E T H I C A L C O D E

OF THE ASSOCIATION OF INTERNATIONAL PHARMACEUTICAL MANUFACTURERS IN THE REPUBLIC OF KZAZAKHSTAN

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INTRODUCTION

The Code of Ethics (hereinafter referred to as the "Code") of the Association of International Pharmaceutical Manufacturers ("AIPM") in the Republic of Kazakhstan was developed on the basis of international marketing practice codes adopted in the research pharmaceutical industry, taking into account the requirements of the legislation of the Republic of Kazakhstan and reflecting ethical standards that all AIPM members must follow when implementing Promotion and Marketing of Pharmaceutical Products in the Republic of Kazakhstan.

Provisions of the Code are intended to help AIPM members develop and apply honest and responsible Promotion and Marketing standards that take public health interests in the Republic of Kazakhstan into account, and are a tool for resolving ethical issues between AIPM members in the event of any disputes.

The Code represents a number of additional guidelines governing AIPM members in the implementation of Marketing and Promotion of Pharmaceutical Products in the Republic of Kazakhstan, as the legislation of the Republic of Kazakhstan in this field always takes precedence.

The Code determines that responsibility and control over compliance with high standards in the Promotion of Pharmaceutical Products in the Republic of Kazakhstan are vested in AIPM members. All AIPM members must make right and conscientious decisions with an emphasis on the interests, first of all, of the Patient. Promotion of Pharmaceutical Products in violation of the Code is unacceptable.

All AIPM members undertake not to distribute any materials that are inconsistent with the provisions and principles of this Code, nor take any action in the field of Pharmaceutical Products Marketing in violation of this document.

Respect for the person, Patient-orientedness, transparency and observance of ethical norms are the values that should underlie everything that the AIPM members undertake.

The management [of each AIPM member company (hereinafter referred to as the "Company") is obliged to support activities of the Company in accordance with the requirements of the legislation of the Republic of Kazakhstan and this Code. The management assumes the obligation to take action against any identified and proven act of infringement.

Each company that has joined AIPM is obliged to enforce provisions of the Code and conduct introductory training on the provisions of this Code, for all employees and persons engaged by the Company within 6 months of becoming a member of AIPM, and to familiarize new employees and engaged persons of the Company.

This Code, as well as any amendments thereto, shall enter into force for the Company after expiration of 6 months from the date of their adoption.

This Code, as well as any alterations and amendments thereto are approved by resolution of the General Meeting of AIPM. Alterations and amendments to this Code may be made at the initiative of any Company.

1. MAIN TERMS AND DEFINITIONS USED IN THIS CODE

1.1. **Medicinal products*** means products that are or contain pharmacologically active substances that come into contact with human body or penetrate into its organs and tissues intended for prevention, diagnosis and treatment of diseases, as well as changes in the state and functions of the body: drug substance, drug raw material, bulk products of medicinal products, medicines.

1.2. **Pharmaceutical product** is a medicinal product, medical device and medical equipment

1.3. **Post-marketing clinical research** is a study of a Pharmaceutical Product conducted in the Republic of Kazakhstan after marketing authorization by its developer, manufacturer or their official representative in the Republic of Kazakhstan, including with the involvement of a contract research organization.

1.4. **Post-marketing clinical interventional study** is a study of a Pharmaceutical Product involving a human as a clinical trial participant, where a doctor, on the basis of the interventional clinical trial protocol corresponding to the procedure for conducting clinical trials determined by an authorized body, prescribes special intervention for the trial participants. In an interventional study, trial participants are subjected to a diagnostic, therapeutic or other type of intervention that can be administered in a random or non-random manner, with subsequent monitoring of Patients and evaluation of biomedical outcomes and health outcomes.

1.5. **Post-marketing clinical non-interventional trial** is a study conducted after marketing authorization of the Pharmaceutical Product, which is prescribed in the framework of medical practice in accordance with the instruction for medical use approved by an authorized body. The non-interventional study protocol corresponding to the clinical trials procedure determined by an authorized body does not in advance determine prescription of a pharmaceutical product to the trial participant and its inclusion in the trial, but rather, describes epidemiological methods for collecting data on safety and efficacy of the pharmaceutical product. Trial participants are not subjected to additional diagnostic or monitoring procedures.

1.6. **Epidemiological study** is a study of prevalence, degree of incidence and severity of various diseases or medical indicators of health conditions in order to determine the causes of their development, risk factors and inter-influence in different population groups;

1.7. **Promotion** means any activity, including but not limited to the Advertising carried out, organized and financed by a pharmaceutical company in order to facilitate prescription, supply, use, recommendation or consumption of Pharmaceutical Products.

1.8. **Marketing** - research, analysis, planning and forecasting in the field of production and circulation of Pharmaceutical Products in order to determine measures to create the best economic conditions for the production and circulation of pharmaceutical products, including characteristics of pharmaceutical products, development of a pricing strategy and a Promotion strategy.

1.9. **Healthcare Professional** is a person who has a medical, dental, pharmaceutical profession or a secondary medical education, as well as any other persons who, in the course of their professional activities, are authorized to prescribe and recommend Pharmaceutical Products, or to purchase, supply, sell and (or) decide on their application.

1.10. **Medical Representative** is the Company’s employee or an engaged person who has a completed medical, pharmaceutical education, evidenced by a diploma, or a specially trained employee of the Company to the extent that it makes it possible to explain the mode of action

of the provided Pharmaceutical Products, their therapeutic effect and impact on pathogenic disease processes. It is the responsibility of the Medical Representative to maintain contact with Healthcare Professionals or other relevant persons for the purpose of Promoting Pharmaceutical Products.

