

Kazakhstan – April 2024

The Law of the Republic of Kazakhstan “On Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on Health Issues” was signed

The President of the Republic of Kazakhstan (“RK”) signed the Law of the RK dated April 19, 2024 No. 74-VIII “On Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on Health Matters” (the “**Law on Health Matters**”). The Law on Health Matters introduces the following changes:

The Code of the Republic of Kazakhstan dated July 7, 2020 “On the Health of the People and the Healthcare System” (the “**Code**”)

- Introduction of the concepts/terms of “vape” and “flavor for electronic consumption systems (vapes)”¹, as well as the rules banning their import, production, sale, distribution, advertising and sponsorship²;
- Introduction of rules on obligatory professional liability insurance for medical workers³;
- Introduction of a rule that medical workers *should* be guided by clinical protocols when choosing the most effective methods of prevention, diagnosis, treatment and rehabilitation, which are advisory (recommendatory) in nature⁴ (in the current version - healthcare entities provide medical care in accordance with, among other things, clinical protocols⁵);
- Exclusion of the words “based on clinical protocols” from the “Medical care included in the Guaranteed Volume of Free Medical Care is provided based on clinical protocols by medical workers admitted to clinical practice on the territory of the Republic of Kazakhstan” provision of the Code.⁶

Criminal Code of the RK dated July 3, 2014 No. 226-V

- Introduction of criminal liability for the sale and distribution of non-smoking tobacco products, electronic consumption systems (vapes), flavors and liquids for them - punishment with a fine in the amount of up to 200 (two hundred) monthly calculation indices (“**MCI**”) or correctional labor in the same amount or community service for a

¹ sp. 1, clause 5, Art. 1 of the Law on Health Matters;

² sp. 8, clause 5, Art. 1 of the Law on Health Matters;

³ sp. 2, sp. 6, sp. 9, sp. 13, clause 5, Art. 1 of the Law on Health Matters;

⁴ sp. 9, clause 5, Art. 1 of the Law on Health Matters;

⁵ clause 3, Art. 115 Code;

⁶ sp. 11, clause 5, Art. 1 of the Law on Health Matters;

period of up to 200 (two hundred) hours or arrest for a term of up to 50 (fifty) days; for their import, production - punishment with a fine in the amount of up to 2,000 (two thousand) MCI or correctional labor in the same amount or community service for a term of up to 600 (six hundred) hours or restriction of freedom for a term of up to 2 (two) years, or imprisonment for the same term with or without confiscation of property⁷.

- Reduction of penalty for a failure to perform, improper performance of professional duties by a medical or pharmaceutical worker due to careless or dishonest attitude towards such duties if these actions negligently resulted in the infliction of moderate harm to human health - is punishable by a fine of up to 100 (one hundred) MCI (in the previous version - up to 200 (two hundred) MCI) or correctional labor in the same amount or community service for a period of up to 100 (one hundred) hours (in the previous version - up to 180 (one hundred and eighty) hours) or arrest for a period of up to 30 (thirty)) days (in the previous version - up to 50 (fifty) days)⁸. Penalty is also reduced if such acts negligently resulted in the death of a person, as well as the same acts that negligently resulted in the death of 2 (two) or more persons⁹.
- Reduction of penalty for improper performance of professional duties by a medical worker as well as an employee of an organization for domestic or other services due to careless or dishonest attitude towards such duties if this act resulted in the infection of another person with HIV is punishable by restriction of liberty for a term of up to 5 (five) years or imprisonment for the same period (in the previous version - imprisonment for a term of up to 5 (five) years¹⁰) with deprivation of the right to hold certain positions or engage in certain activities for a term of up to 3 (three) years¹¹.

The Law on Health Matters comes into force in 10 (ten) calendar days from the day of its first official publication with the exception of some provisions that come into effect in 60 (sixty) calendar days (for example, rules on criminal liability related to vapes, on the ban on the circulation of vapes, the advisory (recommendatory) nature of clinical protocols) and in 6 (six) months (rules on obligatory insurance of professional liability of medical workers) from the day

⁷ sp. 2, clause 1 of the Law on Health Matters;

⁸ sp. 3, clause 1 of the Law on Health Matters, Art. 317, clause 1, Criminal Code of the Republic of Kazakhstan dated July 3, 2014 No. 226-V (with amendments and additions as of September 12, 2023);;

⁹ sp. 3, clause 1 of the Law on Health Matters, Art. 317, clause 3, 4, Criminal Code of the Republic of Kazakhstan dated July 3, 2014 No. 226-V (with amendments and additions as of September 12, 2023);;

¹⁰ Art. 317, clause 5, Criminal Code of the Republic of Kazakhstan dated July 3, 2014 No. 226-V (with amendments and additions as of September 12, 2023);

¹¹ sp. 3, clause 1 of the Law on Health Matters;

of its first official publication¹². Published in the newspaper “Kazakhstanskaya Pravda” dated April 20, 2024 No. 78 (30205)¹³.

Amendments have been introduced into the Code of the Republic of Kazakhstan dated July 7, 2020 No. 360-VI “On the Health of the People and the Healthcare system”

The Law of the Republic of Kazakhstan (hereinafter – the “**RK**”) dated April 6, 2024 No. 71-VIII “On Introduction of Amendments and Additions to Certain Legislative Acts of the Republic of Kazakhstan on Matters of Doing Business” (hereinafter – the “**Law on Doing Business**”) amended the Code of the RK dated July 7, 2020 No. 360-VI “On the Health of the People and the Healthcare System” (hereinafter – the “**Code**”).

