ADVERTISING OF DRUGS AND DIETARY SUPPLEMENTS

GRATA INTERNATIONAL

ADVERTISING OF DRUGS AND DIETARY SUPPLEMENTS IN BELARUS

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I. RULES OF ADVERTISING

Key regulations, definitions

Belarusian Legislation sets specific requirements for medical and healthcare advertising, including advertising of drugs and dietary supplements.

Advertising of drugs and dietary supplements is mainly regulated by:

- **Law of the Republic of Belarus of May 10, 2007 No. 225-Z 'On advertising' (hereinafter - Law on advertising);**
- **Resolution of the Ministry of Health of the Republic of Belarus (hereinafter - Ministry of Health) of July 23, 2013 No.63 'On implementation of Law of the Republic of Belarus of May 10, 2007 No. 225-Z 'On advertising' (hereinafter – Resolution No.63).**

'Advertisement' means information about an advertised product, placed (disseminated) in any form by any means, to bring attention to the advertised product, formation or maintenance of interest, and (or) promotion in the market (Art. 2 of the Law on Advertising).

'Drug' means a medicinal product in a dosage form (Art. 1 of the Law of the Republic of Belarus of July 20, 2006 No. 161-Z 'On Circulation of Drugs').

'Medicinal product' means a product that either consists of or contains a substance or a combination of substances, that comes into contact with the human body and is used for treatment, medical prevention of human diseases or restoring, correcting, or modifying physiological functions of the human body through pharmacological, immunological or metabolic action or to making a medical diagnosis of human diseases and conditions (Art. 1 of the Law of the Republic of Belarus of July 20, 2006 No. 161-Z 'On Circulation of Drugs').

'Dietary supplements' means natural, identical to natural food and (or) biologically active substances, as well as probiotic microorganisms, used for direct human consumption or incorporated into food products to enrich the diet and which are not meant to be the only source of nutrition (Art. 1 of the Law of the Republic of Belarus of June 29, 2003 No. 217-Z 'On the quality and safety of food raw materials and food products for human life and health').

Approval of the Ministry of Health

An important requirement for the advertising of drugs and dietary supplements is the approval of the Ministry of Health. The republican unitary enterprise 'Center for Examinations and Tests in Health Service' is a specially authorized body for advertisement approval.

There are several exceptions when approval by the authorized body is not required. For example, advertising of drugs carried out within the clinical trials of these drugs, conducted for their subsequent state registration, is not subject to approval only if advertising aims to attract volunteers (patients) to participate in clinical trials.

NB! Starting from July 12, 2024, the requirements for advertising will become stricter due to the changes to the Law on Advertising coming into force. Thus, outdoor advertising and advertising on vehicles of drugs and dietary supplements will be subject to the approval of the Ministry of Health.

Disseminating channels

It is allowed to advertise OTC drugs and dietary supplements through all possible sources (mass media, social networks, radio, television, outdoor advertising, advertising on vehicles, etc.).

Advertising of prescription-only drugs is permitted:

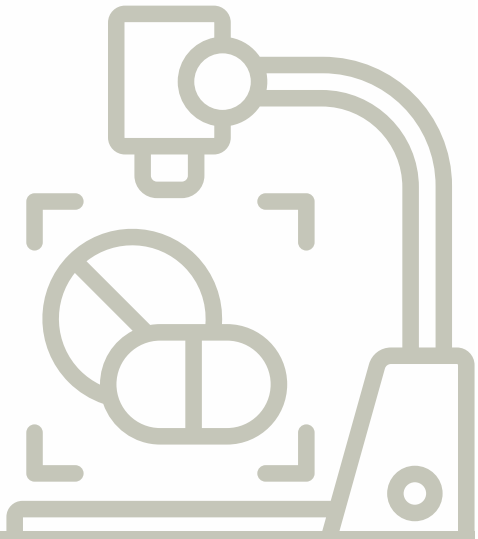
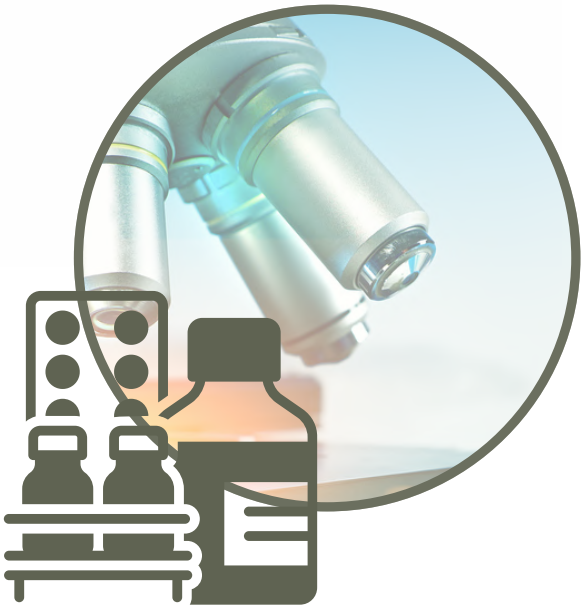
- through specialized press, a list of which is approved by the Ministry of Health (see Resolution No.63);
- in places of medical or pharmaceutical exhibitions, seminars, conferences, and other similar events.