1.11. **Event** means congresses, conferences, symposiums, seminars, round tables and any other marketing, scientific, educational events conducted for the purpose of exchanging scientific and/or medical information, Healthcare Professionals' training in modern aspects of diagnostics, treatment of diseases, including providing information on Pharmaceutical Products.

1.12. **Company** - an active member of AIPM.

1.13. **Ethical Committee** - Ethical Committee of AIPM is a permanent collegial governing body guided by the legislation of the Republic of Kazakhstan, the Charter of the Association, and resolutions of the General Meeting of AIPM members in its activities.

1.14. **Medical Organization** is a legal entity regardless of its form of incorporation, carrying out medical activity as a core (statutory) activity on the basis of a license issued in accordance with the procedure established by the legislation of the Republic of Kazakhstan. Individual entrepreneurs carrying out medical activity are considered equivalent to medical organizations;

1.15. **Civil Servant**** is a citizen of the Republic of Kazakhstan who, in the manner prescribed by the legislation of the Republic of Kazakhstan, holds a public position in the state body paid for from a republican or local budgets or from the funds of the National Bank of the Republic of Kazakhstan and performing official duties in order to fulfill the tasks and functions of the state.

1.16. **Advertisement of Medicinal Products**, **medical devices and medical equipment (hereinafter referred to as advertisement)*** ** - information distributed and placed in any form, by any means, intended for an indefinite number of persons, containing particular information or a totality of data on Medicinal Products, medical devices and medical equipment, contributing to their Promotion and sale.

1.17. **Patient Organizations** are non-profit organizations specializing in certain diseases or aspects of health care that represent the interests and needs of Patients, their families and/or persons caring for sick or elderly people. These groups are primarily comprised of Patients and/or caregivers (family/friends), but may also include consumers, the elderly, women, social minorities or caregivers of Patients, and may be led by professionals in the field of protection of rights and interests, who may or may not have a personal connection with a specific disease.

1.18. **Patient** is an individual who has a certain disease, disorder, or other medical pathology.

** -For the purposes of this Code, the term "medicinal product" is used, as defined in sp. 18, p.1 art.1 of the Health and Health Care System Code of the Republic of Kazakhstan, and includes prescription and non-prescription medicinal products.*

*** - for the purposes of this Code, the term "civil servant" is used, as defined in p. 12, Art. 1 of the Law of RK on the Civil Service of the Republic of Kazakhstan.*

**** - for the purposes of this Code, the term "advertising" is used, as defined in sp. 1, p 2) of the Rules of Advertising of medicinal products, medical devices and medical equipment adopted by the Order No. 105 of the Ministry of Health and Social Development of RK dated 27.02.2015.*

2. ETHICS COMMITTEE FUNCTIONS

2.1. Purpose of the Ethics Committee

The Ethics Committee is established to ensure coordination and control of AIPM members' activities aimed at observing ethical principles of marketing practices adopted in the research pharmaceutical industry.

2.2. Competences of the Ethics Committee

Competence of the Ethics Committee includes:

- processing of applications and resolution of issues, problems associated with improper compliance with ethical norms and guidelines of this Code;

- election of the Chairman of the Ethics Committee (from among members of the Ethics Committee elected by the General Meeting of AIPM members) and termination of his powers.

2.3. Structure of the Ethics Committee

2.3.1. The Ethics Committee is established with at least five members.

2.3.2. Members of the Ethics Committee are elected by the General Meeting of AIPM for a term by the next annual General Meeting by a simple majority of votes present at the General Meeting of AIPM members.

2.3.3. Persons elected to the Ethics Committee may be re-elected an unlimited number of times.

2.3.4. The AIPM President and members of the Management Board may not be elected to the Ethics Committee.

2.4. Rights and Obligations of the Ethics Committee Members

2.4.1. Members of the Ethics Committee have the right to review the materials of the Applicant Companies about unethical Promotion of Pharmaceutical Products that gave rise to a complaint, and also request from such Company materials confirming unethical behavior of another Company.

2.4.2. Members of the Ethics Committee are required to ensure confidentiality of information received and non-disclosure of information that has become known to them in the process of participating in the work of the Ethics Committee.

2.4.3. Members of the Ethics Committee in exercising their rights and performing their duties must act in the interests of observing the ethical norms of this Code, exercise rights and perform duties with respect to the Companies in good faith and reasonably.

2.5. Chairman of the Ethics Committee

2.5.1. The Chairman of the Ethics Committee is elected by members of the Ethics Committee at a meeting of the Ethics Committee by a majority vote of the members of the Ethics Committee present at the meeting.

2.5.2. Only the head of the Company may be the Chairman of the Ethics Committee.

2.5.3. Chairman of the Ethics Committee organizes his work, convenes the meetings of the Ethics Committee and presides thereon, and makes arrangements for keeping the minutes at meetings.

2.5.4. The Ethics Committee may elect deputy Chairmen of the Ethics Committee, who perform his functions, in his absence or on his behalf.

2.6. Meetings of the Ethics Committee

2.6.1. Meetings of the Ethics Committee are held as needed.

2.6.2. A meeting of the Ethics Committee is convened by the Chairman of the Ethics Committee on his own initiative, on the initiative of a member of the Ethics Committee, or due to a receipt of a claim from any Company on improper compliance with the provisions of the Code.

2.7. Operating Pricedure of the Ethics Committee

2.7.1. The quorum for meetings of the Ethics Committee is a simple majority of members of the Ethics Committee. Resolutions of the Ethics Committee are made by a simple majority of members of the Ethics Committee present. The results of the meetings of the Ethics Committee shall be recorded in the minutes of the meetings. In the event of an even number of members of the Ethics Committee present at the meeting and equal votes, the voice of the Chairman of the Ethics Committee shall be decisive.

