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CODE
of marketing practice
Association of Representative Offices of Foreign
Pharmaceutical Companies and Manufacturers

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INTRODUCTION

This Code of Marketing Practice (hereinafter referred to as the Code) has been developed in order to reflect the minimum requirements that all members of the ASSOCIATION must follow when marketing pharmaceutical products. The Code was developed on the basis of international codes of marketing practice adopted in the research and development pharmaceutical industry.

The provisions of the Code are intended to help companies develop and implement fair and responsible marketing practices that take public health into account.

The Code is not intended to replace the current legislation of the Republic of Uzbekistan. On the contrary, the Code clearly states that national legislation always takes precedence and this Code represents a set of additional fundamental principles that guide the members of the ASSOCIATION.

In all cases of use, interpretation or application of any part of this Code, it should be clear that the national laws of the Republic of Uzbekistan, by-laws, decrees, instructions and requirements will always be given preference, in particular:

- The Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities" (adopted in a new edition in accordance with the Law of the Republic of Uzbekistan dated January 4, 2016 No. ZRU-399 "On Amendments and Additions to the Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities",
- Law of the Republic of Uzbekistan "On the protection of the health of citizens" No. 265 of August 29, 1996,
- The Law of the Republic of Uzbekistan "On Combating Corruption" No. ZRU-419 dated January 3, 2017

The activities of pharmaceutical companies in the field of advertising are regulated by:

- Law "On ADVERTISING" (No. 723-1 of December 25, 1998), in particular, Article 22 "Advertising of medicines, medical products, cosmetics and household chemicals";
- Resolution of the State Committee for Demonopolization of the Republic of Uzbekistan "Regulations on the placement of advertising" (No. 4 dated 03.26.01, registered by the Ministry of Justice on 06.04.01 under No. 1024);
- Regulations on the procedure for issuing permission to advertise medicines for minors dated December 22, 2014 (approved by the Decree of the Cabinet of Ministers of the Republic of Uzbekistan No. 341 dated December 15, 2014)
- Order No. 422 of the Ministry of Health of the Republic of Uzbekistan dated December 27, 2013 "On approval of the procedure for advertising medicines intended for medical institutions and medical workers of the healthcare system".

Recognizing the importance of national legislation, the members of the ASSOCIATION believe that the main responsibility and control over the observance of high standards in advertising lies with the members of the ASSOCIATION.

Member companies of the ASSOCIATION should strive to comply with the rules of fair competition in the implementation of marketing activities and not damage the image and position, economic interests of competitors through improper advertising and other unfair methods of promoting pharmaceutical products.

1. PURPOSE AND SCOPE.

1.1. Purpose

The purpose of this Code is to establish the minimum requirements that pharmaceutical companies - members of the Association must follow when carrying out marketing activities on the territory of the Republic of Uzbekistan.

1.2. Application area

This Code applies to:

- advertising of pharmaceutical products addressed to the public;
- advertising of pharmaceutical products addressed to healthcare professionals;
- activities of medical representatives of pharmaceutical companies;
- interaction with healthcare professionals;
- interaction with patient organizations;
- post-registration clinical (interventional), observational (non-interventional) and epidemiological studies;
- marketing research;
- activities to promote pharmaceutical products for healthcare professionals; sponsoring scientific events, etc.

2. BASIC TERMS.

2.1. Medicinal products¹ - products derived from one or more medicinal substances (substances) and excipients of natural and synthetic origin, approved for use for prevention, diagnosis and treatment. These include immunobiological, radiopharmaceutical and parapharmaceutical preparations, homeopathic, diagnostic and sterilizing agents, as well as medicinal substances (substances) intended for the production and manufacture of medicines;

2.2. Pharmaceutical product - Medicinal product, medical device and medical equipment;

2.3. Marketing activity - any activity, including advertising, which is conducted, organized or sponsored by a pharmaceutical company using any media and is intended to facilitate the prescription, recommendations, dispensing, use or consumption of pharmaceutical products produced by it; The priority areas of marketing activity are planning, development and implementation of effective tools for promoting the company's products based on integrated marketing communications with the main target audiences of consumers (doctors, pharmacists, distributors, individual buyers).

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

2.5. Advertising of Medicinal products, medical devices and medical equipment (hereinafter referred to as advertising) - information distributed and placed in any form, by any means, intended for an indefinite circle of persons, containing individual information or a combination of information about Medicines, medical devices and medical technology, contributing to their promotion and implementation.

¹ for the purposes of this Code, the term "Medicinal products " is used as defined in article 2. LAW OF THE REPUBLIC OF UZBEKISTAN On medicines and pharmaceutical activities (adopted in a new edition in accordance with the Law of the Republic of Uzbekistan dated January 4, 2016 No. ZRU-399 "On amendments and additions to the Law of the Republic of Uzbekistan "On medicines and pharmaceutical activities"

2.6. Health professionals - doctors and other medical workers, pharmacists, pharmacists and other professionals 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.

2.7. 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 presented pharmaceutical products, their therapeutic effect and impact on pathogenetic mechanisms diseases. It is the responsibility of the Medical Representative to maintain contact with Health Professionals or other relevant persons for the purpose of Promoting Pharmaceutical Products.

2.8. A 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 Uzbekistan.

2.9. A civil servant - a citizen of the Republic of Uzbekistan employed in public service in public positions or in the National Personnel Reserve.