It should be noted that the legislation separately regulates the procedure for informing healthcare professionals and pharmacists about drugs. Thus, the allowed forms of informing healthcare professionals and pharmacists are:

- oral presentation with/without displaying printed and other informational materials about a drug during meetings, conferences, seminars, symposiums, and other events approved by the Ministry of Health;
- placement of informational materials as part of the aforesaid events;
- providing informational materials to healthcare organizations in electronic form or on paper without personal interaction with healthcare professionals and pharmacists.

Advertisement Disclaimer

	DISCLAIMER IN A DRUG AD	DISCLAIMER IN DIETARY SUPPLEMENT AD
1	Name of a drug;	Name of a dietary supplement;
2	Notice that the object of advertising is a drug;	Notice that the object of advertising is a dietary supplement, not a drug, not meant for the treatment of diseases;
3	Name of the manufacturer of a drug;	Name of the manufacturer of a dietary supplement;

4	Recommendation on the need to read the instructions for use and (or) package insert of the drug and (or) consult with a doctor. *Exceptions:* *Such recommendation may be excluded from the disclaimer if the following conditions are met:* *a) Drug advertisement is placed in medical or pharmaceutical exhibitions, seminars, conferences, and other similar events or in specialized press, as defined in Resolution No. 63;* *b) The consumers of the advertisement are exclusively healthcare professionals and pharmacists;*	Information on the need to read the recommendations on the use of dietary supplements; 
5	Notice that the information is an advertisement. *Exceptions:* *a) outdoor advertising;* *b) advertising on a vehicle;*	Notice that the information is an advertisement;
6	Warning that a drug has contraindications to its use and undesired or adverse reactions (side effects);	Warning that a dietary supplement has contraindications to its use and undesired or adverse reactions (side effects);
7	Warning about the severity of symptoms, syndromes, or diseases the advertised drug is used to treat, in case there is relevant information in the characterization of the drug and (or) instructions for use (package insert);	
8	Warning on the limited duration of drug intake in case of the presence of relevant information in the general characterization of the drug and (or) instructions for use (package insert);	
9	Indication in advertisements of homeopathic products that the given product is homeopathic.	

II. PRACTICAL ISSUES

A. The most common violations are:

- failure to comply with the requirements for disclaimers;
- non-compliance with the requirements for the speed and sound of the voiceover;
- discrepancy between information given in the drug registration documents and the content of the advertisement.

B. Difficulties in the distinction between advertising and informing, allowing to freely interpret specific cases of providing information about drugs.

III. ADMINISTRATIVE PRACTICES

State authorities closely monitor compliance with legislation on advertising in the fields of pharmaceuticals and healthcare.

The following example is given to illustrate this point.

The Internet advertisement for the drug contained the following information:

- a statement that the therapeutic effect is guaranteed.

Citation: 'Will lower your blood pressure to age-appropriate levels without chemistry and side effects! Bring your blood pressure back to normal in minutes without harming your health!';

- a statement that the use of the drug is safe, in particular, due to its natural origin, and is not followed by the development of undesirable or adverse reactions.

Citation: 'No addiction and withdrawal syndrome because of its purely natural formula'.

- a recommendation of state authorities used to enhance the advertising effect;
- an information creating an impression of high speed of development of the therapeutic effect;
- an information creating a feeling of fear and apprehension about the possibility of deterioration of the state of health in case of termination of use of the drug.

Citation: 'Complete loss of capacity, and life without movement are terrible consequences of neglected hypertension. It is up to you to live a full life or spend the rest of it in fear of becoming disabled!'

The drug was not registered by the Ministry of Health.

The advertisement was recognized as inappropriate and banned from being placed (disseminated).

Link to the source: https://www.mart.gov.by/news/novost/mart-preduprezhdaet-gipertonium-uretramol-mnimye-lekarstva/?sphrase_id=208258

ADVERTISING OF MEDICINES AND BIOLOGICALLY ACTIVE FOOD ADDITIVES IN AZERBAIJAN

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The advertising of medical products in the Republic of Azerbaijan is a complex and evolving field. On the one hand, there is a need to ensure that patients have access to accurate and up-to-date information about medical products. On the other hand, there is a need to protect patients from false or misleading advertising.

The main legal act regulating the legal basis of order, production and distribution of advertising is the Law of the Republic of Azerbaijan "On advertising" dated May 15, 2015, #1281-IVQ ("Law on Advertising");

The definition of advertising is provided in Article 2 of the Law on Advertising. Advertising is the information disseminated to attract the attention of the advertising consumer to the object of advertising, form and maintain interest, ensure the recognition of the product in the market, and stimulate its sales using various means and methods.

As per Article 29.1 of the Law on Advertising, only medicines issued without a doctor's prescription can be advertised in the Republic of Azerbaijan.

In the advertising of medicines issued without a doctor's prescription, the following shall not be allowed:

- **addressing minors;**
- **referring to specific cases of recovery or improvement in health as a result of using the advertised medicine;**
- **demonstrating gratitude of individuals in connection with the advertised medicines;**
- **creating the idea about the necessity of using the advertised medicine in the mind of a healthy person;**
- **creating an opinion that it is unnecessary to see a doctor;**
- **guaranteeing the positive effect, natural origin, safety, efficacy and absence of side effects of the advertised medicine;**
- **representing the advertised medicine as a biologically active substance or nutritional substance or as a different product, which is not a medication.**

If the use of non-prescription medicines is followed by side effects, the advertising must contain information about them and specify the need to consult with a doctor or specialist.