2.7.2. Representative of the Company that has declared any violation of the Company Code and representative of the Company in respect of which a complaint has been made due to violation of the Code by it, cannot participate in voting by the Ethics Committee on the subject of such a complaint.

2.7.3. Members of the Ethics Committee participate in its proceedings on a non-refundable basis.

3. REQUIREMENRS APPLICABLE TO THE WORK OF MEDICAL REPRESENTATIVES

3.1. Role, training and monitoring the work of Medical Representatives

3.1.1. Taking into account public health interests in the Republic of Kazakhstan, ethical interaction between participants in the pharmaceutical market implies an ongoing process of providing Healthcare Professionals and Medical Organizations with balanced, accurate, reliable and objective information about Pharmaceutical products with the aim of making rational decisions about their use, as well as fair competition between Companies.

3.1.2. Medical representatives provide Healthcare Professionals with non-misleading, objective, reliable and up-to-date information on Pharmaceutical Products and treatment methods, within the approved instructions for medical use, unless otherwise specified by the Code.

3.1.3. Responsibility for the content and form of information provided by Medical Representatives is borne by the Company.

3.1.4. Companies organize trainings for Medical Representatives to ensure that such information is provided in an accurate, responsible and ethical manner. Training of Medical Representatives shall be conducted on a regular basis and include information on the relevant national and international pieces of legislation, internal policies and procedures of the Company, as well as the requirements of this Code.

3.1.5. Medical representatives are guided in their activities by the requirements of the legislation of the Republic of Kazakhstan, ethical standards of the Company, which they represent, as well as the requirements of this Code.

3.1.6. The Company shall ensure control:

3.1.6.1. activities of Medical Representatives with regard to the quality of information provided by them during visits and presentations, and ethical feasibility of their conduct;

3.1.6.2. professional level of Medical Representatives;

3.1.6.3.3. visits to Healthcare Professionals.

3.2. Responsibilities of Medical Representatives

3.2.1. Informational exchange with Healthcare professionals on all medical aspects of using the Company's Pharmaceutical products, whose interests they represent, through individual visits and participation in social events of Healthcare Professionals;

3.2.2. Building professional relationships with Healthcare Professionals in accordance with the ethical principles described in this Code. Compliance with professional ethics in relation to Patients, Healthcare Professionals, Companies whose interests they represent, and to representatives of competing enterprises, institutions and organizations.

3.2.3. Medical representative must, upon request, provide:

3.2.3.1. instructions for medical use of the informed Pharmaceutical product;

3.2.3.2. Information on the conditions of issue from pharmacies (referring to the category of prescription drugs, or OTC drugs, issued to benefit-entitled citizens, etc.) of Pharmaceutical product and its availability in pharmacies.

3.2.4. Medical representatives are obliged to immediately inform the relevant responsible employee of the Company about the practical application of the Company's Pharmaceutical product, including information about any side effects, complaints about quality, falsification, etc., obtained during Healthcare Professionals visits, or from other sources.

3.3. Restrictions applied to Medical Representatives

3.3.1. Medical Representative must comply with the mode and hours of visits indicated by Health Specialist, request information on the duration of visit preferred by Healthcare Specialist and not interfere with the normal functioning of the Medical Organization.

3.3.2. It is inadmissible to speak depreciatingly of any products, activities or representatives of Competitor’s Companies. The wordings used must invariably be carefully worded and scientific in their nature, and cannot be of an extreme type or emotional character. Comparative data should only be based on published scientific data that meet the requirements of evidence-based medicine (randomized multicenter studies, publications in peer-reviewed journals, etc.), while meeting other requirements of this Code for the information on Pharmaceutical Products. When using the results of clinical trials conducted on original drugs, it is necessary to indicate that this study relates to the original drug.

3.3.3. Medical representatives may not provide the following to Healthcare Professionals:

3.3.3.1. Cash or cash equivalents, such as a gift certificate/voucher;

3.3.3.2. Payment for entertainment, recreation, travel to a place of rest.

3.3.3.3. Gifts (except for those provided for in Section 5.6 of this Code)

3.3.4. Make arrangement for participation of Healthcare Professionals in festive or entertaining events at the expense of the Company;

3.3.5. Enter into written or verbal agreements with Healthcare Professionals on the prescription or recommendation to Patients of Pharmaceutical Products for payment or other financial compensation (with the exception of contracts for clinical studies of medicinal products, or clinical trials of medical devices);

3.3.6. Provide Healthcare Professionals with prescription forms for Pharmaceutical Products containing promotional information, as well as prescription forms on which the name of the Pharmaceutical Product is pre-printed.

3.3.7. Provide Healthcare professionals with recommendations and scientific information on the use of Medicines based on indications not registered in the Republic of Kazakhstan, unless otherwise stipulated by the Code.

3.3.8. To create inconvenience to the work of Healthcare Professionals with frequency, time and duration, or the manner of visits.

4. GENERAL PROMOTION AND MARKETING REQUIREMENTS

4.1. Promotion Standards

4.1.1. Information materials about Pharmaceutical products shall be accurate, understandable and objective and presented in a form that is in compliance with legal and ethical standards. Information should be provided on both the efficacy and safety of pharmaceutical products. Information should be balanced, based on the latest estimates of all relevant evidence and should clearly reflect such factual data. Moreover, when new data are available on Pharmaceutical Products that significantly alters the information on safety and/or efficacy of the products, all information materials on such Pharmaceutical Products should be reviewed and updated as necessary, or be recalled from circulation.

4.1.2. Statement about therapeutic effect shall not exceed the data contained in the approved instructions for the use of Pharmaceutical Product.

