Ассоциация международных фармацевтических производителей в Республике Казахстан

Association of International Pharmaceutical Manufacturers in Kazakhstan

ҚАЗАҚСТАН РЕСПУБЛИКАСЫНДАҒЫ ХАЛЫҚАРАЛЫҚ ФАРМАЦЕВТИКАЛЫҚ ӨНДІРУШІЛЕР ҚАУЫМДАСТЫҒЫНЫҢ ЭТИКА КОДЕКСІ

ЭТИЧЕСКИЙ КОДЕКС АССОЦИАЦИИ МЕЖДУНАРОДНЫХ ФАРМАЦЕВТИЧЕСКИХ ПРОИЗВОДИТЕЛЕЙ В РЕСПУБЛИКЕ КАЗАХСТАН

CODE OF ETHICS Of the ASSOCIATION OF INTERNATIONAL PHARMACEUTICAL MANUFACTURERS IN THE REPUBLIC OF KAZAKHSTAN

Алматы

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CODE OF ETHICS
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INTRODUCTION

The Code of Ethics (hereinafter referred to as the "Code") of the Association of International Pharmaceutical Manufacturers (hereinafter referred to as "AIPM") of the Republic of Kazakhstan had been developed on the basis of international marketing practices codes adopted in the research pharmaceutical industry with view to the requirements of the legislation of the Republic of Kazakhstan, and sets out the ethical standards, which all members of the AIPM are required to follow when engaging in Promotion and Marketing of Pharmaceutical Products in the Republic of Kazakhstan.

The provisions of the Code are intended to help AIPM members develop and apply standards of transparent and responsible Promotion and Marketing, taking into account the interests of public health in the Republic of Kazakhstan, and also serve as a tool for addressing any ethical issues between AIPM members in the event of disputes.

The Code represents a number of additional fundamental principles that guide AIPM members when carrying out Marketing and Promotion of Pharmaceutical Products in the Republic of Kazakhstan, as the legislation of the Republic of Kazakhstan in this area always takes precedence.

The Code prescribes that responsibility and control over compliance with high standards in the Promotion of Pharmaceutical Products in the Republic of Kazakhstan rests with the members of the AIPM. All AIPM members must make correct and conscientious decisions, first of all, focusing on the interests of their Patient. Promotion of Pharmaceutical Products in violation of the Code is unacceptable.

All AIPM members undertake not to distribute any materials that diverge from the provisions and principles of this Code, and to avoid any actions in the field of Marketing of Pharmaceutical Products that are contrary to this document.

Respect for the individual, patient focus, transparency and adherence to ethical standards are the values that should underlie everything that AIPM members do.

The management of [each company - a member of the AIPM (hereinafter referred to as the "Company")] is obliged to ensure the activities of the Company in accordance with the requirements of the legislation of the Republic of Kazakhstan and this Code. Management undertakes to take action in relation to each identified and proven violation.

Each newly joined AIPM Company is obliged to ensure compliance with the 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 from the date of joining the AIPM, and make new employees and persons engaged by the Company aware thereof.

This Code, as well as all any amendments made to the Code, come into force for the Company after 6 months from the date of their adoption.

This Code, as well as any amendments and supplements thereto, are approved

by a resolution of the AIPM General Meeting. Any amendments and supplements to this Code may be made at the initiative of any Company.

1. KEY TERMS USED IN THIS CODE AND THEIR DEFINITIONS

1.1. **Medicines*** - products that are, or contain pharmacologically active substances that come into contact with the human body or penetrate its organs and tissues, intended for the prevention, diagnosis and treatment of diseases, as well as changes in the condition and functions of the body - medicinal substance, medicinal raw materials, bulk medicinal products, medicinal preparations.

1.2. **Pharmaceutical Product** – Medicines, medical products and medical equipment.

1.3. **Post-Authorization Clinical Study** – a study of a Pharmaceutical product conducted in the Republic of Kazakhstan after state registration 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-Authorization Clinical Intervention Study** – a study of a Pharmaceutical product involving a human as a research subject, in which a doctor, on the basis of an interventional clinical trial protocol corresponding to the procedure for conducting clinical trials determined by an authorized body, prescribes a special intervention to the research subjects. In an interventional study, study subjects undergo a diagnostic, treatment, or other type of intervention that may be randomly or nonrandomly assigned, with further observation of the Patients and assessment of biomedical and health outcomes.

1.5. **Post-Authorization Clinical Non-Interventional Study** – a study performed after state registration of a Pharmaceutical product that is prescribed within the framework of medical practice in accordance with the instructions for medical use approved by the authorized body. The protocol for a non-interventional study, consistent with the procedure for conducting clinical trials determined by the authorized body, does not predetermine the administration of the Pharmaceutical product to the study subject and its inclusion in the study, but describes epidemiological methods for collecting data on the safety and effectiveness of the Pharmaceutical product. Study subjects are not subject to additional diagnostic or monitoring procedures.

1.6. **Patient Support Program (PSP)** is any event or system of events initiated, organized, conducted and/or financed by pharmaceutical companies independently, or with the involvement of third parties/organizations, within the framework of which service and/or information about the disease and/or its treatment is provided to patients, that is, individuals, at the time of diagnosis and/or who have been properly diagnosed and treated, and/or individuals caring for them.

The following are not PSPs in the context of the current Code:

- clinical researches;
- observational studies, studies of real clinical practice;
- early access programs to pharmaceutical products;
- programs to increase public awareness about the disease;
- discounts for distributors;
- co-financing programs (with legal entities or government bodies);
- other programs not suitable for the PSP.

1.7. **Epidemiological study** is a study of the prevalence, occurrence and severity of various diseases or medical indicators of health conditions in order to determine the causes of their development, risk factors and mutual influence in different population groups.

1.8. **Promotion** is any activity, including but not limited to Advertising, carried out, organized or financed by a pharmaceutical company for the purpose of promoting the prescription, supply, use, recommendation or consumption of a Pharmaceutical Product.

