



Association of  
International  
Pharmaceutical  
Manufacturers

Ассоциация  
международных  
фармацевтических  
производителей



# Кодекс надлежащей практики

# Code of Practice

2019



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International  
Pharmaceutical  
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2019

*Adopted in 1998  
This revision approved  
by a General Meeting of the AIPM  
on December 11, 2019*

# Association of International Pharmaceutical Manufacturers (AIPM) Code of Practice

Revision  
2019

The Federal Service for Supervision of Healthcare, being a federal executive agency authorized by the Government of the Russian Federation to exercise state control over medical experts and pharmacists complying with limitations applied to their professional activities, supports the Association adopting this AIPM Code of Practices dedicated to ensuring high ethical standards for activities of pharmaceutical companies through self-regulation.

We hope that we will manage to create a civilized compliance practice by mutual efforts as well as to ensure professional cooperation of the medical society and the pharmaceutical industry for the benefit of Russian patients in strict compliance with the legislation of the Russian Federation.

Head of the Federal Service  
for Surveillance in Healthcare,  
Dr. of Medicine  
M. A. Murashko

The right of the citizens of the Russian Federation to health protection and medical care stipulated in Art.41 of the Constitution of the Russian Federation cannot be executed without proper supply of medications. The medication market is presently not as much a field for applying market economy laws as a strictly regulated activity aimed at achieving a socially important purpose, namely, to provide a possibility for the citizens of the Russian Federation to obtain high-quality, low-cost and effective medicines.

The Code of Practice of the Association of International Pharmaceutical Manufacturers (AIPM) is an example of rule-making at a local level aimed at creating an ideal behavior pattern for international pharmaceutical market players in terms of coherence of private and public interests.

Such a document is important in the context of forced modernization of the Russian legislation regulating medical and pharmaceutical activities, when the Federal Law No. 323-FZ «On Protection of Health of the Citizens of the Russian Federation» adopted on 21.11.2011 has entered into full force, the Federal Law No. 125-FZ «On Blood and Components Donation» was adopted on 20.07.2012, the Federal Law No. 61-FZ dated 12.04.2010, «On Circulation of Medicines» has been undergoing substantial improvements, and the sublegislative regulation has been constantly developing. It is extremely important to strictly regulate relationships in the sphere of health protection, and the Code developed by the Association of International Pharmaceutical Manufacturers can obviously play a stabilizing role in regulating activities of pharmaceutical manufacturers in Russia.

Provisions of the Code reflect adherence of the Association members to the principles of corporate social responsibility and proper behavior on the pharmaceutical market, as well as of unconditional compliance with the regulations of the Russian legislation.

It will be useful for international corporations and foreign manufacturers having rich experience in development of corporate rules and regulations to get acquainted with the Code, which duly reflects the specifics of legal regulation in the countries of the post-Soviet area. The Code of Practice of the Association of International Pharmaceutical Manufacturers demonstrates recognition of the regulations and the principles of the Russian legal framework and proposes establishing stricter requirements to activities of the Association members.

We believe that the AIPM Code of Practice setting high ethical standards for pharmaceutical companies deserves close attention not only from Association member companies, but also from other representatives of the pharmaceutical society and the agencies regulating this sphere of activities.

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*AIPM member companies and anyone acting on their behalf recognize their responsibility to society. On this basis, they accept and undertake to fulfill the requirements of the AIPM Code of Practice (the «Code») and to follow it not only in letter but also in spirit.*

*AIPM member companies should strive to observe the rules of fair competition in their activities and to refrain from harming the image, position, or economic interests of competitors through any improper conduct, including but not limited to, inappropriate advertising or any other unfair methods of promoting pharmaceutical products.*

*AIPM member companies shall make efforts to promote the Code in order for it to be correctly understood and applied both by their own employees and by other representatives of the pharmaceutical community of the Russian Federation.*

*AIPM member companies seek to further develop the standards of the Code, among other things, by suggesting relevant updates, additions, and modifications to its requirements.*

*Upon discovering any violation of the Code, a company whose interests have been affected is entitled to immediately invoke the procedure for resolving disputes and violations established by this Code (Appendix 1). However, the AIPM welcomes companies settling their disputes on their own.*

*The Code exists in English and Russian versions. The Russian version will be given preference in any disputes regarding the interpretation of the Code's provisions.*

*If any contradictions are discovered between the provisions of this Code and the existing legislation of the Russian Federation, the existing legislation of the Russian Federation shall apply.*

*When undertaking any program or action, pharmaceutical companies are obligated to ensure that it complies with the existing laws, including but not limited to, antitrust laws, advertising laws, and laws regarding the protection of personal data.*

*This version of the Code will take effect upon being approved by a General Meeting of the AIPM.*

## Preamble

The pharmaceutical industry aims to provide the public, medical and pharmaceutical community with objective information about pharmaceutical products used in the healthcare system. Moreover, it is essential to take into account the risk to which public health may be exposed in the absence of necessary regulation of the procedures for the disclosure of such information.

Building an effective healthcare system is impossible without a continuous, scientific-based dialogue between pharmaceutical companies and healthcare professionals, as well as without adherence to high ethical standards of interaction in the interests of achieving an optimum result in the field of healthcare and maintaining the living standards.

Aware of the increased social responsibility borne by the manufacturers of pharmaceutical products, representatives of the pharmaceutical industry of developed countries began to adopt standards regulating their marketing and other activities as early as in the middle of the last century. In 1981, the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), which at that time united 50 national associations, adopted the IFPMA Code of Pharmaceutical Marketing Practices, the observance of which from 1988 became a condition of membership for national associations and, accordingly, a requirement for their member companies. Many IFPMA member associations have developed and adopted their own codes taking into account national conditions but not contradicting the general principles set forth in the IFPMA Code.

The Association of International Pharmaceutical Manufacturers (AIPM), a non-commercial IFPMA member organization acting on the territory of the Russian Federation, which currently represents the interests of more than 60 of the world's leading pharmaceutical companies, adopted the AIPM Code of Marketing Practices in 1998. Due to the lack of detailed special requirements in Russian legislation, the document played a positive role during in the introduction of standards for the civilized promotion of pharmaceutical products on the Russian pharmaceutical market.

The progressive development of the circulation of pharmaceutical products in Russia and abroad has caused an expansion of the methods and tools available for advertising and promotion. This has led to revision of a number of legislative acts. Associations of pharmaceutical manufacturers have also updated and supplemented their own codes of ethics.

The development of the Russian pharmaceutical market has brought about the need to update the existing Code, to supplement it with new provisions in order to reflect the realities of pharmaceutical companies practice. To that end, the Code was revised in 2005 with due regard for current methods of promotion and means of communication, including advertising and information on the Internet, various methods for collaborating with healthcare professionals, and others.

In 2009, the need again arose to amend and supplement the 2006 version of the Code due to the accumulated experience in resolving ethical disputes, changes to Russian legislation (particularly the Civil Code of the Russian Federation), and general trends in ethical regulation in Europe and elsewhere in the world.

Due to the substantial changes made to the laws of the Russian Federation in 2011 and the adoption of a new version of the IFPMA Code, a conceptual revision of the Code was required so as to substantially expand its application for the regulation of a broader spectrum of pharmaceutical companies' activities.

Remaining dedicated to its commitment to high ethical standards, AIPM became a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2012. AIPM fully shares EFPIA position that there is a growing expectation that interactions between pharmaceutical companies and society are not only conducted with integrity but are also transparent. In 2013 AIPM has therefore decided that its existing Code should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between pharmaceutical companies and healthcare professionals and healthcare organizations. AIPM hopes that, by taking this step, it can enable public scrutiny and understanding of these relationships and thus contribute to the confidence of stakeholders in the pharmaceutical industry.

Since 2019, the IFPMA and EFPIA Codes emphasize the educational and informational basis for the interaction between the pharmaceutical industry, medical community and patient organizations on the principles of trust, respect and independence. Following the spirit and letter of the updated IFPMA<sup>3</sup> and EFPIA<sup>4</sup> rules, and in order to meet the ethical needs of modern society, in 2019 AIPM approved a new version of the AIPM Code of Practice, which clarifies the requirements for the interaction of AIPM member companies with the medical community and patient organizations for development and maintaining an ongoing dialogue in order to increase the availability of timely and effective treatment.

# I. Purpose and Scope of Application

## 1.1. PURPOSE

The purpose of this Code is to establish the minimum requirements to be observed by the pharmaceutical companies who are AIPM members in their R&D, educational, informational, charitable, and marketing activities in the Russian Federation.

## 1.2. BASIC TERMS

For the purposes of this Code, the following basic terms are used:

**Marketing study** - a study designed to obtain information about the market and to explore the behavior and perceptions of consumers and interested parties in said market;

**Medical representative** - any representative of a pharmaceutical company, regardless of the title he or she holds within the company and irrespective of whether or not he or she is an employee of the company, who directly contacts healthcare professionals;

**Events** - all promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and noninterventive studies) (each, an "Event") organized or sponsored by or on behalf of a pharmaceutical company;

**Samples of pharmaceutical products** - pharmaceutical products which are gratuitously transferred to non-commercial medical organizations so that they can familiarize themselves with the use of such pharmaceutical products, and gain experience in working with them, in accordance with the approved package leaflet;

**Educational items aimed at improving the quality of administration (use) of pharmaceutical products and/or raising the disease awareness (the "Educational Items")** constitute inexpensive items aimed at the education of healthcare professionals with a view to enhancing the level of medical and patient care, as well as inexpensive items of educational content which help to demonstrate the process of the disease development process to a patient. Examples of Educational items aimed at improving the quality of administration (use) of pharmaceutical products may include inhalers without active ingredient, devices which allow a patient to make himself/herself an injection, etc. Examples of Educational items aimed at raising the disease awareness may include layouts of human organs and tissues with affected area and other;

**Healthcare organization** (for the purposes of chapter VII of this Code) - any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals;

**Patient organization** - a non-commercial organization representing the interests and needs of patients, their families, and/or persons taking care of patients and/or disabled persons;

**Patient organization representative** - a person authorized to represent the interests of a patient organization;

**Transfers of value (for the purposes of chapter VII of this Code)** - direct and indirect transfers of value, whether in cash, in kind or otherwise, made for the purposes allowed by the applicable legislation and by this Code in connection with the development and sale of prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value;

**Research and development transfers of value (for the purposes of chapter VII of this Code)** - transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study;

**Post-registration clinical (interventional) study** - a study of a pharmaceutical product conducted in the Russian Federation by its developer or manufacturer, including with the involvement of a contracted research organization, for the purpose of gathering additional data on the efficacy, safety, and tolerability of the relevant pharmaceutical product after its state registration, in the course of which the studied pharmaceutical product is prescribed according to the terms of its registration in the country, while the specific therapy, diagnostic and monitoring procedures are conducted in strict compliance with the relevant study protocol;

**Post-registration observation (non-interventional) study** - a post-registration study of a pharmaceutical product in the Russian Federation by its developer or manufacturer, including with the involvement of a contract research organization, during which the pharmaceutical product and/or specific therapy is prescribed for a patient as part of usual clinical practice, according to the terms of the relevant pharmaceutical product's registration in the country in the course of which the decision to prescribe the product is separated from the decision to include the patient in the study and patients should not be subjected to any additional diagnostic or monitoring procedures beyond usual clinical practice in the treatment of the corresponding disease;

**Promotion** - any activity which is conducted, organized, or sponsored by or at a request of a pharmaceutical company, and which aims to facilitate the prescription, recommendation, dispensing, sale or administration of the pharmaceutical company's pharmaceutical product;

**Healthcare professionals** - doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products;

**Pharmaceutical product** - any medicinal preparation, including both pharmaceutical and biological products (irrespective of the existence of a patent and/or registered trademark), which is intended to be used for the purpose of diagnosis, treatment, or prevention of a human disease; for rehabilitation; or for the maintenance, prevention, or termination of pregnancy; or exerting an effect on the structure or function of the human body;

**Expert council** - a group of outside experts (such as healthcare professionals and/or representatives of patient organizations) competent in the relevant field of knowledge, whose joint meeting is arranged by a pharmaceutical company so as to have a discussion and receive consultation on topics or questions determined in advance, on matters related to clinical or scientific aspects, as well as on issues related to patient access to innovative methods of therapy that cannot be properly examined by relying only on the company's own resources;

**Epidemiological study** - a study of the spread, incidence, and intensity of various diseases or medical indicators of the state of health for the purposes of identifying the causes of their development, the factors of risk and their mutual interaction in different groups of the population;

### 1.3. SCOPE OF APPLICATION

This Code is applicable to:

- the advertising of pharmaceutical products to the general public;
- the advertising of pharmaceutical products to healthcare professionals;
- the activities of pharmaceutical companies' representatives;
- interaction with healthcare professionals;
- interaction with patient organizations;
- post-registration clinical (interventional) studies, observational (non-interventional) studies, and epidemiological studies;
- marketing studies;
- the distribution by pharmaceutical companies, or organizations representing their interests, of information related to human health or diseases, and the making of donations and grants;
- support for continuous medical education;
- handling inquiries from patients and healthcare professionals;
- measures to promote pharmaceutical products to healthcare professionals;
- the sponsorship of scientific events in which healthcare professionals participate;
- the use of the Internet and other digital communication channels to promote pharmaceutical products;
- other methods to promote pharmaceutical products.