Free distribution, sale of medicines, advertising campaigns accompanied by a demonstration of paid or free medical services shall also be prohibited.

The advertisement of biologically active food additives is regulated by Article 30.1 of the Law on Advertising. As per the said law, the following shall be prohibited:

- creating an idea of it to be a medication or possessing therapeutic qualities;
- advising on the benefits of using referring to specific cases of recovery, improvement of the health of those who use them, the results of research on these products;
- encouraging people to reject eating healthy and natural products by providing information on their benefits;
- expressing gratitude to the users.

Outdoor advertising of biologically active food additives shall be prohibited.

It must be indicated in the advertising of biologically active food additives that they are not medications.

In addition to specific regulations governing the advertisement of medical products and biologically active food additives, the Law on Advertising establishes general requirements that must be adhered to. Among these requirements is the necessity for advertising materials to comply with the provisions outlined in the Law of the Republic of Azerbaijan "On the State Language."

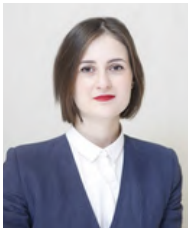
Furthermore, the Law on Advertising explicitly prohibits the dissemination of unfair, inaccurate, or hidden advertising. Detailed guidelines addressing each of these prohibitions are provided within the legislation.

Additionally, the Law on Advertising outlines restrictions aimed at mitigating potential harmful psychological and physical effects on minors.

Non-compliance with advertising requirements can result in the imposition of administrative, civil, or criminal liability.

In conclusion, the regulations set guidelines and penalties to ensure compliance and uphold public health standards. Adaptation of regulations is essential to address evolving challenges in the advertising landscape while prioritizing consumer well-being.

ADVERTISING AND PROMOTION OF PHARMACEUTICAL PRODUCTS AND BIOLOGICALLY ACTIVE ADDITIVES IN GEORGIA



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General rules of advertisement and specific regulations with respect to advertising of pharmaceutical products and and biologically active additives are provided under the Law of Georgia on Advertising and the Law of Georgia on Drugs and Pharmaceutical Activity. General definition of an advertisement is information about the goods disseminated by any means and form that is intended for an unlimited group of individuals, and serves to form and maintain interest towards that goods to facilitate the sale.

Advertising and Promotion of Pharmaceutical Products:

Definition of an advertisement for pharmaceutical products is defined as materials or actions disseminated through media or in any form and by any means that intend to promote the use of pharmaceutical products.

Georgian legislation restricts advertising of a fairly large amount of medicines and for that purpose defines three groups of pharmaceutical products. Order No. 331 of the Ministry of Internally Displaced Persons from the Occupied Territories, Labor Health and Social Affairs of Georgia determines the list of pharmaceutical products belonging to the first and third groups for advertising and retailing purposes. The following categories fall under restriction:

- **Pharmaceutical products belonging to the first group - pharmaceutical products under special control, as well as therapeutic agents equated with pharmaceutical products under special control (mainly consisting of narcotic drugs, psychotropic substances and precursors and substances and therapeutic agent equated to pharmaceutical product under special control).**
- **Pharmaceutical products belonging to the second group - products, inappropriate use of which may cause considerable damage to human health and life, and/or which may not be administered according to the patient information leaflet only, without a physician's prescription, and which are sold with prescription (Rx products).**

It is only allowed to advertise pharmaceutical products belonging to the third group, that may be administered according to the patient information leaflet without a physician's prescription, and are sold without prescription (non-Rx products). Such product shall be duly admitted on Georgian market, otherwise, advertising of products without relevant marketing authorization in Georgia is prohibited.

Each advertisement of medicines is subject to prior coordination of an advertising text with the relevant controlling authority the LEPL State Regulatory Agency for Medical Activities. Advance coordination of the text with the Agency implies verification of the text against information stated in the patient information leaflet. The advertisement text of a pharmaceutical product may not differ in content from the indications of this product included in the patient information leaflet. The advertisement must also comply with following rules depending on the type of advertisement: (i) if the advertisement is in printed form, it must contain a warning: "Read the patient information leaflet before use, and consult your doctor for further information on side effects"; (ii) if the advertisement is in non-printed form, the same warning must be given verbally; (iii) if the advertisement is broadcasted on television, where the advertisement can be both seen and heard, the warning must be visible (legibly) for no less than 3 seconds and it shall also be provided verbally.

Flyers and reference material of factual and informative nature, if the information presented in them refers only to changes of a pharmaceutical product or precautionary measures or information related to health or a disease, if it does not contain a direct or indirect reference to treatment using the pharmaceutical product and providing information on a pharmaceutical product to medical and pharmaceutical personnel (HCPs) is not considered as advertising. Distribution of pharmaceutical products falling into the first and second groups, as well as pharmaceutical products without relevant marketing authorization in Georgia to the population for advertising purposes is strictly prohibited.

Advertising of Biologically Active Additives:

In the advertising text of a biologically active additives or a product not registered as a pharmaceutical product it is not allowed to refer to diseases and present them as pharmaceuticals.

Violation of advertising rules may lead to imposition of administrative penalty on the violator. A manufacturer or distributor of the pharmaceutical product shall be held liable for violating the advertising legislation of Georgia with regard to the content of the information submitted for creation of the advertisement, unless it is proven that the violation occurred because of an advertising producer or a disseminator.