1.9. **Marketing** is research, analysis, planning and forecasting in the field of production and circulation of Pharmaceutical products in order to determine measures to create better economic conditions for the production and circulation of Pharmaceutical products, including the characteristics of Pharmaceutical products, development of a pricing strategy and promotion strategy.

1.10. **Healthcare professionals –** doctors and other medical workers, heads of medical organizations, pharmaceutical workers, including pharmacists and pharmacists, heads of pharmacy organizations and other specialists whose professional activities are pharmaceutical products and who, in the course of their professional activities, have the right to prescribe, recommend, purchase, dispense or use pharmaceutical products.

1.11. **Medical representative** – an employee of the Company or its involved person who has a completed medical, pharmaceutical education, confirmed by a diploma, or a specially trained employee of the Company to the extent that he can competently explain the mechanism of action of the Pharmaceutical Products presented, their therapeutic effect and impact on the pathogenetic mechanisms of the disease. The duties of the Medical Representative include maintaining contacts with Healthcare Professionals or other relevant persons for the purpose of Promotion of Pharmaceutical Products.

1.12. **Events –** congresses, conferences, symposiums, seminars, round tables, and any other marketing, scientific, educational events held for the purpose of exchanging scientific and/or medical information, training healthcare professionals in modern aspects of diagnosis, treatment of diseases, including providing information on Pharmaceutical products .

1.13. **Company**– current member of the AIPM.

1.14. **Ethics Committee** – the AIPM Ethics Committee is a permanent collegial governing body and in its activities is guided by the legislation of the Republic of Kazakhstan, the Charter of the Association, and decisions of the General Meeting of AIPM members.

1.15. **Medical Organization** - a legal entity, regardless of the organizational and legal form, carrying out medical activities as the main (statutory) type of activity on the basis of a license issued in the manner established by the legislation of the Republic of Kazakhstan. Individual entrepreneurs carrying out medical activities are treated as medical organizations.

1.16. **Government Official**** is a citizen of the Republic of Kazakhstan who, in accordance with the procedure established by the legislation of the Republic of Kazakhstan, holds a public position in a state body paid from the republican or local budgets or from the funds of the National Bank of the Republic of Kazakhstan and exercises official powers in order to implement the tasks and functions of the state.

1.17. **Advertising of Medicines, medical products and medical equipment (hereinafter referred to as advertising)***** - information distributed and posted in any form, by any means, intended for an indefinite number of persons, containing individual information or a set of information about Medicines, medical devices and medical equipment, facilitating their promotion and sale.

1.18. **Patient organizations** are non-profit organizations specializing in certain diseases or aspects of health care, representing the interests and needs of Patients, their families and/or caregivers of sick or elderly people. These groups are primarily composed of Patients and/or caregivers (family/friends), but may also include consumers, older adults, women, social minorities, or caregivers of Patients, and may be led by advocacy professionals and interests that may or may not have a personal connection to a particular disease.

1.19. **Patient** – an individual who has a specific disease, disorder, or other medical pathology.

1.20. **Social Media** – digital communication systems that allow users to create content and share it with other users.

1.21. **Blogger** – an Internet user who runs his own channel, website or page on social networks or other communication platforms. For his subscribers, he is an opinion leader in a certain area.

1.22. **Brief Application Information** – information that includes approved indications for use, if necessary, in combination with dosage and method of

administration, a summary of contraindications, precautions and undesirable effects, links to instructions for medical use, contacts of the pharmaceutical company for sending a request for instructions for medical use .

** - for the purposes of this Code, the term "medicinal product" is used as defined in paragraphs. 18 clause 1 of article 1 of the Code of the Republic of Kazakhstan on health and the healthcare system, and includes prescription and over-the-counter medicines.*

***- for the purposes of this Code, the term "civil servant" is used as defined in paragraph 12 of Art. 1 of the Law of the Republic of Kazakhstan "On the civil service of the Republic of Kazakhstan".*

****- for the purposes of this Code, the term "advertising" is used as defined in paragraph 1 of clause 2) of the Rules for advertising of medicines, medical products and medical equipment, adopted by Order No. 105 of the Ministry of Health of the Republic of Kazakhstan dated 02/27/2015.*

2. FUNCTIONING OF THE ETHICS COMMITTEE

2.1. Purpose of the Ethics Committee

The Ethics Committee was created to ensure coordination and supervision of the activities of AIPM members aimed at complying with the ethical principles of marketing practices adopted in the research and development pharmaceutical industry.

2.2. Competence of the Ethics Committee

The competence of the Ethics Committee includes:

- consideration of applications and resolution of issues and problems related to improper compliance with ethical standards and rules of this Code;

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

2.3. Members of the Ethics Committee

2.3.1. An ethics committee is created consisting of at least five members.

2.3.2. Members of the Ethics Committee are elected by the General Meeting of the AIPM for a period until the next annual General Meeting by a simple majori-

ty of votes present at the General Meeting of members of the AIPM.

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

2.3.4. The President and members of the AIPM Board cannot be elected to the Ethics Committee.

2.4. Rights and Responsibilities of Members of the Ethics Committee

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

2.4.2. Members of the Ethics Committee shall be obliged to ensure the confidentiality of information received and the non-disclosure of information that has become known to them in the process of participating in the operation of the Ethics Committee.

2.4.3. Members of the Ethics Committee, when exercising rights and performing duties, must act in the interests of compliance with the ethical standards of this Code, exercise rights and fulfill duties in relation 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 the 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. The Chairman of the Ethics Committee can only be the head of the Company.

2.5.3. The Chairman of the Ethics Committee organizes its work, convenes meetings of the Ethics Committee and presides over them, and organizes the keeping of minutes at meetings.

2.5.4. The Ethics Committee may elect Deputy Chairmen of the Ethics Committee, who, in his absence or on his instructions, perform its functions.

2.6. Meetings of the Ethics Committee

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

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 in connection with the receipt of a statement from any Company regarding improper compliance with the provisions of the Code.