2.10. Patient - an individual who has a specific disease, disorder or other medical pathology.

2.11. Patient organizations - non-profit organizations that specialize in certain diseases or aspects of health care, representing the interests and needs of Patients, their families and / or carers of the sick or elderly people. These groups are primarily made up of Patients and/or caregivers (family/friends), but may also be made up of consumers, seniors, 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.

2.12. Events. Recommended terminology.

2.12.1. Seminar is an event aimed at the exchange of scientific and/or medical information, training of healthcare professionals in modern aspects of diagnosis, treatment of diseases and provision of information on the company's medicines. The total number of participants in the event is 50-100 people.

2.12.2. Conference is an event aimed at the exchange of scientific and/or medical information, training of healthcare professionals in modern aspects of diagnosis, treatment of diseases and provision of information on the company's medicines. The total number of participants in the event is 100-200 people.

2.12.3. Symposium is an event aimed at the exchange of scientific and / or medical information, training of healthcare professionals in modern aspects of diagnosis, treatment of diseases and provision of information on the company's medicines. The total number of participants in the event is 200-500 people.

2.12.4. Congress is an annual event aimed at the exchange of scientific and/or medical information, training of healthcare professionals in modern aspects of diagnosis, treatment of diseases and providing information on the company's medicines. The total number of participants in the event is more than 500 people.

3. GENERAL PROVISIONS

3.1. Advertising standards.

3.1.1. Advertising of pharmaceutical products must comply with the requirements of the advertising legislation in force in the Republic of Uzbekistan.

3.1.2. Advertisements for pharmaceutical products must be written in such a way that the product is clearly identified as a pharmaceutical product.

3.1.3. Advertising of pharmaceutical products must contain objective, reliable and up-to-date information based on duly approved information about the pharmaceutical product (labeling, instructions for medical use) and must not contradict it.

3.1.4. Advertising information must be clear, accurate, balanced, honest, objective and complete enough so that its addressee can form an objective opinion about the therapeutic value of the pharmaceutical product in question. Advertising information must be based on an up-to-date assessment of all relevant facts and state these facts clearly.

Claims of curative effect in advertising should not exceed the amount supported by scientific evidence. Companies should make every effort to avoid ambiguities in such information.

Advertising information should not be misleading by distortion, exaggeration, omission, or other methods. Ambiguity must be avoided.

3.1.5. Promotion should not be hidden. It is not allowed to promote a pharmaceutical product under the guise of post-registration clinical (interventional), observational (non-interventional), epidemiological studies, as well as marketing studies. Such studies should primarily be carried out for scientific and research purposes and should not be aimed at encouraging the prescription of a pharmaceutical product by healthcare professionals.

Pharmaceutical company-sponsored materials relating to pharmaceutical products and their uses, whether promotional or not, must clearly identify the sponsor.

3.1.6. The use of "hotlines" for the promotion of prescription pharmaceutical products is not allowed.

3.2. Scientific evidence.

Information about promotional material must be based on an up-to-date assessment consistent with scientific evidence and not create an incorrect or misleading impression. The instructions for use of the drug must be based on this information and must comply with the local marketing authorization, and, where applicable, the authorization issued by the regulatory authorities of the countries. Scientific data underlying advertising and recommendations for the use of drugs should be available and presented at the request of healthcare organizations.

Companies must objectively review valid requests for information and report data that would be consistent with the source of the request.

Companies must provide information whether or not it is available to the general public, but must not endorse indication data for a drug that has already been approved by marketing authorization.

Information provided must comply with applicable confidentiality requirements or reasonable precautions.

In vitro data and animal data must be clearly identified as such, and they must be reported in such a way as not to give an incorrect or misleading impression.

3.3. Security information.

Manufacturers should strive to ensure that advertising reflects as fully as possible the main characteristics relating to the safety of the use of a pharmaceutical product.

Particular care should be taken to ensure that critical information relating to the safety of pharmaceutical products, such as contraindications, precautions and side effects, is consistent and appropriately presented. Substantiated information about serious and unexpected adverse effects associated with the use of pharmaceuticals should be communicated to the relevant health authorities.

3.4. Pre-registration information

3.4.1. A pharmaceutical product cannot be promoted until the registration is approved in the Republic of Uzbekistan.

3.4.2. This provision does not imply an attempt to interfere with the right of the scientific community and the public to receive full information regarding scientific and medical progress. It is not intended to limit the full and proper exchange of scientific information in relation to Pharmaceutical Products, including the appropriate dissemination of research results through scientific or public media, as well as at scientific conferences, in accordance with the current legislation of the Republic of Uzbekistan. Also, public disclosure of information to shareholders and others in relation to any Pharmaceutical Product is not limited, unless it is prohibited by applicable law.

3.4.3. Providing information about unregistered Pharmaceutical Products, or about indications not specified in the instructions for use of a registered Medicinal product, is not a Promotion and is allowed if the following conditions are met:

3.4.3.1. Such information is provided in response to an individual request of a Health Specialist, made by him independently on his own initiative, as well as during speeches at Events in order to exchange scientific experience.

3.4.3.2. Such requests are documented by the Company.

3.4.3.3. The answer is provided by an employee of the Company who has a medical education and is not directly related to the sales of Pharmaceutical products.

