELECTRONIC MATERIALS, INCLUDING AUDIOVISUALS

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- country-specific information should comply with local laws and regulations.

4.3. RESTRICTIONS ON PROMOTIONAL MATERIALS FOR POPULATION

Advertisement of medicinal preparation for population shall not:

- create the impression of irrelevance of medical advice;
- contain information which does not comply with prescribing information;
- claim the positive effect, efficacy or safety of medicinal preparation or the absence of adverse effects;
- reference specific cases of recovery or improvement of health resulting from the use of medicinal preparation;
- contain expressions of gratitude by individuals in connection with the use of medicinal preparation;
- address the minor individuals;
- establish an idea of medicinal preparation's benefits of by referencing the studies and the tests required for state registration;
- create the impression of need for medicinal preparation in healthy people, except for advertising of preventive medicinal preparations;
- contain statements or assumptions of safety or efficacy of medicinal preparation being caused by its natural origin;
- show medicinal preparation as a dietary supplement, cosmetic or other products that are not medicinal preparations;
- contain descriptions or depictions of the disease that can provoke wrong self-diagnosis;

- contain statements or assumptions of consumers of advertising having any conditions that would necessitate the use of medicinal preparation, or a statement creating the impression of the need for administration in a healthy person;
- indicate possible use of any forms of financial compensation in case of purchase of medicinal preparation;
- contain images and statements of medical and pharmaceutical practitioners;
- contain recommendations of scientific, medical, pharmaceutical practitioners or persons who do not fall into these categories but can encourage the use of medicinal preparation due to their popularity;
- contain recommendations of the government bodies and other organizations used to enhance advertising effect;
- contain inappropriate, alerting or misleading terms, vivid depictions of changes in human body caused by a disease, injury or effect of pharmaceutical product on a human body or body parts;
- contain other information forbidden by the current legislation of the Republic of Belarus.

4.4. OTHER METHODS OF PROMOTION OF MEDICINAL PREPARATIONS TO POPULATION

Promotion of medicinal preparations through TV shops as well as the sale of medicinal preparations on the Internet shall not be permitted.

Use of medicinal products as prizes or incentives shall not be permitted.

Distribution of free samples of medicinal preparations to the population, including conducting tasting and testing sessions in advertising purposes shall not be permitted.

4.5. HANDLING MEDICAL INQUIRIES FROM PATIENTS

When patients apply to pharmaceutical company for information, their inquiries should be properly handled.

Such interactions shall not be used for advertising and promotion of medicinal preparations, including after the interaction (e.g., by publication of correspondence in mass media).

Information provided to the patient in response to inquiry shall fully comply with the approved prescribing information. The response shall be accurate, civil and not misleading.

Should the questions related to diagnosis, management or treatment of a disease arise, any representative of the company (including an employee of the Medical Department) must recommend to seek medical advice or emergency medical care.

5. Studies of medicinal preparations

5.1. POST-MARKETING STUDIES

Post-marketing clinical studies/testing and epidemiological surveys (hereinafter – post-marketing studies) shall comply with the legislation of the Republic of Belarus as well as the provisions established herein.

Post-marketing studies shall have a justification and scientific objective/objectives reflected in the study protocol.

Post-marketing studies are monitored and under the responsibility of Medical Department or an appropriate medical division/employees of pharmaceutical company.

Selection of investigators shall be based exclusively on their professional qualification and clinical experience.

The data obtained during post-marketing studies shall be statistically processed and analyzed. Efficacy and safety data of such studies shall be available to healthcare professionals.

When carrying out post-marketing studies, the laws, rules and requirements for confidentiality of personal data (including collecting, processing and use of personal data) shall be observed.

The protocol of post-marketing study shall be must be approved by the Medical Department or responsible medical divisions/employees. The Medical Department (appropriate medical divisions/employees) shall control the course of post-marketing studies.

Documentation of post-marketing studies (protocol, individual registration card, patient information sheet, etc.) shall pass mandatory ethical expert examination.