This Code is not applicable to:

- the labeling of pharmaceutical products, the package leaflet, and other information placed on a product or its packaging;
- factual and information announcements and references, e.g. regarding changes in packaging or warnings on adverse reactions, as part of general measures to monitor safety;
- setting prices and other commercial terms of supply of pharmaceutical products, including trade catalogues and price lists, provided that they do not include any specific advertising statements about a pharmaceutical product;
- pre-registration and registration clinical studies; and
- pharmaceutical companies' relations with state and municipal bodies, state and municipal servants.

## II. General Provisions on Promotion of Pharmaceutical Products

### 2.1. BASIC PRINCIPLES OF PROMOTION

**2.1.1.** Promotion should encourage the appropriate use of a pharmaceutical product by presenting it objectively.

**2.1.2.** An advertisement for pharmaceutical products should be such as to clearly identify the product as a pharmaceutical product.

**2.1.3.** Promotion should not be disguised. It is not permitted to promote a pharmaceutical product under the semblance of post-registration clinical (interventional) studies or observational (non-interventional) clinical, epidemiological studies, or marketing studies. Such studies should be undertaken primarily for scientific and research purposes and should not be designed to encourage prescription of the pharmaceutical product by healthcare professionals. Any materials sponsored by a pharmaceutical company that contain information about pharmaceutical products and their use, whether or not promotional in nature, should have a clear indication of the sponsor.

**2.1.4.** The use of «hotlines» for advertising pharmaceutical products is not permitted.

**2.1.5.** When a pharmaceutical company's employees are making a presentation for healthcare professionals at any event or when authoring a publication they should be clearly identified as employees of the relevant pharmaceutical company.

### 2.2. REGISTRATION STATUS

**2.2.1.** Only registered pharmaceutical products may be promoted in the Russian Federation and only to the extent of their registered indications for use.

**2.2.2.** The requirement of sub-clause **2.2.1** above does not in any way restrict the disclosure of information regarding any pharmaceutical product for the purpose of transmitting it to shareholders or to other persons entitled by law to receive such information.

This requirement also does not suggest a breach of the scientific community's right to exchange of scientific information related to non-registered pharmaceutical products, provided that the provision of such information is not a way of promoting the pharmaceutical product.

### 2.3. STANDARDS OF ADVERTISING INFORMATION

**2.3.1.** Advertising for pharmaceutical products should comply with requirements of the existing Russian legislation on advertising.

**2.3.2.** Advertising for pharmaceutical products should contain, and not contradict, objective, accurate, and current information, which is based on duly approved information on the pharmaceutical product (including the labeling and the package leaflet).

**2.3.3.** Manufacturers should strive for advertising to reflect the main characteristics of the pharmaceutical product. An advertising of a pharmaceutical product should not guarantee pharmaceutical product's positive effect, effectiveness, safety or absence of side effects.

2.3.4. Advertising information should be clear, exact, balanced, honest, objective, and sufficiently complete to enable the recipient to form an objective opinion as to the therapeutic value of the pharmaceutical product concerned. Advertising information should be based on an up-to-date evaluation of all relevant factual evidence and reflect that evidence clearly. Advertising information should not mislead by distorting, exaggerating, or omitting any significant information, or in any other way.

Ambiguity must be avoided. Any advertising information, including but not limited to, comparative advertising must not be offensive. The term “new” may be used to describe a pharmaceutical product, irrespective of its dosage form, only if it has been launched into market no more than a year ago or if a new indication has been registered no more than a year ago.

Absolute or all-encompassing claims should be used with caution and only when corresponding explanations and substantiations are available.

2.3.5. Advertising information about a pharmaceutical product should be supported by appropriate scientific evidence. Such evidence should be made available upon request. Companies should deal with such requests for information in good faith and should provide objective data consistent with the received request.

2.3.6. Comparative advertising should be correct, compare identical characteristics, and should not mislead consumers through the absence of any significant information in the advertisement.

2.3.7. Advertising materials on electronic media, except for audio and video materials, are subject to the requirements set forth in clauses 3.2 and 4.2 of this Code. Audio and video material is subject to the requirements of existing Russian legislation on advertising.

## 2.4. USE OF EXPERT CONCLUSIONS, REFERENCES TO THE RESULTS OF STUDIES, AND QUOTATIONS

2.4.1. Upon use in advertising materials of expert conclusions and references to the results of studies / observations, the source of said information and the dates on which it was obtained should be indicated.

2.4.2. Upon use in advertising materials of quotations from medical or scientific literature or a person's public appearances, the source of the quotation / name of the author, and the date and place of the publication / the appearance must be indicated.

## 2.5. PROMOTION ON THE INTERNET

2.5.1. The promotion of pharmaceutical products on the Internet, including but not limited to, their promotion through the placement of banners, active hyperlinks, postings on websites, in blogs and social networks, and on message boards, forums, and other similar web sites should comply with the general requirements for advertising and the special requirements for advertising of pharmaceutical products established under the legislation of the Russian Federation. In particular, in the case of websites related to pharmaceutical products:

- the identity of the pharmaceutical company, which is the source of the corresponding information, and its intended audience, should be apparent;
- the content should be appropriate for the intended audience.

2.5.2. The advertising of prescription pharmaceutical products on the Internet is prohibited. The posting of any information about prescription pharmaceutical products on the Internet is only possible as part of online events (webinars) for healthcare professionals, and on those parts of web sites that are only accessible by healthcare professionals.

2.5.3. The fact that a pharmaceutical company uses advertising agencies and other persons to promote pharmaceutical products on the Internet does not eliminate the company's liability for violations of this Code.

2.5.4. This Code extends to the promotion of pharmaceutical products on the territory of the Russian Federation on any website, regardless of where the site is hosted, its top-level domain, and the location and internal policies of the pharmaceutical company promoting said pharmaceutical product.

2.5.5. Advertising materials distributed on the Internet, except for audio and video materials, are subject to the requirements set forth in clauses 3.2 and 4.2 of this Code. Audio and video materials are subject to the requirements on advertising of the applicable Russian legislation.

## 2.6. INFORMATION RELATED TO HUMAN HEALTH AND DISEASES

Pharmaceutical companies may disclose information about diseases and about their prevention and treatment to the general public subject to the following rules:

- said activity should not amount to a licensed medical activity;
- the information in question should be accurate, given in good faith, ethical, and complete; and it should neither replace a doctor's advice nor call for self-therapy;
- this information should indicate the pharmaceutical company that serves as its source;
- this information should not feature the names of any prescription pharmaceutical products as well as images of such products' packaging or its elements, or otherwise aim to promote a prescription pharmaceutical product;
- this information should indicate the need to consult a healthcare professional.

*Q&A 10 (Appendix 3 to the AIPM Code)*

# III. Specific Features of Interaction With Healthcare Professionals, Advertising to Them, and Other Methods of Promoting Pharmaceutical Products

## 3.1. GENERAL PRINCIPLES OF INTERACTION WITH HEALTHCARE PROFESSIONALS

3.1.1. Interaction between pharmaceutical companies and healthcare professionals should be designed to benefit patients and enhance the practice of medicine. The purpose of this interaction should be to provide healthcare professionals with new information about pharmaceutical products, supply them with scientific and educational data, and support scientific and clinical research.

3.1.2. Cooperation between pharmaceutical companies and healthcare professionals should not result in a conflict of interest for healthcare professionals, in particular, a conflict between their professional duties and personal interests. In particular, no such conflict should arise when a doctor prescribes a pharmaceutical product or a pharmaceutical professional recommends and sells a pharmaceutical product.

3.1.3. It is prohibited to offer, promise, provide, or transfer remuneration in any form to healthcare professionals for the prescription or recommendation of a particular pharmaceutical product to patients. It is prohibited to enter into agreements with healthcare professionals for the prescription or recommendation of any pharmaceutical product to patients (other than agreements for the clinical studies of pharmaceutical products).

3.1.4. Personal data of healthcare professionals may only be included into databases subject to their duly obtained consent and compliance with the other requirements of legislation governing protection of personal data.

## 3.2. PRINTED ADVERTISING MATERIALS

3.2.1. Printed advertising materials, except for those described in sub-clause 3.2.2, should contain the following minimum information:

- the name of the pharmaceutical product (normally the trade name);
- the common names of the active substances (if the product contains no more than three active substances);
- the name and address of the pharmaceutical company or the organization representing its interests in the Russian Federation;
- the date of production of the advertisement; and
- “abbreviated prescribing information” which should include approved indications for use and, if necessary, the dosage and method of administration, and a succinct statement of the contraindications, precautions, and side effects.

3.2.2. «Reminder» advertising is brief advertising containing only the trade name of a pharmaceutical product and the product’s therapeutic group.

*Q&A 1 (Appendix 3 to the AIPM Code)*

## 3.3. EVENTS

3.3.1. The purpose of all the events should be to inform healthcare professionals about pharmaceutical products and/or to provide them with scientific or educational information in the fields of healthcare or pharmaceuticals.

3.3.2. Companies should not organize or finance events for healthcare professionals outside their country of residence unless it is justified in terms of logistics or security. International scientific congresses and symposia that attract participants from many countries are therefore justified and permitted.

3.3.3. The information distributed to participants of international scientific congresses and symposia may relate to pharmaceutical products that are not registered in the country where the event takes place or are registered on different terms, provided that the following requirements are satisfied:

- the distribution of said information is permitted by the laws of the country where the event is held;
- the event should be a truly international scientific event with a significant number of healthcare professionals from other countries taking part (as speakers or attendees);
- materials related to a pharmaceutical product not registered in the country where the event takes place should be accompanied by a clear indication that the product is not registered in said country;
- materials containing information related to a pharmaceutical product’s use (indications, warnings, etc.), which has been approved in another country/countries where the product is registered, should be accompanied by a statement that conditions of registration may differ in various countries.

*Q&A 9, 11 (Appendix 3 to the AIPM Code)*

3.3.4. An event should be held in a place and under conditions that will facilitate achievement of its scientific and educational objectives. The use of facilities that the public would associate with entertainment, luxury, or exclusivity, regardless of their class, is prohibited. It is recommended to organize events at business centers, educational institutions, hotels, and other venues intended for business and educational events. A company may hold an event in a public place only if it is held in an isolated room or the place is closed to the public for the duration of the event.

The use of any entertainment or sporting events to attract healthcare professionals to promotional or scientific events is prohibited.

*Q&A 13 (Appendix 3 to the AIPM Code)*

3.3.5. It is permitted to provide stationery (pens, writing pads, and pencils) of insignificant value for the purpose of taking notes or keeping records.

*Q&A 4 (Appendix 3 to the AIPM Code)*

3.3.6. It is permitted to serve soft drinks, tea/coffee, snacks, and/or hot dishes in a buffet style at an event, provided that the refreshments are justified by the duration of the event, are unequivocally secondary to the purpose of the event, and are only available:

- to event participants rather than to persons accompanying them;
- within reasonable limits.

#### *Q&A 3 (Appendix 3 to the AIPM Code)*

3.3.7. Pharmaceutical companies should not provide or pay for any entertainment, either within or outside the scope of an event.

### 3.4. ENGAGING HEALTHCARE PROFESSIONALS TO PROVIDE SERVICES

3.4.1. Pharmaceutical companies may engage healthcare professionals, other than pharmaceutical professionals and heads of pharmacy organizations, to provide scientific and pedagogic services and services in the course of performance of clinical studies of pharmaceutical products. Pharmaceutical companies may pay fees to these healthcare professionals for the provision of these services.

3.4.2. The following requirements should be observed while engaging healthcare professionals to provide services:

- there should be a written contract describing the substance of the services to be rendered and the terms of payment for these services;
- compensation for the services should be reasonable and consistent with their fair market value;
- there should be a reasonable need for the services;
- there should be a direct connection between the criteria used to select the healthcare professionals to render services and the purpose to be achieved when these services are rendered;
- the number of the healthcare professionals engaged to render services should correspond to the number actually needed to achieve the relevant purpose;
- the existence of the services contract should not directly or indirectly oblige the healthcare professional to recommend or prescribe any pharmaceutical product.

3.4.3. Expenses incurred by a healthcare professional directly relating to the services rendered may be paid for or reimbursed, including the costs for travel to the place where the services are rendered, lodging, and meals.

3.4.4. The following requirements must be observed when paying for or reimbursing the expenses:

- the use of hotels or other facilities associated by the public with luxury or exclusivity, regardless of their class, is prohibited;
- meals should be reasonable;
- economy class plane tickets should be acquired for trips of healthcare professionals that do not exceed four daylight hours;
- reimbursement of any of the costs incurred by accompanying persons is not permitted.

Any exceptions must be justified by an objective need and approved by the company's management.

### 3.5. GIFTS

It is prohibited to give or to offer any gift to healthcare professionals.