3.4.3.4. The response is transmitted to the person requesting this information.

3.4.4. Answers should be based on the principles of evidence-based medicine, available scientific information, data from clinical studies

3.5. Hidden and misleading advertising

3.5.1. Advertising and information products (mailing list, announcements in medical journals, other printed publications and mass media) should not hide or veil the true information.

3.5.2. Post-marketing research and observation should be for scientific or educational purposes. These studies should not be carried out simply as a means of promoting a product or influencing physicians, with little or no scientific or educational backing.

3.5.3. Comparative advertising should be carried out on identical characteristics and should not mislead advertising consumers due to the absence of some essential information in the advertisement.

3.6. Printed promotional materials

Printed promotional materials must be presented in a clear and legible manner. The scientific justification and presentation of product information must comply with the general principles set out in the Code and, where appropriate, the requirements for permitted product information.

3.6.1. Advertisements

All advertisements must contain:

- product name (usually brand name);
- listing of active ingredients using approved names, if available. The approved name of the active ingredient must be the International Nonproprietary Name (INN), if one exists and does not conflict with local regulations or requirements.
- the name and address of the company or authorized third parties responsible for the marketing of the products.
- release date;
- "abbreviated information for use", including approved indications for use, if necessary in combination with dosage and method of application, a summary of contraindications, precautions and undesirable effects.

The postal address at which additional information can be obtained must be indicated in the advertisement itself or should be readily available in the publication that published the advertisement.

3.6.1.1. Full advertisements

Full advertisements are those advertisements that include indications for the use of a medicinal product.

In addition to the requirements of paragraph 3.6.1. full advertisements must also contain information on the use of the drug, including:

- registered indication or indications together with dosage and method of application;
- brief information about contraindications, warnings and adverse reactions.

3.6.1.2. **A reminder advertisement** is a short advertisement containing only the trade name and therapeutic group of a pharmaceutical product.

It may contain at least the name of the pharmaceutical product, as well as a warning about the need to read the instructions or seek expert advice.

3.6.2. Company Procedural Rules

3.6.2.1. Advertising, promotional and scientific information materials, including presentations by speakers (Health Professionals sponsored by the Company) before distribution, publication or display, must be approved by the appropriate functions of the Company, including, in certain circumstances, the permission of a responsible person who has the appropriate scientific or medical qualification.

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

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

3.6.3. Links

Where promotional material refers to published scientific research as a source, a clear reference to this must be made in the printed material. Extracts from the medical literature or personal presentations should not change or distort the meaning or meaning of the work or study intended by the author or clinical investigator.

When using quotes from medical or scientific literature or someone else's speeches in advertising materials, it is necessary to indicate the source of the citation / author's name, date and place of publication / speech.

3.6.4. Electronic media

For advertising materials on electronic media, including audio and video materials, the same requirements apply as for printed ones (established in the relevant paragraphs 3.6. of this Code).

Advertising of prescription pharmaceutical products on the Internet is prohibited. It is allowed to provide information about prescription pharmaceutical products within the framework of online events (webinars) for healthcare professionals, as well as in sections of Internet resources, access to which is open exclusively to healthcare professionals.

This Code applies to the promotion of pharmaceutical products on the territory of the Republic of Uzbekistan on any websites, regardless of the hosting location and domain name zone, as well as the location and internal policies of the pharmaceutical company promoting the pharmaceutical product.

When using Internet sites related to pharmaceutical products, it should be obvious which pharmaceutical company the information comes from and to whom it is addressed; the content must be relevant to the target audience; the presentation of information (content, labels, links, etc.) must be adapted to the level of the target audience and be understandable to the website visitor.

3.7. Information for the population.

Where legislation permits contacting patients directly regarding prescription drugs, all such information must be accurate, honest and not misleading.

Where firms assist in public/patient disease awareness programs to meet the growing public need for information on disease prevention, signs, symptoms, and possible treatments, this form of business should be of the highest standard. credibility and provide support to relevant health authorities.

3.8. Registration status

3.8.1 Only registered pharmaceutical products are subject to promotion on the territory of the Republic of Uzbekistan.

3.8.2 The condition of subparagraph 3.8.1 does not imply a violation of the rights of the scientific community and society as a whole to information about progress in the field of science and medicine. It also does not purport to limit the full and proper exchange of scientific information relating to pharmaceutical products, including the dissemination of relevant information about ongoing research in publications for health professionals, at scientific conferences, responses to specific requests from health professionals.

4. MEDICINES SUPPLIED WITHOUT A DOCTOR'S PRECIPION (SELF-MEDICANS)

This section of the Code includes any type of promotion in the Republic of Uzbekistan of over-the-counter medical products intended for human use. This implies a promotion designed for both the general public and health professionals.

Advertising to the public of pharmaceutical products classified as prescription drugs is not allowed.

4.1. Advertising of over-the-counter medicines includes all types and forms of promotion carried out by a pharmaceutical company in order to ensure the supply, sale and consumption of them, and provides for:

- advertising of medicines aimed at the general public;
- advertising of medicinal products aimed at specialists prescribing treatment or supplying these products;
- visits by medical representatives to healthcare professionals;
- sponsorship of promotional events attended by healthcare professionals;
- sponsorship of scientific congresses, seminars, etc., attended by healthcare professionals (including payment of travel and accommodation costs).

