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ADVERTISING AND PROMOTION OF MEDICINES AND MEDICAL PRODUCTS

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ADVERTISING AND PROMOTION OF MEDICINES, MEDICAL PRODUCTS, AND DIETARY SUPPLEMENTS IN BELARUS

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The basic regulations for drugs advertising (drugs available only on prescription (Rx) and without any prescription (non-Rx), biologically active additives in the legislation of Belarus are as follows:

- 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 of July 23, 2013 No. 63 "On Implementation of the Law of the Republic of Belarus of May 10, 2007 No. 225-Z "On Advertising", hereinafter "Resolution No. 63".

The national regulators for the drugs and biologically active additives advertising are The Ministry of Health and the Ministry of Antimonopoly Regulation and Trade of Belarus.

GENERAL REQUIREMENTS FOR DRUGS ADVERTISING

REFERENCE: according to the legislation on advertising, the content of the term "drug" is identical to the content of the term "drug product".

Drugs advertising must contain:

- the drug's name;
- information that the advertised product is a drug;
- the name of the drug's manufacturer;
- recommendation on the necessity to get familiar with the instructions for the drug medical use and (or) medication guide.

Drugs advertising must not contain

- statements on the drug's therapeutic effect regarding diseases that are either untreatable or difficult to treat;
- information directly addressed to minors;
- information that does not comply with the instructions for medical use and (or) the drug medication guide;
- statements that the therapeutic effect of the drug use is absolutely guaranteed;
- statements that the safety and (or) effectiveness of the advertised product is guaranteed by its natural origin;
- comparisons with other drugs, methods of medical care, works and (or) services constituting medical activity, medical devices and medical equipment;
- information on preclinical (non-clinical) investigations and clinical investigations (trials) and their results;

- references to certain cases of cure after application of the advertised product, expressions of gratitude for this;
- information giving the impression that there is no need to consult a doctor in the case of using of the advertised product and (or) it is possible to obtain diagnostic diseases and recommendations for their treatment without direct contact with a doctor;
- statements or assumptions about the existence of any conditions that require the advertised product use, or statements giving a healthy person the impression of the necessity to use such an advertised product;
- indications on the possibility to receive any form of financial benefits, except discounts, if the advertised product is bought, in advertising of the drugs, medical devices and medical equipment;
- recommendations from state bodies and other organizations used to enhance the advertising effect.

It is prohibited to use images or statements of medical or pharmaceutical workers, employees of non-profit health care organizations in advertising.

Exceptions include the use of such images or statements in:

- social advertising;
- advertising of the advertiser's medical activities;
- advertising whose consumers are strictly medical or pharmaceutical workers and which is placed (distributed) in venues of medical or pharmaceutical exhibitions, seminars, conferences, and other relevant events or in specialized print publications for medical or pharmaceutical workers.

In general, the placement (distribution) of drugs advertising is allowed only if the advertiser has an approval of the Ministry of Health of Belarus. The Republican Unitary Enterprise "The Centre for Examinations and Tests in Health Service" is authorized by the Ministry to approve such advertising.

There are some exceptions to this rule, such as:

- outdoor advertising;
- advertising, the consumers of which are strictly medical or pharmaceutical workers and (or) which is placed (distributed) in venues of medical or pharmaceutical events;
- drugs advertising, which is placed (distributed) on the websites of drug manufacturers.

Drugs advertising, except outdoor and mobile advertising, must contain an indication that the information provided is advertising.

The above disclaimer, as well as other required information, must be contained in the advertising regardless of the need to approve the advertising.

SPECIFICS OF ADVERTISING WITH CONSUMERS OF ADVERTISING BEING MEDICAL WORKERS

From January 18, 2023, drugs advertising for medical workers in the form of oral presentations with (without) demonstration of information and other materials about the drug, as well as electronically, is allowed only when meetings, conferences, seminars, symposiums, and events were determined by the Ministry of Health of Belarus.

REFERENCE: You may check the information on drug registration on the website of the State Register of Drugs of the Republic of Belarus (maintained by the Republican Unitary Enterprise "The Centre for Examinations and Tests in Health Service") - https://www.rceth.by/refbank.