To the extent that it is permitted, employees of other departments of the company may participate in implementing administrative tasks (in particular, delivery of post-marketing study documentation from the Medical Department to study centers/investigators and back to the company).

Such participation shall be carried out under supervision of the Medical department which shall provide appropriate training to the employees of other departments of pharmaceutical company.

Participation of a healthcare professional in post-marketing study shall not be an inducement to recommendation/prescription, purchase, sale and/or administration of any medicinal preparation.

Remuneration provided for post-marketing studies shall be paid under an official contract with medical and preventive institution where the study is conducted, and it shall be reasonable and reflect the fair market value of the works performed.

No post-marketing studies shall be disguised as marketing studies. Where distinctions between marketing studies and post-marketing studies are not clear, the objectives of marketing studies shall be subject to review by medical specialists of the pharmaceutical company.

5.2. MARKETING STUDIES

Marketing studies conducted by pharmaceutical companies themselves or with involvement of marketing agencies, shall only be permitted in compliance with the current legislation.

Herewith pharmaceutical companies and/or agencies engaged shall not be entitled to pay remuneration to healthcare professionals for their participation in a marketing study. Marketing studies requiring special scientific knowledge and considerable level of effort from a healthcare professional may be deemed an exception provided that:

- Marketing studies are held with involvement of independent agencies;
- healthcare professional is not informed, and it is not evident from study materials which pharmaceutical company is the customer/sponsor of the study;
- pharmaceutical company does not participate in selection and has no access to identification data of healthcare professionals that participate in a marketing study.

Marketing studies shall not be used:

- to promote or sale a medicinal preparation or to manage the opinion or behavior of study subjects. Therefore any mentions of the medicinal preparation's trade name should be avoided unless required by the study objective;
- to collect personal data of patients;
- to further study the efficacy or safety of medicinal preparation;
- for pre-authorization promotion of the medicinal preparation or therapeutic indications subject to registration;
- to collect confidential information about competitors;
- to discredit medicinal preparations of competitors.

6. Features of interactions with legal entities. Charitable activities

6.1. INTERACTIONS WITH NON-PROFIT ORGANIZATIONS

Pharmaceutical companies shall be entitled to provide gratis sponsor aid to non-profit organizations with socially useful objectives in compliance with the Belarusian legislation.

Among other things, gratis sponsor aid may be provided for support of medical education, development of scientific activities in healthcare aimed to increase the quality of medical care.

Charitable activities shall under no circumstances be directly or indirectly dependent on administration or purchase of medicinal preparations of the company.

Gratis sponsor aid shall not be provided in cash.

Medicinal preparations may be provided to healthcare organizations as gratis sponsor aid is provided that such aid does not pursue commercial objectives. The company must inform the recipient of the remaining shelf life of the medicinal preparation.

Gratis sponsor aid may only be provided on the basis of the written request from non-profit organization and the written contract on provision of gratis sponsor aid.

6.2. INTERACTIONS WITH PATIENT ORGANIZATIONS

All interactions with patient organizations shall be ethical. The independence of patient organizations must be respected.

Pharmaceutical companies may interact with patient organizations to implement the following tasks:

- studying patients' opinion on the impact of disease on quality of patients' lives and opinions of their caregivers to improve the clinical study programs and accelerate the development of those better meeting the needs of patients;
- providing informational support to patient associations by responding the inquiries in the manner established by article 4.5 hereof for handling patients' inquiries;
- creation of patient registers provided that the legislation on protection of personal data and patient confidentiality is strictly adhered to;

- conducting of a campaign to inform general public about the disease;
- cooperation in organization of named-patient use;
- providing gratis sponsor aid;
- other legal cases.

6.2.1. DECLARATION OF INVOLVEMENT

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

6.2.2. WRITTEN DOCUMENTATION

Companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

No pharmaceutical company may be the only the founder of the patient organization.