4.2. Information Requirements

4.2.1. Advertising of medicinal products subject to non-prescription sale must:

- be presented in an accessible language and contain the following information: the full (including internationally non-proprietary) name of the medicinal product, the name of the manufacturer, the main indications for use;
- be accompanied by a warning about the presence of contraindications to their use and use, the need to familiarize yourself with the instructions for use or obtain expert advice. This warning must be given at least 10 percent of all drug advertisements and at least 5 seconds of air time at the beginning or end of a television commercial, as well as an audio message at the beginning or end of a drug advertisement on radio.

4.2.2. Advertising of medicinal products subject to non-prescription sale must not:

- present the medicinal product as unique, the most effective, the safest in terms of the absence of side effects;
- to mislead about the composition, origin, novelty or patentability of the medicinal product;
- to undermine the reputation of manufacturing enterprises, the faith of consumers in the action of medicines;
- refer to the recommendations of scientists, health professionals, as well as government officials or other persons who, due to their own fame, may encourage the use of medicines;
- contain material about the intended use exclusively or primarily for children;
- assert that the safety and efficacy of this medicinal product is due to its natural origin;
- state that the medicinal product is a biologically active food supplement, cosmetic product or hygiene product;
- allow incorrect comparisons with other drugs in order to enhance the advertising effect;
- create the impression that medical consultations or surgical operations are unnecessary;
- contain statements that the effect of this medicinal product is guaranteed;
- suggest that a person's health can be worsened by not using the drug.
- lead to an erroneous self-diagnosis, due to a description or a detailed story about the history of a particular disease;
- justify recovery in wrong, exciting or misleading images;
- use incorrect, exciting or misleading examples of changes in the human body caused by diseases, injuries, the action of a particular medical preparation on the human body or on its individual parts.

4.3. All components of an advertisement for a medicinal product must comply with the details listed in the approved instructions for medical use.

4.4 Advertising directed at healthcare professionals.

4.4.1. General principles of interaction with healthcare professionals

4.4.1.1. Pharmaceutical companies' relationships with healthcare professionals should be focused on delivering value to patients and improving medical practice. The interaction should be focused on informing healthcare professionals about pharmaceutical products, providing them with information of a scientific and educational nature, as well as supporting scientific research in the field of medicine and medical education.

4.4.1.2. The cooperation of pharmaceutical companies with healthcare professionals should not result in a conflict of interest among professionals, in particular between their professional duties and economic interests. In particular, such a conflict should not arise when prescribing a pharmaceutical product by a doctor and when recommending and selling a pharmaceutical product by a pharmacy worker.

4.4.1.3 It is not allowed to offer, promise, provide or transfer compensation in any form to healthcare professionals for prescribing or recommending a particular pharmaceutical product to patients.

Support for professional development of healthcare professionals, including sponsoring their participation in congresses and other professional information

events, the allocation of educational grants, scholarships, subsidies should not be made dependent on the volume of prescriptions of a pharmaceutical product or its sales.

4.4.1.4. Personal data of healthcare professionals without their proper consent should not be included in databases for the purpose of subsequent distribution of promotional materials.

4.4.2. Information Requirements

The following principles apply to information that may be included in advertisements directed to healthcare professionals:

4.4.2.1. Any advertisement for an over-the-counter medicinal product directed to healthcare professionals who are authorized to prescribe treatment or supply products must include, but is not limited to:

- basic information that matches the approved instructions for use;
- Belonging of the medicinal product to the group dispensed without a doctor's prescription.

4.4.2.2. Information about medical products must be accurate, up-to-date, verified and complete enough so that the recipient of information can form his own idea of the therapeutic value of the relevant medical product.

4.4.2.3. Any documentation relating to a medical product that is transmitted as part of an advertisement for that product must be clearly reproduced and its exact source must be indicated. Clear reference should be given to where these sources may be located.

4.4.2.4. Advertising of prescription drugs can only be carried out among specialists who have the right to prescribe and distribute drugs, and is allowed in specialized publications through information centers, at conferences, symposiums, exhibitions, etc. (Resolution of the State Committee for Demonopolization, registered by the Ministry of Justice on October 18, 2010 N 1024-4)

4.4.2.5. It is forbidden to advertise prescription drugs in public items (watches, calendars, umbrellas, lighters, key chains, urns, ashtrays, stationery, badges, dishes, souvenirs, etc.), as well as advertise Rx drugs in doctors' offices.

4.5. Events

4.5.1. The purpose and primary purpose of all symposiums, congresses and other meetings of a professional, scientific or marketing nature (hereinafter referred to as "Events") for healthcare professionals organized or funded by a pharmaceutical company should be to inform healthcare **professionals** about pharmaceutical products and / or provide them with scientific or educational information. character.

4.5.2. Financing participation in the Events

Pharmaceutical companies may fund the participation of healthcare professionals in Events, provided that such funding satisfies the following requirements:

- The event complies with the requirements for hospitality limits established in paragraph 4.7 of this Code;
- financing of healthcare professionals is limited to payment of travel expenses, meals, accommodation and registration fees;
- no payments are made to compensate healthcare professionals for the time spent attending the Event;
- any support for practicing doctors or doctors practicing in private medical organizations in order to attract them to participate in the event should not be subject to any obligation on their part to promote the prescription or purchase of the medicinal product.

4.5.3. Accompanying persons

Companies do not have to pay travel expenses for persons accompanying invited medical professionals and representatives of allied professions.