### 3.6. BASIC RULES AND STANDARDS OF ACTIVITIES OF MEDICAL REPRESENTATIVES

3.6.1. The purpose of medical representatives' activities should be to improve the professional level of healthcare professionals and to perform the duty to monitor the safety of pharmaceutical products imposed on the pharmaceutical companies.

3.6.2. In order to achieve the purposes specified in sub-clause 3.6.1 of this Code, medical representatives may take part in meetings and other events organized for healthcare professionals at medical organizations in accordance with the procedure established by the relevant organization. Individual visits by medical representatives to healthcare professionals are possible if allowed by this procedure.

3.6.3. In the course of these events medical representatives may provide healthcare professionals with printed promotional materials and informational materials such as partial reprints of individual chapters and sections of specialized publications, scientific treatises, and reference books; research articles; reports, and other printed materials provided that these printed materials improve the professional level of the healthcare professionals. Such information may be provided on CD-ROMs and memory cards, provided that these electronic devices are not intended for personal use. Moreover, any materials, including promotional materials, should improve the professional level of healthcare professionals and should not pursue solely advertising purposes.

3.6.4. Medical representatives of pharmaceutical companies should have sufficient training and knowledge to provide healthcare professionals with full, objective, accurate, and current information about pharmaceutical products. This information should improve the professional level of healthcare professionals. A pharmaceutical company is responsible for the substance and form of any information provided to healthcare professionals by its medical representatives.

3.6.5. A medical representative should provide a healthcare professional upon request with the leaflet for each pharmaceutical product that the representative reports on, with information on the conditions under which the product is dispensed by a pharmacy (prescription product, over-the-counter product or a product provided to groups of citizens entitled to social benefits, etc.), and information on the pharmaceutical product's availability at pharmacies.

3.6.6. Medical representatives must inform the head of the corresponding division of a company engaging him or her regarding the practical application of their company's pharmaceutical products, including information received from healthcare professionals on adverse reactions, etc.

### 3.7. SAMPLES AND EDUCATIONAL ITEMS

3.7.1. Pharmaceutical companies may not provide samples of pharmaceutical products and/or Educational Items, either for subsequent transfer to patients or for personal use, directly to healthcare professionals.

3.7.2. It is possible to demonstrate Educational Items, without their further transfer, in venues of conduct of medical or pharmaceutical exhibitions, seminars, conferences and other events intended for healthcare professionals.

## 3.8. EXPERT COUNCILS

**3.8.1.** The purpose of an expert council is to discuss and receive consultations from external experts on a predetermined scientific question which cannot be resolved by relying on the relevant company's internal expertise and experience alone and which cannot be resolved by any other method.

**3.8.2.** No expert council may be used as a vehicle for the distribution of any information or for the promotion of pharmaceutical products.

**3.8.3.** Pharmaceutical companies may pay healthcare professionals (except for pharmaceutical professionals and heads of pharmacy organizations) serving as experts for their work on the expert council (including reimbursing expenses incurred in connection with participating in the expert council), provided that the experts' work on the expert council is scientific in nature. The requirements of sub-clause 3.4.4 above should be observed when reimbursing expenses.

**3.8.4.** In all cases, the main operating principle of any expert council is the independence and impartiality of the experts.

**3.8.5.** An expert council may only be established where there is a reasonable scientific need for doing so and should not be intended to finance the events of professional communities.

**3.8.6.** The frequency of an expert council's meetings should be reasonable.

**3.8.7.** The choice of experts to serve on an expert council should be based exclusively on their professional competence and qualifications and should not be connected in any way to past, current, or potential future prescriptions or recommendations of the respective company's pharmaceutical products. The employees of commercial departments should not influence the selection of experts or the expert council's work.

**3.8.8.** The number of engaged healthcare professionals should correspond to the number actually needed to achieve the specified objective.

**3.8.9.** The total number of a company's employees attending an expert council meeting should not exceed one-third of the independent, outside experts participating in the meeting. Specifically, none of the employees may use their participation in the expert council's work for the promotion of the company's pharmaceutical products in any manner whatsoever.

## 3.9. RESPONSES TO REQUESTS FOR MEDICAL INFORMATION

**3.9.1.** A company should be attentive to each request from a healthcare professional. Each request should be registered and a response should be provided to it, regardless of how the request was received (by e-mail, regular mail, fax, or telephone).

**3.9.2.** The information provided to healthcare professionals in response to a request should be in full compliance with applicable local legislation, the package leaflet approved for a particular pharmaceutical product, and this Code.

**3.9.3.** No response to a request from a healthcare professional should serve the purpose of promoting pharmaceutical products. It should only be limited to a reply to the corresponding question.

**3.9.4.** Any information given about the pharmaceutical products of any other companies should be objective.

**3.9.5.** All responses should be provided in a polite and understandable form corresponding to the knowledge and level of training of the person making the request.

**3.9.6.** No employees of a pharmaceutical company may initiate any discussion of any non-registered pharmaceutical products and/or of any non-registered indications for their use with any healthcare professionals or other third persons.

**3.9.7.** Information about any non-registered pharmaceutical products and/or about any non-registered indications for use may be disclosed only to healthcare professionals exclusively upon a request submitted to the pharmaceutical company.

**3.9.8.** The medical information service or the personnel of any other duly authorized medical / regulatory department should provide responses to all requests from healthcare professionals so as to ensure that the information is of proper quality and is objective. All telephone calls on weekends and public holidays, as well as during off-hours, are to be accepted and registered by the personnel of the call center, voicemail machine, or otherwise, with information about the queries received to be subsequently passed on to the medical / regulatory department.

**3.9.9.** The employees of sales and marketing departments may only answer questions received in the course of interaction with healthcare professionals within the limits of the package leaflet approved for a pharmaceutical product. The employees of sales and marketing departments should forward any questions received that go beyond the limits of the duly approved information to the medical / regulatory department for a response.

**3.9.10.** The response to a healthcare professional should include exhaustive and scientifically proven information on the question. All statements and facts given in written replies should be supported by appropriate references identifying the name of the author, giving the full heading of the respective article or treatise, and indicating the place of publication (customary abbreviations are permitted), the year of publication, and the volume, issue, and page numbers.

**3.9.11.** The personal data of healthcare professionals and other persons may be included into the databases of pharmaceutical companies only when the relevant person has given his or her consent in the form established by law and in compliance with the other applicable requirements of the legislation on personal data protection.

# IV. Specific Features of Advertising and Other Methods of Promotion to the General Public

## 4.1. GENERAL REQUIREMENTS

4.1.1. It is not permitted to advertise any prescription pharmaceutical products to the general public.

4.1.2. No advertising to the general public may mention the fact that the advertised pharmaceutical product is included into any of the lists of medicinal preparations to be provided to certain categories of citizens and expenses borne in its purchase are reimbursed or subsidized by the state.

4.1.3. In the advertising of pharmaceutical products to the general public it is desirable to avoid use of any special medical terms which can be misunderstood or which can mislead consumers.

## 4.2. PRINTED ADVERTISING MATERIALS

4.2.1. Printed advertising materials, except for those described in sub-clause 4.2.2, should contain the following minimum information:

- the name of a pharmaceutical product (normally, the trade name) and its common name if the product contains only one active ingredient;
- the information necessary for the proper use of the product (including the indications, as well as the main contraindications (if any) and precautionary measures necessary for safe use);
- the name and address of the pharmaceutical company or the organization representing its interests in the Russian Federation; and
- a warning about the existence of contraindications for use and application, and the need to study the package leaflet or to obtain specialist consultations.

4.2.2. "Reminder" advertising is defined as a short advertisement which may contain the trade name of the pharmaceutical product, slogan (a neat, catchy phrase) and a warning about the existence of contraindications for its use and application, and the need to study the package leaflet or to obtain specialist consultations.

*Q&A 1 (Appendix 3 to the AIPM Code)*

## 4.3. RESTRICTIONS ON THE CONTENTS OF ADVERTISING TO THE GENERAL PUBLIC

The advertising of pharmaceutical products to the general public should not:

- create an impression that one does not need to consult a doctor;
- guarantee the positive effect, effectiveness, or safety of a pharmaceutical product or the absence of side effects;
- contain references to specific cases of recovery from disease or improvement of health as a result of the pharmaceutical product being used;
- contain expressions of gratitude from individuals in connection with the use of the pharmaceutical product;
- be addressed to minors;

- create an impression of the advantages of the pharmaceutical product by reference to the fact that the trials required for its state registration have been conducted;
- facilitate the impression that a healthy person needs to use the pharmaceutical product, except when advertising prophylactic pharmaceutical products;
- contain statements that the safety and/or effectiveness of the pharmaceutical product are guaranteed by its natural origin;
- represent the pharmaceutical product as being a dietary supplement or other product that is not a pharmaceutical product;
- contain descriptions or images of a pattern of a disease that can provoke erroneous self-diagnosis;
- feature images of medical or pharmaceutical professionals;
- contain recommendations from scientists, medical professionals, or other persons who fall into neither of those categories, but who in connection with their fame are capable of encouraging the pharmaceutical product's use; or
- contain any inappropriate, alarming, or misleading terms or graphic depictions of the changes caused in the human body by a disease or injury or by a pharmaceutical product's effect on the human organism or on any part of the human body.

## 4.4. OTHER METHODS OF PROMOTION OF PHARMACEUTICAL PRODUCTS TO THE GENERAL PUBLIC

4.4.1. It is not permitted to promote any pharmaceutical products by means of television shopping programs.

4.4.2. It is not permitted to use pharmaceutical products as prizes or incentives.

4.4.3. It is not permitted to directly distribute free-of-charge samples of pharmaceutical products for promotional purposes to the general public, including, but not limited to, tastings and tests of pharmaceutical products.

## 4.5. RESPONSES TO REQUESTS FOR MEDICAL INFORMATION FROM PATIENTS

4.5.1. Whenever contacted by a patient with a request for information, a pharmaceutical company should provide a response to this request. This interaction, however, should not be used to advertise or promote any pharmaceutical product. This includes, for example, cases when after the relevant interaction an exchange of correspondence is published in the mass media.

4.5.2. The response to a request from a patient should not include any information intended to promote pharmaceutical products or be a medical consultation with an attempted diagnosis, or offer proposals regarding possible treatment plans.

4.5.3. If a patient asks about his or her diagnosis and requests special treatment recommendations, any representative of the company (including, but not limited to, the employees of the medical department) should recommend that the patient should see their attending doctor or apply to an emergency medical service.

4.5.4. The rules stipulated in clause 3.9 of this Code also apply to procedures for handling requests for medical information from patients, except for its sub-clauses 3.9.7-3.9.9.

## V. Pharmaceutical Products Studies

### 5.1. POST-REGISTRATION STUDIES

5.1.1. Post-registration studies, including post-registration clinical (interventional) studies, post-registration observation (non-interventional) studies, and epidemiological studies, should comply with the requirements of applicable Russian legislation and of this clause.

5.1.2. A post-registration study should have a rationale and a scientific purpose(s), which are to be reflected in the protocol of the study.

5.1.3. The medical department or the corresponding medical functional unit / employees of a pharmaceutical company should organize and supervise, and are responsible for, any post-registration studies.

5.1.4. The choice of investigators should be based solely on their professional qualifications and clinical experience and should never be linked in any way to the past, current, or possible future prescription or recommendation of the company's pharmaceutical products.

5.1.5. The data obtained from post-registration studies should be statistically processed and analyzed.

5.1.6. Post-registration studies should be conducted in compliance with the laws, rules, and requirements applicable to personal data confidentiality (including, but not limited to, the collection and use of personal data).

5.1.7. The protocol of a post-registration study is subject to approval by the medical department or by the responsible medical functional units / employees. The medical department (or the corresponding medical functional units / employees) should coordinate and monitor the progress of the post-registration studies.

5.1.8. The documentation related to the post-registration studies (including the protocol, the individual registration card, patient information sheet, etc.) is at all times subject to obligatory ethical expert examination.

5.1.9. The employees of a company's other departments may participate in the handling of only administrative tasks when acceptable (such as the transfer of documents related to post-registration studies from the medical department to and from the research center / investigators). That participation should proceed under the control of the medical department which should ensure that the employees from the pharmaceutical company's other departments are properly trained.

5.1.10. The participation of a healthcare professional in any post-registration study should not serve as an incentive for the recommendation / prescription, purchase, sale, or use of any specific pharmaceutical product.

5.1.11. The compensation provided to medical organizations during post-registration studies should be reasonable and should reflect the fair market value of the work performed.

5.1.12. It is prohibited to perform any post-registration study under the guise of a marketing study. If no clear distinction between marketing studies and post-registration studies as defined in sub-clause 5.1.1 above is present, the purposes of the marketing studies are subject to verification by the pharmaceutical company's medical professionals.

### 5.2. MARKETING STUDIES

5.2.1. Marketing studies conducted directly by pharmaceutical companies or by pharmaceutical companies with the involvement of marketing agencies are only possible provided that applicable legislation is complied with.