4.1.3. Any exaggeration, comprehensive statements and ambiguities in the presentation of any information about Pharmaceutical Product should be avoided.

4.1.4. When using the results of clinical trials conducted on original drugs, it is necessary to indicate that this trial relates to the original drug.

4.1.5. Information statements and comparisons included in the material, shall be based on reliable statistical data, and shall be based on significant and comparable properties of the compared active substances and Pharmaceutical Products.

4.1.6. Comparative representation of Pharmaceutical Products cannot:

4.1.6.1. Improperly derive benefit from the popularity of a trademark, trade name or other distinguishing features of a competitor;

4.1.6.2. Use discredit or derogation of trademarks, commercial names, or other distinguishing features or position of a competitor;

4.1.6.3. Make a comparison between trademarks and trade names of advertiser and competitor.

4.1.7. Information materials (printed or electronic) containing statements about the benefits of Pharmaceutical Products should include:

4.1.7.1. A brief or complete instruction on medical use (or a reference to where such information can be found);

4.1.7.2. The date of preparation/approval and/or unique code of the material;

4.1.7.3. Contact information of the Company responsible for the content of the material.

4.1.8. The Company shall ensure recall and (or) proper disposal of materials that do not comply with the requirements of the current legislation of the Republic of Kazakhstan and this Code.

4.1.9. Presentations of Healthcare Professionals, supported by the Company at scientific and educational events of third parties, must cover a medical problem, have a scientific or educational fields, reflect the methods of treatment. It is prohibited to place images of Pharmaceutical Products in presentations.

4.2. Company-Distributed Materials

All materials that do not constitute Advertisement in any form (including printed, audiovisual, electronic or other) must contain the information required in accordance with the legislation of the Republic of Kazakhstan, and, among other things, the name, address, contact information of the Company in charge of Promotion of a Pharmaceutical Product, through which additional information can be obtained.

4.3. Scientific-Evidence and Facts

4.3.1.1. Information materials should be based on a present-day assessment, consistent with scientific data, and not create an incorrect or misleading impression.

4.3.1.2. In all cases, when specific statements are made on pharmaceutical product in the advertising materials, it is necessary to give clear references to the supporting information.

4.3.1.3. Scientific data, which is the basis for information materials and recommendations for the application of Pharmaceutical Products, shall be available and provided at the request of Medical Organizations.

4.3.1.4. Compliance with the requirements for information on the product on labels, packages, guidelines for medical use, bulletins and in the Advertisement, described by laws of the Republic of Kazakhstan and documents from competent bodies of the Republic of Kazakhstan in the field of healthcare, having legal force in the Republic of Kazakhstan.

4.3.1.5. Information containing indications, contraindications, warnings, precautions, adverse reactions and dosage should be in accordance with the approved instructions for medical use.

4.4. Safety Information

4.4.1. Information regarding safety of Pharmaceutical Products (contraindications, precautions, adverse reactions, etc.) shall be consistently and appropriately stated and also meet the international medical practice requirements. It is not allowed to present a Pharmaceutical Product as the safest, most effective and unique. At the

same time, statements about effectiveness and safety can only be applied if they are supported by published scientific or clinical data.

4.4.2. Companies must strictly comply with local legal requirements for providing pharmacovigilance information.

4.5. Pre-Marketing Information

4.5.1. A pharmaceutical product cannot be promoted until its marketing authorization is approved in the Republic of Kazakhstan.

4.5.2. This provision does not imply an attempt to impede the right of scientific community and the public to receive full information on scientific and medical progress. It does not aim to limit the full and proper exchange of scientific information on Pharmaceutical Products, including the appropriate dissemination of research results through scientific or public media, and at scientific conferences, in accordance with the current legislation of the Republic of Kazakhstan. Also, public disclosure of information to shareholders and other persons with respect to any Pharmaceutical Product is not restricted, unless prohibited by applicable law.

4.5.3. Provision of information on unregistered Pharmaceutical Products, or on indications not specified in the Instruction for use of a registered Medicinal Product, is not a Promotion and shall be allowed provided that the following conditions are met:

4.5.3.1. Such information is provided in response to individual request of a Healthcare Specialist, made by them independently on their own initiative, and during speeches at Events to exchange scientific experience.

4.5.3.2. Such requests shall be documented by the Company

4.5.4. Responses are provided by a Company employee who has a medical education that is not directly related to the sales of Pharmaceutical Products.

4.5.4.1. The answer is forwarded to the person requesting this information.

4.5.5. Responses should be based on the evidence-based medicine principles, available scientific information, and clinical research data

4.6. References

4.6.1. In case when scientific research uses published scientific research as a source, a clear reference should be made thereto in the printed material.

4.6.2. Quotations from medical literature or personal presentations shall not alter or distort the meaning or meanings implied by the author or clinical investigator of the work or study.

4.7. Disguised and Misleading Advertising

4.7.1. Products must be promoted in accordance with the legislation of the Republic of Kazakhstan. Hidden, unreliable and unscrupulous advertising is prohibited.

4.7.2. Promotional products (mailing, announcements in medical journals, other print media and mass media) should not hide or veil true information, nor have an unintentional impact on user’s perception and instincts, thus no deliberate concealed use of promotional materials is allowed. Materials of third parties (medical associations, Patient organizations and other public associations) relating

to the Pharmaceutical Products and application thereof, whether or not of promotional nature, shall include the information about the Company that provided financing. It is forbidden to mask marketing activities and promotion of Pharmaceutical Products.

4.7.3. An example of covert advertising can be the information that does not meet the requirements of the law, including that providing unintentional impact on its perception and instincts, as well as information that constitutes an advertising based on its content, but not evaluated by the expert organization for compliance with the law. This statement does not apply to scientific articles and their reprints, as well as to the Company's paid publications of press releases, information about conferences and symposiums held, and information articles on the problem, provided that they do not contain advertising statements about Pharmaceutical Products.