4.6. Payments for speeches and presentations

Compensation (within reasonable limits) and reimbursement of reasonable expenses to healthcare professionals, including travel and accommodation costs, may be provided provided that healthcare professionals actually provided services to the company by making a report or presentation. The basis for such payments should be a written agreement with the pharmaceutical company.

4.7. Hospitality limits

4.7.1. The Event must be held in an appropriate location that contributes to the achievement of the scientific and educational objectives of this Event. Companies should be prohibited from using Event venues that are associated in the public eye with entertainment, luxury or exclusivity, regardless of class. It is recommended to organize events in business centers, educational institutions, hotels and other places intended for business and educational events. In doing so, you should use the services of hotels that are not luxury hotels and can provide technical support and equipment necessary for the event. Holding an event by a company in a public place is possible only in the conditions of an isolated room or closing the place of public access for the duration of the event. It is prohibited to use entertainment and sports events to attract healthcare professionals to promotional and scientific events.

4.7.2 Provision of drinks and/or meals (coffee break, lunch, dinner) in connection with the Science Event should be secondary to the main purpose of the Event and should be provided only to the participants of the Event, but not to their accompanying persons.

4.7.3 Hospitality provided during professional and scientific events should be reasonable and subordinate to the main purpose of the meeting and should not exceed the amount that recipients (health professionals) would normally be willing to pay for themselves.

4.8. Gifts, medical supplies and promotional aids.

A gift is any item given to a Health Care Professional at no cost.

4.8.1. In accordance with the IFPMA Code of Business Practice, from January 01, 2019, a ban on any gifts and hospitality for healthcare professionals, including gifts on the eve of traditional national, cultural or religious events, has been introduced.

4.8.2. Promotion of OTC drugs.

The IFPMA Code does not regulate the promotion of OTC drugs.

OTC drugs are promoted in accordance with the internal corporate standards of the Companies.

4.8.3. Medical supplies to improve the provision of medical services and patient care.

Medical supplies may be offered or provided by member companies if such items are of modest (moderate) value, do not compensate for routine business practices and contribute to the improvement of the quality of medical services and patient care.

Such items should not be offered on an ongoing basis, even if the provision of individual medical supplies is appropriate.

Medical supplies may include a company logo, but must not contain the name or logo of the product (trademark), unless the presence of the product name is necessary for the correct use of the item by the patient.

4. 8. 4. Information materials - reference and information materials, as well as other educational materials (medical publications) can be transferred to Health Specialists and organizations free of charge, if they really serve educational purposes. Any such materials (including printed materials) must be presented in a clear and legible manner. Scientific substantiation and information about the Pharmaceutical product must comply with the requirements of the legislation of the Republic of Uzbekistan and this Code.

5. INTERACTION WITH PATIENTS AND PATIENT ORGANIZATIONS

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

5.1.1. Companies are allowed to interact with Patient Organizations to solve the following tasks:

- studying the views of Patients on the impact of the disease on the quality of life of Patients and the opinions of their caregivers, which can help optimize the program of clinical trials of Pharmaceutical products and accelerate the development of those that best meet the needs of Patients;
- implementation of information support for associations of Patients by responding to requests according to established rules;
- creation of registers of Patients subject to strict observance of the legislation on the protection of personal data and medical secrecy;
- organizing campaigns to inform the general public about the disease;

- cooperation in organizing the provision of an unregistered Pharmaceutical Product to Medical Organizations to provide medical care to specific Patients for health reasons;
- provision of charitable assistance; other cases that do not contradict the legislation of the Republic of Uzbekistan. Interaction should never be a covert promotion of the Company's products.

5.1.2. When the Company cooperates with a Patient Organization, the fact and nature of such cooperation must be clearly disclosed by the Company in its documents.

At the same time, the Company may be the only source of funding for a charitable and/or social project of a Patient Organization upon receipt of a relevant written request from the Patient Organization for the implementation of programs of such an organization aimed at preventing and protecting the health of citizens, promoting a healthy lifestyle, helping socially vulnerable groups of the population, if such financing (donation) is not aimed directly or indirectly at encouraging the Patient Organization to make any decisions in the course of carrying out its statutory activities in favor of the Company or its products.

At the same time, in any case, such a Company should not restrict the rights of other Companies to finance the same projects of the Patient Organization if they wish.

5.1.3. Any relationship between Companies and Patient Organizations must be clearly documented.

5.1.4. Companies may provide financial support for events of Patient Organizations, provided that the primary purpose of the event is educational or scientific, and for other generally beneficial purposes that contribute to the mission of such an organization. In the event that funding is provided for an event by a Patient Organization, Companies are required to ensure that the venue and conditions for the event meet the requirements for hospitality limits.

Funding for Patient Organizations must not be related to Product Promotion. The Company must not have a controlling or dominant financial position when it comes to funding Patient Organizations in order to avoid interfering with the independence of such an organization.

5.1.5 Interaction with Patients should not replace the role of the Patient's physician in making individual treatment decisions. Company employees must not provide any personal, medical or drug-related advice to Patients and are always required to refer a Patient to their primary care physician for all matters related to individual medical care. Interaction should never be a covert promotion of the Company's products.

6. BASIC RULES AND NORMS FOR THE ACTIVITIES OF MEDICAL REPRESENTATIVES

6.1. The activities of medical representatives of pharmaceutical companies should be primarily informational in nature.

6.2. Medical representatives must be appropriately trained to ensure that information about company medicines is provided in an accurate, responsible and ethical manner.