Neither the pharmaceutical companies nor the agencies engaged in such cases may pay any compensation to any healthcare professionals for their participation in the marketing study. Exceptions may include cases where marketing studies require specialist scientific knowledge and substantial work inputs on the part of a healthcare professional provided that: (1) marketing studies are conducted with the involvement of independent agencies; (2) the healthcare professional is not informed on, and it is unclear from the materials of the study, which pharmaceutical company has ordered / sponsored the study; and (3) the pharmaceutical company is not involved in the selection of the persons to take part in the study and is unaware of which healthcare professionals will be involved in the marketing study.

5.2.2. Marketing studies should not be used for the purposes of:

- promoting or selling of any pharmaceutical products or managing the opinions or conduct of the participants of the study. For that reason, it is necessary to avoid references to the trade name of the relevant pharmaceutical product unless the purpose of the study requires otherwise;
- gathering the personal data of patients;
- conducting the follow-up studies of the efficacy or safety of any pharmaceutical product;
- pre-registration promotion for any pharmaceutical product or the indications for its use that are subject to registration;
- obtaining confidential information about competitors;
- discrediting the pharmaceutical products of any competitor or otherwise causing detriment to any competitors.

# VI. Specific Features of Interaction with Legal Entities

## 6.1. DONATIONS AND GRANTS

6.1.1. Pharmaceutical companies may make donations to non-commercial organizations for publically beneficial purposes. Such donations may be in the form of educational grants made available to support medical education and ultimately intended to raise the quality of medical care provided to patients.

6.1.2. No in-kind donations to non-commercial organizations are permitted if intended, directly or indirectly, for specific healthcare professionals or made in their interests. This is why it is not permitted to donate any items which are generally seen as being intended for individual use rather than for use by the relevant non-commercial organization.

6.1.3. The provision of a donation may under no condition be made dependent, directly or indirectly, on the prescription or purchase of the company's pharmaceutical products.

6.1.4. It is prohibited to make donations in the form of cash.

6.1.5. Pharmaceutical products may be provided to non-commercial medical organizations as donations unless such donations pursue any commercial purposes. The donating company must inform the donation recipient of the remaining shelf lives of the pharmaceutical products.

6.1.6. Donations may only be made on the basis of an appropriate written request from a noncommercial organization and a relevant donation agreement.

## 6.2. SAMPLES FOR NON-COMMERCIAL MEDICAL ORGANIZATIONS

6.2.1. Pharmaceutical companies may provide samples of pharmaceutical products only to non commercial medical organizations so that they can familiarize themselves with the use of, and gain experience in working with, such pharmaceutical products in accordance with the approved package leaflet.

6.2.2. A company must inform the recipient of such samples of the remaining shelf lives of the pharmaceutical products which is planned to provide.

6.2.3. Any samples may only be provided within the first two years of the pharmaceutical product's launch on the market of the Russian Federation. It is permitted to provide sample of pharmaceutical product only in the smallest package in compliance with the dosage regime and indications as specified in package leaflet, available at the market. The number of samples made available to a medical organization should be reasonable but should not exceed four (4) packs (samples) per medical professional of that medical organization in the corresponding medical specialization per annum.

### Q&A 2 (Appendix 3 to the AIPM Code)

6.2.4. Pharmaceutical companies should keep record and control the transfer of samples of a pharmaceutical product to a medical organization. The transfer of samples to a medical organization should be documented in writing. The documents must specify that the sample products are not intended for sale.

6.2.5. Samples may under no circumstances be provided as an incentive to the recommendation, prescription, purchase, supply, sale, or administration of the respective pharmaceutical product.

## 6.3. EDUCATIONAL ITEMS

6.3.1. Pharmaceutical companies may provide Educational Items only to non-commercial medical organizations meeting the following requirements:

- The frequency and the total number of transferred Educational Items should be justified and reasonable;
- Transfer of Educational Items should not serve as an incentive for healthcare professionals to recommend, prescribe, purchase, dispense or administer pharmaceutical products;
- The transfer of Educational Items should be documented in writing;
- It is prohibited to provide healthcare professionals with medical supplies / items that are necessary for their daily medical practice, such as stethoscopes, gloves, blood pressure monitors, needles, etc.

### 6.3.2. Educational Items:

- should not be entertaining and should not have any purposes other than educational and/or demonstration purposes;
- should not contain an active ingredient and should not have possibility to be used for therapeutic use;
- should not contain trade name and other elements of a brand of the pharmaceutical product, but may contain the company's name;
- should indicate that they are intended only for educational and/or demonstration purposes.

6.3.3. Educational Items aimed at improving the quality of administration (use) of pharmaceutical products should also indicate that they:

- are not intended for therapeutic use;
- do not contain an active ingredient of the pharmaceutical product.

## 6.4. INTERACTIONS WITH PATIENT ORGANIZATIONS

6.4.1. The pharmaceutical companies share interests of patient organizations and respect their independence, including in relation to their procedures and activities. All interactions between patient organizations and companies should be based on mutual respect, with the views and decisions of each partner having equal value.

6.4.2. The objectives and scope of any interactions with patient organizations must be transparent. Pharmaceutical companies may interact with patient organizations in the following fields:

- study of opinions of patients and persons taking care of them with respect to the impact of diseases on patients' quality of life, career, family as well as to how medical care is provided and how medication or any other treatment may change the quality of their life and satisfy their needs. This can help to optimize pharmaceutical products' clinical studies' program and expedite efforts to develop pharmaceutical products that address patient needs in the best possible way;

- informational support for patient associations through responses to queries in accordance with the rules established in clause 4.5 of this Code for responses to patient queries;
- support for initiatives of patient organizations on creation and maintaining of patient registers subject to strict compliance with legislation on personal data protection and medical secrecy;
- the launch of campaigns to keep the general public informed about a disease;
- cooperation in providing medical organizations with a non-registered pharmaceutical product as required to provide medical care to specific patients in accordance with their vital needs;
- the provision of charitable aid; and
- in other cases, provided they are consistent with applicable legislation.

6.4.3. Pharmaceutical companies must not ask for the promotion of, and patient organizations must not promote specific pharmaceutical products.

6.4.4. A pharmaceutical company may not be the founder or participant of a patient organization.

6.4.5. A pharmaceutical company should explicitly disclose the fact, nature, value of its support of patient organization on companies website. A pharmaceutical company may be the sole source of financing for any charitable and/or social project of the patient organization upon receiving an appropriate written request from the patient organization for assistance with its program to organize prophylactic measures, protect public health, promote a healthy way of life, and help socially vulnerable segments of the population in the Russian Federation. Financing should not be aimed, directly or indirectly, at encouraging the patient organization to make decisions in favor of the pharmaceutical company / its products as it carries out its charter activities. In any case, the pharmaceutical company should not restrict the rights of other pharmaceutical companies to finance similar projects of the patient organization should they so wish.

In case of financial support of development or printing of patient organization's materials pharmaceutical company must not influence the content of such materials in a manner favourable to its own commercial interests. This does not preclude pharmaceutical companies from correcting factual inaccuracies.

#### *Q&A 12 (Appendix 3 to the AIPM Code)*

6.4.6. Any relations between pharmaceutical companies and patient organizations should be properly documented.

6.4.7. Pharmaceutical companies may provide financial support for events arranged by patient organizations provided that the primary purpose of such events is educational or scientific in nature or is otherwise of publicly beneficial purposes facilitating the performance of the mission pursued by the respective organizations. Where companies provide financing for an event arranged by a patient organization, they should ensure that the place and conditions of holding the event meet the requirements for limits on hospitality under sub-clause 3.3.4 of this Code.

## 6.5. SPECIFIC FEATURES OF INTERACTION WITH PHARMACIES/PHARMACY NETWORKS

6.5.1. Pharmaceutical companies' representatives may visit pharmacy organizations to inform their pharmaceutical professionals and heads of pharmacy organizations on pharmaceutical products produced or sold by such companies.

6.5.2. A pharmaceutical company may enter into contracts for provision of services with a pharmacy organization, including such services as:

- the arrangement of a display ordered by the pharmaceutical company for over-the-counter pharmaceutical products;
- the placement of advertising for over-the-counter pharmaceutical products (provided it meets the requirements of the applicable legislation of the Russian Federation and of this Code), as well as information materials devoted to the prevention and treatment of various diseases, at the pharmacy organization and on its website;
- joint promotion for over-the-counter pharmaceutical products, including, but not limited to, customer surveys; and
- provision of incentive gifts, which may feature the company's logo, or a logo of its over-the-counter pharmaceutical product, to customers buying certain product.

6.5.3. It is permitted to carry out programs to lower the cost of pharmaceutical products for end consumers. Should any such program be undertaken in respect of any prescription pharmaceutical products, pharmaceutical companies should make certain that the total number of such products' dosages provided must not under any circumstances exceed their amount prescribed to a particular patient by a healthcare professional.

Pharmaceutical companies may not organize programs to award in-kind prizes to pharmaceutical professionals, to heads of pharmacy organizations, and to pharmacy organizations for the attainment of certain sales.

#### *Q&A 8 (Appendix 3 to the AIPM Code)*

# VII. Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations\*

## 7.1. DISCLOSURE OBLIGATION

**7.1.1.** Each pharmaceutical company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organization being a recipient, as described in more detail in clause 7.3.

**7.1.2.** Without limitation, transfers of value that (i) are solely related to over-the-counter pharmaceutical products; (ii) are not listed in clause 7.3 of this Code, such as items of medical utility, meals and drinks, samples to the extent they are not restricted by applicable legislation and this Code; or (iii) are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and a healthcare professional or a healthcare organization, as relevant, do not fall within the scope of the disclosure obligation described in sub-clause 7.1.1.

**7.1.3.** For the avoidance of doubt, in the setting of a group of companies, the primary responsibility to make a disclosure is borne by a legal entity, which enters into a contract with the healthcare professional or healthcare organization under which the transfer of value is performed.

## 7.2. FORM OF DISCLOSURE

**7.2.1.** Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. Pharmaceutical companies, which became subject to the provisions of this Code in the course of the reporting period, should make disclosures after the end of the relevant reporting period as set forth in sub-clause 7.2.2 below and should cover only the relevant part of the calendar year.

**7.2.2.** Disclosures shall be made by each pharmaceutical company within 6 months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with sub-clause 7.2.4, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the recipient's consent relating to a specific disclosure has been revoked.

**7.2.3.** For consistency purposes, disclosures pursuant to this Code will be made using a structure set forth in Appendix 2, reflecting the requirements of this Code.

**7.2.4.** Disclosures are made in accordance with sub-clause 7.2.5 of this Code on the relevant pharmaceutical company's website, provided that it is unrestricted and publicly available.

**7.2.5.** Disclosures shall be made pursuant to the code governing disclosure of the transfers of value to the recipients enacted in the country where the recipient has its physical address, e.g., as it is set forth in the contract, covering transfer of value. If a pharmaceutical company is not resident or does not have a subsidiary, an affiliate or any other presence in a country, defined in accordance with the above rule, this pharmaceutical company shall disclose such transfer of value in a manner consistent with the code governing disclosure of the transfers of value to the recipients enacted in the country of registration of a legal entity, which enters into a contract with the healthcare professional or healthcare organization under which the transfer of value is performed, or, if no such code is enacted

in that country, any other similar code applicable to a pharmaceutical company should govern.

**7.2.6.** Disclosures shall be made in Russian language. A pharmaceutical company can make disclosures in English in addition to the mandatory disclosures in Russian language.

**7.2.7.** Each pharmaceutical company shall document all transfers of value required to be disclosed pursuant to sub-clause 7.1.1 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable Russian laws or regulations.

## 7.3 INDIVIDUAL AND AGGREGATE DISCLOSURE

**7.3.1.** Except as expressly provided by this Code, transfers of value shall be disclosed on an individual basis, provided that applicable personal data protection rules are complied with. Each pharmaceutical company shall disclose, on an individual basis for each clearly identifiable recipient, the amounts attributable to transfers of value to such recipient in each reporting period which can be reasonably allocated to one of the categories set out below. Such transfers of value may be aggregated on a category-by-category basis, provided that itemized disclosure shall be made available upon request to (i) the relevant recipient, and/or (ii) the relevant authorities.

*Q&A 7 (Appendix 3 to the AIPM Code).*

**7.3.2.** Categories for transfers of value to a healthcare organization include:

**Donations and grants.** Donations and grants to healthcare organizations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.

**Contribution to costs related to events.** Contribution to costs related to events, through healthcare organizations or third parties such as:

- Registration fees;
- Sponsorship agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event; and
- Travel and accommodation.

**Fees for service and consultancy.** Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare organizations under which such healthcare organizations provide any type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

*Q&A 5, 6 (Appendix 3 to the AIPM Code).*

**7.3.3.** Categories for transfers of value to a healthcare professional include:

Contribution to costs related to events. Contribution to costs related to events when it is not prohibited by the applicable legislation, such as:

- Registration fees;
- Travel and accommodation.

