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Kazakhstan
Pharmaceutical Advertising

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Kazakhstan.

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Kazakhstan: Pharmaceutical Advertising

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Kazakhstan, advertising on medicines is governed by several regulations, including:

- *the Code of the Republic of Kazakhstan On Public Health and Healthcare System* dated July 7, 2020 No. 360-VI ЗРК (**Health Code**), establishes general guidelines for advertising in the healthcare area and designates supervisory bodies;
- *the Law On Advertising* dated December 19, 2003, № 508, to the extent not specified by the regulations listed below;
- *the Rules for Advertising of Medicines and Medical Products*, approved by the Order of the Minister of Healthcare dated December 20, 2020, No. ҚР ДСМ-288/2020 (**Rules for Medicines Advertising**). This regulation sets out detailed guidelines for medicine advertising;
- *the Rules for Ethical Promoting of Medicines and Medical Products*, approved by the Order of the Minister of Healthcare dated December 21, 2020, No. ҚР ДСМ-294/2020 (**Ethics Rules**). This regulation governs the format and conditions of interactions between entities in the pharmaceutical industry and healthcare professionals.
- *the Rules for Labeling of Online Advertising*, approved by the Order of the Minister of Culture and Information dated February 16, 2024, № 59-НҚ. This regulation applies to online advertising, including social media advertising.

2. Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?

Where the legislation of Kazakhstan establishes mandatory regulations governing advertising and promotion for all participants in the healthcare market, the Code of Ethics of the Association of International Pharmaceutical Manufacturers in the Republic of Kazakhstan (hereinafter, the "AIPM Code of Ethics"), as amended in 2024, delineates additional fundamental principles that all members of the AIPM are obligated to adhere to when conducting the marketing and promotion of pharmaceutical products within Kazakhstan. The AIPM Code of Ethics has been developed in alignment with international marketing practice codes prevalent in the research pharmaceutical industry, taking into account the legal requirements of Kazakhstan, and establishes the ethical standards to be upheld by AIPM members.

3. Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?

Under the Law on Advertising, "advertising" is defined as information disseminated and/or placed in any form by any means, intended for an indefinite number of individuals and designed to create or sustain interest in a person or legal entity, goods, trademarks, works, services, and to facilitate their realization (sale).

Concerning medicines specifically, the Rules for Medicines Advertising define advertising as information disseminated and/or placed in any form by any means, intended for an indefinite group of individuals, containing an item or a set of information about medicines that contributes to their promotion and sale.

While the Rules for Medicines Advertising provide a broad definition of advertising, they also delineate a precise list of exceptions. Specifically, instructions for medical use, trade catalogues, price lists, reference materials, scientific information materials, and educational and methodological materials of a medical nature, as well as information related to health or diseases, or details about the individual or legal entity manufacturing or selling the medicine, are not classified as advertising.

Accordingly, as indicated by its definition, the advertising and promotion of medicines are aimed at an indefinite audience. Practically, the determination of whether certain promotion materials constitute advertising depends on the arrangements made to define the audience; promotional materials communicated to a limited audience may be considered not to be advertising.

4. Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?

Press releases regarding medicines are permitted to the extent that they are compliant with advertising regulations. The dissemination approach should vary based on the content of the press release and whether it pertains to prescription or non-prescription medicines. Generally, the information provided must be reliable and easily recognizable without requiring specialized knowledge or tools, and must refrain from making comparisons with other medicines. Additionally, it is essential to avoid misleading consumers or abusing their trust, particularly with respect to the characteristics, composition, consumer properties, pricing, expected results of use, and outcomes of research and testing.

5. Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?

Pharmaceutical companies in Kazakhstan have the flexibility to establish their own internal advertising approval procedures. While neither local laws nor the AIPM Code of Ethics impose strict requirements in this regard, companies typically develop internal guidelines to ensure compliance with legal restrictions and to maintain consistency with their overall promotional strategy.