2.7. Proceedings of the Ethics Committee

2.7.1. The quorum for meetings of the Ethics Committee is a simple majority of the members of the Ethics Committee. Decisions of the Ethics Committee are made by a simple majority of votes of the present members of the Ethics Committee. The results of meetings of the ethics committee must be reflected in the minutes of the meetings. If an even number of members of the Ethics Committee participate in voting at a meeting and the votes are divided equally, the vote of the Chairman of the Ethics Committee is decisive.

2.7.2. A representative of a Company that has reported any violation of the Code by another Company, and a representative of a Company that has been the subject of a complaint about its violation of the Code, may not take part in a vote by the Ethics Committee on the issue regarding such a complaint.

2.7.3. Members of the Ethics Committee participate in its work free of charge.

3. REQUIREMENTS FOR THE WORK OF MEDICAL REPRESENTATIVES

3.1. Role, Preparation and Control of the Work of Medical Representatives

3.1.1. Taking into account the interests of public health in the Republic of Kazakhstan, ethical interaction between participants in the pharmaceutical market involves a continuous process of providing healthcare professionals and medical organizations with balanced, accurate, reliable and objective information about Pharmaceutical products, in order to make 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 about Pharmaceutical products and treatment methods, within the limits of the approved instructions for medical use, unless otherwise provided by the Code.

3.1.3. The Company shall be responsible for the content and form of information transmitted by Medical Representatives.

3.1.4. Companies shall provide training to Medical Representatives to ensure that such information is provided in an accurate, responsible and ethical manner. Training of Medical Representatives must be carried out on a regular basis and include information on relevant national and international legislation, internal Company policies and procedures, and the requirements of this Code.

3.1.5. In their activities, medical representatives shall be guided by the requirements of the legislation of the Republic of Kazakhstan, the ethical standards of the Company they represent, as well as the requirements of this Code.

3.1.6. The company provides control over:

3.1.6.1. the activities of Medical Representatives in relation to the quality of the information they provide during visits and presentations, and the ethics of their behavior;

3.1.6.2. professional level of Medical representatives;

3.1.6.3. visits to healthcare professionals that do not contradict the requirements of the legislation of the Republic of Kazakhstan.

3.2. Responsibilities of Medical Representatives

3.2.1. Information interaction with Healthcare Professionals on all medical aspects of the use of the Company's Pharmaceutical Products, whose interests they represent, through individual visits and participation in collective events of Healthcare Professionals in accordance with the requirements of the legislation of the Republic of Kazakhstan.

3.2.2. Build 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, the Company whose interests they represent, as well as representatives of competing enterprises, institutions and organizations.

3.2.3. The medical representative must provide upon request:

3.2.3.1. instructions for medical use about the pharmaceutical product being informed;

3.2.3.2. information on the conditions for dispensing from pharmacies (classification as prescription or without a doctor's prescription, dispensed to privileged categories of citizens, etc.) of the pharmaceutical product and its availability in pharmacies.

3.2.4. Medical representatives are obliged to immediately convey to the relevant responsible employee of the Company information on the practical use of the Company's Pharmaceutical Product, including side effects, quality complaints, falsifications, etc., received during a visit to Healthcare Professionals or from other sources.

3.3. Restrictions Imposed on Medical Representatives

3.3.1. The medical representative must comply with the schedule and hours of visits specified by the Healthcare Professional, request information about the duration of the visit desired by the Healthcare Professional, and not interfere with the normal functioning of the Medical Organization.

3.3.2. It is unacceptable to speak disparagingly about the products, activities or representatives of competing companies. The language used must invariably be balanced and scientific in nature, and cannot be of an extreme type or emotional nature. Comparative data must be based only on published scientific data that meets the requirements of evidence-based medicine (randomized multicenter studies, publications in peer-reviewed journals, etc.), while complying with other requirements of this Code for information about Pharmaceutical Products. When using the results of clinical studies conducted on original drugs, it is necessary to indicate that this study relates to the original drug.

3.3.3. Medical representatives are not entitled to:

3.3.4. Provide healthcare professionals with:

3.3.4.1. cash or cash equivalents such as a gift certificate/voucher;

3.3.4.2. payment for entertainment, recreation, travel to a vacation spot;

3.3.4.3. gifts (except as regulated in section 5.6. of this Code).

3.3.5. Organize the participation of Healthcare Professionals in festive or entertainment events at the expense of the Company;

3.3.6. Conclude written or oral agreements with Healthcare Professionals on the prescription or recommendation of Pharmaceutical Products to Patients for payment or other material remuneration (except for agreements on clinical trials of medicines, clinical trials of medical devices);

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

3.3.8. Provide healthcare professionals with recommendations and scientific information material on the use of Medicines for indications not registered in the Republic of Kazakhstan, unless otherwise established by the Code;

3.3.9. Create inconvenience to the work of healthcare professionals with the frequency, time and duration, and manner of visits.

4. GENERAL REQUIREMENTS FOR PROMOTION AND MARKETING

4.1. Promotion Standards

4.1.1. Information about Pharmaceutical Products must be accurate, understandable, objective and presented in a manner that complies with legal and ethi-

cal standards. Information should be provided on both the effectiveness and safety of Pharmaceutical Products. The information must be balanced, based on the latest assessment of all relevant evidence, and must clearly reflect that evidence. In addition, if new information becomes available about Pharmaceutical Products that significantly changes the safety and/or efficacy information of the products, all information materials regarding such Pharmaceutical Products must be reviewed and updated as necessary or withdrawn from circulation.

4.1.2. Promotion of prescription products to a general audience directly or through third parties is prohibited. Promotion of prescription products may only be directed to Healthcare Professionals.

4.1.3. Any claims about the therapeutic effect must not exceed the data contained in the approved instructions for use of the Pharmaceutical product.

4.1.4. Any exaggeration, blanket statements or ambiguity should be avoided when presenting any information about a Pharmaceutical Product.

4.1.5. When using the results of clinical studies conducted on original drugs, it is necessary to indicate that this study relates to the original drug.