Fees for service and consultancy. Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals under which such healthcare professionals provide any lawful type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

**7.3.4.** For transfers of value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in sub-clauses **7.3.2** and **7.3.3**, cannot be disclosed on an individual basis for legal reasons, a pharmaceutical company shall disclose the amounts attributable to such transfers of value in each reporting period on an aggregate basis. Such aggregate disclosure shall identify, for each category, (i) the number of recipients covered by such disclosure, on an absolute basis and as a percentage of all recipients, and (ii) the aggregate amount attributable to transfers of value to such recipients.

**7.3.5.** Where a transfer of value required to be disclosed pursuant to sub-clauses **7.3.1** - **7.3.4** is made to an individual healthcare professional indirectly via a healthcare organization, such transfer of value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual healthcare professional named basis pursuant to sub-clause **7.3.3**.

**7.3.6.** Research and development transfers of value in each reporting period shall be disclosed by each pharmaceutical company on an aggregate basis. Costs related to events that are clearly related to activities covered in this section can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

**7.3.7.** Each pharmaceutical company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying transfers of value for each category described in sub-clauses **7.3.2** and **7.3.3**. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of transfers of value for purposes of this Code, as applicable.

## VIII. Pharmaceutical Companies' Procedures and Liability

### 8.1. AUTHORIZED PERSON OF A COMPANY

Companies should establish and maintain appropriate operating procedures to ensure that their marketing operations are in accord with applicable Russian legislation and with this Code. In particular, companies should continuously monitor and analyze their own activities for promotion of pharmaceutical products and materials distributed in connection therewith.

All advertising materials are subject to prior approval by an authorized employee of the company, who must have a suitable level of education and qualifications (scientific or medical).

### 8.2. PROMOTIONAL PROGRAMS AND DOCUMENTATION

Activities to promote pharmaceutical products, promote sales, etc., should be conducted

in accordance with the corresponding programs approved by the company's authorized person, with relevant documentation kept in the process to reflect the progress of such promotions.

### 8.3. STORAGE OF DOCUMENTATION

The programs of events (activities), documentation on their conduct, and samples of advertising materials should be kept by the company's authorized department or authorized person for a minimum of one year after the completion of each event, activity, or advertising campaign, unless a longer period is specified by applicable legislation.

Programs and documentation should be provided to supervisory authorities in accordance with existing advertising legislation and to members of a specially established AIPM panel in case of dispute hearings.

### 8.4. EMPLOYEES PROFESSIONAL DEVELOPMENT

In the interests of maintaining high standards in carrying out marketing activity, companies should pursue the principle of continuous professional development of employees in this sphere.

## IX. Maintenance and Development of the Code

### 9.1. NEED TO CONSTANTLY MAINTAIN AND DEVELOP THE CODE

The expansion in the arsenal of methods and means of marketing practice and their modification under the conditions of Russia's developing pharmaceutical market leads to the need to constantly maintain and develop the Code so that it meets the demands of the times and does not have gaps in the regulation of advertising and other methods of promotion of pharmaceutical products.

### 9.2. ANALYSIS OF PHARMACEUTICAL COMPANY PRACTICES AND OPERATION OF THE CODE

In order to maintain the currency of the Code and its Appendices, as well as for the timely identification of the need to introduce amendments and additions, analysis of current marketing practices of pharmaceutical companies in the Russian market and of their interactions with healthcare professionals and patient organizations will be conducted. The analysis will include an evaluation of the conformity of marketing practices of companies manufacturing pharmaceutical products to the standards and principles of the Code, how completely the methods and means of advertising and promotion used are reflected in the Code, the identification of trends in regard to the most often violated principles, an evaluation of the influence of the standards of the Code on marketing practices, etc.

The analysis of the functioning of the Code will be carried out by the AIPM Ethics Committee.

### 9.3. UPDATING THE CODE

On the basis of the analysis conducted, the AIPM Ethics Committee will present an annual report to the Board of Directors. If necessary, the Ethics Committee will develop proposals on improvement of the Code and gives them to the Executive Director of the AIPM.

# Appendix 1

## Procedure for Review of Complaints and Disputes Regarding Violations of the AIPM Code of Practice

### PROCEDURE FOR REVIEW OF COMPLAINTS AND DISPUTES REGARDING VIOLATIONS OF THE AIPM CODE OF PRACTICE

The AIPM will only review complaints regarding violations of the Code («Complaints») with regard to activities of companies within the Russian Federation and/or targeted at a Russian audience.

A complaint about a violation of the Code can be filed by both an AIPM member and any other interested person.

The complaint may be filed either against an AIPM member or any pharmaceutical manufacturer who is not a member of the AIPM but carries out its activity in the Russian market.

The procedure for filing a Complaint in respect of violations of the Code depends on the parties to the dispute.

#### 1. PROCEDURE FOR REVIEW OF COMPLAINTS AND DISPUTES BETWEEN COMPANIES THAT ARE AIPM MEMBERS

AIPM members are under the obligation to try to settle their dispute themselves before applying to the AIPM and to notify the AIPM Executive Director accordingly. Upon receiving a Complaint, an AIPM member company is to provide a response within five business days. This term starts as from the moment the Complaint is received by that company.

If the complaining company fails to receive a response within the above period or the foregoing procedure fails to result in a resolution satisfactory to both parties in dispute, the complaining company may file an application addressed to the AIPM Executive Director for a special panel (the «Special Panel») to be formed in order to review and resolve the case.

#### 2. PROCEDURE FOR THE REVIEW OF COMPLAINTS FILED WITH THE AIPM

Subject to compliance with the requirements of clause 1 of this Procedure, AIPM members and other interested parties may file a Complaint in respect of the activities of any pharmaceutical manufacturer, including, but not limited to, those that are not AIPM members, but carry out their activities in the Russian market.

A Complaint should be filed in writing and addressed to the AIPM Executive Director (the «Executive Director»).

A Complaint should contain:

- the identity of the complainant (name of the individual or legal entity, mailing address, and contact person);

- the identity of the company that is alleged to have committed a violation of the Code;
- the name(s) of the pharmaceutical product(s) in regard to the marketing of which there are suspicions of a violation of the Code;
- documents and materials evidencing the alleged violation, for example, advertising materials;
- the date of the alleged violation;
- a brief description of the essence of the alleged violation, including references to the corresponding points of the Code.

The materials relating to the complaint (files) are confidential. Only the parties to the dispute have access to the materials of the case. The only exception will be if a Special Panel is formed to review the case.

The parties to the dispute, the Executive Director and the Secretariat of the AIPM, and the members of the Special Panel should observe the confidentiality of the materials of the case.

**The disclosure of the case materials to a third person shall be considered a serious violation of AIPM procedures.**

Upon receiving the complaint, the Executive Director ascertains the presence of the necessary documents and materials, as well as indications of violation of the Code. Having verified the compliance with the mandatory requirements, and within 2 business days of having received the Complaint, the Executive Director confirms to the complainant that the Complaint has been accepted for review, and informs the company with regard to which the Complaint was accepted and provides it with the Complaint as well as the documents and materials received.

At the written request of the complainant, its identity can be withheld from the company with regard to which the Complaint is made. In such a case, it shall be the responsibility of the complainant (and not the responsibility of AIPM or the Executive Director) to ensure that the documents and materials submitted in support of the Complaint do not identify the complainant.

Any period of time mentioned in this Procedure starts on the day following the calendar date or the occurrence date that defines the beginning of the period. If the period is set for performing an act, the latter may be performed by twelve p.m. of the last day of the period. However, if the act is to be performed at an organization, the period expires when, under the established rules, the relevant operations at that organization are stopped. Written complaints and notices delivered to a communication organization by twelve p.m. of the last day of the period are deemed timely.

The company with regard to which the Complaint was filed should provide a response within five business days. This term starts as from the moment the Complaint is received by that company. Upon having a valid excuse, the company in the same period may request that the period established for its response be extended (but by no more than 15 business days) by filing an appropriate request which should provide the reason for the requested extension. The response should be in writing and addressed to the Executive Director.

The response should contain:

- a recognition of the fact of a violation and information about steps taken to correct the situation;
- or
- a refusal to recognize a violation, as well as clearly formulated and, in appropriate cases, grounds for such a refusal with supporting documentation.

Upon receiving a response, the Executive Director must within 2 business days forward it to the complainant. The complainant must review this response and respond to the Executive Director within 5 business days as to whether or not the response is satisfactory. Thereafter, the Executive Director decides whether the dispute has been resolved, or whether the AIPM must act to determine whether in fact a violation has occurred.

If the response is satisfactory to the complainant, and the resolution does not harm the interests of any other AIPM member or further violate the Code, then this fact is recorded by the Executive Director, and the case is closed. The case may also be closed if the Executive Director deems the response to be satisfactory and the complainant has not reacted to the response within the required 5 days.

Thereafter, it is the obligation of both sides in the Complaint to ensure that any agreements and/or undertakings embodied in their agreed resolution of the Complaint are adhered to. If such agreements and/or undertakings are not adhered to, either party may make a new claim to the Executive Director, which would follow the same process as described above.

If the above-mentioned procedure has not resulted in a decision satisfying the disputing parties, the Executive Director shall form a Special Panel for reviewing and taking a decision on the case. A Special Panel is also formed when the company with regard to which a complaint was received did not respond to it within the established term.

A Special Panel is formed to review a concrete case and the 5 members of this Special Panel are chosen from the 20 members of the Standing Dispute Resolution Panel (the «Standing Panel»).

## STANDING PANEL

20 members of the Standing Panel shall be chosen by a General Meeting of the AIPM from (i) the senior employees of AIPM members who preferably work in the medical, legal, ethical and regulatory departments of such member companies and (ii) other stakeholders. General Managers (Heads of Representation), sales, and marketing managers are not eligible to be members of the Standing Panel. The Executive Director is an ex officio member of this Standing Panel.

Members of the Standing Panel will be chosen for two year 'staggered' terms, such that each year ten members of this Standing Panel will be chosen annually at a General Meeting of the AIPM.

If a Standing Panel member ceases to be employed by an AIPM member company, or if that company ceases to be a member of the AIPM, such Standing Panel member shall immediately be ineligible to remain on the Standing Panel. A replacement will be selected at the next General Meeting of the AIPM to fulfill the remainder of the term of the departed Standing Panel member.

## SPECIAL PANEL

When it is understood that a Special Panel should be formed in order to resolve a dispute, this Special Panel is formed by the Executive Director within ten business days (for instance, after the end of the period for a reply, or after receipt by the claimant of the respondent's negative reply). In order to do so, and after consultation with the disputing parties, the Executive Director determines if any members of the Standing Panel have a conflict of interest with any of the disputing parties. If any are found to have such conflicts of interest, they are deemed ineligible to participate in the Special Panel for that specific case. Examples of a conflict of interest would include members who have products in competition with the products of the parties involved in the dispute.

The parties are to agree upon the candidates to serve on the Special Panel within three business days of receiving a notice of the nominations. Should there be a conflict of interest between any member of the Special Panel and either of the parties, either party to the dispute may challenge the relevant candidates, but on no more than twice.

An independent expert may be invited to serve on the Special Panel as a legal consultant. The invited legal consultant may be rejected by either of the disputing parties. In such a case, the Executive Director shall propose another legal consultant. If the necessary legal consultant is not agreed upon within three business days the Special Panel shall carry out its activity without a legal consultant.

If either party fails to provide a response regarding the composition of the Special Panel by the expiry of three business days, the Executive Director may deem the membership of the Special Panel to have been agreed upon.

The Executive Director presides over meetings of the Special Panel. Neither the Executive Director nor the legal consultant has the right to vote during decision-making. The AIPM secretariat provides technical support for the Special Panel's work.

To preserve the utmost confidentiality and ensure the most objective results possible, the meetings of Special Panels will be closed and their deliberations will be kept strictly confidential. During these deliberations the disputing parties will not be present.

Special Panel members familiarize themselves with all materials concerning the case under examination and make a decision as to whether a violation of the Code took place. The decision is made in the form of recognition or non-recognition of a violation. Also possible is the making of recommendations regarding the elimination of negative consequences of the violation that took place. Before being pronounced, the written decision is studied by an AIPM legal consultant, if any has been accepted.

If a Special Panel member cannot attend a Special Panel meeting for a good reason, he/she can study the materials subject to all the established requirements for reviewing the case and take a decision on another day, but not later than seven business days from the time the main Special Panel meeting is held. If a member of the Special Panel misses its meetings dealing with the same case on a regular basis (on three or more occasions), that person is excluded from the Special Panel.

If a Special Panel decides that it is impossible to review the case without requesting additional materials from the Parties, the Executive Director shall send the relevant request within two business days. The Parties should provide additional materials within five business days from the receipt of

the request. Next, the Executive Director shall schedule a second meeting of the Special Panel within ten business days. The Parties are informed of the Special Panel's decision as usual.

The decision of the Special Panel will be communicated in writing to the disputing parties by the Executive Director within two business days of such decision.

## APPEAL PROCEDURE

If one of the disputing parties disagrees with the decision, it may make an appeal in writing to the Executive Director within ten business days of being advised of the decision.