When working with patient organizations, companies must ensure that the fact and the nature of such cooperation are clearly mentioned by the pharmaceutical company in open access sources. However the pharmaceutical company may be the only funder of the charitable and/or social project of patient organization upon receiving an appropriate written request from a patient organization for implementation of the programs of such organization aimed at prevention and protection of public health, promotion of healthy lifestyle, provision of assistance to socially vulnerable groups unless such funding is aimed, directly or indirectly, at promotion of any decisions that are favorable for pharmaceutical company or its products and taken by the patient organization in carrying out its statutory activities.

In any case, such pharmaceutical company shall not limit the rights of other pharmaceutical companies to fund similar projects of patient organization upon their discretion.

Any interactions of pharmaceutical companies with patient organizations shall be clearly documented.

Pharmaceutical companies may provide gratis sponsor aid for the events held by patient organizations provided that the primary purpose of such an event is educational or scientific in nature or otherwise supports the mission of such organization. When companies fund the events of patient organizations,

they must ensure that the venue and location comply with the limits of hospitality established in article 3.3 hereof.

6.3. INTERACTIONS WITH PHARMACIES

Medical representatives of pharmaceutical companies shall be entitled to visit pharmacies to inform pharmaceutical practitioners and managers of pharmacies of the medicinal preparations manufactured or marketed, as well as to collect the data on adverse effect.

Pharmaceutical companies shall not be entitled to organize programs where material prizes are offered to pharmaceutical practitioners, managers of pharmacies and pharmacies themselves for achievement of certain results in marketing of the medicinal preparation.

Interaction with pharmacies is subject to the procedure and terms and conditions of information provision in respect of medicinal products established by the law.

7. Procedures and responsibility of pharmaceutical companies

7.1. AUTHORIZED PERSON

Companies shall establish and maintain the appropriate operating procedure to ensure compliance with the legislation of the Republic of Belarus and this Code. In particular, the companies shall continuously monitor and analyze their own activities for promotion of medicinal preparations and the materials distributed in this regard.

All the advertising materials shall be initially approved by an authorized person having an appropriate level of education and qualifications (scientific or medical).

7.2. EVENT PROGRAMS AND DOCUMENTATION

The promotional events shall be held according to the programs approved by the authorized person; appropriate documentation reflecting the proceedings shall be prepared.

7.3. RECORD RETENTION

Programs and documentation of events (actions) as well as samples of promotional materials shall be filed in an authorized division or by an authorized person for at least 6 months after the event, action or an advertising campaign unless a longer term is specified by the current legislation.

Programs and documentation shall be shown to the controlling bodies according to the current advertising legislation, as well as in case of consideration of disputes by the members of specially created AIPM group.

7.4. EMPLOYEE TRAINING AND EDUCATION

To maintain the high standards in implementation of marketing activities, the companies shall follow the principle of continuous advanced training of the employees in this regard.

8. Maintenance and Development of the Code

8.1 THE NEED FOR CONTINOUS MAINTENANCE AND DEVELOPMENT OF THE CODE

Extension of the range of methods and means of practice of AIPM member companies in the setting of developing pharmaceutical market of the Republic of Belarus and international economic relations justify the need for continuous maintenance and development of the Code as to comply with modern requirements for regulation of advertising and other methods of promotion of medicinal preparations in order to provide the population with effective, high-quality and safe medicinal preparations.

8.2 ANALYSIS OF PRACTICE OF PHARMACEUTICAL COMPANIES AND CODE UPDATING

For the purpose of ensuring the up-to-date nature of the Code and appendices hereto as well as timely detection of the need for amendment, the Supervisory Council shall make a decision on updating.

APPENDIX 1

TO THE CODE OF PRACTICE OF AIPM

1. CASES OF CODE VIOLATION

1.1. Should the issue of non-compliance by the members of Association with ethical standards and rules hereof arise, the stakeholders shall attempt to settle it amicably.

1.2. Should the actions described above not lead to a decision satisfying the parties to dispute, the applicant company shall be entitled to submit the issue to be considered and resolved to the Front Office of AIPM.