4.8. Procedural Standards of the Company

4.8.1. Promotional, and scientific information materials, including presentations by speakers (Healthcare Professionals, supported by the Company), prior to distribution, publication or demonstration, must be approved by the relevant functions of the Company, including, under certain circumstances, the authorization of a responsible person with an appropriate scientific or medical qualifications.

4.8.2. In cases stipulated by law, Advertising must undergo an expert examination or other applicable procedures of competent bodies (organizations) of the Republic of Kazakhstan.

4.8.3. When distributing advertising, promotional, or scientific information materials, the Companies must adhere to the provisions of the Code, take into account the requirements of applicable international codes and regulations governing relevant issues, and comply with the requirements of the legislation of the Republic of Kazakhstan. Companies should monitor and monitor the reliability of promotional, promotional, scientific information materials distributed by the Company or on behalf of the Company in the Republic of Kazakhstan on an ongoing basis.

5. BASIC REQUIREMENTS BY TYPES OF PROMOTION AND MARKETING AND BY SCIENTIFIC AND EDUCATIONAL ACTIVITIES FOR PHARMACEUTICAL PRODUCTS

5.1. Post-Marketing Studies

5.1.1. Post-marketing studies, including Post-marketing intervention, non-interventional and Epidemiological studies (hereinafter collectively referred to as “Post-Marketing Studies”) must comply with the requirements of the legislation of the Republic of Kazakhstan, as well as the requirements established herein.

5.1.1.1. Post-marketing study should have a rationale and a scientific goal/objectives, which are reflected in the study protocol.

5.1.1.2. Post-marketing study protocol must be approved in medical department or by responsible medical functional units/employees, and the medical department (the corresponding

medical functional units/employees) shall coordinate and monitor the progress of post-marketing study.

5.1.1.3. The documentation for the Post-Marketing Study (protocol, individual registration card, informed consent for the Patient, etc.) must pass an obligatory assessment by an authorized body and ethical review (by the national or local ethical committee) in accordance with the requirements of the legislation of the Republic of Kazakhstan for getting permission for conducting study.

5.1.1.4. When carrying out Post-Marketing Research, any laws, guidelines and requirements regarding confidentiality of personal data (including collection and use of personal data) must be observed.

5.1.1.5. The choice of researchers should be based solely on their professional qualifications and clinical experience and should not be in any way related to past, current or possible future prescriptions or recommendations of the Company's Pharmaceutical Products.

5.1.1.6. Participation of Healthcare Specialist in Post-Marketing Research should not be an incentive to the recommendation/prescription, acquisition, sale and use of any particular Pharmaceutical Product.

5.1.1.7. Remuneration paid for the performance of work in Post-Marketing Studies should be reasonable and reflect a fair market value. All participation conditions in the Post-Marketing Research, including terms of payment, must be reflected in a written agreement between the Company and Healthcare Specialist and/or Medical organization where the study is being conducted.

5.1.1.8. Organization and control of Post-Marketing Research is carried out and is the responsibility of the medical department or the relevant medical functional unit/employees of the Company.

5.1.1.9. The data obtained during Post-Marketing Research should be statistically processed, analyzed, final report submitted to the authorized body, results should be published.

5.1.2. Where it is acceptable, employees of other departments of the Company may participate in addressing administrative tasks only (in particular, transfer of Post-Marketing Research documents from medical department (the relevant medical functional unit/employee) to the research center/researchers, and back). This participation must be carried out under the supervision of the medical department (the relevant medical functional unit/employee, who must ensure proper training of employees of other departments of the Company).

5.1.3. It is forbidden to conduct Post-Marketing Research under the guise of marketing research. If the differences between Marketing Research and the Post-Marketing Research specified in subparagraph 5.3. of the Code are not clear, the objectives of marketing research are subject to verification by medical specialists of the Company.

5.2. Studies Initiated by Investigator/Medical Organization

5.2.1. In order to perform scientific and medical clinical trials initiated by investigator/Medical organization (not the Company), the investigator/Medical organization may request research support from the Company. Control over the receipt and processing of applications for research initiated by researcher/institution, as well as administrative control, is carried out by employees

of the medical department or the relevant medical functional unit/employees of the Company.

5.2.2. The following requirements must also be met:

5.2.2.1. Research shall have a rationale and a scientific goal/objectives reflected in the study protocol. The Company cannot initiate a study, or directly participate in the planning or conduct of a study. The idea and concept of research should be developed by the investigator. The Company may provide advice on the concept of the research, but it cannot make significant changes to the original plan and the idea or concept.

5.2.2.2. Companies can only support duly qualified investigators/research groups in order to help them implement research interests of scientific value and meaningful scientific goals.

5.2.2.3. Investigator's support should not be in any way related to past, current or possible future prescriptions or recommendations of the Company's products. Participation of Healthcare Specialist in the study should not be an incentive to the recommendation/prescription, acquisition, sale and use of any particular Pharmaceutical Product..

5.2.2.4. Any financial support should be reasonable and reflect a fair market value. All conditions for the support provided must be in writing between the Company and the researcher/Medical Organization.

5.3. Company's Marketing Research

5.3.1. Marketing research conducted directly by Companies or by Companies with the involvement of marketing agencies is only possible in compliance with the requirements of the current legislation. At the same time, the Company has not right to pay remuneration to Healthcare Professionals for their participation in the Marketing Research. An exception may be cases of marketing research that require special scientific knowledge and significant labor costs on the part of Healthcare Specialist, provided that:

5.3.1.1. Marketing research is conducted with the involvement of independent agencies;

5.3.1.2. Healthcare professional is not informed and from the research materials it is not evident which Company is the commissioning client/sponsor of the study;

5.3.1.3. The Company does not participate in the selection and does not know which Healthcare Professionals will participate in the marketing research.