The Executive Director will then convene the Special Panel that rendered the decision within ten business days of receiving this request for an appeal. The disputing parties may choose to attend this meeting of the Special Panel in order to argue their respective cases in person. During the deliberations of the Special Panel on this appeal the Executive Director and the legal consultant, if one has been agreed, will now have one vote each. If the Special Panel reached a decision on the basis of even numbers (due to the absence of the legal consultant) and the voting results in a draw, the Executive Director casts the deciding vote. The decision of this appeal Special Panel will be final.

## PENALTIES FOR VIOLATIONS OF THE CODE

If a violation of the Code is established by a Special Panel it may recommend that the AIPM impose the following sanctions:

- Oblige employees of the violating company to complete an online training session on the Code;
- Inform the parent company of the company about the violation;
- In the case of a serious violation, impose a financial fine in an amount not to exceed the current AIPM annual membership fee, which shall be used in a manner to be decided by next General Meeting of the AIPM<sup>2</sup>.
- Make the fact of the violation public on the AIPM website, including, but not limited to, the identity of the offending company, if the violation is serious or repeated. This posting shall remain on the AIPM website for three months. A violation is considered repeated if it is committed within 24 months of the initial violation involving the same pharmaceutical product, or a similar violation but with another pharmaceutical product.
- Recommend to the General Meeting the expulsion of the firm concerned from AIPM<sup>3</sup>. Expulsion from the AIPM does not release the expelled or withdrawing member company from its financial obligations, nor does it release the company from the duty to pay a fine imposed;
- A combination of the possibilities mentioned above.

A company declared as violating the Code by virtue of a decision must notify AIPM of measures taken to implement the Special Panel decision within the time period set by the Special Panel. If AIPM does not receive the relevant notice, the AIPM Executive Director shall send the company a reminder. If AIPM does not receive this notice within ten business days from the time the company receives the reminder, the AIPM Executive Director is entitled to contact the company's headquarters.

Decisions made by Special Panel with respect to each dispute are to be published on the AIPM website. Unless the publication of a name of offending company is applied as a sanction for the offence as described above, these publications should not include names of the relevant companies.

The Executive Director shall present each General Meeting of the AIPM with a report listing the number of disputes reviewed since the previous General Meeting, describing their general nature and specifying the relevant decisions made. The report shall identify the companies found to have been in material breach of the AIPM Code.

<sup>2</sup> This penalty can be imposed only on AIPM member companies.

<sup>3</sup> This penalty can be imposed only on AIPM member companies.

Full Name <i>(Sub-clause 7.1.1)</i>	HCPs: inhabited localities of Principal Practice  HCOs: inhabited localities where registered <i>(Clause 7.3)</i>	Country of Principal Practice	Principal Practice Address <i>(Clause 7.3)</i>	Unique country identifier <i>OPTIONAL (Clause 7.3)</i>	Donations and Grants to HCOs <i>(Clause 7.3.2)</i>	Contribution to costs of Events <i>(Sub-clause 7.3.2)</i>			Fee for service and consultancy <i>(Sub-clause 7.3.2 &amp; 7.3.3)</i>		TOTAL <i>OPTIONAL</i>
						Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract	

HCPs	INDIVIDUAL NAMED DISCLOSURE – one line per HCP (i.e. all transfers during a year for an individual HCP will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
	Dr A					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	Dr B					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	etc.					N/A	N/A	Yearly amount	Yearly amount	Yearly amount	Yearly amount		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	<b>Aggregate amount attributable to transfers of value to such Recipients – Sub-clause 7.3.4</b>					N/A	N/A	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs	Aggregate HCPs		Optional
<b>Number of Recipients in aggregate disclosure - Sub-clause 7.3.4</b>					N/A	N/A	number	number	number	number		Optional	
<b>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Sub-clause 7.3.4</b>					N/A	N/A	%	%	%	%		N/A	

HCOs	INDIVIDUAL NAMED DISCLOSURE – one line per HCO (i.e. all transfers during a year for an individual HCO will be summed up: itemization should be available for the individual Recipient or public authorities' consultation only, as appropriate)												
	HCO 1					Yearly amount		Optional					
	HCO 2					Yearly amount		Optional					
	etc.					Yearly amount		Optional					
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	<b>Aggregate amount attributable to transfers of value to such Recipients – Sub-clause 7.3.4</b>					Aggregate HCOs							
<b>Number of Recipients in aggregate disclosure - Sub-clause 7.3.4</b>					number	number	number	number	number	number	number		Optional
<b>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Sub-clause 7.3.4</b>					%	%	%	%	%	%	%		N/A

R & D	AGGREGATE DISCLOSURE											
	Transfers of Value re Research & Development as defined (Sub-clause 7.3.6)											Total Amount

# Appendix 3

## Questions and Answers to the AIPM Code of Practice

### 1) Question:

*What is the intended use of printed advertising materials and “reminder” advertising? And in what lies the difference between printed advertising materials and “reminder” advertising?*

**Answer:** Pursuant to the AIPM Code of Practice (hereinafter – “Code”) “reminder” advertising is the variety of printed advertising materials.

Printed advertising material for healthcare professionals, as provided by sub-clause 3.2.1, and for general public, as provided by sub-clause 4.2.1, - it is the material containing true and complete information, which, as a whole, enables healthcare professionals or for consumers (patients) (for consumers/patients – only for over-the-counter pharmaceutical products) to get an idea of properties of the pharmaceutical product to the extent of its registered indications for use. Such material should contain information consistent with the requirements of sub-clauses 3.2.1 and 4.2.1 of the Code and in accordance with the requirements of the Federal Law “On advertising”.

In the meantime, “reminder” advertising for healthcare professionals as provided by sub-clause 3.2.2, and for consumers (patients), as provided by sub-clause 4.2.2 (for consumers/patients – only for over-the-counter pharmaceutical products), - it is the material containing minimum information pursuant to the requirements of the Federal Law “On advertising” with the obligatory reference to the necessity of familiarization with the package leaflet or to obtain healthcare professional consultations. “Reminder” advertising material may contain the name of a pharmaceutical product (the trade name), therapeutic area of pharmaceutical product and/or brief information, such as slogan and/or key short message aimed exclusively at reminding of pharmaceutical product. However, this specified information should not induce expressly or implicitly to prescribe or to purchase pharmaceutical product, for example, by pointing at advantages of the product. Therefore, “reminder” advertising can be put at the particular place, where healthcare professionals or consumers (patients) have an opportunity to acquire additional information about product.

For example, in pharmacies, at the specialized exhibitions, congresses, conferences on billboards of pharmaceutical companies. For example, such type of advertising materials as “shelf talker”, “wobblers”, which are usually used in pharmacies and placed in close proximity to over-the-counter pharmaceutical products, may be defined as “reminder” advertising and characterized without limitation (inter alia) by the reason that in advertising location consumer/patient has direct access to the package leaflet or has an opportunity to obtain pharmacist/pharmaceutical professional consultations on properties characterization of over-the-counter pharmaceutical product.

### 2) Question:

*What is meant by the term of “pharmaceutical product’s launch” in clause 6.2.3 of the present Code?*

**Answer:** For the purposes of clause 6.2.3 of the present Code pharmaceutical product’s launch – first actions of giving information to the healthcare professionals and/or patients on over-the-counter

pharmaceutical product to the extent that these actions are taken by pharmaceutical company after the state registration of pharmaceutical product or of new indication for use within the territory of Russian Federation. Examples of these actions are the following: launch of pharmaceutical product/ or of new indication for use.

Besides, samples of pharmaceutical products may be provided to non-commercial medical organizations in the event that new indication for use is registered for treatment of another nosologic unit (pursuant to the ICD) or of a disease in another therapeutic area, or is aimed at treatment of particular groups of patients (for example children, patients with kidney or hepatic dysfunction and etc.). But at the same time variation of indications within the frame of the disease state and/or extent of disease may not be considered as a ground for providing samples.

Concurrently with the aforementioned, variation of pharmaceutical form may be considered as the sufficient ground for providing samples in exceptional circumstance when such variation leads to substantive change of administration route of pharmaceutical product. For example, parenteral use is added to the oral use. Therefore, healthcare professional is given an opportunity to obtain new experience in application of pharmaceutical product.

### 3) Question:

*What is meant by «reasonable limits» in sub-clause 3.3.6 of the AIPM Code of Practice?*

**Answer:** For the purposes of sub-clause 3.3.6 of the Code, the term «reasonable limits» refers to the average cost of meals at events of such type (taking into account the duration of an event and number of participants) conducted by pharmaceutical companies in a particular region or in the whole country. AIPM member companies should have specific cost limits set by their internal documents.

### 4) Question:

*Is it permitted to put company logos, trade names of pharmaceutical products and other components of a pharmaceutical company’s product brands on the stationary items which may be provided at events according to sub-clause 3.3.5 of the AIPM Code of Practice?*

**Answer:** It is permitted to provide inexpensive stationery (pens, paper pads, and pencils) at events, for the purpose of taking notes or keeping records, only as long as these stationary items do not bear pharmaceutical company logos, trade names of pharmaceutical products or other components of a pharmaceutical company’s product brands.

Comment: These restrictions will take effect on January 1, 2015.

### 5) Question:

*How to disclose sponsorship fees paid to third parties, appointed by HCOs to manage the event (technical organizers).*

**Answer:** Under sub-clause 7.3.2 of the AIPM Code of Practice categories for transfers of value to HCO among others include contribution to costs related to events through HCO or third parties, including sponsorship agreements with third parties appointed by HCO to manage an event. The definition of the Transfers of Value provided by the AIPM Code apart from direct payment to HCO includes also transfers (whether in cash or in kind) to third parties, where company member could identify HCO that benefit from the transfer of value being a beneficiary.

When HCO appoints the technical organizer of the event, such technical organizer organizes an event using transfers of value received from sponsors for and under control of the HCO. Sponsorship fee paid to the technical organizer in this case shall be disclosed as transfer of value to the HCO, which appointed the technical organizer. As Transfers of value includes benefits in kind, disclosure does not necessarily mean that HCO received money through the technical organizer; values in kind could be provided to HCO by technical organizer by means of renting the event facilities and financing other costs related to the event in HCO's interests.

The relations between technical organizer and HCO shall be properly documented, for example, by the trilateral agreement (company, HCO, technical organizer). If company concludes sponsorship agreement with technical organizer only, relations between HCO and such technical organizer (if available) shall be documented by such sponsorship agreement and confirmed by a document from HCO (e.g. letter by HCO).

#### 6) Question:

*How to disclose transfers of value to several HCOs appointed the one technical organizer to manage the event?*

**Answer:** Such transfers of value shall be disclosed based on the actual circumstances confirmed by documents. The exact distribution of the transfers of value among HCOs could be defined by the sponsorship agreement or by the official correspondence with such HCOs. The principles and methods used by company in preparing the disclosures, including specifications of allocation of transfers of value for the benefit of each HCO in accordance with AIPM Code of Practice, should be documented and can be published in the company's note summarizing such methodologies.

#### 7) Question:

*What is the meaning of "clearly identifiable Recipient" under subclause 7.3.1 of the AIPM Code of Practice with respect to HCO?*

**Answer:** Companies have to ensure that HCO receiving the transfer of value is identified in such a way that there cannot be any doubt about the identity of the HCO receiving the Transfers of value.

In practical terms, there might be cases, where company pays sponsorship fee to the legal entity (not HCO), which independently organizes the event, not acting as an intermediate for any HCO. In this situation company cannot identify any HCO as Recipient of values and, correspondingly, disclosure is not required. Where the technical organizer is appointed by HCO and acts as an intermediary in HCO interests, payments to such technical organizer falls within the definition of the indirect transfer of value to HCO through the intermediary and, correspondingly, shall be disclosed.

The clear possibility to avoid doubts on the role and status of the party, to which sponsorship fee is paid, is to define such role and its relations with HCO (if any) in the sponsorship agreement. Such roles and status shall be confirmed by HCO by way of signing the sponsorship agreement (in case of trilateral agreement) or by a separate document (e.g. letter from HCO).

#### 8) Question:

*Whether it is permitted to distribute informational materials containing information on discount programs of pharmaceutical company designed to lower the cost both of prescription and over-the-*

*counter pharmaceutical product for patients (hereinafter referred to as "Programs") in accordance with sub-clause 6.5.3 of the AIPM Code of Practice?*

**Answer:** Subject to any requirements provided by effective legislation of Russian Federation and AIPM Code of Practice pharmaceutical company or a third party hired by the pharmaceutical company should conclude a contract exclusively with the relevant pharmacy organizations, where through the informational materials about the Programs are distributed for patients.

Compensation to pharmacy organizations should not be based on/related to the number of distributed materials and its parts.

Program materials should not be designed to draw attention to prescription pharmaceutical product, formation or maintaining of interest to the product and to promote it on the market. Additionally, advertising slogans of the company manufacturing pharmaceutical product, logo of the pharmaceutical product and other components of the pharmaceutical product's brand are prohibited for use.

In the event of Program materials are distributed in respect of prescription pharmaceutical product, pharmaceutical companies should ensure that such materials can be provided exclusively in return for prescription of HCP.