The pharmaceutical company is responsible for the content and form of information transmitted by medical representatives.

6.3. Key Responsibilities of a Medical Representative:

- Information interaction with healthcare professionals on all medical aspects of the use of medicines, through individual visits and participation in collective events of healthcare professionals;
- organizing and conducting trainings and presentations on the company's products;
- maintaining relationships with healthcare professionals providing information support
- Research of the situation on the market and the competitive environment.
- Implementation of the collection and analysis of information about the regional market, the development of a strategy for promoting the company's products based on its results.
- Promoting and providing access to pharmaceutical products in accordance with ethical and legal standards.

6.4. In its activities, the medical representative is guided by the laws of the Republic of Uzbekistan and other regulatory legal acts regulating activities in the field of providing the population with medicines, pharmacy, retail trade rules, other local acts of the organization, administrative documents of the head of the company in relation to the specialization of the position.

6.5. A medical representative of a pharmaceutical company must comply with the ethical principles declared by the company in which he works, as well as follow the principles reflected in this Code.

6.6. The medical representative must not use inducements to obtain visitation rights and must not offer any reward or damages for this purpose.

6.7. The medical representative must comply with the schedule and hours of visits specified by the healthcare professional, request information on the duration of the visit, desirable for the healthcare professional, and not interfere with the normal functioning of the medical institution.

6.8. During the visit, the medical representative should, at the request of a healthcare professional, be able to provide him with instructions for medical use / a summary of characteristics of each pharmaceutical product that he informs about, as well as information on the conditions of dispensing (categorization as prescription or over-the-counter, dispensed for preferential categories of citizens, etc.) of a pharmaceutical product and its availability in pharmacies.

6.9. Information provided by a medical representative about the promoted medicinal product, as well as about the drugs of the corresponding therapeutic group of competing companies, should not contain any offensive remarks both about competing companies and their employees.

6.10. Medical representatives are obliged to bring to the head of the relevant division of their company information on the practical use of the company's pharmaceutical products, including side effects, etc., received during visits to healthcare professionals.

7. SAMPLES

According to the order No. 442 of the Ministry of Health of the Republic of Uzbekistan dated December 27, 2013, employees of healthcare facilities are strictly prohibited from receiving free samples from medical representatives, as well as their free distribution or sale to visitors and patients of medical institutions.

8. DEALING WITH REQUEST FOR MEDICAL INFORMATION

8.1. The company must carefully consider each request of a healthcare professional. Each request must be logged and answered, regardless of the method of receipt (e-mail, regular mail, fax or telephone).

8.2. Information provided to healthcare professionals in response to a request must fully comply with local legislation, approved instructions for use of a pharmaceutical product and this Code.

8.3. The response to a health care professional's inquiry should not serve the purpose of promoting pharmaceutical products. It should be limited to answering the directly asked question.

8.4. All responses must be provided in a polite and understandable manner, in accordance with the level of knowledge and education of the person making the request.

8.5. Pharmaceutical company employees are not entitled to initiate discussions with healthcare professionals and other third parties about unregistered pharmaceutical products and/or unregistered indications for their use.

8.6. Information on non-registered pharmaceutical products and/or off-label indications is provided only to healthcare professionals upon request to a pharmaceutical company.

8.7. In response, the healthcare professional must provide comprehensive and evidence-based information on the question asked. In written responses, all statements and facts must be supported by appropriate references indicating the name of the author, the full title of the article or monograph, place of publication (traditional abbreviations are allowed), year of publication, volume number, issue and page number.

8.8. Personal data of healthcare professionals and other persons may be included in the databases of pharmaceutical companies only if they have their consent in the form established by law and in compliance with other requirements of legislation in the field of personal data protection.

8.9. When a patient contacts a pharmaceutical company for information, such requests must be met. Such interaction should not be used to advertise and promote a pharmaceutical product, including after its implementation, for example, by publishing correspondence in the media.

8.10. In response to a patient's request, he should not be provided with any information aimed at the promotion of pharmaceutical products, as well as medical consultation with an attempt to make a diagnosis, proposals for possible treatment plans.

8.11. If a patient raises questions about their diagnosis and asks for special treatment recommendations, any company representative (including an employee of the Medical Department) must recommend that they contact their doctor or emergency medical services.

9. PHARMACEUTICAL RESEARCH

9.1. Post-registration studies.

9.1.1. Post-registration studies, including post-registration clinical (interventional) studies, post-registration observational (non-interventional) studies and epidemiological studies must comply with the requirements of the legislation of the Republic of Uzbekistan, as well as the requirements established by this paragraph.

9.1.2. Post-registration studies must have a rationale and scientific purpose, which are reflected in the study protocol.

9.1.3. The organization and control of the post-marketing studies is carried out and is the responsibility of the Medical Department or the relevant medical functional unit / employees of the pharmaceutical company.

9.1.4. The selection of investigators should be based solely on their professional qualifications and clinical experience and should not be in any way related to past, current or potential future prescriptions or recommendations for the company's pharmaceutical products.

9.1.5. Data obtained during post-registration studies should be statistically processed and analyzed.

9.1.6. Post-marketing studies must comply with laws, regulations and requirements regarding the confidentiality of personal data (including the collection and use of personal data).

9.1.7. The post-marketing study protocol must be approved by the Medical Department or the responsible medical functions/employees, and the Medical Department (relevant medical functions/staff) must coordinate and supervise the progress of the post-marketing studies.

