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

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.

Acting Head of the Federal Service for Supervision of Healthcare, Doctor 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.

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.

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.

Director of the Institute of Legislation and Comparative Law affiliated to the Government of the Russian Federation, Doctor of Law, Member of the Russian Academy of Sciences

T. Ya. Khabrieva
Contents

I. Purpose and Scope of Application ................................................................. 57
  1.1. Purpose ........................................................................................................... 57
  1.2. Basic terms ..................................................................................................... 57
  1.3 Scope of Application ....................................................................................... 59
II. General Provisions on Promotion of Pharmaceutical Products ................. 60
    2.1 Basic Principles of Promotion .................................................................... 60
    2.2 Registration Status ...................................................................................... 60
    2.3 Standards of Advertising Information .......................................................... 60
    2.4 Use of Expert Conclusions, References to The Results of Studies, and Quotations .......... 61
    2.5 Promotion on the Internet ............................................................................ 61
    2.6 Information Related to Human Health and Diseases .................................. 62
III. Specific Features of Interaction With Healthcare Professionals, Advertising to Them, and Other Methods of Promoting Pharmaceutical Products .......... 63
    3.1 General Principles of Interaction With Healthcare Professionals ............... 63
    3.2 Printed Advertising Materials ................................................................. 63
    3.3 Events ......................................................................................................... 64
    3.4 Engaging Healthcare Professionals to Provide Services ................................ 65
    3.5 Gifts ........................................................................................................... 65
    3.6 Basic Rules and Standards of Activities of Medical Representatives ............ 66
    3.7 Samples ...................................................................................................... 66
    3.8 Expert Councils ......................................................................................... 67
    3.9 Responses to Requests for Medical Information ....................................... 67
IV. Specific Features of Advertising and Other Methods of Promotion to the General Public .................................................. 69
    4.1 General Requirements ............................................................................... 69
    4.2 Printed Advertising Materials .................................................................... 69
    4.3 Restrictions on The Contents of Advertising to the General Public ............ 69
    4.4 Other Methods of Promotion of Pharmaceutical Products to the General Public ..... 70
    4.5 Responses to Requests for Medical Information From Patients ............... 70
V. Pharmaceutical Products Studies ................................................................. 71
    5.1 Post-Registration Studies ........................................................................... 71
    5.2 Marketing Studies ....................................................................................... 72
VI. Specific Features of Interaction with Legal Entities .................................... 73
    6.1 Donations and Grants ................................................................................. 73
    6.2 Samples for Non-Commercial Medical Organizations ................................ 73
    6.3 Interaction With Patient Organizations ..................................................... 74
    6.4 Specific Features of Interaction With Pharmacies/Pharmacy Networks ............ 75
VII. Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations ........................................... 76
    7.1 Disclosure Obligation ............................................................................... 76
    7.2 Form of Disclosure ..................................................................................... 76
    7.3 Individual and Aggregate Disclosure ....................................................... 77
VIII. Pharmaceutical Companies’ Procedures and Liability ......................... 79
    8.1 Authorized Person of a Company .............................................................. 79
    8.2 Promotional Programs and Documentation ........................................... 79
    8.3 Storage of Documentation ........................................................................ 79
    8.4 Employees Professional Development ................................................... 79
IX. Maintenance and Development of the Code .......................................... 80
    9.1 Need to Constantly Maintain and Develop the Code ................................ 80
    9.3 Updating the Code ................................................................................... 80
Appendix 1 - Procedure for Review of Complaints and Disputes Regarding Violations of the AIPM Code of Practice ....................................................... 82
    1. Procedure for Review of Complaints and Disputes Between Companies That are AIPM Members ................................................................. 82
    2. Procedure for The Review of Complaints Filed With the AIPM ..................... 82
Appendix 2 – Template .................................................................................... 88
AIPM member companies 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.

AIPM member companies are to bring all of their activities, including advertising and other methods of promoting pharmaceutical products, into compliance with the requirements of the new version of the Code by no later than January 1, 2014.

Complaints about a violation of the Code’s requirements that have been newly introduced into or modified in the new version of the Code will be accepted from January 1, 2014.

Disclosure obligation provided by chapter VII of this Code comes into force from 2016 in respect of transfers of value for the calendar year 2015.

Preamble

Pharmaceutical products are socially significant products and public health depends on their properties. The pharmaceutical industry is responsible for providing society as a whole and the medical and pharmaceutical communities in particular with objective information on pharmaceutical products. 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.

Activity to promote pharmaceutical products, subject to certain restrictions, is an integral part of advancing the pharmaceutical industry, making it possible for the results of many years of work and huge material expenditure to become directly accessible to all of humanity.

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 IFMPA 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 55 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 marketing practice, and to systematize the complex of regulatory provisions. 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.

\footnote{In 2005, the name of this organization was changed to "International Federation of Pharmaceutical Manufacturers and Associations", because the right to become a member was extended beyond associations to pharmaceutical companies.}
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.

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.

The new version of the Code was developed based on the version adopted in 2012.

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:

**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;

**Promotion** - any activity, including advertising, which is conducted, organized, or sponsored by a pharmaceutical company with the use of any information media (including the Internet) and which aims to facilitate the prescription, recommendation, supply, administration, or consumption of pharmaceutical products produced by that company;

**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;

**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.

**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;

**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;
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 concerning the safety of use of the pharmaceutical product in the most complete way.

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.

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 identical characteristics, and 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.

2.4. 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 preparations 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
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. Printed advertising materials that are disseminated by means of an electronic information system (including a website) or entered into an electronic data storage medium (including a database) must 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.