It is prohibited to distribute informational materials related to Programs for patients through and with the assistance of doctors.

#### 9) Question:

*What kind of event can be considered as international scientific event in accordance with sub-clause 3.3.3 of the AIPM Code of Practice?*

**Answer:** The event is considered to be truly international scientific event provided that the "international" status is conferred by its organizer mandatorily defining it as "international" or an event with "international participation", the purpose of which consists in sharing international scientific experience and international practice of innovative methods of treatment used by specialists from different countries.

#### 10) Question:

*Whether it is required to indicate the name of pharmaceutical company in the case of the disclosure of information about diseases and about their prevention in accordance with the clause 2.6 of the AIPM Code of Practice in the event that such indication may cause the risk of violation of the Russian Federation legislation?*

**Answer:** In the event when the indication of the name of pharmaceutical company in the case of the disclosure of information about diseases and about their prevention in accordance with the clause 2.6 of the AIPM Code of Practice may cause the risk of violation of the Russian Federation legislation, in accordance with the requirements of the AIPM Code the pharmaceutical company should apply the existing legislation of the Russian Federation.

## 11) Question:

*What are the conditions for the exchange of scientific information related to the non-registered pharmaceutical products in the frame of international scientific congresses and symposia in accordance with sub-clause 3.3.3 of the AIPM Code of Practice?*

**Answer:** When exchanging of scientific information on research in the field of medicine, diagnosis, prevention, treatment of certain diseases in the framework of the scientific events it is not permitted to:

- Promise or offer access to non-registered pharmaceutical products of the company;
- Form and maintain the interest to pharmaceutical products for the purposes of their promotion;
- Use promotional materials relating to a pharmaceutical product, including slogans, chroma formats of the pharmaceutical products' brand;
- Circulate materials containing information about non-registered pharmaceutical products / non-registered indications for their use among participants of scientific events;
- Provide incorrect comparison with existing therapies in the absence of direct comparative studies, including incorrect extrapolation of research data on the clinical efficacy of the pharmaceutical product;
- Give assumptions about the effectiveness of the pharmaceutical product in a patient population that has not been investigated in the presented study;
- Use of preclinical data that can be used only to describe the pharmacological properties of the pharmaceutical product in assertions about clinical efficacy or safety of the pharmaceutical product.

The information about scientific research in the field of medicine, diagnosis, prevention, treatment of certain diseases presented in the framework of the scientific events and related to the scientific research of non-registered pharmaceutical product / indication should be accompanied by a separate slide indicating the notification about the absence of registration and the need to use medicines only in accordance with the approved instruction for use of the registered pharmaceutical product.

Scientific event can be held only within the framework of international independent scientific conferences or conferences with international participation, organized by the national or international professional scientific community, the international status of which is determined by the organizers of this conference and reflected in the program of the event.

Scientific event should be organized and controlled by the medical department of the pharmaceutical company.

The aim of the scientific event is to inform the scientific community about the achievements in the field of medicine, diagnosis, prevention and treatment of certain diseases, as well as in the scientific research of new pharmaceutical products. Scientific event should be conducted exclusively for healthcare professionals. The mandatory registration of participants should be provided in the frame of scientific event.

The fact of support of scientific event by the pharmaceutical company should be disclosed by the organizer and/or individual representing scientific information within the scientific event.

In the capacity of individuals, who can present scientific information relating to the clinical trials in the framework of scientific event, it is permitted to engage exclusively employees of the medical department of the company and / or researchers who participated in the study, which is presented in the framework of the scientific event, or speakers who are the leading experts in the treatment of this disease. The results of scientific research should be in compliance with the information contained in the official source of their publication.

The information provided on the scientific event should be balanced between the overview of the problem / disease and information on the clinical trials results.

Presentation of the data on clinical trials should be accompanied by information on the study design and study population of patients who take / took part in the study. The data on pre-clinical studies can be used only to describe the pharmacological properties and should not be used to draw conclusions about the clinical efficacy and safety of pharmaceutical products.

Exchange of scientific information in the frame of the scientific event should be accompanied by references to the data published in specialized publications.

## 12) Question:

*How should to disclose information regarding patients organization support (according to the clause 6.4.5 of AIPM Code of Practice)?*

**Answer:** Each company should disclose a list of patient organizations to which it provides direct or indirect, financial and/or non-financial support or that it has engaged to provide contracted services for its benefit.

The disclosure must include a description of the support/contracted services provided that is sufficiently complete to enable the reader to form an understanding of the volume and the nature of the support/contract. Contract confidentiality provisions shall not prevent the disclosure to the extent provided by the AIPM Code of Practice.

In addition to the name of patient organization and the nature of the support/contract the following elements must be included:

- a. For support:
  - i. The monetary value of financial support;
  - ii. For non-financial support that cannot be assigned to a meaningful monetary value, description shall include information on the benefit that patient organization receives.
- b. For contracted services: the total amount paid per patient organization over the reporting period.

This information must be disclosed on companies website (either on a national or global level) on an annual basis. Each reporting period shall cover a full calendar year.

**Methodology.** Each company shall publish a note summarizing the methodologies used by it in preparing the disclosure and identifying support or contracted services.

### 13) Question:

*What criteria should be considered when assessing the appropriateness of the Location and Venue of an Event in accordance with clause 3.3.4 of AIPM Code of Practice?*

**Answer:** Answer: When assessing the appropriateness of the Location and Venue of an Event the following non-exhaustive criteria should be considered:

1. The geographical location of the event is in or near a city or town, which is a recognized scientific, business or regional center and is easily accessible for the intended audience. The location should be appropriate in respect to the geographical scope of the event (e.g. a regional congress should not take place outside of the region; when appropriate venues are available within the town, the event should not be organized out of town or in other town).
2. The location of the Event should not be
  - a. primarily known for its touristic or recreational offering or
  - b. the main attraction of the event or be perceived as such.
3. At some occasions such Event in the location that is primarily known for its touristic or recreational offering may be organized or supported provided that
  - a. it's targeted for the audience residing at this location or in direct proximity to it;
  - b. the Event is an annual international or national event, organized by internationally or nationally recognized professional associations AND the Event does not take place during high touristic season for this geographical location.

The time of the event should not coincide with internationally recognized sporting or cultural events taking place in the same location (e.g. the location directly or indirectly facilitates participation in such event<sup>10</sup>) at the same day. Such sporting or cultural events should not be the attraction for the event or be perceived as such.

Events should not take place at:

- 1) hotels rated as 5\* and/or higher
- 2) hotels targeted primarily for leisure (Spa hotel, club hotels, sanatorium etc.) not depending on its rating;
- 3) venues known primarily for entertaining activities (yacht club, museum, theatre, concert hall, cinema, circus, hippodrome, shopping and entertainment center etc.).

# Appendix 4

## Questions and answers to section VII of the AIPM Code of Practice

Starting from 2016 the international pharmaceutical AIPM member-companies undertake to publish information on transfers of value made to or for the benefit of healthcare professionals and healthcare organizations.

### ABOUT THE DISCLOSURE INITIATIVE

#### 1. Wherefore was the initiative created?

In recent years the society pays more attention to the interaction of the pharmaceutical industry with healthcare professionals and healthcare organizations.

The pharmaceutical industry is committed to maintain open and fair interaction, demonstrating its commitment to transparency. This is a key element in building fruitful interaction to the benefit of patients.

**The purpose of this initiative** - to make the legitimate interactions of pharmaceutical companies and the medical society transparent and understandable to patients, government and the general public.

**Cooperation between the medical community and the pharmaceutical industry** - the force for progress in medicine and healthcare.

Patients should be confident that these interactions do not affect the decisions of doctors, and healthcare professionals in making decisions on treatment are based only on the clinical data, their professional experience and interests of patients.

The task is to strengthen such legal relations by increasing their transparency to the benefit of patients.

#### 2. Why was the initiative created?

Interaction of pharmaceutical companies and healthcare professionals are always necessary for the health of patients, and for the development of science. At the same time, today we can observe the increasing interest demonstrated by not only the public authorities, but also by society, to the substance of these interactions. Both want to be sure that this kind of interaction does not affect the doctor's decision of physician on the use of drugs and treatments.

In order to build confidence that the doctor decision is not biased, but objective and balanced, the international pharmaceutical industry has taken the initiative - to make the relationship between pharmaceutical companies and healthcare professionals understandable and transparent to the public. The path to ensuring that the interactions are open and transparent is a long process, which was prompted by some changes in the regulation as a whole. First of all, the need on the part of patients, as well as changes in the regulatory and legal environment in different countries, including the Russian Federation, were taken into account. So, in 2012 in Russia for the first time the rules on

restrictions on the interactions between pharmaceutical companies and healthcare professionals, and rules on disclosure of conflict of interests have been introduced at the legislative level. The process of disclosure of transfers of value will be a logical continuation of the Russian legislation.

Remaining dedicated to its commitment to high ethical standards AIPM became a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) in 2012. AIPM fully shares EFPIA position that there is necessity to ensure that interactions between pharmaceutical companies and society are not only conducted with integrity but are also transparent.

AIPM has therefore decided that its existing Code should be supplemented by requirements for detailed disclosure regarding the nature and scale of the interactions between pharmaceutical companies and healthcare professionals and healthcare organizations. AIPM expects that by taking this step it can enable public scrutiny and understanding of these relationships and thus contribute to the public confidence in the pharmaceutical industry.

#### 3. What countries does the initiative cover?

The initiative to disclose transfers of value to healthcare professionals and healthcare organizations is supported by the representatives of the pharmaceutical industry and industry associations, both of developed and developing countries on the 5 continents of the globe.

These are the countries where there are communities that are members of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), including the Association of International Pharmaceutical Manufacturers (AIPM) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), brought together more than 30 national associations and 40 leading pharmaceutical companies.

#### 4. Which companies support the initiative?

The initiative is supported by all member-companies of Association of International Pharmaceutical Manufacturers (AIPM). AIPM member-companies strongly believe that the initiative to disclose information about transfers of value will enhance mutual responsibility and ethical standards of interactions between the pharmaceutical industry and medical society and, ultimately, will serve the interests of patients and increase mutual trust in the eyes of society.

For the purposes of successful implementation of the transparency initiative there is need for understanding and broad cooperation of all stakeholders to strengthen the trust within the society as a whole, and between healthcare professionals and pharmaceutical industry, in particular.

#### 5. Legal basis of interactions between the industry and medical society.

In accordance with legislation on interactions between pharmaceutical industry and medical society healthcare professionals are not prohibited to participate in professional scientific events organized and (or) sponsored by pharmaceutical companies, and healthcare professionals being the medical professionals are not prohibited to receive remuneration under the contracts in the course of performance of clinical trials, remuneration associated with educational and (or) scientific activities of medical professionals.

#### 6. Who and how will have access to the disclosed data?

Each AIPM member-company will publish disclosed data on the relevant pharmaceutical company's website unrestricted and publicly available. Therefore, the data will be available for general public.

## 7. When the disclosure of transfers of value will be published?

Disclosure obligation provided by chapter VII of the AIPM Code comes into force from 2016 in respect of transfers of value for the calendar year 2015. Therefore, each AIPM membercompany undertakes to publish on Common Publication Disclosure Period from June 20, 2016 to June 30, 2016 on their websites information on transfers of value for the calendar year 2015.

Starting from 2016 disclosures shall be made by each AIPM member-company on an annual basis and each reporting period shall cover a full calendar year.

## 8. Where the published information on transfers of value can be found?

Disclosure of information will be published on the relevant pharmaceutical company's website making transfers of value, or on the corporate web-site of the Group of companies which incorporates the respective company (in the event of absence of the own company's web-site).

## AIPM CODE OF PRACTICE

### 9. Who shall disclose transfers of value?

Each pharmaceutical company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organization being a recipient of transfers of value.

### 10. What is the meaning of transfers of value in accordance with the AIPM Code of Practice?

Transfers of value in the frame of the initiative - direct and indirect transfers of value, whether in cash, in kind or otherwise, made, whether for the purposes permissible by the applicable legislation and by this Code in connection with the development and sale of exclusively prescription-only pharmaceutical products for human use.

Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient.

Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate (e.g. event organizing agency) and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value

### 11. What transfers of value should be disclosed?

The following transfers of value should be disclosed:

I. Donations and grants to healthcare organizations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.

II. Contribution to costs related to events. Contribution to costs related to events, through healthcare organizations or third parties such as:

- Registration fees;
- Sponsorship fees under agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event; and
- Travel and accommodation.

III. Fees for service and consultancy. Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals and/or healthcare organizations under which such healthcare professionals and/or healthcare organizations provide any type of services to a pharmaceutical company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand transfers of value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

IV. Contribution to costs related to events and participation of healthcare professionals therein

- Registration fees;

- Travel and accommodation.

V. Research and development transfers of value.

### 12. Shall each transfer of value be disclosed on an individual basis, for each clearly identifiable recipient?

Each transfer of value shall be disclosed on an individual basis provided that applicable data protection, including personal data protection rules of Russian legislation are complied with.