5.3.2. Any use of marketing research is not allowed: for the purpose of promoting or selling Pharmaceutical Products or for managing the opinion or conduct of research participants. For this reason, in the conduct of Marketing Research the following should be avoided: the mention of the trade name of the Pharmaceutical Product, unless this is required by the research objective; collecting personal data of Patients. Marketing research should not aim at further study of the efficacy or safety of the Pharmaceutical Product; Pre-approval Promotion of a Pharmaceutical Product or indications for its use, subject to authorization; obtaining confidential information about competing companies in order to discredit Pharmaceutical Products of competing companies, resulting in unfair competition.

5.4. Conferences, Congresses and Other Means of Verbal Communication

The main purpose of organizing allconferences, congresses and other promotional, scientific, educational or professional Events for Healthcare Professionals organized or sponsored by the Company, as well as financing participation of Healthcare Professionals therein should be the provision of scientific or educational information and/or informing Healthcare Professionals about Pharmaceutical Products.

The main purpose of sponsoring and organizing marketing activities by Companies for Healthcare Professionals may be informing Healthcare Professionals about Pharmaceutical Products, promoting the Company and its products.

5.4.1. Information concerning Sponsorship of Events or Financing Participation of Healthcare Professionals

5.4.1.1.1. If the Company or AIPM sponsors an conference, congress or other similar Event related to health care, or an educational program, then the following conditions must be observed:

5.4.1.1.2. the fact of sponsorship must be clearly specified in advance;

5.4.1.1.3. outputs of the Event (printed, audio-visual material, etc.) should accurately reflect the fulfillment of the set goals, the content of speeches and discussions;

5.4.1.2. Companies may make information about the sponsorship provided publicly available (in the form of cash or equivalent thereof).

5.4.1.3. If Company finances the participation of Healthcare Professionals in scientific, educational or professional Events, the following is mandatory:

5.4.1.3.1. No invitations to participate in professional Events can be used to encourage Healthcare Professionals to prescribe, supply, administer, recommend or sell Pharmaceutical Products;

5.4.1.3.2. payment of speaking honoraria at the Events (taking into account fair market value) and reimbursement of expenses, including registration fee, transportation costs, visa support, medical insurance, accommodation and meals for speakers/lecturers is an acceptable practice;

5.4.1.3.3. Reimbursement of expenses related to participation of Healthcare Professionals in an educational Event with an educational purpose at the expense of the Company (registration fee, transportation costs, visa support, medical insurance, accommodation and meals) is an acceptable practice;

5.4.1.3.4. It is unacceptable to provide Healthcare Professionals with financial compensation for the time spent on participating in the Event.

5.4.2. Venue of the Event

5.4.2.1. Events should be held in a place corresponding to the main objective of the Event. Companies are not allowed to organize Events in places that are considered (or are advertised) primarily as entertainment, tourist destinations, or are known for their extravagance. Events should not be held, for example, in such places as ski resorts, SPA, isolated recreation areas, other popular tourist resorts, or in places with similar characteristics.

5.4.2.2. 4-star hotels are the recommended level for hosting and sponsoring Events, and for Healthcare Professionals' accommodation, the choice of 5-star hotels is permissible in the

absence of places in other hotels of the lower class, in order to ensure safety of participants in the Event or other reasonably justified circumstances (for example, when the choice of a 5-star hotel is made by the external facilitator of the Event (not by the Company) and accommodation of participants is organized in the same hotel where the Event is held.

5.4.2.3. The decision on whether to fly economy or business class is regulated by internal policies of Companies.

5.4.3. Other Restrictions

5.4.3.1.1. Healthcare professionals should not be provided with material considerations that do not relate to the payment of speech honoraria or preparation of materials. The amount of allowable remuneration must correspond to the fair market value, which should be based on market research.

5.4.3.1.2. Provision of drinks and/or meals (coffee break, lunch, dinner, etc.) in connection with the professional Event should be secondary to the main objective of the Event and be provided to:

5.4.3.1.3. participants of the Event only;

5.4.3.1.4. be moderate and justified for local conditions.

5.4.3.2. Only background music and/or performance of a local performer secondary to the provided meals, which is initially available at the place of catering, is allowed, provided that the Company does not pay for them separately.

5.4.3.3. Companies may not organize and pay for cultural and recreational activities or tours, even if they are secondary to the educational Event.

5.4.3.4. Companies are prohibited from organizing or financing Healthcare Special Events outside their country, except for the situation when:

5.4.3.4.1. most of the invited Healthcare Professionals represent other countries, and from the logistic point of view it is advisable to conduct Events outside of Kazakhstan.

5.4.3.4.2. resources or expertise that are the object or the subject of the Event are located in another country, and therefore logistically it is expedient to conduct the Event outside of Kazakhstan (“International Events”).

5.5. Interaction with Patients and Patient Organizations

5.5.1. The pharmaceutical industry shares many interests of Patients and Patient Organizations, but at the same time must respect their independence.

5.5.2. Companies interaction with the Patient organizations is possible to solve the following tasks: to study the opinion of Patients on the impact of a disease on the quality of Patients’ lives, and the views of caregivers that can help optimize the clinical research program of Pharmaceutical Products and accelerate the development of those that best meet the needs of Patients; implementation of information support of Patient associations by responding to requests according to established rules; maintaining patient registries provided that the legislation on the protection of personal data and medical confidentiality is strictly observed; organization of campaigns to inform the general public about a disease; cooperation in organizing the provision to Medical Organizations of an unlisted Pharmaceutical Product for the provision of medical assistance to specific Patients

for their vital indications; charitable assistance; other cases that are in compliance with the legislation of the Republic of Kazakhstan. Interaction should never be a hidden Promotion of the Company's products.

