Revised Law on Medicines and Medical Devices to take effect shortly

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In Brief

On June 5, 2024, the Parliament of Mongolia enacted the revised Law on Medicines and Medical Devices ("**LMMD**"), which will come into effect on October 1, 2024. In relation to the adoption of the LMMD, relevant amendments have been made to multiple laws including the Law on Permits and the Law on Infringements. The enactment of this law is anticipated to significantly impact businesses operating within the pharmaceutical and medical sectors. Therefore, through this alert, we present some of the key regulations stipulated in the law.

Some significant changes with business impact

1. PRICE REGULATION

LMMD introduces new regulations to limit price increases and ensure price transparency for medicines and medical devices. According to the LMMD, the Minister of Health and the Minister of Finance shall establish a maximum percentage limit on price increases for essential medicines and medical devices through a joint order. In other words, It is prohibited increase the price of medicines and medical devices by a rate beyond the established maximum percentage in the supply and sale of medicines and medical devices. Moreover, this maximum rate for price increase is specifically regulated for both wholesale and retail prices. Additionally, it is prohibited to increase the prices of medicines and medical devices without justification.

2. TRANSPARENCY

One of the rationale behind the adoption of the revised LMMD is to enhance the transparency of information related to medicines, particularly pricing information. Therefore, the following changes have been introduced through the law:

- A unified electronic information system applicable to all levels of supply is to be established.
- Suppliers are required to upload the smallest measurable unit, base price, wholesale, and retail prices of medicines and medical devices to the unified electronic information system.
- The wholesale prices of medicines and medical devices of distributors will be made transparent to pharmacies and healthcare institutions through the electronic information system.
- Pharmacies are obligated to make retail prices transparent and accessible to the public through the unified electronic information system.

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Some significant changes with business impact (Cont'd)

3. ADVERTISING

Under the Law on Medicines and Medical Devices (2010), regulations regarding the advertising of medicines and medical devices were relatively minimal. In contrast, the LMMD has expanded the general principles for advertising and regulated the requirements and prohibitions for medical advertisements.

According to the LMMD, licensed manufacturers and suppliers may advertise medicines within the scope of the permit issued by the Medicine and Medical devices Regulatory Authority. Advertisements must include audio descriptions for visually impaired individuals, sign language, or written descriptions for hearing-impaired individuals. Additionally, the law has established specific prohibitions on advertisements. Some notable examples of newly added prohibitions include:

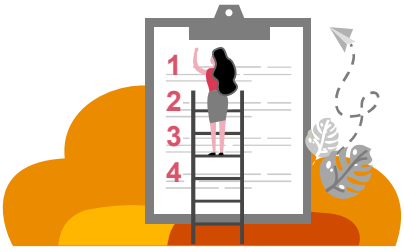
- Advertising medicines to the public without a permit;
- Medical professionals advertising medicines;
- Advertising narcotic drugs, and psychotropic substances;
- Advertising medicines in an inappropriate, unrealistic, unethical, or covert manner;
- Individuals or legal entities participating in, supporting, promoting, or providing financial support for the advertisement of medicines without an advertisement permit;
- Advertising health supplements as having diagnostic or therapeutic effects, thereby misleading the public;
- Advertising through social media or means other than television, radio, billboards, professional publications, and official websites.
- Offering, promoting, or selling any substances listed in the World Anti-Doping Code and international standards as banned substances to athletes or individuals engaged in sports activities for non-therapeutic purposes.

4. PHARMACEUTICAL PROMOTION

The LMMD introduces more detailed regulation on pharmaceutical promotional activities. Specifically, the pharmaceutical promotion should be conducted by professionals of manufacturers, suppliers, and representative offices of foreign manufacturers. The professionals conducting the promotional activities must hold a medical or pharmacy license. Furthermore the professional must conduct these activities in accordance with the ethical standards of healthcare professionals.

Additionally, the following activities are expressly prohibited in pharmaceutical promotion:

- Promoting unregistered medicines, medical devices, or health supplements;
- Involving healthcare professionals in multi-level marketing businesses, offering any form of incentives, or providing educational credits;
- Healthcare professionals receiving gifts, donations, incentives, or any form of support such as travel, or participation in domestic or international training.



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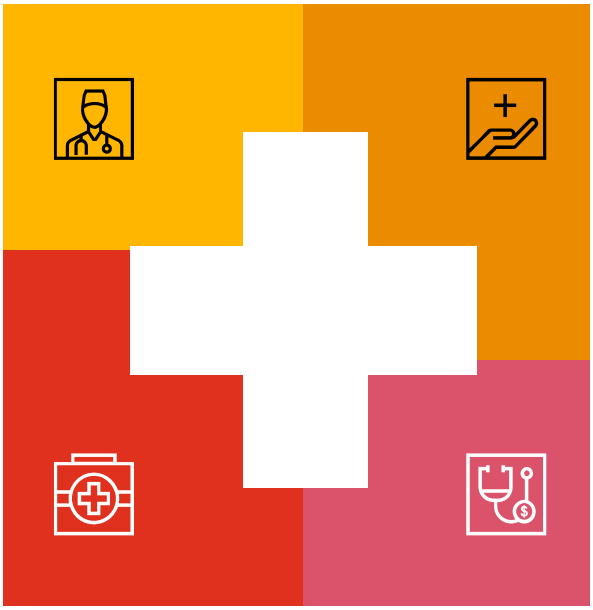
Some significant changes with business impact (Cont'd)

5. REPRESENTATIVE OFFICE

The Law on Medicines and Medical Devices (2010) did not contain detailed regulations for the representative offices of foreign manufacturers of medicines and medical devices. However, the LMMD includes regulations for representative offices, which have brought significant changes for foreign companies and businesses with representative offices in Mongolia.

Specifically, a representative office is required to submit its certificate and accreditation to the Medicine and Medical devices Regulatory Authority. Additionally, the following regulations for representative offices must be emphasized:

- The representative office became responsible for conducting research on the quality, safety, and therapeutic efficacy of the products of the manufacturer it represents in compliance with relevant laws, regulations, rules, and guidelines and obligated to ensure quality and safety;
- The representative office became obligated to submit quarterly reports on the monitoring and promotional activities to the Medicine and Medical devices Regulatory Authority;
- The representative office is prohibited from offering education credits or any form of incentives through training conducted for the purpose of market promotion of its products.



6. PHARMACOVIGILANCE ACTIVITIES

Additionally, the LMMD has increased the responsibilities of business entities in relation to the monitoring adverse drug reactions. According to the law, registrants of medicines and active pharmaceutical ingredients, holders of import and supply permits, and representative offices of foreign manufacturers are required to document and regularly update their pharmacovigilance activities.

Specifically, healthcare institutions, medical professionals, drug treatment committees, suppliers, and representative offices of foreign manufacturers are obligated to report each case of adverse drug reactions. Medicine and Medical devices Regulatory Authority is required to approve the regulations governing these pharmacovigilance activities.

Contact us!

If you wish to receive legal advice related to the registration, import, export, promotion, and compliance with legislation of medicines, medical devices, and health supplements, please contact us.

To view the full text of the revised Law on Medicines and Medical Devices, click here..

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