

## MEDICAL ADVERTISING IN MONGOLIA

Bolormaa Volodya

GRATA INTERNATIONAL IN MONGOLIA



## **1. General Medicinal Product and its advertising**

### **1.1 What law and legislation governs advertising of medicines in your jurisdiction?**

The Law on Advertising (2002) and Law on Medicines and Medical Devices (2010) are main laws to regulate advertising of medicines in Mongolia.

### **1.2 What is the definition of an 'advertisement'?**

Pursuant to Article 3.1.1 of the Law on Advertising, advertisement means information distributed through public media or in other ways by individual, business entity or organisation in order to increase market demands of goods, works, services, project or operation (hereinafter – the 'Products') and to attract attentions of potential customers.

### **1.3 Are there any legal or legislative requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?**

There is no statutory requirements for companies in respect of advertising activities.

### **1.4 If the authorities consider that an advertisement, which has been issued, is in breach of the law and/or code of practice, do they have powers to stop further publications of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?**

The state Authority for Fair Competition and Customers' Protection is a regulatory authority that monitors the application of advertising laws in Mongolia. They do have powers to cease further publication of the advertisement, if it breaches the law. They can insist to undertake corrective action in respect of the unlawful advertisements. Local and foreign companies may file an appeal with the court against actions of the authority.

### **1.5 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility of enforcement and how strictly are the rules enforced?**

If a medicine is advertised in a form prohibited by the law, there is a fine for individuals in the amount of MNT300,000 (USD125), and for legal entities - MNT3,000,000MNT (USD1,252).

In case of subscription, production and distribution of a prohibited advertisement, there is a fine for individuals in the amount of MNT500,000 (USD209), and for legal entities - MNT5,000,000MNT (USD2,087).

The advertising materials and copies thereof shall be kept for 6 months after their last distribution. In failure to comply with this procedure, there is a fine for individuals in the amount of MNT500,000 (USD209), and for legal entities - MNT5,000,000MNT (USD2,087).

In case of engaging children in advertising without permission of their parents, guardians and custodian, there is a fine for individuals in the amount of MNT100,000 (USD42), and for legal entities - MNT1,000,000MNT (USD417).

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

## **2. Providing Information prior to Medicinal Product Authorisation**

- 2.1 To what extent it is possible to make information available to healthcare professionals about a medicine before the product authorisation? For example, may information on such medicines be discussed, or made available on scientific meetings?

The information related to a prescription medicine, narcotic drug, psychotropic substances and plants for treatment, as well as medical devices that require special knowledge and qualification shall be distributed and advertised only through the media dedicated for health professionals. In accordance with Law on Medicines and Medical Devices of Mongolia, medicines and non-prescription medicines shall be registered with the state competent authority in order to be used for medical treatment. The non-registered medicines and information thereof can be discussed and made available on scientific meetings for health professionals.

- 2.2 May information on unauthorised medicines or indications be sent to institutions to enable them plan ahead in their budget for products to be authorised in the future?

If a medicine is unauthorised or not registered with the competent state authority and not included in the State Register of Medicines, it is prohibited for use in Mongolia. Thus, it is impossible for institutions to plan budget for procurement of unauthorised medicines.

## **3. Advertisement to Healthcare Professionals**

- 3.1 What information must appear in advertisements directed to healthcare professionals?

There is no such specific requirement on the content of an advertisement directed to the healthcare professionals. As stated above, advertisement of prescription medicines, narcotic drugs, psychotropic substances and plants for treatment, as well as medical devices that require special knowledge and qualification shall be directed to the health professionals only.

- 3.2 Are there any restrictions on the information that may appear in an advertisement?

It is generally prohibited in advertising medicines and medical devices:

- To advertise medicines, which have not been (yet) registered in the state register;
- To advertise medicines, which are to be used in hospital only, to be sold through pharmacy and other ways;
- To advertise hiding side effects or prohibitions of the medicine;
- To issue a warranty about the medicine effect in advance; and
- To advertise a medicine without general names, but with commercial name only;
- to advertise medicines through mass media for the purpose of importing and selling;
- to advertise medicines, which are targeting children;
- to advertise prescription medicines;
- to disseminate information, which gives an idea to deny doctor's advice, therapy and surgery;
- to mislead consumers that a particular medicine is rare or important, or the only one, highly active or more effective, compared to other medicines, or safe and free of side-effects and/or new and patented medicine;
- to advertise incentives for buying medicines and medical devices, or price discounts.