4.1.6. Information, statements and comparisons contained in the material must be based on reliable statistical data, and must be based on significant and comparable properties of the active substances and Pharmaceutical products being compared.

4.1.7. A comparative presentation of Pharmaceutical Products cannot:

4.1.7.1. improperly benefit from the fame of a competitor's brand, trade name or other distinctive features;

4.1.7.2. use discredit or disparagement of trademarks, trade names, other distinctive features or position of a competitor;

4.1.7.3. make comparisons between the brands and trade names of the advertiser and the competitor.

4.1.8. Information materials (printed or electronic) containing claims about the benefits of Pharmaceutical Products must include:

4.1.8.1. brief or complete instructions for medical use (or an indication of where such information can be found);

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

4.1.8.3. contact information of the Company responsible for the content of the material.

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

4.1.10. Presentations of healthcare professionals speaking with the support of the Company at scientific and educational events of third parties must highlight a medical problem, have a corresponding scientific or educational direction, and reflect treatment methods. It is prohibited to place images of Pharmaceutical products in presentations.

4.2. Materials Distributed by the Company

All materials in any form (including printed, audio-visual, electronic or other) must contain the information required by the laws of the Republic of Kazakhstan, as well as, among other things, the name, address, contact information of the Company responsible for the material, through which the additional information may be obtained.

Promotion Materials, including those Posted on the Internet

All Promotion materials must contain the following:

- name of the pharmaceutical product;
- generally accepted names of active substances;
- name and address of the pharmaceutical company or organization representing its interests in the territory of the Republic of Kazakhstan;
- date of release of the material;
- abbreviated information on the use of the Pharmaceutical Product. Brief application information and extended information on the Pharmaceutical Product can be provided through the use of digital access forms (for example, QR codes, links, etc.).

If, in addition to the expanded volume of information, instructions for medical use, any additional information is provided, it must fully comply with the requirements of the legislation of the Republic of Kazakhstan and this Code.

Scientific Evidence and Facts

4.2.1. Information materials must be based on current assessments consistent with scientific evidence and not create false or misleading impressions.

4.2.2. Whenever specific claims about a Pharmaceutical Product are made in advertising materials, clear references must be made to supporting information.

4.2.3. Scientific data underlying information materials and recommendations for the use of Pharmaceutical Products must be accessible and provided upon request of Medical Organizations.

4.2.4. Compliance with the requirements for information about the product on labels, packaging, instructions for medical use, bulletins and advertising, described by the laws of the Republic of Kazakhstan and documents of the

competent authorities of the Republic of Kazakhstan in the field of health care, which have legal force in the Republic of Kazakhstan.

4.2.5. Information containing indications for use, contraindications, warnings, precautions, adverse reactions and dosage must comply with the approved instructions for medical use.

4.3. Safety Information

4.3.1. Information, concerning safety of Pharmaceutical products (contraindications, precautions, adverse reactions, etc.) must be consistently and appropriately presented and also meet the international requirements of medical practice. It is not allowed to present a Pharmaceutical product as the safest, most effective or unique. However, statements of effectiveness and safety can only be made if they are supported by published scientific or clinical data.

4.3.2. Companies must strictly comply with the requirements of the legislation of the Republic of Kazakhstan regarding the provision of pharmacological safety information.

4.4. Pre-Authorization Information

4.4.1. A pharmaceutical product cannot be promoted until registration is approved in the Republic of Kazakhstan.

4.4.2. This provision is not intended to impede the right of the scientific community and the public to be fully informed regarding scientific and medical progress. It is not intended to limit the full and proper exchange of scientific information regarding Pharmaceutical Products, including the appropriate dissemination of research results through scientific or public media, or at scientific conferences, in accordance with the laws of the Republic of Kazakhstan. There is also no restriction on public disclosure of information to shareholders and other persons in relation to any Pharmaceutical Product, unless prohibited by applicable law.

4.4.3. Providing information about unregistered Pharmaceutical products, or about indications not specified in the instructions for use of a registered Medicine, is not Promotion and is permitted if the following conditions are simultaneously met:

4.4.3.1. such information is provided in response to an individual request from a Healthcare Professional, made by him independently on his own initiative, as well as during speeches at Events for the purpose of exchanging scientific experience;

4.4.3.2. such requests are documented by the Company;

4.4.3.3. the answer is provided by a Company employee with a medical education

who is not directly related to the sales of Pharmaceutical products;

4.4.4.4. the response is transmitted to the person requesting this information.

4.4.4. Answers must be based on the principles of evidence-based medicine, available scientific information, clinical research data

4.5. References

4.5.1. In the case where published scientific research is used as a source in reference and information material, a clear reference to this circumstance must be made in the printed material.

4.5.2. Quotations from the medical literature or personal statements must not change or distort the meaning or significance intended by the author or clinical investigator of the work or study.

4.5.3. In cases where specific statements about a Pharmaceutical Product are made in Promotion materials, they must be accompanied by links to supporting sources of information - scientific, medical sources.

4.6. Hidden and Misleading Advertising

4.6.1. Advertising of Pharmaceutical products must be carried out in accordance with the legislation of the Republic of Kazakhstan. Inappropriate advertising - hidden, unethical, deliberately false, unreliable and dishonest Advertising, in which there were violations of the requirements for its content, time, place and method of distribution, or placement, is prohibited.

4.6.2. Advertising and information products (mailing, advertisements in medical journals, other printed publications and media, including Internet resources) should not hide or veil true information, and also have an unconscious impact on the consumer's perception and instincts, thus intentional Hidden use of advertising and information materials is not permitted. Third party materials financed by the Company, which are not promotional in nature, must indicate information about the Company that provided the financing. It is prohibited to disguise marketing activities and Promotion of Pharmaceutical Products.