Representatives of pharmaceutical manufacturers are not allowed to inform the workers of health care organizations directly: only providing advertising materials electronically or in hard copy (without visiting the organization) is allowed.

Information materials shall be provided to such workers by an authorized representative of the organization itself.

Non-registered drugs advertising is prohibited.

It is allowed to advertise drugs carried out within the framework of clinical trials conducted for the purpose of their further state registration in Belarus.

SPECIFICS OF RX DRUGS ADVERTISING

The above requirements for drugs advertising apply in the same way to the advertising of Rx drugs.

It is necessary to consider some features while placing (distributing) such advertising.

Thus, Rx drugs advertising (distribution) is allowed only:

1. in specialized print publications, the list of which is approved by the Ministry of Health of Belarus;
2. in places where medical or pharmaceutical exhibitions, seminars, conferences, and other similar events are organized.

Analysis of the legislation and regulatory bodies' comments leads to the conclusion that only medical workers may be consumers of such advertising.

It is not necessary to approve the placement (distribution) of Rx drugs advertising.

ADVERTISING OF BIOLOGICALLY ACTIVE ADDITIVES (HEREINAFTER - "DIETARY SUPPLEMENTS")

Dietary Supplements advertising in Belarus must also comply with general requirements of the legislation on advertising.

Advertising of Dietary Supplements that have not duly passed state registration is prohibited.

Dietary Supplements advertising must contain:

- an indication that the information provided is advertising;
- the Dietary Supplement's name;
- the name of the Dietary Supplement's manufacturer;
- information that the advertised product is the Dietary Supplement which are not a drug and are not meant for medical treatment;
- information on the need to get familiar with the recommendations for Dietary Supplement use.

Dietary Supplements advertising must not contain following information:

- information directly addressed to minors;
- statements or assumptions about the existence of any conditions that require the advertised product use, or statements giving a healthy person the impression of the necessity to use such an advertised product;

- indications of the possibility to receive any form of financial benefits, except discounts, if the advertised object is bought;
- details that do not correspond to the information on the consumer label of the Dietary Supplements;
- information on the conducting the clinical or other investigations (trials) and their results.

The body authorized to approve the Dietary Supplements advertising is also the Republican Unitary Enterprise "The Centre for Examinations and Tests in Health Service".

Contrary to drugs advertising, the placement (distribution) of Dietary Supplements advertising without the approval of the Ministry of Health of Belarus is admissible only in two cases: outdoor and mobile advertising.

ADVERTISING AND PROMOTION OF PHARMACEUTICAL PRODUCTS IN GEORGIA

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General rules of advertisement and specific regulations with respect to advertising of pharmaceutical products are provided under the Law of Georgia on Advertising and the Law of Georgia on Drugs and Pharmaceutical Activity.

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 number 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:

- 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";
- if the advertisement is in non-printed form, the same warning must be given verbally;
- 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.

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 regarding 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.

ADVERTISING AND PROMOTION OF MEDICINES, MEDICAL PRODUCTS, AND BAFS IN KAZAKHSTAN

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On the territory of the Republic of Kazakhstan, relations arising during the production, distribution, placement and use of advertising are regulated by the Law "On Advertising", while, in accordance with this law, advertising of medical services (hereinafter the "services"), medicines and medical products, biologically active food supplements (hereinafter the "BAFS") are regulated by the Code of the Republic of Kazakhstan "On public health and healthcare system" (hereinafter the "Code of Health"). Within the framework of the Code of Health, by orders of the Minister of Health, separate rules have been approved that regulate the procedure for advertising medicines and medical devices, advertising services and advertising BAFS.

Advertising of medicines and medical products means information distributed 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.

The Code of Health contains general requirements and an exhaustive list of prohibitions on advertising in healthcare.

Distribution and placement of advertisements of services, medicines and medical products is allowed in the media, electronic information resources in healthcare organizations. Control over the production, distribution and placement of advertising is carried out by state bodies within their competence.

According to the general requirements, advertising shall be in Russian and Kazakh languages; when advertising medicines and medical products, provided information shall be complete and reliable. Advertising of services and BAFS, at the discretion of the advertiser, can be carried out in other languages without distorting the basic meaning when translating its content.