6. Do companies have to have material approved by regulatory bodies prior to release?

Yes, in order to disseminate an advertisement to a wide audience, prior approval from an authorized body is necessary. This approval verifies that the advertisement's content aligns with the established criteria for public distribution and adheres to current advertising regulations.

The approval process requires the submission of advertising materials to an authorized organization for assessment. The organization will then issue a conclusion regarding the advertisement's compliance with current advertising legislation. The advertisement can only be publicly disseminated upon receipt of this approval.

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

The Rules for Advertising on Medicines prohibit exaggerating a medicine's pharmacological properties and therapeutic indications or comparing it to other medicines.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to send information to healthcare professionals?

Advertising of unauthorized medicines or indications is strictly forbidden.

Nevertheless, the participants of pharmaceutical market may provide information on non-registered medicines to healthcare professionals and members of professional associations:

- in the form of reference, medical literature, scientific journals – during daily medical meetings, scientific-practical conferences and/or specialized seminars, or
- in the form of scientific-informational materials, guideline for medical use of non-registered medicine – for the purpose of treatment of life-threatening conditions or medical aid to a limited contingent of patients with rare (orphan) diseases or conditions, provided it is a full, objective, precise and confirmed information.

Finally, the Health Code allows the information on *inter alia* the medicines not compliant with Kazakh healthcare legislation requirements to be provided in specialized print media designated for healthcare professionals. Thus, conceivably the information on unauthorized medicine can be presented to healthcare professionals under specific conditions.

9. Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, and include the information that must or must not be included.

Generally, medicine advertisements may be placed in mass media, including television, radio, periodicals, and Internet-periodicals registered as media, as well as

electronic information resources of healthcare organizations.

At the same time, advertising of prescription medicines in mass media is strictly prohibited, and it may only be placed in specialized print publications for healthcare professionals, as well as specialized events such as medical, pharmaceutical conferences, symposia, meetings, etc.

State authorities oversee the production, distribution, and placement of medicine advertisements. All advertisements must:

- Be in Kazakh and Russian languages.
- Provide accurate and reliable information consistent with the product's approved instruction for use.
- Avoid exaggerating pharmacological properties or therapeutic indications and misleading statements.
- Refrain from comparing the medicine to other products.
- Be clear, understandable, and easy to comprehend without specialized knowledge or tools.

The Ethics Rules apply to healthcare organizations, manufacturers, distributors, healthcare and pharmaceutical professionals, and members of professional associations.

Manufacturers' and distributors' representatives are prohibited from promoting medicines in healthcare organizations and educational institutions, except during daily medical conferences, scientific and practical conferences, or specialized seminars.

Mandatory Information for Medicine Advertisements

Advertisements for medicinal products must include the following essential information, though, depending on the source of media, whether it is TV channels, Internet resources, or radio channels, certain points may be excluded as non-mandatory:

- trade name
- INN or information about active ingredients in the composition
- main indications for use
- method of administration and doses
- main side effects
- main conterindications
- special instructions for use by children, pregnant women and, if applicable, during breastfeeding
- release conditions
- explicit recommendation to read before use the instruction for medical use and a warning that self-medication can be harmful to one's health
- name and address of manufacturer and/or a trade representative in Kazakhstan
- number and date of issue of the registration certificate
- expiration date of a medicine registration.

It is prohibited to:

1. advertise medicines that are not registered in Kazakhstan;
2. advertise prescription medicines in mass media;
3. distribute samples of prescription medicines for advertising purposes;
4. use children, their images and voices in advertising the medicines, except for medicines for children;
5. distribute and place advertisements of medicines in public transport vehicles, organizations not related to prescription, use and dispensing of medicines, except for advertisements of medicines at medical, pharmaceutical conferences, congresses, symposia and others scientific meetings;
6. place advertising information on industrial products, prescription forms;
7. place outdoor (visual) advertising of medicines;
8. engage healthcare professionals authorized to prescribe medicines as advertisers, except for the cases of providing reliable information on medicines for scientific or educational purposes or informing the patients;
9. indicate in public advertising the methods of treatment of such diseases as sexually transmitted diseases, oncological, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, TB disease, diabetes mellitus;
10. refer during advertising to the recommendations of scientists, healthcare specialists, as well as officials of state bodies, who may encourage the use and (or) prescription of medicines;
11. present medicines in advertising as unique, safest and most effective;
12. assert that the safety and efficacy of a medicine are due to its natural origin;
13. cause assumptions that the effectiveness of treatment with an advertised medicine is guaranteed and the use of the product does not develop side effects;
14. provide information that does not directly relate to the advertised medicine.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

When interacting with patients and patient organizations,

the companies must adhere to the Rules for Medicines Advertising, the Ethics Rules and other Kazakh legislation. While interactions such as consultations or sponsorships are generally permissible, they must be conducted in compliance with the restrictions outlined in these regulations.

The AIPM Code of Ethics offers valuable guidance on the nature of relationships between patient organizations and AIPM members.

- The company should not solicit and the patient organization should not undertake any actions aimed at promoting a specific pharmaceutical product available on prescription. The interaction should never constitute a covert promotion of a pharmaceutical product.
- Companies may provide financial support to patient organizations, which must be transparently and clearly disclosed and documented by the company.
- The company may be the sole source of funding for a patient organization to organize a specific program upon receipt of a corresponding written request from the patient organization, and the company must not limit the rights of other companies to finance the same projects of the patient organization if they so desire and upon a corresponding written request from the patient organization.
- When providing financial support for holding events of patient organizations and holding events with the participation of a patient organization, provided that the primary purpose of the event is educational or scientific in nature, and for other public benefit purposes that contribute to the fulfilment of the mission of such patient organization, the support must not contain any mention of prescription products.
- Funding of patient organizations and the organization of events by the company with the participation of patient organizations must not be related to product promotion and must be carried out by functions of the company that are not directly related to the sale of pharmaceutical products.
- The company should not have a controlling or dominant financial position when it comes to the funding of patient organizations, to avoid interference with the independence of such organization.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

When providing information to a limited group of healthcare professionals, such as during medical conferences, seminars, or through scientific literature, the primary guidelines are outlined in the Ethics Rules. This includes the obligation to provide accurate, objective, and scientifically sound information in the form of reference, medical literature, scientific journals, scientific and informational material, instructions for the medical use of registered medicinal products, including medicines unregistered in Kazakhstan for the provision of medical care for vital indications of a specific patient or the provision of medical care to a limited contingent of patients with rare (orphan) diseases and (or) conditions. Information may be provided during daily medical conferences, scientific and practical conferences and/or specialized seminars.

It's important to note that direct, individual interactions between medical sales representatives and healthcare professionals during working hours and at their workplaces, with the intent of promoting medicines, are prohibited.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

According to the Ethics Rules, a violation of ethics includes provision or offer of financial remuneration or any other incentives of a material or non-material nature to healthcare professionals for prescription and dispensing of certain medicines, as well as payment for entertainment, recreation, travel to a place of rest, with the exception of payments related to implementation of scientific and educational activities.

The Code of Honor of Medical and Pharmaceutical Workers of the Republic of Kazakhstan, approved by the Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 23, 2020 № ҚР ДСМ-319/2020 establishes that a healthcare professional in his/her activities must not allow acceptance of gifts or services from individuals and legal entities in connection with performance of official duties.

Receiving a gift of negligible value (approximately 35 USD or less) would not constitute a criminal offense. However, such conduct may still be subject to disciplinary action.

13. Are pharmaceutical companies allowed to

provide samples to healthcare professionals?