REQUIREMENTS FOR ADVERTISING MEDICINAL PRODUCTS AND FOOD SUPPLEMENTS IN ARMENIA

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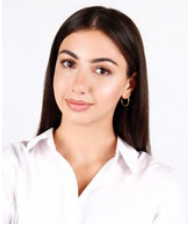

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According to the legislation of the Republic of Armenia, advertising is the spread of information, through various media, on legal and physical persons, goods, ideas, or initiatives intended to form or maintain interest in those physical and legal persons, goods, or undertakings.

Based on the presented analysis of judicial practice, the concept of "advertising" can be defined as the spread of information — among an indefinite number of people via different information media — on legal and physical persons, goods, ideas or initiatives intended to form or maintain interest in those physical and legal person, goods or initiatives.

Advertising, as information, has several features that allow it to be identified as such. It can be expressed in various ways, such as words, graphics, photographs, audio and video images, music, color and other means.

It must be published and reach the consumer through various information channels.

Key advertising features include:

(i) providing the opportunity to personalize a specific legal or natural person, product, idea or undertaking;
(ii) dissemination through at least one medium;
(iii) intended for distribution to a circle of unknown persons;
(iv) focus on creating and maintaining interest in the advertised object.

The absence of at least one of these features excludes the qualitative characterization of information as advertising.

Also, advertising must meet the following requirements:

a) be legal (must not mislead the consumer in any way);
b) be reliable (must contain reliable information about the characteristics, nature, composition, preparation time, purpose, features, conditions of use, compliance with the standard, country of origin, results of research and testing of the product);
c) be appropriate (it should not discredit moral standards, should not contain expressions, comparisons and images that promote discrimination on any basis, should not discredit any person or government body); and

d) be in the Armenian language (can be combined in two or more foreign languages, the total volume, visual, color or lighting solution of which should not extend beyond the surface of the Armenian text and should not contain information that is not included in the Armenian text).

In particular, when talking about medicines, it is necessary to refer to the concept defined for them by current legislation. In the Republic of Armenia, such legislation includes the Law on Medicines.

> According to the legislation of the Republic of Armenia, Medicinal product is defined as any substance of human and/or animal and/or vegetable and/or chemical and/or biotechnological origin in an appropriate dosage and dosage form and the requisite packaging and labeling, which presented as having properties for treating or preventing disease in human beings or animals or may be used in or administered either to restore, correct or modifying physiological functions by exerting a pharmacological and/or immunological and/or metabolic action, or to making a medical diagnosis.

In the case of advertising of food additives, only the general advertising requirements established by law, which regulate advertising practices in general, apply.

As a general rule, advertising a medicinal product that is not registered in the Republic of Armenia, is not controlled in the Republic of Armenia, or is manufactured in a pharmacy with a prescription or pharmacology is prohibited.

This rule ensures control over the quality, safety, and effectiveness of medicines offered on the market and protects consumers' rights and interests.

Registered medicines generally undergo a process of quality, safety, and effectiveness assessment by relevant regulatory authorities before being approved for sale and use. Advertising of such medications is usually based on data confirmed by these authorities and provides reliable and objective information about the product.

On the other hand, medicinal products that have not undergone this assessment or are not registered in accordance with regulatory requirements may pose a risk to consumer health due to insufficient quality and safety controls. Therefore, advertising of such products is prohibited to protect public health and safety.

Advertising of medicinal products can be carried out only after obtaining a license to sell the relevant medicinal product.

According to Armenian legislation, advertising a medicinal product is the dissemination of information that promotes its purpose, supply, sale, use, and consumption, aimed at creating or maintaining interest in it.

Advertising of medicines includes the following forms:

a) Advertising of drugs to consumers, that is, to ultimate users or patients who may consume the medicine.

b) Advertising of a medicinal product among persons working in the medical and pharmaceutical system and medical institutions, including doctors, pharmacists and other healthcare professionals.

c) Visits by representatives of medicinal sellers operating in the medical and pharmaceutical system, including visits to medical institutions to provide information about products.

d) Providing a free sample of a medicinal product for review and use by persons working in the healthcare sector or patients.

e) Any other type of medicinal advertising that may be undertaken to promote the product in the market.

Advertising of medicines, medical equipment, and treatment methods is controlled by the Ministry of Health of the Republic of Armenia and the Health and Labor Inspection body. The first one issues a separate permit for advertising a medicinal product for the duration of the license to import the medicinal product. To issue such permission, the advertiser must submit to the Ministry of Health of the Republic of Armenia the text of the advertisement in documentary and electronic form or an advertising video.

Advertising of a medicinal product must meet certain requirements to ensure the safety and awareness of consumers.

In accordance with these requirements, advertising must not contain the following materials:

a) Give the impression that the use of this medicinal product does not require medical advice or medical intervention.

b) Guarantee the absolute effectiveness of the drug, the absence of side effects, or the superiority of its effect over other treatments or medicinal products.

c) Assure that the person will be completely healthy after taking the medicine.

d) Claim that non-use of a drug will result in deterioration of a person's health, with the exception of advertising carried out as part of universal vaccination programs.

e) be oriented in children.

f) Contain references to guarantees from scientists, medical professionals or other renowned individuals or public organizations that may promote the use of the medical product.

g) Suggest using the medicine for food or cosmetic purposes.

h) Assert that the safety and effectiveness of the medicine are due to its natural origin.

i) May lead to incorrect self-diagnosis by describing or detailing medical history.

j) Contain statements about improving health accompanied by incorrect, alarming, or misleading wording.

k) Contain false concepts that are not related to the use of the medicine.