Moreover, the information used in an advertisement shall be true and accurate. The content of a medicine advertisement shall be monitored and approved by the state competent authority of Mongolia prior to the distribution to the public audience.

- 3.3 Are there any restrictions to the inclusions of endorsements by healthcare professionals on promotional materials?

The following restriction applies that the hospital professional shall not advertise, use in diagnosis and medical treatment, sell, distribute, and offer any drug, medical device and biologically active products, which are not registered in the state register, with inaccurate test results, non-standard, and do not have quality warranty to the customers.

- 3.4 What rules govern comparative advertisement? Is it possible to use another company's brand name as part of that comparison?

It is prohibited to compare its medicine to other medicine in order to advertise its products. Comparative advertisement of medicines is one of prohibited forms under the law.

#### **4. Gifts and Financial Incentives**

- 4.1 Is it possible to provide healthcare professionals with samples of medical products? If so, what restrictions apply?

Pursuant to the Ethic Rules of Hospital Professionals, the hospital professionals are prohibited to accept a bribe, illegal compensation, donation, gift, informal payment for their services and support regardless whether the respective medical organisation or hospital is state or private. The hospital professionals mean a doctor, nurse, pharmacist, obstetrician, and other professionals of the hospital, who has a degree from social health and medical university or colleges.

However, samples of medical products can be provided, if it is not referred to the daily health service or support by the health professionals.

- 4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

Health professionals in state hospitals and clinics shall be prohibited from direct or indirect accepting gifts (including hospitality (meals and beverages) in the performance of their public official duties irrespective of monetary or other limits.

Health professionals holding managerial, administrative, and supportive positions in a state organisation, which is funded from the state budget, shall have a status of civil servants or considered as government officials. An official shall have an obligation to report within 30 days in writing to the competent official the cases where the value of a one-off gift or service received from persons other than his/her family members or relatives exceeds the equivalent of his/her 1 monthly salary or where the value of gifts or services received from a single source in the course of one year exceeds the equivalent of his/her three monthly salaries.

- 4.3 Is it possible to give gifts and donations of money to health care organisations such as hospitals? Is it possible to donate equipment, or fund the cost of medical or technical service (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

State hospitals and its officials are prohibited to accept any gifts and donations. The private hospitals in Mongolia are commercial organisations and obtain the license to operate a hospital from the competent authority. Thus, there is no restriction to accept gifts and donations, but it shall not be for their professional health service and support.

The government officials may accept gifts and donation, if it is:

- used for public needs such as further staff training, operation of the organisation or technical support;
- received from a third party that is independent of any relationships with the said public officials, central or local public authorities.

A government official shall obtain permission from his/her senior management or relevant competent authority before accepting donation or financial aid, if there can be any potential conflict of interest.

4.4 What general anti-bribery rules apply to the interaction between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarize. What is relationship between the competent authorities for pharmaceutical advertising and anti-bribery/corruption supervisory and enforcement functions?

Mongolian legislation does not establish special anti-bribery rules inn respect of the interaction between pharmaceutical companies and healthcare professionals or healthcare organisations. Giving or receiving bribes for the action or omission of civil servants shall be considered as a crime under the Criminal code.

The Authority on Fair Competition and Customers' Protection is fully responsible for the supervision and enforcement of medical advertising.

## 5. General Advertising

5.1 Is it possible to advertise non-prescription medicines to the general public?

An advertisement distributed through the public media can only refer to the non-prescription medicines and provide for the proper use thereof.

5.2 Is it possible to advertise prescription only medicines to the general public? If so, what restrictions apply?

It is prohibited to advertise prescription only medicines to the general public.

5.3 What restrictions apply to describing the products and research initiatives as background information in corporate brochures /annual report?

The product information on corporate brochures/annual report shall not be intended to increase market demands of goods, works, services, project or operation, or to attract attentions of the potential customers. If the product information contain the signs such as increasing market demand or attracting new customer, then it will be considered as advertising.