1.3. A complaint on the Code violation by the AIPM member company may be submitted both by any AIPM member and other stakeholders.

2. PROCEDURE OF DISPUTE RESOLUTION

2.1. A written complaint shall be sent to the Front Office of AIPM (hereinafter – Front Office) in the name of the Chief Executive Officer of AIPM and contain a detailed description of the circumstances, which served as the reason for complaint.

2.2. The complaint shall contain:

- Complainant's details (the name);

- The correspondence address and contact person;

- The name of the company alleged to be in breach of the Code;

- The name(s) of medicinal product(s) involved in alleged breach of the Code;

- The documents and materials supporting the alleged breach, e.g., advertising materials;

- The information on the period of alleged breach;

- A brief description of the alleged breach, including references to the specific articles of the Code.

2.3. Upon the receipt of complaint, the Front Office ensures the availability of the necessary documents and materials regarding the breach of the Code.

2.4. The materials related to the complaint (case records) shall be confidential.

2.5. Upon validation, the Front Office shall inform the complainant that the complaint is accepted for consideration within two working days from the date of receipt as well as shall inform the respondent company of the complaint, documents and materials received.

2.6. The respondent company shall respond to the complaint received within 10 working days . this period begins from the moment of notification by the Front Office.

2.7. The response in writing shall be sent to the Front Office in the name of the Chief Executive Officer of AIPM.

2.7.1. The response shall contain:

- Acknowledgement of a breach and information on the measures taken to rectify the situation;

- Refusal to acknowledge the breach as well as clearly phrased and, where appropriate, documented basis for such refusal.

2.8. Upon the receipt of the response, the Front Office shall send it to the complainant within two working days. Within five working days, the complainant shall consider the response and inform the Front Office whether the response is deemed satisfactory or not.

2.9. If the response is deemed satisfactory, the Front Office shall register the fact of dispute resolution in writing, and the case shall be considered closed.

2.10. Should the respondent company refuse to acknowledge the breach of the Code, the matter shall be considered by the Supervisory Council of AIPM with invitation of the parties of the dispute.

2.11. The members of the Supervisory Council get acquainted with all the case materials and make the decision on whether the breach took place or not. The decision is executed in the form of admission or non-admission of the fact of the breach. Recommendations on elimination of negative consequences of the breach may also be given.

2.12. Should the Supervisory Council make a decision on impossibility of resolution without additional materials from the parties of dispute, the Front Office shall send an appropriate request within two working days. The parties must submit additional materials within five working days from the date of request receipt.

After that, a second meeting of the Supervisory Council shall be held within ten working days. The decision of the Supervisory Council shall be notified to the parties in the regular manner.

2.13. The Supervisory Council of Association shall decide whether the conflict can be considered settled or additional actions must be taken.

2.14. The case shall also be closed should the Supervisory Council consider the received response satisfactory and the complainant express no opinion on it during the abovementioned period provided.

2.15. The decision made by the Supervisory Council shall be redirected by the Front Office to the parties of dispute in writing within two working days.

3. SANCTIONS FOR CODE VIOLATION

Where Code breach by the member company is established by the decision of Supervisory Council, the sanctions are as follows:

3.1. The company in breach must undergo online-training on the Code;

3.2. Details of the case, including the name of the company in breach, shall be published on the Association's site in case of serious or repeated violation. This information shall be posted on the website for three months.

3.3. To inform the headquarters of the company in breach about violation;

3.4. To recommend the General Meeting of AIPM to exclude the company in breach from the members of AIPM.

3.5. Any combination of abovementioned sanctions.

The decisions made by the Supervisory Council on each specific dispute shall be published on the website of the Association. The name of the companies concerned shall not be subject to publication, except when the name of the company in breach should be published as a sanction for violation of the Code as herein above described.

At each General Meeting of AIPM, the Front Office shall submit a report indicating a number of disputes settled after the previous General Meeting, their general nature and the decisions made. This report contains the names of the companies in regard to which the breach of the Code of AIPM is established.