ADVERTISING OF MEDICINES AND BAFS SHOULD CONTAIN INFORMATION, INCLUDING:

- the trade name;
- information about the active ingredients included in the composition (for medicines, this can also be an indication of the international nonproprietary name);
- main indications for use;
- method of administration and doses;
- main side effects;
- main contraindications;
- special instructions for use by children, pregnant women, as well as during breastfeeding;

- release conditions;
- a clear and understandable recommendation for use;
- name, address of the manufacturer and the person authorized by the manufacturer to accept claims in the Republic of Kazakhstan;
- the number and date of issue of the certificate of state registration, and for medicines also information about the expiration date of registration.

THE ADVERTISEMENT OF MEDICAL PRODUCTS SHOULD CONTAIN INFORMATION ABOUT:

- the trade name;
- the main indications for use (field of application);
- the main side effects (if any);
- the main contraindications (if any);
- a clear and understandable recommendation before prescribing and using, carefully read the instructions for medical use (operational document) of a medical device and the text of the warning reading "Self-medication may be harmful to your health" (if applicable);
- the name and address of the manufacturer and (or) authorized representative in the Republic of Kazakhstan;
- the number and date of issue of the registration certificate and the expiration date registration.

At the same time, advertising intended for TV channels, Internet resources and radio channels may not contain complete advertising information.

The information contained in the advertisement of the medicinal product shall comply with:

- the instructions for the medical use of the medicinal product (leaflet);
- the instructions for medical use or the operational document for the medical device.

If changes are made to the instructions for the medical use of medicines and medical products that affect the content of the advertisements distributed, the changes made are reflected in the advertising materials.

Advertising should not exaggerate the pharmacological properties and therapeutic indications of the advertised medicines or the field of application for medical products.

ADVERTISING OF MEDICINES AND MEDICAL PRODUCTS, AND BAFS SHALL:

- be easy to read, printed in a clear and legible font;
- be reliable and recognizable (without special knowledge or the use of special tools);
- contribute their rational use;
- not to mislead consumers through abuse of their trust, including in relation to characteristics, composition, consumer properties, cost (price), intended results of use, research and test results;
- exclude the content of comparison with other medicines and medical products, or for BAFS excludes the content of comparison with medicines and goods of other individuals or legal entities, as well as statements, images that discredit their honor, dignity and business reputation.

DOES NOT INCLUDE TO ADVERTISING OF MEDICINES AND MEDICAL PRODUCTS:

1. information related to human health or diseases;

2. instructions for medical use, trade catalogs, price lists, reference materials, scientific information material, methodological and educational materials of a medical nature;
3. information about the individual and (or) legal entity that manufactures or sells medicines and (or) medical products.

Advertising of services shall be carried out in the presence of a state license for the type of medical activity being advertised, and when advertising services, the license number and the name of the authority that issued the license shall be indicated.

IT IS PROHIBITED TO:

1. advertise medicines and medical products, biologically active additives, means of prevention that are not registered in the Republic of Kazakhstan;
2. advertise prescription medicines in the media;
3. distribute, for advertising purposes, samples of medicinal products dispensed with medical prescription;
4. use children, their images and voices in advertising medicines and medical products, except for medicines and medical products for children;
5. distribute and place advertisements of medicines and medical products, biologically active additives in public transport vehicles, organizations that are not related to their prescription, use and dispensing, 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 and medical products;
8. use healthcare professionals authorized to prescribe medicines and medical products as advertisers, except for the cases of providing reliable information on medicines and medical products for scientific or educational purposes, and also for informing patients;
9. advertise services in the absence of a license for the relevant type of activity;
10. advertise services provided by persons without a certificate of a healthcare specialist, including foreign specialists;
11. indicate, in public advertising, methods of treatment of such diseases as sexually transmitted diseases, oncological, mental, behavioral disorders (diseases), dangerous infectious diseases, HIV infection, TB disease, diabetes mellitus;
12. refer, in 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 and medical products;
13. present services, medicines and medical products, biologically active additives in advertising as unique, safest and most effective;
14. assert that the safety and efficacy of a medicinal product are due to its natural origin;
15. cause assumptions that the effectiveness of the service provided, of treatment with an advertised medicinal product, biologically active additive is guaranteed, that the use of the product does not develop side effects;
16. provide information in advertising that is not directly related to the advertised service, medicine and medical product;