9.1.8. The participation of a healthcare professional in a post-marketing study should not be an inducement to recommend/prescribe, purchase, sell or use any particular pharmaceutical product.

9.1.9. The remuneration provided for post-registration studies to medical organizations must be reasonable and reflect the fair market value of the work performed.

9.1.10. It is forbidden to conduct post-registration studies under the guise of marketing studies.

9.2. Marketing research.

9.2.1. Marketing research conducted directly by pharmaceutical companies or by pharmaceutical companies with the involvement of marketing agencies is possible only if the requirements of the current legislation of the Republic of Uzbekistan are observed.

At the same time, pharmaceutical companies and/or involved agencies are not entitled to pay remuneration to healthcare professionals for their participation in the Marketing Research. An exception may be cases of conducting Marketing research that requires special scientific knowledge and significant labor costs on the part of a healthcare professional, provided that:

- Marketing research is carried out with the involvement of independent agencies;
- the healthcare professional is not informed and it is not obvious from the study materials which pharmaceutical company is the customer/sponsor of the study
- the pharmaceutical company does not participate in the selection and does not know which healthcare professionals will take part in the Marketing Research.

9.2.2. The use of Marketing Research is not allowed:

- for the purpose of promoting or selling pharmaceutical products or to control the opinion or behavior of research participants. For this reason, mention of the trade name of a pharmaceutical product should be avoided unless required by the objectives of the study;
- to collect personal data of patients;
- for the purpose of further research into the efficacy or safety of a pharmaceutical product;
- for pre-registration promotion of a pharmaceutical product or indications for its use subject to registration;
- to obtain confidential information about competing companies;
- for the purpose of discrediting the pharmaceutical products of competing companies and for the purpose of harming competitors in any other way.

10. PROCEDURAL RULES AND LIABILITY OF PHARMACEUTICAL COMPANIES

10.1. Authorized person of the company

Companies must establish and maintain an appropriate operating procedure that ensures that the company's marketing activities comply with the legislation of the Republic of Uzbekistan and this Code.

In particular, companies should continuously monitor and analyze their own promotional activities for pharmaceutical products and related materials.

Promotional items must be approved by management or, in certain circumstances, by a responsible person with appropriate scientific or medical qualifications, before they are distributed.

10.2. Stock programs and documentation

Stocks for the promotion of pharmaceutical products, sales promotion, etc. must be carried out in accordance with the programs approved by the authorized person of the company, in the process of their implementation, documentation reflecting the course of shares must be maintained. Programs should include:

- description of the action indicating the purpose, objectives, target group;
- timing;
- conditions for participation in it of health professionals and citizens, if any, proposals made by them;
- timetable;
- distribution of duties and responsibilities among the organizers and participants;
- exemplary forms of agreements (if any) with healthcare professionals, medical institutions, clinics;
- instructions for participants in the organization and conduct;
- advertising and information materials, etc.;
- changes made to the program, including during the event or action.

10.3. Storage of documentation

Programs of events (promotions), documentation for their implementation, samples of advertising materials must be stored in an authorized division or with an authorized person of the company for at least a year after the end of the event, promotion or advertising campaign, unless a longer period is provided for by applicable law.

Programs and documentation must be provided to regulatory authorities in accordance with applicable advertising legislation.

10.4. Staff development

In order to maintain high standards in the implementation of marketing activities, companies must adhere to the principle of continuous professional development of their employees in this area.

11. MAINTENANCE AND DEVELOPMENT OF THE CODE

11.1. Adherence to the Code of Marketing Practice of the Association of Representative Offices of Foreign Pharmaceutical Companies and Manufacturers and implementation of its provisions are a prerequisite for membership in this organization;

11.2. The expansion of the arsenal of methods and means of marketing practice, their modification in the conditions of the developing pharmaceutical market of Uzbekistan necessitate the constant maintenance and development of the Code so that it meets the requirements of the time and does not have gaps in the regulation of advertising and other methods of promoting pharmaceutical products.

12. WORKING GROUP ON MARKETING ETHICS

12.1. The analysis of the functioning of the Code is carried out by the Working Group on Marketing Ethics.

The Working Group on Marketing Ethics is created to ensure coordination and control of the activities of the members of the Association, aimed at observing the ethical principles of marketing practices adopted in the pharmaceutical research industry.

The competence of the Working Group on Marketing Ethics includes consideration and resolution of issues of improper compliance with the ethical norms and rules of this Code.

12.2. Composition of the Marketing Ethics Working Group.

The Working Group is composed of at least three people.

Members of the Working Group are elected by the General Meeting of Members of the Association for a period until the next annual General Meeting by a simple majority of votes.

Persons elected to the Working Group may be re-elected an unlimited number of times. The Director and members of the Board of the Association cannot be elected to the Working Group.

Changes in the composition of the Working Group may be made by the Working Group itself.

12.3. Rights and Obligations of Members of the Marketing Ethics Working Group

Members of the Working Group have the right to get acquainted with the materials of the plaintiff company for collecting information about the unethical promotion of medicines, medical devices and medical equipment that caused the complaint, as well as request materials from the plaintiff company confirming the unethical behavior of the company.

Members of the Working Group are obliged to ensure confidentiality of the information received and non-disclosure of information that became known to them in the course of their functions.