Compliance with these requirements in an advertising campaign helps to prevent misinformation and protect the health and interests of consumers.

ADVERTISING AND PROMOTION OF MEDICINES AND BIOLOGICALLY ACTIVE FOOD SUPPLEMENTS IN KAZAKHSTAN

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Advertising and promotion of medicines and biologically active food supplements (hereinafter referred to as – Advertising of Medicines and BAFS) on the territory of the Republic of Kazakhstan are regulated by the following regulatory legal acts:

- **Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI ЗРК on public health and healthcare system (Healthcare Code);**
- **Law of the Republic of Kazakhstan dated December 19, 2003, № 508 on Advertising (Advertising Law);**
- **Rules for advertising of medicines and medical products, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 20, 2020, No. ҚР ДСМ-288/2020 (Rules for Advertising Medicines);**
- **Rules for advertising biologically active food supplements, approved by the Order of acting Minister of Healthcare of the Republic of Kazakhstan dated October 27, 2020, No. ҚР ДСМ-160/2020 (Rules for Advertising BAFS);**
- **Rules for the ethics of promoting pharmaceuticals and medical devices, approved by Order of the Minister of Healthcare of the Republic of Kazakhstan dated December 21, 2020, No. ҚР ДСМ-294/2020 (Ethics Rules);**
- **Rules for labeling online advertising, approved by Order of the Minister of Culture and Information of the Republic of Kazakhstan dated February 16, 2024, № 59-НҚ.**

Advertising means information disseminated and (or) placed in any form, by any means, intended for an indefinite number of persons and designed to create or maintain interest in an individual or legal entity, goods, trademarks, works, services, and facilitate their implementation.

Advertising of medicines means information disseminated and (or) placed in any form, using any means, intended for an indefinite group of persons, containing individual information or a set of information about medicines and medical products, contributing to their promotion and implementation.

Considering that according to the Rules for Advertising BAFS, advertising of BAFS is carried out subject to its compliance with legislation in the fields of healthcare and advertising, in particular the requirements of the Healthcare Code, then the requirements established for advertising of medicines apply by analogy to advertising of BAFS.

Forms of advertising of medicines

Even though the definition of medicine advertising states that information can be distributed and posted in any form, by any means, and is intended for an indefinite number of people, there are several restrictions on medicine advertising, which are listed in paragraph 3 of Article 56 of the Healthcare Code.

Thus, by subparagraph 2) of paragraph 3 of Article 56 of the Healthcare Code, advertising of prescription medicines in the media is prohibited. The media, according to the Law on the Mass Media, means a printed periodical, television, radio channel, documentary film, audiovisual recording, and other forms of periodic or continuous public dissemination of mass information, including Internet resources.

At the same time, the Committee for Medical and Pharmaceutical Control of the Ministry of Healthcare of the Republic of Kazakhstan does not limit the distribution and placement of advertising of prescription medicines, which does not violate the Ethics Rules, the Rules for Advertising Medicines and the requirements of the Healthcare Code - in specialized printed publications intended for medical and pharmaceutical workers, as well as on specialized events such as medical and pharmaceutical conferences, symposia, meetings, etc.

Rules For Labeling Online Advertising

From March 1, 2024, the Rules for Labeling Online Advertising are in effect, according to which online advertising placed by influencers (bloggers) on a commercial and/or contractual basis is subject to labeling.

Labeling of online advertising is carried out in a text format with the possibility of its identification and contains a text indication that the posted material is an advertisement. The text indication contains one of the following wordings: “advertising”, “promotional material”, “affiliate material”, “sponsored material”, “advertising”, “paid for by the sponsor” or “PR”.

Thus, we understand that advertising of medicines and BAFS can be carried out on online platforms with mandatory text labeling only, like advertising in other media - if there is a conclusion from the Center on the compliance of medicine advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare.

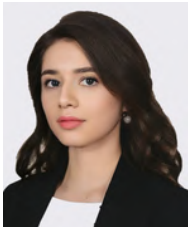
Advertising permission

To distribute and place advertising for prescription and (or) over-the-counter medicines, it is necessary to undergo an assessment of medicine advertising materials and obtain a conclusion on the compliance of advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare from the RSE on the REU “National Scientific Center for Health Development named after Salidat Kairbekova” of the Ministry of Healthcare of the Republic of Kazakhstan (hereinafter - the “Center”) for which, according to the Rules for Advertising Medicines, the applicant must enter into an agreement with the Center. The list of necessary documents and materials that must be submitted to the Center to receive the service, as well as the procedure for the Center’s actions, are specified in paragraphs 11 to 19 of the Rules for Advertising Medicines.

Despite the fact that the Rules for Advertising Medicines contain a procedure for issuing a conclusion on the compliance of medicine advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare, in practice a dilemma arises when the Center refuses to accept documents and materials from applicants for the assessment and issuance of permission to advertise prescription medicines, justifying this by the fact that they do not have guidelines (instructions) for providing this service, and there is also no approved price list for the provision of services. As a result, we see that the Center cannot provide the service due to the lack of protocol procedures in its commercial policy, and the applicants cannot take advantage of the opportunity to promote their products by the law.