17. advertise proposals for entering into transactions on human organs (parts of an organ) and (or) tissues (parts of tissue);
18. advertising of narcotic drugs, psychotropic substances and their analogues included in the list of narcotic drugs, psychotropic substances and precursors subject to control in the Republic of Kazakhstan, except for specialized printed publications designed for healthcare professionals and pharmaceutical workers, including distribution for advertising purposes of samples of medicinal products containing narcotic drugs or psychotropic substances;
19. advertising of medicines and medical products with the participation of medical and pharmaceutical personnel, heads of medical organizations;
20. advertising of specific trade names of medicines and medical products, BAFS, specialized medical food products and breast milk substitutes by public associations for the protection of citizens' rights in the field of health protection.

Also, the Code of Health has general requirements for the ethics of promoting medicines and medical products, which are required to comply with healthcare entities, members of professional associations, subjects in the field of medicines and medical products circulation, in order to rationally use medicines and medical products.

Ethics in the promotion of medicines and medical products is understood as activities carried out in the process of promoting safe, high-quality and effective medicines and medical products from the developer and (or) manufacturer of medicines and medical products to consumer use, based on fair competition and responsibility of all parties involved.

According to the Code of Health, it is prohibited to promote medicines and medical products in medical organizations and healthcare education organizations by representatives of manufacturers of medicines and medical products and (or) distributors, with the exception of daily medical conferences, scientific and practical conferences and (or) specialized seminars.

The ethics of medicines and medical products promotion are regulated by the Rules of Ethics for the Promotion of Medicines and Medical Products approved by the Ministry of Health ("Rules of Ethics"). These Rules of Ethics regulate in detail the format and conditions of interaction between entities in the field of circulation of medicines and medical products with healthcare entities and members of professional associations.

ADVERTISING AND PROMOTION OF MEDICINES AND MEDICAL PRODUCTS IN MOLDOVA

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LEGAL ANALYSIS

At the moment, the Agency for Medicines and Medical Devices (AMDM) in its decisions are guided solely by the recommendations of the European Medicines Agency (EMA). This is a practice-driven approach. Therefore, when we talk about the compliance of the Marketing authorization holders (MAH) with the requirements submitted by the EMA and AMDM, it is not about obligations provided for by the legislation but about the recognition of the authority of these institutions in the field of the safety of medicines.

Advertising of medicines released with medical prescription is prohibited in Moldova. The advertising of only medicines which are released without medical prescription is allowed in Moldova, according to the Regulation on the ethical promotion of medicines. The advertising materials can be broadcast at TV and radio and the external advertising can be displayed only on condition that the person who broadcasts/displays the concerned material preliminarily notifies the Medicines and Medical Devices Agency. At the same time, the National Agency for Public Health undertakes needed measures for the observance of the legislation on the advertising of medicines. The document is aimed at correctly informing the consumers and at giving them the possibility to make their own opinions about the therapeutic value of medicines, as well as to enhance the responsibility of physicians and pharmacists who can influence them in choosing a medicine. Also, the document has the goal to influence the safe use of medicines.

ADVERTISING MATERIAL NOTIFICATION PROCEDURE

Advertising material – any means used to promote the prescription, distribution, release, sale or consumption of medicines.

Drug advertising – the dissemination by direct or indirect methods of information to the public, as well as any other form of activity intended to stimulate the prescription, distribution, release or use of drugs.

1. FILE SUBMISSION

The advertising material notification file is submitted to the Single Desk and must contain the following documents:

- the request for notification of advertising material;
- the advertising material to be evaluated (in 2 copies);
- the act confirming the powers of the person who represents the interests in the relationship with the Agency regarding the advertising of medicines;
- proof of payment (WARNING! Payment is made per unit of material advertisement);
- for video/audio advertising material, its electronic version is presented;
- In the case of video/audio spots, indicate the duration of each spot (25 seconds/20 seconds/10 seconds, etc.) and the broadcast language (Romanian/Russian);

- Clear indication of the target audience: qualified persons/general public;
- Indication of the valid email and phone number of the person responsible for notifying the advertising material.