Specifically, each pharmaceutical company shall disclose the amounts attributable to each category of transfers of value to or for the benefit of healthcare professionals and healthcare organizations being a recipient on an individual basis for each clearly identifiable recipient.

*The exception is provided by the following categories of transfers of value which are disclosed on an aggregate basis:*

A) *Research and development transfers of value;*

B) *Transfers of value to healthcare professionals in the event when healthcare professional doesn't give consent to individual disclosure of transfers of value or withdrew it;*

C) *to the extent otherwise provided by legislation*

### 13. What transfers of value should not be disclosed?

The following transfers of value made in accordance with effective legislation and AIPM Code of Practice should not be disclosed:

(i) transfers of value that are solely related to over-the-counter pharmaceutical products;

(ii) transfers of value that are not listed in the answer to the question 11 (eleven), such as:

- items of medical utility,

- meals and drinks,

- samples of the pharmaceutical products; or

(iii) transfers of value that are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and an healthcare professional or a healthcare organization, as relevant.

#### 14. How often shall the transfers of value be disclosed?

Starting from 2016 disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year.

Disclosures shall be made by each pharmaceutical company within 6 months after the end of the relevant reporting period and the information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed,

unless:

- (i) a shorter period is required under applicable national data privacy or other laws or regulations, or
- (ii) the recipient's consent relating to a specific disclosure has been revoked.

#### 15. How will transfers of value be disclosed?

For consistency purposes, disclosures will be made using a unified template together with synchronous publication of the note summarizing the methodologies used in preparing the disclosures.

#### 16. The currency of disclosed transfers of value?

Taking into account that Association represents the interests of international pharmaceutical companies on the territory of the Russian Federation it is expected that member-companies will disclose transfers of value in rubles.

### TRANSFERS OF VALUE TO OR FOR THE BENEFIT OF HEALTHCARE PROFESSIONALS

#### 17. Who are considered to be healthcare professionals in accordance with the AIPM Code?

Pursuant to the provisions of the AIPM Code healthcare professionals - doctors and other medical professionals, heads of medical organizations, pharmaceutical professionals (including pharmacists), heads of pharmacy organizations, and other specialists the professional activity of which is concerned with pharmaceutical products and who in the process of their professional activity have the right to prescribe, recommend, purchase, supply, or administer pharmaceutical products.

#### 18. How the transfers of value are disclosed?

In disclosing transfers of value to or for the benefit of healthcare professionals the data should be published exclusively subject to the effective Russian legislation requirements on personal data protection, provided that healthcare professionals gave the appropriate written consent.

Disclosure is made in accordance with the structure set forth in appendix 2 to the AIPM Code of Practice (Appendix to the Q&A). If there is no consent or the consent is withdrawn disclosure of transfers of value to healthcare professionals should be made on an aggregate basis without identification of specific recipients of transfers of value.

#### 19. Whether a company refuses further interactions with healthcare professional if he doesn't give consent to individual disclosure with identification of specific recipient?

The question of further interactions with healthcare professional in the event when healthcare

professionals do not grant consent to disclose payments on an individual basis is under an individual company decision in accordance with their own policies and criteria for working with healthcare professionals in accordance with the applicable Russian legislative frameworks.

#### 20. How should disclosure be managed where the Recipient gives partial consent? For example, where consent is given for the consultancy fees to be disclosed, but not associated payments for travel & accommodation, being the essential part of the contract?

Member-companies are encouraged to ensure the absence of ambiguity of provisions of the contract and consent notice concluded in the frame of interaction with healthcare professionals.

If notwithstanding the Member Company's efforts a Recipient gives only partial consent to any provisions of the specific contract Transfers of Value of the Member Company made to that Recipient in accordance with the contract should be declared in the aggregate disclosure subject to applicable legislation of the Russian Federation.

Partial disclosure under the individual disclosure category would be misleading with respect to the nature and scale of the interaction between the Member Company and the Recipient.

#### 21. Whether there is a requirement to have consent of healthcare professional in accordance with the Code requirements if the healthcare professional is the sole proprietor?

Taking into account that healthcare professional registered as the sole proprietors are considered to be personal data subjects it is requisite to receive the relevant written consent to personal data processing and disclosure. If the consent was not received the disclosure should be made on an aggregate basis.

### TRANSFERS OF VALUE TO OR FOR THE BENEFIT OF HEALTHCARE ORGANISATIONS

#### 22. Who are considered to be healthcare organizations in accordance with the AIPM Code?

Pursuant to the provisions of the AIPM Code healthcare organizations - any legal entity (i) that is a healthcare, medical, pharmaceutical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, foundation, university or other teaching institution (except for patient organizations) whose business address, place of incorporation or primary place of operation is in Russia or (ii) which provides services through one or more healthcare professionals.

#### 23. Shall the transfers of value to patient organizations be disclosed?

Patient organizations are not considered to be healthcare organizations pursuant to the definition of the AIPM Code and therefore transfers of value to patient organizations should not be disclosed.

#### 24. How to disclose sponsorship fees paid to third parties, appointed by HCOs to manage the event (technical organizers)?

Under sub-clause 7.3.2 of the AIPM Code of Practice categories for transfers of value to HCO among others include contribution to costs related to events through HCO or third parties, including sponsorship agreements with third parties appointed by HCO to manage an event. The definition of the Transfers of Value provided by the AIPM Code apart from direct payment to HCO includes also transfers (whether in cash or in kind) to third parties, where company member could identify HCO that benefit from the transfer of value being a beneficiary.

When HCO appoints the technical organizer of the event, such technical organizer organizes an event using transfers of value received from sponsors for and under control of the HCO. Sponsorship fee paid to the technical organizer in this case shall be disclosed as transfer of value to the HCO, which appointed the technical organizer. As Transfers of value includes benefits in kind, disclosure does not necessarily mean that HCO received money through the technical organizer; values in kind could be provided to HCO by technical organizer by means of renting the event facilities and financing other costs related to the event in HCO's interests.

The relations between technical organizer and HCO shall be properly documented, for example, by the trilateral agreement (company, HCO, technical organizer). If company concludes sponsorship agreement with technical organizer only, relations between HCO and such technical organizer (if available) shall be documented by such sponsorship agreement and confirmed by a document from HCO (e.g. letter by HCO).

#### **25. How to disclose transfers of value to several HCOs appointed the one technical organizer to manage the event?**

Such transfers of value shall be disclosed based on the actual circumstances confirmed by documents. The exact distribution of the transfers of value among HCOs could be defined by the sponsorship agreement or by the official correspondence with such HCOs. The principles and methods used by company in preparing the disclosures, including specifications of allocation of transfers of value for the benefit of each HCO in accordance with AIPM Code of Practice, should be documented and can be published in the company's note summarizing such methodologies.

#### **26. What is the meaning of "clearly identifiable Recipient" under sub clause 7.3.1 of the AIPM Code of Practice with respect to HCO?**

Companies have to ensure that HCO receiving the transfer of value is identified in such a way that there cannot be any doubt about the identity of the HCO receiving the Transfers of value.

In practical terms, there might be cases, where company pays sponsorship fee to the legal entity (not HCO), which independently organizes the event, not acting as an intermediate for any HCO. In this situation company cannot identify any HCO as Recipient of values and, correspondingly, disclosure is not required. Where the technical organizer is appointed by HCO and acts as an intermediary in HCO interests, payments to such technical organizer falls within the definition of the indirect transfer of value to HCO through the intermediary and, correspondingly, shall be disclosed.

The clear possibility to avoid doubts on the role and status of the party, to which sponsorship fee is paid, is to define such role and its relations with HCO (if any) in the sponsorship agreement. Such roles and status shall be confirmed by HCO by way of signing the sponsorship agreement (in case of trilateral agreement) or by a separate document (e.g. letter from HCO).

#### **27. Whether there is a requirement to receive the consent of healthcare organizations to disclose the data on transfers of value?**

There is no requirement to receive the consent of healthcare organizations to disclose the data on transfers of value provided that the relevant disclosed data fails to appear as the State secret, banking, commercial secrecy or other such other protected information in accordance with legislation of the Russian Federation. Alongside with that, in the event when in accordance with conditions of the contract there are limitations and/or prohibition to disclose information on transfers of value to or for the benefit of healthcare organizations, it is recommended to make the renegotiation of

provisions of the contract in accordance with proposed form "Disclosure clause in contract templates with HCOs", which is provided below, and inform healthcare organization on the rules of disclosure on an individual basis for each clearly identifiable healthcare organization by inclusion of the certain conditions into the contract or through another means.

#### **<< Disclosure clause in contract templates with HCOs**

*The parties acknowledge that being a member of the Association of International Pharmaceutical Manufacturers (AIPM) and in accordance with the AIPM Code of Practices the Company is required to publically disclose certain information to enhance transparency, such as donations and grants, payments of fee for services, sponsorships agreements or contribution to costs of events, representing a transfer of value made to healthcare organisations by pharmaceutical companies. [HCO name as defined in the contract] hereby gives its consent to the Company to report and disclose on an individual basis (naming the [HCO name as defined in the contract] in the disclosure materials) any information on any transfers of value to [HCO name as defined in the contract] under this agreement and any related information in accordance with the laws and self-regulation in force, both during the term of this agreement and afterwards. Detailed information on transfer of value to individual healthcare organization can be accessed through a secure website \_\_\_\_ [insert country portal or link].>>*

#### **28. Shall the sponsorship fees related to the conduct of events organized by the Ministry of Health, its region and/or competent divisions, being the State bodies, be disclosed?**

State bodies are not considered to be the "Healthcare organizations" in accordance with definition provided by the AIPM Code of Practice. Therefore, sponsorship fees related to the conduct of events organized by the State bodies should not be disclosed. In the meantime, in the event when the official scientific professional event is conducted under the patronage and/or with the support of such State bodies as the Ministry of Health, its region and/or competent divisions in accordance with the approved plan of events, and healthcare organizations presented without limitation as professional medical associations and such organizations are acting as organizers in idea, contribution to costs related to the conduct and organizing of such events should be disclosed as transfers of value to the specified healthcare organizations.

#### **29. Shall the payment of the state duty and other mandatory payments dedicated to satisfying the requirements provided in the frame of state marketing authorization procedure, certification of pharmaceutical products be disclosed?**

Transfers of value related payment of the state duty and other mandatory payments made by companies in the process of marketing authorization, expertise, certification and other procedures prescribed by the law should not be disclosed.

## RESEARCH & DEVELOPMENT TRANSFERS OF VALUE

### *30. What is the meaning of Research and development transfers of value for the purposes of enforcing disclosure obligation?*

Research and development transfers of value) – transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study, including without limitation transfers of value to healthcare organizations under clinical trial agreement, including laboratory and instrumental investigations; fees for the providing of scientific and/or pedagogic services by healthcare professional being a medical professional and services in the course of performance of clinical studies.

### *31. How the Research and development transfers of value shall be disclosed?*

Research and development transfers of value in each reporting period shall be disclosed by each pharmaceutical company on an aggregate basis. Costs related to events that are clearly related to activities covered in the answer to the question 30 also can be included in the aggregate amount under the “Research and Development Transfers of Value” category.

### *32. How the Research and development transfers of value which are out of the scope of the Code definition regarding Research and development transfers of value provided by the Code and specified in the answer to the question 30 shall be disclosed?*

Transfers of value that do not fall within the definition of “Research and Development Transfers of Value” for the purposes of disclosure obligation enforcement, specified in AIPM Code and in the answer to the question 30 shall be disclosed under the category “fee for service and consultancy”.

### *33. Why do the retrospective non-interventional studies fall under the individual disclosure category?*

Following the AIPM Code the definition of R&D Transfers of Value in the clause 1.2 retrospective non-interventional studies do not fall within the scope of the definition of R&D Transfers of Value.

Transfers of Value relating to retrospective non-interventional studies shall be disclosed under the name of the individual Recipient.

If companies cannot differentiate the retrospective and prospectives non-interventional studies, they ought to disclose all the non-interventional studies in individual.

### *34. Is a clinical research organization (CRO) a HCO?*

A CRO is not an HCO for the purposes of chapter VII of the Code. A clinical research organization (CRO) is an organization that provides support in the form of research services outsourced on a contract basis with a company. However, Member Companies in the process of Transfers of Value to HCPs / HCOs through CROs – such indirect payments are within the scope of Disclosure requirements in accordance with the Code.

As a rule, each Member Company will decide on the inclusion of Transfers of Value to CROs into the different categories of disclosure.

If activities contracted to CROs fall within the scope of the definition of R&D Transfers of Value provided in the Code, they will be part of the aggregate disclosure under that category. Otherwise, they will be reported under the relevant category specified in sub-clauses 7.3.2 and 7.3.3 of the Code.

In their written contracts with CROs, Member Companies are encouraged to include provisions relating to the CROs’ consent to disclose Transfers of Value that will ultimately benefit HCPs/HCOs in accordance with the provisions of the Code.

In the Methodology Note, the Member Company is encouraged to provide additional clarification on the nature of the Transfers of Value included.



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