Also, the Rules for Advertising Medicines do not establish a period for which a conclusion is issued on the compliance of advertising with the requirements of the legislation of the Republic of Kazakhstan in the field of healthcare. It is noteworthy that until February 20, 2015, the Rules for issuing permission to advertise medicines, medical products, and medical equipment in the Republic of Kazakhstan were in force, approved by order of the Minister of Healthcare of the Republic of Kazakhstan dated March 20, 2013 No. 167, which in terms of the algorithm of actions did not differ from those as specified in the Rules for Advertising Medicines. The Rules 2013 also did not have a price list for services, but the validity period of the permit was established and issued for the period of validity of the registration certificate of medicines, medical devices, and medical equipment.

ADVERTISING OF MEDICINES AND DIETARY SUPPLEMENTS IN THE REPUBLIC OF UZBEKISTAN



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In modern society, advertising of medicines plays a significant role, having a direct impact on the health of each of us. This is not only a means of informing about new products in the world of medicine, but also a factor that has a considerable impact on the production and distribution of medicines and dietary supplements.

In Uzbekistan, there is a rapid increase in attention to improving regulations governing the advertising of medical products. This reflects a serious attitude towards ensuring the safety and quality of the products offered. In this article, we have highlighted the main requirements of advertising legislation that pharmaceutical companies need to be aware of. This area of regulation is designed to ensure transparency and reliability of information provided to consumers, and also emphasize the importance of maintaining ethical standards in the process of promoting medical products.

In Uzbekistan, advertising medicines is regulated by several legal acts, primarily by the following:

- **Law "On Advertising" No.ЗРУ-776 dated June 7, 2022 (the "Law on Advertising");**
- **Order of the Ministry of Health of the Republic of Uzbekistan "On advertising of medical products intended for medical institutions and medical workers of the system of the Ministry of Health and control over execution" No.442 dated December 27, 2013 (the "Order of the Ministry of Health No.442");**
- **Decree of the Cabinet of Ministers of the Republic of Uzbekistan "Regulations on the procedure for issuing permission to advertise medical products for minors" No.341 dated December 15, 2014 (the "Decree No.ПКМ-341"), and others.**

The State Authorities in the field of regulating medicines advertising are the Consumer Rights Protection Agency under the Antimonopoly Committee of the Republic of Uzbekistan (the "Agency") and the Ministry of Health of the Republic of Uzbekistan (the "Ministry of Health").

In accordance with Article 34 of the Law on Advertising, medicines advertising must contain the full (including international pharmacological) name of the medicine and the name of the manufacturer, as well as information on the use or application of the medicine.

At the same time, advertising of medicines is prohibited if it is:

- distributed only by prescription;
- containing narcotic drugs or psychotropic and (or) potent substances;
- not allowed for medical use in Uzbekistan;
- not passed the State registration in the Ministry of Health.

Also, it is necessary to highlight that advertising of non-prescription medicines must not:

- present the medicine as unique, the most effective, and the safest in terms of the absence of side effects;
- to mislead about the composition, origin, novelty, or patentability of the medical product;
- state that the medical product is a biologically active food supplement, cosmetic or hygiene product, or any other type of product;
- allow incorrect comparisons with other medical products to enhance the advertising effect;
- contain statements that the effect of this medicine is guaranteed;
- suggest that a person's health may be worsened by not using the medicine.

Additionally, advertising non-prescription medicines must be accompanied in each case by a warning about the presence of contraindications to their use, the need to familiarize oneself with the medicine instructions, or obtain expert advice.

In accordance with Article 35 of the Law on Advertising, advertising of biologically active food supplements and nutritional supplements must not:

- **create the impression that they are medicines and (or) have therapeutic properties;**
- **contain references to specific cases of curing people or improving their condition as a result of their use;**
- **contain an expression of gratitude by individuals in connection with their use;**
- **encourage people to give up healthy eating habits;**
- **create an impression of the advantages of biologically active food supplements and nutritional supplements over medicines by referring to the facts of research, state registration, as well as the use of the results of other studies in the form of a direct recommendation for their use;**
- **use images of children in advertising of biologically active food supplements and nutritional supplements prohibited for purchase or consumption by minors.**

In addition to the above, advertising of biologically active food supplements and nutritional supplements in each case must be accompanied by a warning that the object of advertising is not a medicinal product.

It is also important to emphasize that the legislation strictly prohibits stimulating actions in the field of advertising medicines and biologically active supplements, as this prevents possible negative consequences and impacts on making informed decisions on the use of medical products.

Besides, it was also established that the procedure for medicines advertising intended for medical institutions and medical workers is determined by the Ministry of Health.

It should be noted that the above-mentioned Article 34 of the Law on Advertising also provides restrictions on advertising intended for medical institutions and medical professionals, which must fully comply with the list of scientific data on medicines and contain the following information:

- the name of the active substance;
- the content of the active substance per dosage (a form of release);
- side effects and major adverse reactions;
- information on contraindications, warnings, and cases when this medical product should be used with caution;
- interaction with other drugs;
- reference to relevant scientific sources, as well as the possibility and source of additional information;
- information that the users of this advertisement are exclusively medical and pharmaceutical workers.