The distribution of prescription drug samples for advertising purposes, including those containing narcotic or psychotropic substances, is strictly prohibited. While there may not be explicit restrictions on the distribution of over-the-counter (OTC) medicine samples, it raises questions about the rationale behind providing samples to healthcare professionals, especially considering their limited role in promoting specific medications.

14. Are pharmaceutical companies permitted to sponsor scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Pharmaceutical companies may sponsor scientific meetings and congresses, and support healthcare professionals' attendance at such events, regardless of the event's location. However, such support should not be contingent on any promotional obligations. Companies should enter into agreements with healthcare professionals to clarify that travel expenses do not impose any promotional duties.

When organizing scientific events, pharmaceutical companies should ensure that participation is open to all relevant stakeholders, regardless of their affiliation with competing companies.

For healthcare professionals employed by state-owned organizations, participation in such events may require approval from the organization's head, as per the organization's charter.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

Given that covering expenses for entertainment, recreation, or leisure travel is generally prohibited, except for activities related to scientific and educational purposes, it can be argued that the participation of healthcare professionals in such events within the context of scientific conferences may constitute a violation of regulations.

Furthermore, the AIPM Code of Ethics explicitly prohibits sponsoring or organizing entertainment events as part of hospitality activities.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Following the Ethics Rules, compensation to healthcare professionals should be limited to their participation in scientific and practical conferences, congresses, and symposia. Importantly, such participation should not be contingent upon any promotional obligations.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

Pharmaceutical companies may provide support to healthcare professionals for their participation in scientific and practical conferences, congresses, and symposia, provided that such support is not contingent upon any promotional obligations. For further details, please refer to Q.14.

All other forms of support, including grants and donations, must comply with the restrictions imposed on healthcare professionals regarding the acceptance of gifts or services related to their official duties.

Legislation permits the provision of grants or donations to healthcare institutions. If a donation is provided without a specific purpose, it may be considered a gift. However, if a specific purpose is designated, the healthcare institution must maintain detailed records of all transactions involving the use of the donated funds. If the original purpose becomes unattainable, the donation can only be redirected with the donator's consent.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

There are no statutory requirements for pharmaceutical companies to disclose details of transfers of value to

healthcare professionals or healthcare organizations.

However, when transferring valuables to healthcare institutions, the parties are required to enter into an agreement on transfer of valuables. The transfer of valuables from a pharmaceutical company, including a foreign one, will be largely regulated by tax legislation, since the valuables will have to be included in the balance sheet of the healthcare institution and their origin will have to be disclosed when submitting tax reports.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

According to the newly adopted Rules for Labeling Online Advertising dated March 1, 2024, online advertising placed by influencers (bloggers) on a commercial or contractual basis is subject to mandatory labeling.

This labeling must be clearly visible and indicate that the content is an advertisement. Acceptable labels include: “advertising,” “promotional material,” “affiliate material,” “sponsored material,” “paid for by the sponsor,” or “PR." This option is available only for non-prescription medicines and can be executed subject to prior approval from the authorized body to ensure compliance with advertising regulations.

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

Pharmaceutical companies' activities related to the promotion of prescription medicines to healthcare professionals are self-regulated within the framework of existing legislation. This includes restrictions on advertising prescription medicines outside of professional events, advertising non-prescription medicines in accordance with general promotion guidelines, and labeling online advertising on social media.

When interacting with healthcare professionals online regarding prescription medicines, it is crucial to implement access restrictions to websites containing advertising or other information intended solely for healthcare professionals.

Targeted online advertising placed on online platforms must be automatically marked as such using the platform's technical capabilities.

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

The Law of the Republic of Kazakhstan “On Combating Corruption" outlines potential administrative or criminal liability for healthcare workers who illegally receive material rewards, gifts, benefits, or services, regardless of the source. For further details, please refer to Q. 12.

22. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

The Code of Honor of Medical and Pharmaceutical Workers in Kazakhstan prohibits healthcare professionals from accepting gifts or services from individuals and legal entities in connection with their official duties. Offering benefits and services to healthcare professionals in Kazakhstan is subject to administrative penalties, including a fine of 750 MCI (approximately 5,500 USD). For further details, please refer to Q.12.

23. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Before placing an advertisement, the Company must obtain a conclusion on compliance of a medicine advertising with the requirements of healthcare legislation, issued by the Republican State Enterprise on the Rights of Economic Management “National Scientific Center for Healthcare Development named after S. Kairbekova".

Control over compliance with the Rules on Medicines Advertising is carried out by the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan, and the Committee of Sanitary and Epidemiological Control of the Ministry of Healthcare of the Republic of Kazakhstan. Depending on the violation specifics, these two state bodies are authorized to record the violations.

Depending on the violation of advertising legislation in the field of healthcare:

- a dispute between pharmaceutical companies shall be resolved by a civil court;
- in case of violation of the Health Code, the Rules for Medicines Advertising, disputes are resolved by an administrative or criminal court respectively.

Within the AIPM, in the event of allegations of improper compliance with ethical standards and provisions of the Code of Ethics, the interested parties shall attempt to resolve the issues through negotiations. A formal complaint regarding such non-compliance should be submitted to the AIPM Ethics Committee, accompanied by a detailed description of the circumstances and supporting evidence.

The AIPM Ethics Committee shall consider the complaint at meetings with representatives of both parties and, guided by the Code of Ethics, shall issue a determination regarding any ethical violations.

In the event that the respondent company refuses to acknowledge the violation of the Code of Ethics, the complainant company or the AIPM may escalate the matter to the relevant government authorities. In other cases, the defendant company may be subject to the following sanctions, as determined by the General Meeting of the AIPM:

- A written warning to the defendant company.
- A written notification to the headquarters (head office) of the defendant company group regarding unethical behavior in the market.
- Exclusion from the AIPM.

24. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Administrative proceedings for violations of pharmaceutical advertising rules may be initiated upon a complaint filed by any interested party with the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan.

If a violation constitutes a criminal offense, criminal proceedings may be initiated by the specialized interdistrict criminal court by the place of the respondent's registered address.

Civil proceedings may be initiated in the specialized interdistrict economic courts in the jurisdiction of the respondent's registered address.

Please also refer to Q.23 above.

25. What are the penalties, sanctions or measures that regulators or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Violation of the rules of pharmaceutical activity and the scope of medicines circulation, including advertising rules, without causing harm to human health, may result in administrative penalties. Officials may face fines of up to 100 monthly calculated indices (approximately 750 USD), while legal entities may be fined between 130 to 1,000 MCI (approximately 950 to 7,500 USD). A second violation within the same year could lead to a suspension of the pharmaceutical license for up to six months.

Advertising unregistered or prohibited medicines, among other violations, without causing harm to human health, may result in fines ranging from 100 to 1,500 MCI (approximately 750 to 11,100 USD), along with potential suspension of activities and confiscation of relevant medicines and related income.

If such advertising causes harm to human health, but does not constitute a criminal offense, the penalties may include fines ranging from 200 to 2,000 MCI (approximately 1,500 to 15,000 USD), confiscation of relevant medicines and related income, and prohibition of the activity.

26. What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?

The procedures and measures undertaken by the AIPM Ethics Committee are distinct from those of the Committee for Medical and Pharmaceutical Control and the judicial system.

Given the self-regulatory nature of the AIPM and the voluntary adherence of its members to the Code of Ethics, the procedures and measures implemented by the AIPM are governed by civil law principles. However, in cases where a respondent company disputes a violation of the Code of Ethics, the complainant company or the AIPM may escalate the matter to the relevant government

authorities.

In contrast, the decisions of the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan and the courts are legally binding on all parties involved.

27. Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.

The observed practice indicates that the enforcement of advertising regulations by authorized bodies is quite unrepresentative. In the past two years, there have been no publicly reported instances of enforcement actions.

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