2. FILE VALIDATION

- The presence of mandatory documents;
- The presence of the drug whose advertising material is notified in the State Nomenclature of Medicines;
- Evaluation of the status of the medicinal product whose advertising material is notified: Rx, OTC, Compensated;
- Registration of the notification of the advertising material in the electronic Register regarding the record of the notification of the advertising material.
- Verification of money coming into the AMDM account for the service;
- In the case of an incomplete file or the presence of objections, an informative note is drawn up and sent electronically to the person responsible for notifying the advertising material.

IMPLEMENTATION TERMS

- The notification is submitted at least 30 working days before the broadcast or public display of the advertising materials.
- AMDM will evaluate the advertising material within 10 working days from the date of receipt of the notification.
- In case of detection of non-conformities with the rules of the Regulation regarding the ethical promotion of medicines, a request to modify it, indicating the reasons for the non-compliance, will be sent to the person responsible for the notification of the advertising material.
- Within 10 working days from the date of receipt of the request from AMDM, the person responsible for notifying the advertising material will submit to AMDM the modified advertising material according to the request.

3. EVALUATION OF THE NOTIFIED ADVERTISING MATERIAL

Evaluation of the advertising material notified by the Advertising Materials Evaluation Commission (Commission):

- In accordance with the criteria of Government Decision 944 of 03.10.2018;
- Commission meetings are held once a week.

4. RELEASE OF POSITIVELY EVALUATED ADVERTISING MATERIAL

- Positively evaluated advertising material;
- Stamp;
- Submission to the Single Desk.

The term for broadcasting positively evaluated advertising material is unlimited.

TYPES OF ADVERTISING MATERIALS NOTIFIED TO AMDM

FOR THE GENERAL PUBLIC:

- Printed advertising material;
- Audio/video advertising.

FOR QUALIFIED PERSONS:

- Printed advertising material.

ADVERTISING INTENDED FOR THE GENERAL PUBLIC REQUIREMENTS: TV/RADIO SPOT

1. The trade name of the medicine;
2. Therapeutic indication;
3. The audio message addressed to the consumer: *" This is a medicine. Read the leaflet carefully. If unpleasant manifestations occur, contact your doctor or pharmacist."*

The message must appear written on the screen and to resound at the end of the commercial spot for at least 5 seconds or throughout the commercial spot. The message must occupy at least 10% of the surface of the advertising material and be written on a background that allows its clear visualization.

ADVERTISING INTENDED FOR THE GENERAL PUBLIC REQUIREMENTS: PRINTED MATERIAL

1. The trade name of the medicine;
2. The necessary information for the correct use of the medicine (indications, method of administration, dosage, contraindications, warnings, precautions and side effects);
3. The message addressed to the consumer: *" This is a medicine. Read the leaflet carefully. If unpleasant manifestations occur, contact your doctor or pharmacist."*

ADVERTISING INTENDED FOR QUALIFIED PERSONS REQUIREMENTS: PRINTED MATERIAL

1. The trade name of the medicine;
2. Therapeutic indications, pharmaceutical form and concentration;
3. Doses and method of administration for each therapeutic indication, depending on the age;
4. Date and number of the registration certificate;
5. Side effects and contraindications;
6. Special warnings and precautions;
7. The classification of the medicine from the point of view of the mode of release;
8. The date the information was edited or revised;
9. The extract from the database of adverse reactions, as appropriate;
10. The mention: *" This advertising material is intended for persons qualified to prescribe, distribute and/or dispense medicines."*

ADVERTISING WITHIN SCIENTIFIC-PRACTICAL EVENTS

The holder of the drug registration certificate or its legal representative must notify the Agency, prior to the scientific-practical demonstration, of the following aspects:

1. The type of event in which medicines are advertised;
2. The materials that are distributed during the event;
3. The medical information provided during these presentations - the slides that refer to the product's characteristics, and not the entire presentation;
4. Promotional objects distributed (to be listed);
5. The specialties of the qualified persons to whom the information is addressed.

Specialists who, in the framework of international events, participate and present medical information that refers to the characteristics of a product must notify the set of slides that refer to the characteristics of the product, and not the entire presentation. Notification is made on paper or by electronic means, at least 10 days before the event.