4.6.3. An example of hidden Advertising is information that does not comply with legal requirements, including that which has an unconscious impact on the consumer's perception, instincts, as well as information in its content that is advertising, but has not been assessed by an expert organization for compliance with the law. This statement does not apply to scientific articles and their reprints (copies), as well as to publications of press releases, information about conferences and symposiums, and informational articles on the issue paid for by the Companies, provided that they do not contain advertising statements about Pharmaceutical Products.

4.7. Procedural Standards of the Companies

4.7.1. Advertising, Promotion and scientific information materials distributed by the Company to healthcare professionals, Patient organizations, professional associations, including presentations by speakers, Healthcare Professionals speaking with the support of the Company, must be approved by the relevant functions of the Company before their distribution, publication or demonstration, including, in certain circumstances, the permission of a responsible person with appropriate scientific or medical qualifications. If necessary, the Company has the right to obtain advice from third parties with relevant competence. Involving consultants does not relieve the Company of responsibility.

4.7.2. In cases established by law, Advertising must undergo an expert opinion or other applicable procedures of the competent authorities (organizations) of the Republic of Kazakhstan.

4.7.3. When distributing advertising, promotion, scientific and information materials, 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 must constantly monitor and control the accuracy of advertising, promotional materials, scientific and information materials distributed by the Company or on behalf of the Company in the Republic of Kazakhstan.

5. BASIC REQUIREMENTS FOR TYPES OF PROMOTION, MARKETING, AND RESEARCH AND EDUCATIONAL ACTIVITIES OF PHARMACEUTICAL PRODUCTS

5.1. Post-Authorization Studies

5.1.1. Post-authorization studies, including Post-authorization interventional, non-interventional and Epidemiological studies (hereinafter collectively referred to as “Post-Authorization Studies”), must comply with the requirements of the legislation of the Republic of Kazakhstan, as well as the requirements established by this paragraph.

5.1.1.1. Post-authorization studies must have a rationale and scientific purpose(s), which are reflected in the study protocol.

5.1.1.2. The post-authorization study protocol must be approved by the medical department or responsible medical functional units/workers, and the medical department (relevant medical functional units/workers) must coordinate and monitor the progress of Post-Authorization Studies.

5.1.1.3. The documentation of the Post-Authorization Study (protocol, individual reg-

istration card, informed consent for the Patient, etc.) must undergo mandatory assessment by the authorized body and ethical examination (national or local ethical commission) in accordance with the requirements of the legislation of the Republic of Kazakhstan in order to obtain permission to conduct the study.

5.1.1.4. When conducting Post-Authorization Studies, laws, regulations and requirements regarding the confidentiality of personal data (including the collection and use of personal data) must be observed.

5.1.1.5. The selection of investigators shall be based solely on their professional qualifications and clinical experience and shall not be in any way related to past, current or potential future prescribing or recommendations of the Company's Pharmaceutical Products.

5.1.1.6. Participation of a Healthcare Professional in a Post-Authorization Study should not be an inducement to recommend/prescribe, purchase, sell or use any specific Pharmaceutical Product.

5.1.1.7. The remuneration provided for work performed as part of Post-Authorization Studies must be reasonable and reflect fair market value. All conditions for participation in the Post-Authorization Study, including terms of payment, must be reflected in a written agreement between the Company and the Healthcare Professional and/or Medical Organization in which the study is being conducted.

5.1.1.8. The organization and monitoring of Post-Authorization Studies is carried out and is the responsibility of the medical department or the corresponding medical functional unit/employees of the Company.

5.1.1.9. Data obtained during Post-Authorization Studies must be statistically processed and analyzed, the final report must be submitted to the authorized body, and the results must be published.

5.1.2. Where permissible, employees of other departments of the Company may participate in solving only administrative tasks (in particular, in the transfer of documentation of Post-Authorization Studies from the medical department (the corresponding 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 appropriate medical functional unit/employee who must ensure that employees of other departments of the Company are properly trained).

5.1.3. It is prohibited to conduct Post-Authorization Studies under the guise of Marketing Studies. If the differences between Marketing Studies and Post-Authorization Studies specified in subclause 5.3. Code, not clear, the goals of Marketing Studies are subject to verification by medical specialists of the Company.

5.2. Investigator/Medical Organization-Initiated Studies

5.2.1. To carry out scientific and medical clinical trials initiated by an investigator/ Medical organization (not the Company), the Investigator/Medical organization may request research support from the Company. Control over the receipt and execution of applications for research initiated by the researcher/ institution, as well as administrative control, is carried out by employees of the medical department or the corresponding medical functional unit/employees of the Company.

5.2.2. The following requirements must also be met:

5.2.2.1. Research must have a rationale and scientific purpose(s) that are reflected in the research protocol. The company cannot initiate the study or directly participate in the planning or conduct of the study. The idea and concept of the study must be developed by the researcher. The Company may provide guidance on the study concept, but may not make significant changes to the original plan and idea or concept.

5.2.2.2. Companies may only support suitably qualified researchers/research teams to help them pursue research interests that have scientific value and meaningful scientific objectives.

5.2.2.3. Research support should not be in any way related to past, current or potential future appointments or recommendations of the Company's products. The participation of a Healthcare Professional in the study should not be an inducement to recommend/prescribe, purchase, sell or use any particular Medicine.

5.2.2.4. Any financial support must be reasonable and reflect fair market value. All conditions of the support provided must be formalized in writing in an agreement between the Company and the researcher/Medical organization.

5.3. Marketing Studies by Companies

5.3.1. Marketing Studies conducted directly by the Companies or by Companies with the involvement of marketing agencies is possible only subject to compliance with the requirements of current legislation. At the same time, the Companies do not have the right to pay healthcare professionals remuneration for their participation in the Marketing Studies. An exception may be cases of conducting Marketing Studies that requires special scientific knowledge and significant labor costs on the part of a healthcare specialist, provided that:

5.3.1.1. Marketing Studies is carried out with the assistance of independent agencies;

5.3.1.2. the healthcare professional is not informed and it is not obvious from the study materials which Company is the customer/sponsor of the study;

5.3.1.3. the company is not involved in the selection and does not know which Healthcare Professionals will take part in the Marketing Studies.