Moreover, the Agency representatives also confirm that professional information for physicians and advertising of prescription medicines should be placed only in specialized publications that are distributed among physicians.

It should also be taken into account that according to Uzbek legislation, advertising of medicines is carried out by providing references and distributing advertisements, organizing and holding special wall visualizations, educational seminars, and conferences on the territory of the building of a medical institution.

Also, it should be noted that in accordance with requirements established by Order of the Ministry of Health No. 442, it is strictly prohibited for healthcare officials to receive free samples of medicines from medical representatives, as well as distributing or selling free of charge to patients and visitors to a medical institution.

When analyzing the market of advertising medicines and biologically active supplements in mass media, a number of violations that do not comply with the current legislation in the field of advertising are revealed. Often, we come across a situation when advertising materials provided by pharmaceutical companies do not comply with the approved instructions for use established by the competent authorities. For example, in several cases, regulatory authorities find that the manufacturer's instructions indicate the effectiveness of a drug in treating hypertension, while advertising campaigns for the same drug speak of its effectiveness in combating other diseases. Such inconsistencies mislead consumers, which in turn can lead to serious consequences for their health. It is important to identify and prevent such violations, emphasizing the need for transparency and accuracy in the advertising of medical products.

In addition to the above, despite the fact that there are restrictions on the advertising of prescription medicines, for example on promotional products - pens, notepads, calendars, key chains, badges, and souvenirs, prescription medicines continue to be “advertised” in such a way thereby violating the requirements of the law.

Currently, the website of the Committee for the Development of Competition and Consumer Protection of the Republic of Uzbekistan has published an official appeal on the application of the legislation on advertising in relation to biologically active supplements (Official appeal No. 01-06/3339 dated November 11, 2020 from the Director of the Agency for Consumer Protection under the Antimonopoly Committee of the Republic of Uzbekistan – https://consumer.uz/wp-content/uploads/2021/01/3339-01-06-ot-11-11-2020g-proizvoditelyam-bad.pdf). This appeal

emphasizes that advertising promises about the therapeutic properties of biologically active supplements can mislead consumers, leading them to refuse to take medicines and, consequently, harming their health. It is also noted that during the pandemic, there has been an increase in the number of advertisements for dietary supplements that give the impression of therapeutic properties.

Legislation requires a clear distinction between biologically active supplements and medicines, so advertising of biologically active supplements should not create an impression of therapeutic effect or cure of diseases.

Returning to the topic of liability, we note that in accordance with Article 47 of the Law on Advertising, financial sanctions for violation of the legislation on advertising are applied in the form of monetary penalties (fines) in the following amounts:

- **dissemination of advertisements about products the production, sale or advertising of which is prohibited or restricted by law - shall entail a fine of 100 (one hundred) basic calculated value (BCV), i.e., UZS 34,000,000 (approximately USD 2,720);**
- **inappropriate advertising, refusal to counter-advertise - entails a fine of 70 (seventy) BCV, i.e., UZS 23,800,000 (approximately USD 1,905);**
- **violation of the requirements for advertising energy drinks, alcoholic beverages, tobacco products and devices for the use of tobacco and nicotine, pyrotechnics, weapons and ammunition, military products, as well as violation of the procedure for placing external advertising and information - shall entail a fine in the amount of 50 (fifty) BCV, i.e., UZS 17,000,000 (approximately USD 1,360);**
- **violation of requirements for advertising to minors, medicines, biologically active and nutritional supplements, and children's food products - shall entail a fine in the amount of 30 (thirty) BCV, i.e., UZS 10,200,000 (approximately USD 820).**

In case when a legal entity is recognized as guilty in revealed offenses in the field of legislation on advertising, the application of financial sanctions shall be carried out by the authorized state body, and if there is a dispute - the issue of application of financial sanctions shall be resolved in court.

At the same time, application of financial sanctions does not release subjects of advertising activity - legal entities from the obligation to execute the decision or order of the authorized state body or to perform other actions provided by the legislation on advertising.

It should also be noted that in accordance with part 2 of Article 178 (1) of the Code of Administrative Responsibility of the Republic of Uzbekistan, false advertising, non-compliance with the procedure for placing outdoor advertising or refusing to counter-advertise, as well as advertising products whose advertising is prohibited by law, citizens, and officials - entails a fine in the amount of 5 (five) to 15 (fifteen) BCV, that is, from UZS 1,500,000 to UZS 4,500,000 (approximately equivalent to USD 140 to USD 410).

Due to recent changes in the country's legislation and increased monitoring by regulatory authorities, there has been a development aimed at protecting the rights and interests of consumers. However, it is important to note that there are still instances of unfair advertising of medicines and biologically active supplements, which target both doctors and patients. The legal regulation of advertising in the pharmaceutical industry may benefit from additional clarification on several issues. In order to ensure compliance with legal requirements and avoid any potential negative consequences, it is recommended that pharmaceutical companies establish a process to verify the compliance of their advertising materials with the legislation.