5.5.3. In Company’s cooperation with a Patient Organization, the fact and nature of such cooperation should be clearly disclosed by the Company in its documents. However, the Company can only be the source of funding for the charitable and/or social project of the Patient Organization upon receipt of a corresponding written request from the Patient Organization to implement the programs of such an organization aimed at preventing and protecting the health of citizens, promoting healthy lifestyles, helping disadvantaged social groups, unless such funding (donation) is directly or indirectly aimed at encouraging the adoption by such Patient organization of any decisions in the course of its statutory activities in favor of the Company or its products. However, in any case, such a Company should not restrict the rights of other Companies to finance the same projects of the Patient Organization at their request.

5.5.4. Any relationship between the Company and Patient Organizations must be clearly documented.

5.5.5. Companies may provide financial support for activities of Patient Organizations, provided that the primary goal of the event is educational or scientific, and for other common purposes that contribute to the fulfillment of the mission of such an organization. In the case of providing funding for the activities of Patient Organization, the Company must ensure that the venue and conditions for the event meet the requirements for the established limits of warm hospitality. Financing of Patient Organizations should not be related to Product Promotion. Company should not have a controlling or prevailing financial position when it comes to financing of Patient Organizations, in order to avoid creating obstacles to the independence of such an organization.

5.5.6. Interaction with Patients should not replace the role of the attending physician of the Patient in making decisions about their individual treatment. Company employees must not provide any personal, medical or drug-related recommendations to Patients and are always required to refer Patient to his or her attending physician for all matters related to individual medical care. Interaction should never constitute a hidden promotion of the Company's products.

5.6. Gifts

A gift is any item that is provided to Healthcare Professionals free of charge. The nominal value of items per Healthcare Specialist provided at a time shall not exceed the amount of 2 MCI established by the legislation of the Republic of Kazakhstan for the corresponding year, except for those regulated in subparagraph 5.6.2. of this Code.

At the same time, gifts cannot be given in connection with the implementation by a Healthcare Specialist of any acts (inaction) falling within their competence in favor of the company, by prior agreement for previously performed legal acts, and for the purpose of encouraging the appointment, recommendation or procurement of Pharmaceutical Products and other illegal purpose.

Giving any gifts, rewards, benefits, services, advantages and other material (non-material) benefits, regardless of their value, to persons holding a responsible public office, to persons

authorized to perform public functions (including Civil Servants), to persons equated thereto, to persons authorized to perform state functions, and officials is prohibited.

In addition to the above restrictions, it is not allowed to offer or give to Healthcare Professionals any gifts in the form of cash or cash equivalent (gift certificates/vouchers/payments), or to pay any personal costs of healthcare professionals. Also, gifts for personal use (such as tickets for sports or entertainment events, electronic devices, etc.) are not allowed.

Restrictions and prohibitions established by this paragraph are applicable to all types of gifts and other benefits and advantages provided for in this Code, except as specifically stipulated in the Code.

5.6.1. Items as Part of Cultural Courtesies

5.6.1.1. Gifts, unrelated to medical practice, can be given free of charge on special occasions as part of cultural courtesies and generally accepted practice in the Republic of Kazakhstan, but not more than 2 times per year to one professional.

5.6.1.2. A gift should not be given for purposes, or give grounds to believe that they are used to encourage the prescription or recommendation of Pharmaceutical Products and (or) for other illegal purposes. Giving gifts should not be perceived as “favor for a favor”, i.e. in connection with any acts (inaction) of Healthcare Professional falling within their competence, in favor of the Company, a preliminary agreement for previously performed legal acts.

5.6.2. Items of Medical Utility and Information and Educational Materials

5.6.2.1. **Items of Medical Utility** – provision of medical (functional) products is allowed provided that the restrictions stipulated by the legislation of the Republic of Kazakhstan relating to the current practice of Healthcare professional are complied with, and they are used in the provision of medical services to a Patient (for example, a phonendoscope, tendon hammer, robe, surgical suit, etc.) costing no more than 5 MCI.

5.6.2.2. **Information Materials** - reference and information materials, as well as other educational materials (medical publications) may be given to Healthcare Professionals and healthcare organizations free of charge, provided that they really serve educational purposes. Any such materials (including printed ones) must be presented in a clear and legible form. Scientific justification and information about Pharmaceutical Product must comply with the requirements of the legislation of the Republic of Kazakhstan and this Code.

5.6.3. Promotional Tools

It is allowed to provide promotional tools in the form of industrial products (for example, pens, notebooks, mouse pads, calendars, cubes, etc.), costing no more than 2 MCIs related to the practice of the Healthcare Professional, bearing the Company Logo and (or) the trade name (or trade mark) of the Pharmaceutical Product and (or) the international non-proprietary name of the Medicine, subject to the restrictions provided for by the legislation of the Republic of Kazakhstan. Industrial products intended for personal use by healthcare professionals (music discs, paintings, food baskets, etc.) cannot be used as a promotional tool. Educational materials are not included in this category of tools.

5.6.4. Samples

5.6.4.1. It is allowed to distribute samples Medicines with OTC status and medical devices, with the purpose of acquainting Healthcare Professionals and/or Patients, with a scientific or educational purpose, with the purpose of informing Patients and for other purposes not prohibited by the legislation of the Republic of Kazakhstan.

5.6.4.2. Samples should not be distributed to encourage Healthcare Professionals to prescribe, supply, administer, recommend or sell Medicines or medical products.