5.3.2. Marketing Studies may not be used for the purpose of Promotion or sales of Pharmaceutical Products or to manipulate the opinions or behavior of research participants. For this reason, when conducting Marketing Studies, you should avoid mentioning the trade name of the Pharmaceutical product, unless required by the purpose of the research; collection of personal data of Patients. Marketing Studies should not have the purpose of further research into the effectiveness or safety of a Pharmaceutical Product; pre-registration Promotion of a Pharmaceutical product or indications for its use subject to registration; obtaining confidential information about competing companies for the purpose of discrediting Pharmaceutical products of competing companies, leading to unfair competition.

5.4. Symposia, Congresses and Other Means of Oral Communication

The main goal and purpose of organizing all symposia, congresses and other promotional, scientific, educational or professional Events for Healthcare Professionals facilitated, or sponsored by Companies, as well as financing the participation of Healthcare Professionals in them, should be to provide scientific or educational information and/or inform Healthcare Professionals about Pharmaceutical products.

The main purpose and purpose of sponsoring and organizing marketing events for Healthcare Professionals by Companies may be to inform Healthcare Professionals about Pharmaceutical Products, advertise the Company and its products.

5.4.1. Information about Sponsoring an Event or Funding the Participation of Healthcare Professionals

5.4.1.1. If the Company or AIPM sponsors a symposium, congress or other similar Event related to healthcare or an educational program, then in this case the following conditions must be met:

5.4.1.1.1.the fact of sponsorship must be clearly indicated in advance;

5.4.1.1.2. the final materials of the Event (printed, audiovisual material, etc.) must accurately reflect the achievement of the set goals, the content of speeches and discussions;

5.4.1.2. Companies are not prohibited from making publicly available information about sponsorships provided (in the form of cash or cash equivalent).

5.4.1.3. Funding for the participation of healthcare professionals in scientific, educational or professional events is possible subject to the following conditions:

5.4.1.3.1. no invitations to participate in professional Events may be used to induce

Healthcare Professionals to prescribe, supply, prescribe, recommend, or sell Pharmaceutical Products;

5.4.1.3.2. payment of speaking fees at Events (based on fair market value) and reimbursement of expenses, including registration fees, travel expenses, visa support, health insurance, room and board for speakers/presenters are acceptable practices;

5.4.1.3.3. reimbursement of expenses associated with the participation of Healthcare Professionals in an educational Event for educational purposes at the expense of the Company (registration fee, travel expenses, 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 participating in the Event;

5.4.1.3.5. Hospitality must not include sponsoring or organizing entertainment (e.g., holidays);

5.4.1.3.6. Reimbursement of any expenses for accompanying persons is not permitted (except for medical reasons).

5.4.2. Event Venue

5.4.2.1. Events must be held in a location consistent with the main purpose of the Event. Companies are prohibited from organizing Events in locations that are considered (or advertised) primarily as entertainment, tourist attractions, or known to be extravagant. Events should not be held, for example, in places such as ski resorts, spas, isolated holiday destinations, other popular tourist resorts, as well as in places with similar characteristics.

5.4.2.2. 4-star hotels are the recommended level for hosting and sponsoring Events, as well as accommodation for Healthcare Professionals. Choice of 5-star hotels is acceptable for sponsored Events, provided that the location contributes to the achievement of business, educational and scientific purposes and under other reasonably justifiable circumstances (for example, lack of accommodation in other hotels of a lower class, in order to ensure the safety of the Event participants. Events in luxurious or extravagant locations are not permitted.

5.4.2.3. The decision to purchase an economy or business class air ticket for a Healthcare Professional is governed by the Company's internal policies.

5.4.2.4. It is prohibited to conduct entertainment activities at any Events intended for Healthcare Professionals.

5.4.3. Other Restrictions

5.4.3.1. Healthcare professionals should not be provided with material remuneration

that does not relate to the payment of fees for speaking or preparing materials. The amount of allowable compensation must be based on fair market value, which must be based on market research.

5.4.3.2. The provision of drinks and/or food (coffee break, lunch, dinner, etc.) in connection with the Event must be secondary to the main purpose of the Event, justified in terms of the duration of the Event, other objective factors and provided:

5.4.3.2.1. only to participants of the Event;

5.4.3.2.2. be moderate and reasonable for local conditions.

5.4.3.3. Only background music and/or performance by a local artist secondary to the food provided, and originally present at the catering location is acceptable, provided that the Company does not pay for them separately.

5.4.3.4. Companies may not organize and pay for cultural and entertainment Events, tours, even if they are secondary to an educational Event.

5.4.3.5. Companies are prohibited from organizing or sponsoring Events for Healthcare Professionals outside their country unless:

5.4.3.5.1. the majority of invited healthcare professionals come from other countries, and therefore, from a logistical point of view, it makes sense to hold the Event outside of Kazakhstan;

5.4.3.5.2. the resources or expertise that is the object or subject of the Event are located in another country, and therefore, from a logistical point of view, it makes sense to hold the Event outside of Kazakhstan ("International Events").

5.5. Interaction with Patients and Patient Organizations

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

5.5.2. The Company shall not solicit, nor shall the Patient Organization undertake, activities aimed at promoting a specific Prescription Pharmaceutical Product. The interaction should never constitute a hidden Promotion of the Company's Pharmaceutical Products.

5.5.3. In cooperation between the Company and the Patient Organization any relationship, fact and nature of cooperation, including financial and non-financial support of the Patient Organization must be transparent and clearly disclosed and documented by the Company.

5.5.4. The company may be the only source of funding for a Patient Organization upon receipt of an appropriate written request from a Patient Organization for the implementation of programs of such an organization aimed at preventing

and protecting the health of citizens, promoting a healthy lifestyle, and helping socially vulnerable segments of the population, if such financing (donation) is not directly directed or indirectly to stimulate the Patient Organization to make any decisions in the process of carrying out its statutory activities in favor of the Company or its products. Moreover, in any case, such a Company should not limit the rights of other Companies to finance the same projects of the Patient Organization if they wish and have a corresponding written request from the Patient Organization.