(1) 1 BCV for March 2024 is UZS 340,000 (approximately USD 28)

ADVERTISING OF MEDICINES AND BIOLOGICALLY ACTIVE ADDITIVES IN MONGOLIA

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I. RULES OF ADVERTISING

Key regulations, definitions

Advertising of medicines and biologically active additives are regulated by (i) the Law of Mongolia on Medicines and Medical Devices and (ii) the Law of Mongolia on Advertisement, as well as (iii) the Procedure for Regulating the Issuance of a Permit for Advertisement of Medicines and Biologically Active Products (the "Procedure").

"Medicine" means a preparation of synthetic or animal plant, or mineral substances in a specific form, used in appropriate dosages and quantities, for the prevention, diagnosis, treatment, and immunization of human, animal, and animal diseases (Art.3.1.1 of Law on Medicines and Medical Devices).

"Biologically active products" means products that support human body functions, supplement with necessary minerals, and prevent any diseases (Art.3.1.25 of Law on Medicines and Medical Devices). In other words, it shall be understood as biologically active additives or vice versa under this document.

"Advertisement" means information distributed through mass media or in other channels by individual, business entity or organization in order to increase market demand of goods, works, services, project or operation and to attract attention of potential customers (Art.3.1.1 of the Law on Advertising).

Registration & permit

Prior to dissemination of the advertisement, (i) medicines and biologically active additives must be registered in Mongolia, and (ii) a regular permit for advertisement must be obtained.

An advertisement video (recorded on CD, flash drive, hard disc, etc.) and its content converted to text shall be required among other things for obtaining a permit for dissemination of advertisements. The materials submitted to the state central administrative body in charge of medicines shall be reviewed and discussed by the Pharmacological subcommittee of the Human medicine's council.

The permit for the advertisement is issued for a period of 1 (one) year. In the case of extension, the applicant must apply within 1 (one) month prior to expiration of the permit.

Disseminating channels

a) Channels for healthcare professionals

Prescription, narcotic, and psychoactive medicines may be advertised only through channels for health care professionals who are licensed to carry out professional activities of treatment, dispensing, nursing, midwifery, and rehabilitation. Channels for health care professionals are not specifically stipulated by law, however, under the Procedure, persons advertising its products may cooperate with health care professionals without violating the following prohibitions:

- Give or promise to give gifts, donations, and bonuses to health care professionals to increase the sales of its products;
- Organize contests, promotions, and lotteries for the purpose of prescribing medicine or advising customers;
- Use all kinds of economic incentives to take part in health institutions' procurement of medicines.

b) Professional publications, mass media

Non-prescription medicines and biologically active products may be advertised through professional publications and mass media.

Advertising (subliminal advertising) of medicines and biologically active additives online through social media (Facebook, Twitter, Instagram, Live, Blog, TikTok, telephone enquiry service, online pharmacy, and official website) is prohibited.

Requirements

Drug advertisement information must be based on pharmacological indicators and clinical research results, regardless of the drug form. The ads content may include accurate and factual information on contraindications, side effects, cautions, quality, safety and risks contained in the certified instructions for use.

The following are prohibited in medicine advertising:

- **To advertise in the press and media for the purpose of importing and selling medicines;**
- **To advertise medicines directing to children;**
- **To advertise prescription medicines;**
- **To provide information that may lead to denial of medical advice, treatment, or surgery;**
- **To mislead consumers that the medicine is rare, important, unique, very active, the result is better than other medicine, safe, without side effects, new drug, patented;**
- **To publicize the provision of incentives or price reductions for the purchase of medicines and medical equipment;**
- **To advertise medicines not registered in the State register;**
- **To advertise hospital-based medications in order to sell through pharmacy and other ways;**
- **To advertise the medicine hiding the side effects and prohibitions;**
- **To issue a warranty on the effect of the medicine in advance;**
- **To advertise the medicine with a commercial name only without generic names.**

Also, it shall be prohibited to advertise and sell prescription-medicines, hospital-based and pediatric medications online.

Involving social influencers who are not qualified in the science of medicine and pharmacy in advertisement, information, and discussion is prohibited.

II. PRACTICAL ISSUES

With the emergence of new channels for information including but not limited to social media, there is a growing demand to broaden the channels permitted for advertisement. However, the current laws only allow mass media (TV, radio, etc.) and professional press. Online advertising (subliminal advertising) through social media is prohibited according to the Procedure. This prohibition creates ambiguity regarding the permissibility of advertising on social media platforms, resulting in different practices. For example, there are instances where advertisements are effectively placed on social media platforms like Facebook, Instagram, etc., whereas, our clients have faced refusal when applying for a permit to disseminate ads through these platforms.

III. COURT/ADMINISTRATIVE PRACTICES

No cases till date.

References:

"The Law of Mongolia on Medicines and Medical Devices"
https://legalinfo.mn/mn/detail/85

"The Law of Mongolia on Advertising"
https://legalinfo.mn/mn/detail/259

"The Law on Health"
https://legalinfo.mn/mn/detail/49

"Procedure for Regulating the Issuance of a Permit for Advertisement of Medicines and Biologically Active Products"
https://mmra.gov.mn/?id=201015

This review is relevant for March 2024.

The Russian version of the review includes articles on the following countries: Armenia, Belarus, Kazakhstan, Uzbekistan. It is available at the link:
https://storage.googleapis.com/gratanet/web_files/department/4019064008278164210.pdf

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countries of presence

> 32
years of experience

> 220
professionals

> 15
practice areas

14 500+
clients

37 400+
projects

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