SPONSORSHIP ACTIVITIES

Manufacturers, holders of the drug registration certificate or their representatives in the Republic of Moldova, as well as wholesale and retail distributors of drugs are obliged to declare to the Agency, by March 31 of the current year, all sponsorship activities, as well as any expenses incurred in the year prior to reporting for qualified persons, professional organizations, patient organizations and any other type of organization carrying out activities related to public health, medical or pharmaceutical assistance.

ADVERTISING AND PROMOTION OF MEDICINES, MEDICAL PRODUCTS, AND BIOLOGICALLY ACTIVE PRODUCTS IN MONGOLIA

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Manufacturing, import, export, storage, sale, monitoring, distribution and use of medicine for human and veterinary use, including conventional medicine, bio preparations, diagnostics (hereinafter the "Medicine"), medical devices, and biologically active products are regulated by the Law of Mongolia on Medicines and Medical Devices. The Law also provides a few broad limitations on the advertising of medicines and biologically active products. In addition to this regulation, the Law of Mongolia on Advertisement governs advertising in health sector.

With the regulations being too general, there have been a number of instances of illegal advertising in the health sector, as well as cases where consumers have incurred damage.

Recently, a law on the revision of the Law on Medicines and Medical Devices that outlines provisions such as updating the legal framework for the state regulation and inspection system of human and animal medicine and medical supplies is said to be in the course of developing by the competent authority.

GENERAL MEDICINAL PRODUCT AND ITS ADVERTISING

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).

Advertisement means information distributed through public media or in other ways 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).

Under the previous Law on Licensing (2001), advertising of medicines and biologically active products was not necessarily regulated. On the other hand, under the new Law on Permits (2022), which is passed by the Parliament of Mongolia and has come into force from 1 January, 2023, prior to advertising of medicines and biologically active products in the health sector a regular permit shall be obtained in advance. The central state administrative organization in charges of medicines shall issue the regular permit on this matter.

MEDICINE'S REGISTRATION:

Medicines registration has started in Mongolia since 1994, in order to provide the population and health organizations with qualitative, safe and effective medicines. The registration of medicine, its raw materials and biologically active products is regulated by the "Procedure for registration of medicines, raw materials and biologically active products", approved by the order № A/295 of 2019 by the Minister of Health of Mongolia.

As of 2021, out of total of 4175 registered medicines, 70.23% are prescription medicines, 28.68% are over-the-counter (or the non-prescription) medicines and 1.02% are medicines that must be used only

in hospital setting.[1] This 28.68% non-prescription medicines and biologically active products may be advertised in professional publications and public media. However, the public promotion of prescription-only medicine is prohibited.

ADVERTISEMENT OF MEDICINE

According to the Article 27.1 of the Law on Medicines and Medical Devices, non-prescription medicine and biologically active products may be advertised in professional publications and public media. Further it is stated in article 27.2 that the content of advertisement of medicines and biologically active products shall be reviewed by the central state administrative organization in charge of agriculture and the state administrative organization in charge of control and regulation of medicines and medical devices.

Drug advertisement information must be based on pharmacological indicators and clinical research results, regardless of the drug form.

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 medicines, which are to be used in hospital only, to sell trough 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 IS PROHIBITED

- To advertise drug supply organizations (pharmaceutical factories, drug supply organizations, pharmacies) that have not obtained a permit from the administrative or professional organizations of the province, capital, or veterinary medicine;
- To advertise health organization without license of professional operation, specialist without right of treatment, or treatment or health service without permission or certificate. Advertisement of health organization shall be limited to the location, service field and name and address of physician only;
- To distribute advertisement that praised service of hospital or called to be served.

[1] Medicine and medical devices regulatory agency, Pharmaceutical sector indicators 2021, page 36, https://mmra.gov.mn/?id=200660

The Pharmacological subcommittee of the Human medicine's council discusses advertisement content of over-the-counter medicines and biologically active products and issues permits to advertise in the media. In 2021, the Pharmacological subcommittee gave the total of 93 permits for advertisement out of which 78 permits for medicines and 15 biologically active products.[2]

STATE CONTROL OVER ADVERTISING

The monitoring of advertising in the territory of Mongolia shall be carried out by the Inspection Office of the Intellectual Property and the Authority for Fair Competition and Consumer Protection.[3]

The Authority for Fair Competition and Consumer Protection shall carry out the following main functions in connection with the control of advertising:

1. To monitor the implementation of laws and regulations on advertising;
2. To determine whether the laws and regulations on advertising have been violated and take relevant measures and implement them;
3. To protect the interests of consumers from illegal advertising.