5.5.5. Companies may provide financial support for Patient Organization events and conduct events involving a Patient Organization, provided that the primary purpose of the event is educational or scientific in nature and is for other general benefit purposes that further the mission of such Patient Organization and does not contain any reference to prescription products. In the case of providing funding for an event to a Patient Organization and/or organizing an event by the Company with the participation of a Patient Organization, the Company is obliged to ensure that the location and conditions of the event meet the requirements for the limits of cordiality and hospitality established by business practice and correspond to the educational and scientific goals of the event. The Company's financing of Patient Organizations and the Company's organization of events involving Patient Organizations must not be related to Product Promotions and must be conducted by Company functions not directly related to the sales of Pharmaceutical Products. The Company must not have a controlling or dominant financial position when it comes to the financing of Patient Organizations, unless in order to avoid interfering with the independence of such an organization.

5.6. Patient Support Program

5.6.1. A company may initiate a Patient Support Program (PSP) aimed at improving patient outcomes. Such a program should not be intended to encourage the prescription, promotion or recommendation of a Pharmaceutical Product to patients by healthcare professionals and should not be used to initiate unfounded inquiries about a Pharmaceutical Product. The Company documents the PPP and follows the requirements in accordance with established internal procedures and the legislation of the Republic of Kazakhstan.

5.6.2. It is not permissible for the Company to provide donations directly to Patients.

5.6.3. The company must receive written permission of the Patient Organization before public use of its logo or materials; upon receipt of such permission, the Company documents the purpose of their use. Interaction with Patients and Patient Organizations should not replace the role of the Patient's attending physician in making decisions about individual treatment. Company employees shall not provide any personal, medical or drug-related advice to Patients and shall always refer the Patient to his or her physician for all matters related

to individual medical care. Interactions should never constitute a hidden promotion of the Company's products.

5.6.4. Information provided to Patients and Patient Organizations must be agreed upon by the Company and (1) be provided exclusively for approved over-the-counter products of the Company in accordance with indications for use approved by the competent authority or (2) have an informational and educational nature and be aimed at general awareness of the disease and treatment approaches without mentioning any prescription drugs, and do not encourage the use of prescription drugs without consulting your doctor. The Company's initiation of a discussion of indications that do not comply with the approved instructions is prohibited; patients should be referred for consultation to their attending physician.

5.6.5. The Company protects the confidentiality of all personal data collected from Patients and Patient Organizations by implementing the necessary control and security measures; When managing digital data received from Patients and Patient Organizations, the Company is guided by the principles of ethics and the requirements of the legislation of the Republic of Kazakhstan.

5.7. Gifts

A gift is any item that has its own material value, regardless of the information printed on it, transferred to Healthcare Professionals free of charge without the intention of receiving anything in return.

Gifts should never be used as an inducement to prescribe, recommend, purchase, supply, sell or use medicinal products. The Company is obliged to comply with the restrictions on Gifts established by the legislation of the Republic of Kazakhstan. It is prohibited to provide, directly or indirectly, Gifts that provide personal benefit to Healthcare Professionals, including services for personal use. It is prohibited to provide cash or cash equivalents as Gifts.

5.7.1. **Social Courtesy Gifts** – these are items provided on special occasions (for example, holidays), in accordance with accepted traditions in society. Social courtesy gifts to healthcare professionals are prohibited.

5.7.2. **Promotional Products (Brand Reminders)** - These are low-value items that bear the Company logo, the Pharmaceutical Product or other information designed to draw attention to the Pharmaceutical Product or the Company's business. Providing any promotional items to Healthcare Professionals in connection with the Promotion of Prescription Medicines is prohibited, with the exception of pens and notepads worth up to 2 MCI with the name of the Company at Events organized by the Company or a third party, in the amount necessary for the purposes of the Event. Promotions that relate exclusively to

over-the-counter medicines may be provided to Healthcare Professionals if they are relevant to their practice.

5.7.3. Medical Supplies – These are moderately expensive items intended to improve the quality of medical care (for example, anatomical models). The cost of medical supplies should not exceed 5 MCI. Routine consumables associated with medical practice cannot be provided as medical supplies (for example, surgical gloves, stethoscopes, blood pressure monitors, etc. cannot be provided). Medical supplies may bear the Company name, but should not be branded with the name of the Pharmaceutical Product.

5.7.4. Information and Educational Materials – these are moderately priced sources of information independent of the Company, intended to improve the quality of medical care, transmitted to Healthcare Professionals in printed or electronic format (for example, books, subscriptions to medical publications). Promotion materials published by the Company cannot be transferred as information and educational materials. The cost of information and educational materials should not exceed 5 MCI. Information and educational materials may be provided sporadically, i.e. not systematically. Information and educational materials contain the name of the Company, but should not be branded with the name of the Pharmaceutical product.

5.8. Samples

5.8.1. It is permissible to distribute samples of pharmaceutical products, non-prescription pharmaceutical products, and medical devices to healthcare professionals who have the right to prescribe the relevant products in order to improve patient care.

5.8.2. Samples of Pharmaceutical Products must not be distributed for the purpose of inducing Healthcare Professionals to prescribe, supply, prescribe, recommend or sell a Pharmaceutical Product.

5.8.3. Companies must have appropriate systems for monitoring and recording samples of Pharmaceutical Products provided to Healthcare Professionals, incl. to track these samples while they are in the possession of Medical Representatives.

5.8.4. Sample packages of Pharmaceutical Products must be marked as such ("Not for Sale" or "Free Sample") to prevent resale or other misuse.

5.9. Frequency and Scope of Mailings

5.9.1. The requirements of Section 4 "General Requirements for Promotion and Marketing" of this Code apply to Promotional materials and communications distributed through electronic systems, including mailing lists. Personal data

of Healthcare Professionals can be used on the basis of their consent in accordance with the requirements of the legislation of the Republic of Kazakhstan. The frequency and volume of mailing printed informational and educational material to Healthcare Professionals must be reasonable and consistent with the scientific and practical needs of the Healthcare Professional.

