MEDICAL ADVERTISING IN MONGOLIA

GRATA International Mongolia

MEDICAL ADVERTISING IN MONGOLIA

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.

I. 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 biological 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.

II. 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

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

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 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.

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 permis for advertisement out of which 78 permits for medicines and 15 biological active products.[2]

III. 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] 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

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.

IV. 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.

[5] Article 24.4 of the Law on Advertising

References:

1. "The Law of Mongolia on Medicines and Medical Devices "
   https://legalinfo.mn/mn/detail/85
2. "The Law of Mongolia on Advertising"
   https://legalinfo.mn/mn/detail/259
3. "Medicine and medical devices regulatory agency", "Pharmaceutical sector indicators 2021", page 36
   https://mmra.gov.mn/?id=200660

For more information or any queries, please feel free to contact V.Bolormaa, Partner, and T.Buyanjargal, Lawyer, of Grata International Law Firm by bvolodya@gratanet.com, btungalag@gratanet.com or +976 70155031.