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

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.

2.6. 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.
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 pharmaceutics.

3.3.2. Companies should not organize 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.

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.

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.

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.

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 medicinal preparations. 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

3.7.1. Pharmaceutical companies may not directly provide healthcare professionals with any samples of pharmaceutical products, either for subsequent transfer to patients or for personal use (including demo packs and empty secondary and primary packaging).

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.
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 substance;
- 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 may contain, as a minimum, the name of the pharmaceutical product 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.

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, efficacy, or safety of a pharmaceutical product or the absence of adverse 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.
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 non-commercial 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 and gain experience in working with such pharmaceutical products in accordance with the approved package leaflet.

6.2.2. 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

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.

5.2.3. Market research agencies may be used to conduct such studies.

6.1. MARKETING MATERIALS

6.1.1. Pharmaceutical companies may use marketing materials for the promotion of their pharmaceutical products, including brochures, packages leaflets, marketing brochures, etc. Such materials may only be used in accordance with applicable legislation and as long as the following conditions are met:

- the pharmaceutical company is only permitted to use materials which have been approved by the relevant regulatory authority;
- the marketing materials must comply with all relevant requirements of applicable legislation;
- the marketing materials must be used in accordance with the approved package leaflet;
- the marketing materials must be used in a manner which is not misleading or deceptive;
- the marketing materials must not be used to promote any non-commercial medical organizations.

6.1.2. Marketing materials may 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;
- obtaining confidential information about competitors;
- discrediting the pharmaceutical products of any competitor or otherwise causing detriment to any competitors.
6.3.  INTERACTION WITH PATIENT ORGANIZATIONS

6.3.1. Patient organizations are non-commercial organizations representing the interests and needs of patients, their families, and/or persons taking care of sick or aged persons.

6.3.2. The pharmaceutical industry shares many interests with such organizations, but should respect their independence.

6.3.3. Pharmaceutical companies may interact with patient organizations to complete the following tasks:

- study of patient opinions about the impact of diseases on patients’ quality of life and the quality of life of persons taking care of them, which 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;
- the creation 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.

6.3.4. A pharmaceutical company may not be the only pharmaceutical company acting as the founder of a patient organization.

6.3.5. A pharmaceutical company should explicitly disclose the fact and nature of its cooperation with a patient organization on its 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 unless such financing (donation) is 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.

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

6.3.7. 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.

6.4.  SPECIFIC FEATURES OF INTERACTION WITH PHARMACIES/PHARMACY NETWORKS

6.4.1. 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.

6.4.2. 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.

6.4.3. 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.
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 an 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. Subject to second item of sub-clause 7.2.4, 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 can be made in either of the following ways, provided that they are unrestricted and publicly available:

- on the relevant pharmaceutical company’s website in accordance with sub-clause 7.2.5 while posting corresponding hyperlink on a central platform of AIPM; or

- on a central platform of AIPM, using a structure set forth in Appendix 2 of this Code.

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 county, 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 county, any other similar code applicable to a pharmaceutical company should govern.

7.2.6. Disclosures shall be made in Russian and in English languages.

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.

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.
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.

8.4. 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.

8.5. 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.

8.6. 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.

8.7. 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 terms 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.
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;
- 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. 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.
<table>
<thead>
<tr>
<th>Full Name</th>
<th>HCPs: Inhabited localities of Principal Practice</th>
<th>Country of Principal Practice</th>
<th>Principal Practice Address</th>
<th>Unique country identifier</th>
<th>Donations and Grants to HCOs (Clause 7.3.2)</th>
<th>Contribution to costs of Events (Sub-clause 7.3.2)</th>
<th>Fee for service and consultancy (Sub-clause 7.3.2 &amp; 7.3.3)</th>
<th>Transfers of Value re Research &amp; Development as defined (Sub-clause 7.3.6)</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr A</td>
<td>N/A</td>
<td>N/A</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Fee for service and consultancy (Sub-clause 7.3.2)</td>
<td>Optional</td>
<td>N/A</td>
</tr>
<tr>
<td>Dr B</td>
<td>N/A</td>
<td>N/A</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Optional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>etc.</td>
<td>N/A</td>
<td>N/A</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Yearly amount</td>
<td>Optional</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>HCPs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aggregate amount attributable to transfers of value to such Recipients – Sub-clause 7.3.4</td>
<td>N/A</td>
<td>N/A</td>
<td>Aggregate HCPs</td>
<td>Aggregate HCPs</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>N/A</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>Number of Recipients in aggregate disclosure - Sub-clause 7.3.4</td>
<td>N/A</td>
<td>N/A</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>N/A</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Sub-clause 7.3.4</td>
<td>N/A</td>
<td>N/A</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>HCOs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aggregate amount attributable to transfers of value to such Recipients – Sub-clause 7.3.4</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>Aggregate HCOs</td>
<td>N/A</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>Number of Recipients in aggregate disclosure - Sub-clause 7.3.4</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>number</td>
<td>N/A</td>
<td>Optional</td>
<td></td>
</tr>
<tr>
<td>% of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Sub-clause 7.3.4</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>N/A</td>
<td>N/A</td>
<td></td>
</tr>
</tbody>
</table>

**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)**

**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)**

**OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons**

**AGGREGATE DISCLOSURE**

Transfers of Value re Research & Development as defined (Sub-clause 7.3.6)

| % of the number of Recipients included in the aggregate disclosure in the total number of Recipients disclosed - Sub-clause 7.3.4 | % | % | % | % | % | % | N/A | N/A |