5.9.2. Requests by Healthcare Professionals to have their names removed from promotional mailing lists must be respected and complied with.

5.10. Internet Resources

5.10.1. This Code applies to Promotion on the Internet of Pharmaceutical products on the territory of the Republic of Kazakhstan on any Internet resources, regardless of the location of hosting and domain name zone.

5.10.2. Promotion of Pharmaceutical Products on the Internet must comply with the requirements established by law and this Code. When using Internet sites related to Pharmaceutical Products, it must be obvious which Company the information is coming from and to whom it is addressed, the content must be appropriate to the recipient audience.

5.10.3. The Company's involvement of advertising agencies, as well as persons, to promote Pharmaceutical products on the Internet does not relieve the Company of responsibility for violating the provisions of this Code. Persons who are not healthcare professionals should not be involved in the promotion of prescription products.

5.10.4. The provision of information about Pharmaceutical products dispensed with a doctor's prescription must be carried out in sections of Internet resources that are accessible exclusively to Healthcare Professionals or as part of online events (webinars) for Healthcare Professionals. If personal data of Healthcare Professionals is used, it must be collected and processed in accordance with the requirements of the legislation of the Republic of Kazakhstan on personal data.

5.11. Social Media

5.11.1. Information posted by the Company on social networks, as well as information distributed by Bloggers on social networks as part of work for the Company or with financial support from the Company, must comply with the instructions for medical use of the Pharmaceutical product approved in the Republic of Kazakhstan; comply with the legislation of the Republic of Kazakhstan, Promotion standards established in section 4.1. of this Code, and be accompanied by a disclaimer stating that this information is provided with the support of the Company. If Bloggers are not Healthcare Professionals, then they should not be involved in the Promotion of Prescription Products.

6. PROCEDURE FOR EXAMINATION OF REPORTS OF IMPROPER COMPLIANCE WITH THE PROVISIONS OF THE CODE

6.1. In the event of allegations of improper compliance by the Company with ethical standards and provisions of this Code, interested parties attempt to resolve the problems through negotiations.

6.2. A statement regarding issues of improper compliance with the provisions of the Code is sent in writing to the AIPM Ethics Committee with a detailed description of the circumstances and provision of evidence that gave rise to the statement.

6.3. The AIPM Ethics Committee considers the application at meetings held in accordance with the annual schedule of meetings of the AIPM Ethics Committee or at extraordinary meetings, which are necessarily attended by representatives of the applicant Company and the defendant Company (the Company in respect of which the application was made), and guided by the provisions of this Code, makes a conclusion about the fact of violation of the ethical Promotion of a Pharmaceutical Product. In the absence of one of the parties (representatives of the applicant company or the defendant company), the AIPM Ethics Committee considers the received application and makes a decision based on the data received, guided by the requirements of this Code and the legislation of the Republic of Kazakhstan.

6.4. The defendant company, in the event of an independent admission of a violation, within a month informs (in writing) all market participants who received unethical information about the fact of the violation, as well as the actions taken by the Company related to the correction of the violations.

6.5. In case of refusal of the respondent Company to admit the fact of violation of this Code, the initial complaint may be sent by the Company to the applicant or AIPM to the competent government authorities.

6.6. To conduct an examination and study the circumstances related to the unethical behavior of the Company, the AIFP Secretariat, on behalf of the Supervisory Board, may attract external consultants (for example, a law firm) specializing in these issues.

6.7. Upon final confirmation of a violation of the provisions of the Code, all costs of office work, including compensation for prepayment on the part of the applicant Company, are borne by the violating Company (i.e., the Company found guilty of violating the provisions of the Code).

6.8. At the same time, the violating Company is obliged, within a month, to inform in writing all members of the AIPM who received unethical information

about the fact of the violation and the actions taken by the Company related to correcting the violations.

6.9. Based on the decision of the General Meeting of the AIPM, the following sanctions may be applied to the violating Company:

6.9.1. written warning to the defendant Company;

6.9.2. written notification to the headquarters (head office) of the Defendant Company group about unethical behavior in the market;

6.9.3. exclusion from the AIPM.

6.10. If it is established that there have been no violations of the provisions of this Code, all costs of office work, consideration and examination of the application shall be borne by the applicant Company.

6.11. If more than one fact (case) of violation of the provisions of this Code is established on the part of a Company - a member of the AIPM, the AIPM Secretariat, on behalf of the AIPM Supervisory Board, informs in writing the headquarters (head office) of the group of the violating Company.

6.12. The headquarters (head office) of the group of the violating Company is obliged to submit to the AIPM within a month a plan of internal measures aimed at correcting the violations and bringing the activities of the violating Company into compliance with the provisions of this Code.

6.13. In case of failure to submit the specified plan or its recognition by the Supervisory Board of the AIPM as unsatisfactory, the Company is excluded from the AIPM.

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АССОЦИАЦИЯ МЕЖДУНАРОДНЫХ ФАРМАЦЕВТИЧЕСКИХ ПРОИЗВОДИТЕЛЙ В РЕСПУБЛИКЕ КАЗАХСТАН

ПРЕЗИДЕНТ – ВЯЧЕСЛАВ НОТАНОВИЧ ЛОКШИН

ИСПОЛНИТЕЛЬНЫЙ ДИРЕКТОР – СВЕТЛАНА МАРАТОВНА ОСПАНОВА

ПРЕДСЕДАТЕЛЬ ЭТИЧЕСКОГО КОМИТЕТА – ГАЛЫМЖАН КАСЕНОВИЧ КОЖАКАНОВ

A15P4Y9, Республика Казахстан, г. Алматы, у. Сатпаева, 29/6,
БЦ “Rahat Palace”, 9 этаж, офис 93А
Tel./Fax: +7 (727) 394 47 16,
e-mail: info@aipm.kz
www.aipm.kz