The Inspection Office of Intellectual Property and the authority for Fair Competition and Consumer Protection shall exercise the following powers:[4]

1. Upon its own initiative, or on the basis of reviewing suggestions, requests, demands, and information submitted by other persons, to conduct inspections on ordering, creating, and distributing advertisements;
2. To provide methodical management to local organizations and officials to monitor advertising in the area;
3. To approve recommendations for creating, placing, and distributing advertisements and contract templates;
4. To provide proposal to suspend or cancel the permit of a person who violates the laws on advertising to the authority that issued the permit;
5. To file a claim in court in connection with the violation of laws on advertising;
6. To determine whether the advertisement violates the requirements of the law, suspend its creation and distribution, and demand for elimination of the violation.
7. Other powers stipulated by law.

The subject exercising the above powers shall be the Inspector of the State Inspection Office of Intellectual Property, the State Inspector of the Authority for Fair Competition and Consumer Protection, and shall exercise the relevant rights and obligations specified in the Law on Advertising.[5] Governors of provinces and the capital city and inspectors appointed by them monitors advertising.

LIABILITY FOR THE VIOLATION OF THE LAW

If advertising of medicines is carried out in a form prohibited by law, an individual will be fined in the amount of MNT 300,000 (app USD 86), and a legal entity will be fined in the amount of MNT 3,000,000 (app USD 865).

Any individual can monitor the advertisement law application and submit his/her complaint to the Authority for Fair Competition and Consumer Protection in case of infringement of laws. The State Inspector of the Authority for Fair Competition and Consumer Protection has the power to impose the above penalties to the respective individuals and legal entities.

[2] Medicine and medical devices regulatory agency, Pharmaceutical sector indicators 2021, page 42, https://mmra.gov.mn/?id=200660
[3] Article 24.2 of the Law on Advertising
[4] Article 24.3 of the Law on Advertising
[5] Article 24.4 of the Law on Advertising

ADVERTISING AND PROMOTION OF MEDICINES AND MEDICAL PRODUCTS IN UZBEKISTAN

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It is significant to note that medicines advertising is important in life and directly related to the health of each of us. Moreover, it has also become an influencing factor to a greater extent in the production and sale of medicines. In this regard, huge attention is paid to the improvement of the regulations on advertising medicines in Uzbekistan. This article highlights the basic requirements of advertising legislation that pharmaceutical companies primarily should be aware of.

IN THE REPUBLIC OF 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 the Republic of 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.

It must be emphasized that 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.

It should be noted that the law prohibits promotional campaigns in the field of medicines advertising.

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.

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.

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.

Studying the market of advertising medicines and medical products in the media, there can be found many materials that do not comply with advertising legislation. Often, we see that advertisements distributed by pharmaceutical companies do not comply with instructions for use approved by the State Authorities. For instance, in practice, cases have been identified by the inspection authorities when the manufacturer's instructions prescribe that the medicine treats hypertension. Despite that, the treatment of other diseases is indicated when advertising this medicine. This can mislead consumers, and cause harm to their health.

In addition to the above, even though 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.

Returning to the topic of responsibility, 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) basic calculated value[1], that is, from UZS 1,500,000 to UZS 4,500,000 (approximately equivalent to USD 135 to USD 400).

Considering amendments being made to the legislation of the country and the monitoring carried out by the regulatory a[6]uthorities, there is development aimed at the protection of the rights and interests of consumers. However, there is a significant amount of deceptive advertising of medicines and medical devices, aimed at both doctors and patients. In this regard, the legal regulation of advertising in the field of pharmaceutical activities still needs more detailed regulation on several issues. To avoid negative consequences and violations of legal requirements, pharmaceutical companies are recommended to implement a process for checking their advertising materials distributed by them for compliance with the law.

[1]1 base calculated value for February 2023 is UZS 300,000 (approximately USD 27).

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