Kazakhstan Rules for State Registration of Medicines and Medical Devices have been amended

The Rules for State Registration, Re-registration of a Medicine or a Medical Device, introducing amendments to the Registration Dossier of a Medicine or Medical Device[1] (hereinafter referred to as the "**Rules for Registration of Medicines and MD**") have been amended in connection with the introduction of the concept of "Strategically Important Medicines and Medical Devices" in the Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI "On the health of the people and the healthcare system" (hereinafter - the "Code").

Strategically Important Medicines and Medical Devices inter alia include Medicines and Medical Devices (hereinafter referred to as **"MD"**) intended for medical use in the absence or in the threat of absence of Medicines or MD on the markets of the Member States of the Eurasian Economic Union due to introduction of restrictive economic measures against at least one of the Member States[2].

According to the amendments:

- Rules for Registration of Medicines and MD now cover the Strategically Important Medicines and MD[3];
- State Registration of Medicines and MD in accordance with the Rules for Registration of Medicines and MD is carried out on the basis of the results of an examination carried out in accordance with the national Rules for the Examination of Medicines and MD[4];
- The requirements of subparagraphs d) and e) of the paragraph 2 of the Rules for Registration of Medicines in the EAEU[5] stipulating that the Medicines registered in accordance with the legislation of the Member States must be brought in line with the requirements of international treaties and the acts constituting the legislation of the EAEU until December 31, 2025, as well as stipulating that the registration certificates of Medicines issued in accordance with the legislation of the Member States are valid until

[1] Rules for State Registration, Re-registration of a Medicine or Medical Device, introducing amendments to the Registration Dossier of a Medicine or Medical Device approved by Order of the Minister of Health of the Republic of Kazakhstan dated February 9, 2021 No. ҚР ДСМ-16

[2] sp. 236-1, p.1 Art.1 of the Code;

[3] p. 1 of the Rules for Registration of Medicines and MD;

[4] p. 3-1 of the Rules for Registration of Medicines and MD; Rules for the Examination of Medicines and MD approved by the Order of the Minister of Health of the Republic of Kazakhstan dated January 27, 2021 No. KR DSM-10;

[5] Rules for Registration and Examination of Medicines for medical use approved by the Decision of the EEC's Council dated November 3, 2016 N 78;

their expiration date, but no later than December 31, 2025 do not apply to the issued registration certificates of the Strategically Important Medicines[6].

Thus, according to the amendments introduced Strategically Important Medicines and MD are registered and examined in accordance with the national rules of the Republic of Kazakhstan.

Roadmap for the Development of Competition in the Healthcare Sector was adopted

The Agency for the Protection and Development of Competition of the Republic of Kazakhstan (hereinafter referred to as the "**APDC**") together with the Ministry of Health of the Republic of Kazakhstan (hereinafter referred to as the "**MH RK**") have adopted a Roadmap for the Development of Competition in the Healthcare Sector (hereinafter referred to as the "**Roadmap**")[7].

The Roadmap is aimed at developing competition in the medicines market and in the field of medical services. In terms of developing competition in the medicines market the APDC and the MH RK have two objectives:

- Reducing excessive price regulation in the commercial segment including gradual deregulation of prices for Medicines with preservation of price regulation for Medicines purchased within the Guaranteed Volume of Free Healthcare (hereinafter referred to as the "**GVFH**") and in the system of Obligatory Social Health Insurance (hereinafter referred to as the "**OSHI**") until 2025. For this purpose, it is planned to exclude price regulation first, for OTC (Q3 2023) then for prescription (Q3 2024) Medicines intended for wholesale and retail sales. In addition, it is planned to study international experience in the field of pricing as well as to implement digitalization.

  Improving access to public procurement of Medicines within the framework of the GVFH and OSHI including
- Introducing amendments to the Code regarding the application of the unified rules for the formation of Kazakhstan National Formulary, the Register of Ceiling Prices for Medicines according to their Trade and International Non-proprietary Name purchased under the GVFH and OSHI system, the List for Outpatient Medicine Provision and the List of Single Distributor in order to unify the procedures for the formation of the lists indicating the terms of review at all stages including review by the Formulary Commission;

[6] p. 12 of the Rules for Registration of Medicines and MD;
[7] https://www.gov.kz/memleket/entities/zk/documents/details/435863?lang=ru

- Introducing amendments and additions to the Rules for the Procurement of Medicines and Medical Devices within the framework of the GVFH and OSHI in terms of improving the mechanism for entering into the long-term contracts (Q2 2023)[8];
- Implementation of digitalization elements into the process of the formation of the lists for medicine procurement.

Thus, the Roadmap defines the main measures aimed at developing competition in the medicines market, including improving the pricing mechanism, reducing the time it takes for medicines to enter the market.

Contact us:

Zafar Vakhidov

Partner, Vakhidov & Partners

Uzbekistan/Kazakhstan

ZV@vakhidovlaw.com

Saltanat Zhakhina

Associate, Vakhidov & Partners

Kazakhstan

saltanatzh@vakhidovlaw.com

[8] Decree of the Government of the Republic of Kazakhstan dated June 4, 2021 No. 375