KAZAKHSTAN'S PHARMACEUTICAL LEGISLATION – RECENT CHANGES

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Over the past few years, Kazakhstan's pharmaceutical legislation has undergone significant change. In July 2020, a new Public Health and Healthcare Code entered into effect with various amendments and additions on medical and pharmaceutical activity, digitalization, government control and supervision, and other new elements. From 1 January 2021, companies manufacturing medicines and pharmacy warehouses must comply with *Good Manufacturing Practice (GMP)* requirements. In addition, these companies and warehouses must comply with *Good Distribution Practice (GDP)* requirements.

From 1 January 2023, organizations engaged in retail operations for medicines (pharmacies, pharmacy chains) will need to comply with *Good Pharmacy Practice (GPP)* requirements. Moreover, from 1 July 2021, mandatory certification for pharmaceutical personnel will be introduced. The list of specialties of pharmaceutical personnel required for certification is approved by Order of the Minister of Health dated 30 November 2020. Without a certificate, pharmaceutical personnel cannot practice pharmacy. Certification will be subject to confirmation every five years.

In addition to the above, the Code prohibits advertising of prescription medicines in mass media, which includes TV and radio channels, as well as online resources and periodicals registered as the media. However, advertising of non-prescription medicines is allowed in the media. It should be noted that advertising medicines may be allowed after the advertising materials are evaluated by the government to ensure they comply with Kazakhstan's healthcare legislation.

Based on results, an expert report is prepared and a conclusion is issued. Advertising medicines must meet the general requirements of Kazakhstan's advertising legislation of Kazakhstan and the specific requirements of medical advertisements. In accordance with the general requirements, advertising must be circulated in Russian and Kazakh and provide reliable information.

The new Ethics Rules for promotion of medicines and medical devices mandatory for all pharmaceutical companies in Kazakhstan were approved by Order of the Minister of Health dated 21 December 2020. These rules set out the way in which medicines may or may not be promoted.

For instance, individual contact by medical manufacturers, distributors and their representatives with medical and pharmaceutical personnel during working hours and at the workplace for the purpose of promoting medicines and medical products is not allowed. It is also prohibited to provide or offer financial remuneration or any other incentives of a financial or non-financial nature to medical and pharmaceutical personnel for prescribing and dispensing certain medicines.

Nor is it allowed to organize programs that provide financial and non-financial rewards, or gifts to heads of pharmacy organizations and pharmaceutical personnel for achieving certain sales results. According to the Code, representatives of medical manufacturers and distributors may promote medicines and medical products to medical organizations and educational institutions only during medical conferences, scientific and practical conferences, or specialized seminars.

In addition to advertising and promoting medicines, there have been significant changes in medical pricing regulations. For instance, under the new Rules, price caps and markups for medicines, as well as medical devices within the guaranteed volume of free medical care and (or) in the system of compulsory social health insurance that establish procedures for approving ceiling prices for wholesale and retail sale of medicines in Kazakhstan were approved by Order of the Minister of Health dated 11 December 2020.

Ceiling prices for medicines are approved twice a year no later than 10 July and 10 January. Unlike in many other countries, the ceiling prices for wholesale and retail are set for all medicines sold on the market in Kazakhstan. The sale of medicines without an approved ceiling price is prohibited. The Medical and Pharmaceutical Control Committee under the Ministry of Healthcare monitors and controls pharmaceutical companies' compliance with the ceiling prices for medicines by trade names.

According to the new Rules establishing the formation of price caps and markups for medicines, the sale of unregistered medicines imported to Kazakhstan is allowed at a ceiling price determined as follows on the basis of an opinion issued by the authorized body: 1) for wholesale - by adding a wholesale markup to the import price (invoice) in accordance with the regressive scale of markups for consumer packaging; and 2) for retail sale - by adding a retail margin to the marginal price of a trade name of medicines for wholesale in accordance with a regressive scale of markups for consumer packaging.

Manufacturers of medicines, distributors and pharmacy chains in Kazakhstan need to consider the above changes and other requirements of Kazakhstan legislation that have a significant impact on their activities.