Members of the Working Group, when exercising their rights and fulfilling their obligations, must act in the interests of observing the ethical norms of this Code, exercise their rights and fulfill their obligations in relation to the members of the Association in good faith and reasonably.

12.4. Chairman of the Working Group on Marketing Ethics.

The Chairman of the Working Group is elected by the members of the Working Group from among them by a majority vote of the total number of members of the Working Group.

The Working Group has the right to re-elect its Chairman at any time by a majority vote of the total number of members of the Working Group.

The Chairman of the Working Group is only a member of the Association.

The Chairman of the Working Group organizes its work, convenes meetings of the Working Group and chairs them, organizes the keeping of minutes at the meetings.

12.5. Meetings of the Working Group on Marketing Ethics.

Meetings of the Working Group are held as needed.

The meeting of the Working Group is convened by the Chairman of the Working Group on his own initiative, on the initiative of a member of the Working Group, upon receipt of a complaint from members of the Association.

12.6. Procedure for the Working Group on Marketing Ethics.

The procedure for the work of the Working Group and the adoption of decisions by it is determined by the Working Group itself.

Members of the Working Group participate in its work free of charge.

Procedure for consideration of applications and disputes about infringement
Code of Marketing Practice

The Association considers allegations of violation of the Code only in relation to marketing practices carried out within the Republic of Uzbekistan

An application for violation of the Code can be filed both by a member of the Association and by any other interested person.

The application can be directed both to the actions of a member of the Association, and to the actions of any pharmaceutical manufacturer that is not a member of the Association, but operates in the Republic of Uzbekistan.

The application is submitted in writing addressed to the Director of the Association

The application must contain:

- information about the applicant (name for an individual; name for a legal entity and its contact details);
- the name of the company in respect of which there are suspicions of violating the Code;
- the name(s) of the pharmaceutical product(s) the marketing of which is suspected of violating the Code;
- Documents and materials evidencing the alleged infringement, such as promotional materials;
- details of when the alleged violation took place;
- a brief description of the essence of the alleged violation, including references to the relevant paragraphs of the Code.

The materials related to the application (case materials) are confidential. Only the parties to the dispute have access to the case file. The exception is when a Marketing Ethics Working Group is set up to decide on a case.

The parties to the dispute, the director and secretariat of the Association, as well as members of the Working Group must respect the confidentiality of the case file.

Disclosure of the case file to a third party is considered a serious breach of the Association's procedures.

After receiving the application, the Director makes sure that the necessary documents and materials are available, as well as signs of a violation of the Code.

After checking these conditions, the Director, within two working days from the date of receipt of the application, confirms to the applicant that his application has been accepted for consideration, and also informs and acquaints the company in respect of which the application has been accepted with the application, documents and materials received.

A company in respect of which an application for violation of the Code has been filed has the right to respond to the application within ten working days. This period is calculated from the

moment the application is received directly by the company. The answer is submitted in writing addressed to the Director of the Association.

The answer should contain:

- recognition of the fact of the violation and information on the steps taken to correct the situation;
- or
- refusal to admit the violation, as well as clearly articulated and, where appropriate, documented grounds for such refusal.

Upon receipt of the response, the Director must send it to the applicant within three working days. Within five working days, the applicant must consider the response received and inform the Director of whether he considers the response received satisfactory or not. After that, the Director decides whether the conflict can be considered settled, or the Association should take additional actions to establish and recognize the violation.

If the answer satisfies the applicant, and the mutual decision of the parties does not contradict the interests of other members of the Association and the Code, the Director records the fact of settlement of the dispute in writing, and the case is considered closed. The case may also be closed if the Director considers the answer received satisfactory, and the applicant has not expressed his attitude towards him within the time period provided for this above.

The obligations and agreements reached in the event of an independent settlement of the dispute are binding on the parties to the dispute. In case of violation of the reached obligations and agreements, any party has the right to apply to the Association with a new complaint, which is considered according to the above procedure.

In the event that the procedure described above does not lead to a solution to the satisfaction of the disputing parties, the case moves to the Marketing Ethics Working Group.

Sanctions for violations of the Code

In the event that a violation of the Code is recognized by the Working Group, it may make a recommendation to the Association to impose the following sanctions:

- Promulgation of the violation, including the name of the offending company at the general meeting of the members of the Association;
- Oblige the employees of the offending company to undergo training on the Code;
- Informing about the violation of the headquarters of the offending company;
- In the event of a serious violation - the collection of a fine in an amount not exceeding the annual membership fee.² The collected fine is used in accordance with the decision of the next General Meeting of the Association;

A serious violation is a violation that is committed repeatedly within 24 months when promoting the same pharmaceutical product, or a violation similar to the previously established one, but committed when promoting another pharmaceutical product;

- Recommendation to the General Meeting of the Association on the exclusion of the violating company from the members of the Association. Exclusion from the membership of the

² The sanction applies only to companies - members of the Association

Association does not release the company from existing financial obligations, including payment of the imposed penalty;

- Any combination of the above sanctions.

A company in respect of which a decision on a violation of the Code has been made is obliged to inform the Association about the measures taken to implement the decision of the Working Group on Marketing Ethics within the time limits established by the Working Group. If the Association does not receive the relevant notification, the Director of the Association sends an additional letter with the relevant request to the Company. If the Association does not receive this notification within ten working days from the date of receipt of the additional letter by the Company, the Director of the Association has the right to contact the headquarters of the Company.