5.6.4.3. Companies should have appropriate systems in place for monitoring and accounting of samples provided to Healthcare Professionals, including, to track these samples while they are at the disposal of Medical Representatives.

5.6.4.4. The samples packaging should bear the appropriate markings ("Not for Sale" or "Free Sample"), so that it is impossible to resell them or use them otherwise.

5.7. Frequency and Scope of Mailings

5.7.1. Frequency and scope of mailing printed material to Healthcare Professionals should be reasonable.

5.7.2. Requests of Healthcare Professionals to remove their names from the advertising materials mailing lists should be respected and complied with.

5.7.3. In order to provide (where necessary) information on any side effects, precautions, warnings, etc. for the Promoted Pharmaceutical Products, complete mailing lists should be maintained.

5.8. Internet Resources

5.8.1. This Code extends to the Promotion of Pharmaceutical Products on the territory of the Republic of Kazakhstan on any Internet resources, regardless of the place of hosting and the domain name zone.

5.8.2. Promotion of Pharmaceutical Products on the Internet must comply with the requirements established by the legislation and this Code.

5.8.3. Provision of information on Pharmaceutical Products, dispensed on Doctor's prescription (RX), must be carried out in the Internet resources sections, access to which is exclusively provided to Healthcare Professionals.

6. PROCEUDRE FOR INVESTIGATION OF CODE NON-COMPLIANCE CLAIMS

6.1. In case of any statements on issues of improper compliance by the Company with ethical norms and provisions of this Code, the parties concerned shall attempt to resolve the problems that have arisen through negotiations.

6.2. Any claim on improper compliance with the provisions of the Code shall be sent in writing to the Ethics Committee with a detailed description of the circumstances and the provision of evidence that caused such a claim to be sent.

6.3. The Ethics Committee shall review the reports at meetings held in accordance with the annual schedule of meetings of the Ethics Committee or at extraordinary meetings where representatives of the Applicant Company and the Respondent Company (the Company, with respect to whom the claim is made) must be compulsorily present, and being guided by the provisions of this Code, shall make a conclusion about the fact of violation of ethical

Promotion of the Pharmaceutical Product. In the absence of one of the parties (representatives of the Applicant Company or the Respondent Company), the Ethics Committee shall review the report received and make a decision based on the data received, being guided by the requirements of this Code and the legislation of the Republic of Kazakhstan.

6.4. The Respondent Company in case of acknowledgment of the violation committed, shall within one month inform (in writing) all market participants who received unethical information, about the fact of the violation, and of the steps taken by the Company to remedy the breaches.

6.5. If the Respondent Company refuses to acknowledge the fact of violation of this Code, the initial complaint may be forwarded by the Applicant Company or by the AIPM to competent government bodies.

6.6. In order to conduct expert examination and study of the circumstances related to unethical conduct of a Company, the AIPM Secretariat, on behalf of the Supervisory Board, may recruit external consultants (for example, a law firm) specializing in these matters.

6.7. Upon final confirmation of the fact of breach of the Code, all costs of record keeping, including compensation of advance payment on the part of the Reporting Company, shall be borne by the Breaching Company (i.e., the Company found guilty of violating the Code).

6.8. At the same time, the Breaching Company shall be obliged to inform in writing, within one month, all AIPM members who had received unethical information, about the fact of violation and the steps taken by the Company to remedy the breaches.

6.9. Based on resolution of the General Meeting of AIPM, the following sanctions may be imposed on the Breaching Company:

6.9.1. Written warning to the Respondent Company

6.9.2. Written notification of the headquarters (head office) of the Respondent Company Group about unethical behavior on the market

6.9.3. Exclusion from the AIPM.

6.10. In determining the absence of violations of this Code, all costs for the document management, review and expert examination of the report shall be borne by the Applicant Company.

6.11. If more than one fact (case) of violation of this Code is established by the AIPM Member Company, the AIPM Secretariat, on behalf of the AIPM Supervisory Board, shall inform the headquarters (head office) of the Breaching Company Group thereof in writing.

6.12. The headquarters (head office) of the Breaching Company Group shall be obliged within one month to submit to the AIPM an internal plan aimed at correcting the violations committed and bringing the activities of the Breaching Company into compliance with the provisions of this Code.

6.13. In case of failure to submit the above plan or where the plan is found unsatisfactory by the AIPM Supervisory Board, the Company shall be excluded from the AIPM.

7. REFERENCES

7.1. Code of Professional Conduct of IFPMA (International Federation of Pharmaceutical Manufacturers and Associations), version from 2012.

7.2. The Civil Code of the Republic of Kazakhstan (GENERAL PART) dated December 27, 1994.

7.3. The Code of the Republic of Kazakhstan “On People's Health and Healthcare System” dated September 18, 2009 No. 193-IV

7.4. The Law of the Republic of Kazakhstan “On Advertising” dated December 19, 2003 No. 508

7.5. Advertising Rules for medicines, medical devices and medical equipment in the Republic of Kazakhstan dated February 27, 2015 No. 105

7.6. The Code of the European Federation of Pharmaceutical Industry and Associations (EFPIA HCP Code) dated 06.06.2014

7.7. Anticorruption Law of the Republic of Kazakhstan dated November 18, 2015 No. 410-V

7.8. The Law of the Republic of Kazakhstan “On Public Service of the Republic of Kazakhstan” dated November 23, 2015 No. 416-V

7.9. The Code of the Republic of Kazakhstan “On Taxes and Other Obligatory Payments to the Budget” (Tax Code) dated December 10, 2008.

7.10. The Code of Good Practices of the Association of International Pharmaceutical Manufacturers (AIPM) of the Russian Federation, revision of 2015