Price Regulation

- Changes have been introduced to the following provisions of the Code on price regulation, namely, the terms medical devices (hereinafter – the “**MD**”) have been replaced with “Medical Products, MD for diagnostics outside a living organism (in vitro) produced in the territory of the RK under the long-term supply agreements concluded with the Single Distributor”;
- In clause 5 of Art. 245 of the Code, after the words Maximum Retail price, the word “Medicine” was added: the Maximum Retail price of a Medicine cannot be approved without taking into account the total Wholesale and Retail markup to the Manufacturer’s Maximum Price¹⁴.

Control and Supervision in the field of Medical Services, Sanitary and Epidemiological Control and Supervision, Control in the field of Circulation of Medicines and MD

The provisions regulating Control and Supervision over the provision of Medical Services, Sanitary and Epidemiological Control and Supervision, Control in the area of circulation of Medicines and MD have been amended, including:

- The development and approval of the procedure for conducting an investigation in the field of provision of Medical Services (Assistance) was added to the competence of the State Body overseeing the provision of Medical Services¹⁵;
- The competence of the State Body for Sanitary and Epidemiological Welfare of the Population has been expanded to include inter alia defining the list of requirements a violation of which entails taking rapid response measures and exercising state control over compliance with the requirements for placing advertising which is subject to the State

¹² Art. 2 of the Law on Health Matters;

¹³ [The Law on Health Matters \(zakon.kz\)](#).

¹⁴ sp. 34, clause 10 of the Law on Doing Business;

¹⁵ sp. 3, clause 10 of the Law on Doing Business;

Sanitary and Epidemiological Control and Supervision of products (goods) subject to state registration¹⁶;

- Now the State Body in the field of Circulation of Medicines and MD carries out only State Control in the field of circulation of Medicines, MD as well as the circulation of narcotic Medicines, psychotropic substances and precursors in the field of health care (in the previous version – carried out State Control *and Supervision*¹⁷)¹⁸;
- A rule has been added stating that Preventive Control in the area of circulation of Medicines and MD without visiting the subject (object) of control is carried out in relation to all Medicines *and MD*¹⁹;
- The articles 34-1 “Investigation in the field of provision of Medical Services (Assistance)”, 42-1 “Rapid response measures and the procedure for their application in the field of Sanitary and Epidemiological Welfare of the Population”, 45-1 “Investigations in the field of Sanitary and Epidemiological Welfare of the Population” have been added²⁰;
- Rules have been added stating that State Control over compliance with the requirements for placement of advertising subject to State Sanitary and Epidemiological Control and Supervision of products (goods) subject to state registration is carried out in the form of²¹:
 - 1) Preventive Control with a visit to the subject (object) of Control and Supervision, Unscheduled Inspection in accordance with the Entrepreneurial Code of the RK;
 - 2) Preventive Control without visiting the subject (object) of Control and Supervision in accordance with the Code, the Entrepreneurial Code of the RK and the Law of the RK “On Advertising”.
- A rule stating that monitoring of advertising of products (goods) subject to State Sanitary and Epidemiological Control and Supervision is carried out in relation to products subject to state registration has been added²².
- The provisions stipulating the objects of advertising monitoring have been added²³:
 - 1) television and radio channels;
 - 2) periodicals;
 - 3) Internet resources and online publications;
 - 4) outdoor (visual) advertising.

Carrying out monitoring of advertising consists of checking compliance with the requirements for the placement of advertising subject to State Sanitary and Epidemiological Control and Supervision of products (goods) as well as the availability of information about its state registration in the Unified Register of Certificates of State Registration of Products.

¹⁶ sp. 4, clause 10 of the Law on Doing Business;

¹⁷ sp. 2, Art. 10 of the Code (with changes and additions as of 05/01/2024).

¹⁸ sp. 5, clause 10 of the Law on Doing Business;

¹⁹ sp. 22, clause 10 of the Law on Doing Business;

²⁰ sp. 11, 15, 19 clause 10 of the Law on Doing Business;

²¹ sp. 13, clause 10 of the Law on Doing Business;

²² sp. 18, clause 10 of the Law on Doing Business;

²³ sp. 18, clause 10 of the Law on Doing Business;

In case of violation of the requirements of the legislation of the RK in the field of advertising:

- 1) the advertiser and/or advertising distributor is sent a recommendation to eliminate the identified violations in accordance with Article 44 of the Code;
- 2) a rapid response measure is applied to the subject of Control and Supervision in the form of seizure and recall from sale of products (goods);
- 3) information about the violator is sent to the Authorized Body for Mass Media in the manner prescribed by the legislation of the RK.

Other

- A rule stating that entities in the field of circulation of Medicines and MD carrying out retail sales of Medicines are required to comply with the requirements of good pharmacy practice (GPP) has been introduced. This rule will come into effect from January 1, 2026 for pharmacies (this rule has come into effect retrospectively on January 1, 2023)²⁴.

The Law on Doing Business comes into force after 60 (sixty) calendar days from the day of its first official publication²⁵ (Published: "Kazakhstanskaya Pravda" dated April 8, 2024 No. 67-68 (30194-30195); IS "Standard Control Bank NLA RK in electronic form" April 11, 2024)²⁶

Contacts:



Zafar Vakhidov

Partner, Vakhidov & Partners
Uzbekistan/Kazakhstan
ZV@vakhidovlaw.com



Saltanat Zhakhina

Associate, Vakhidov & Partners
Kazakhstan
SaltanatZh@vakhidovlaw.com

²⁴ sp. 35, clause 10 of the Law on Doing Business;

²⁵ clause 1, Art. 2 of the Law on Doing Business.

²⁶ [The Law on Doing Business](#).