16 April 2015

To our clients and friends

INFORMATION MEMORANDUM
Concerning Amendments to the Republic of Kazakhstan's Legislation on Healthcare Issues

On 8 April 2015, Kazakhstan adopted a new Law No. 299-V "On Introduction of Amendments into Certain Legislative Acts of the Republic of Kazakhstan on Healthcare Issues" (hereinafter, the "Law"), which will enter into legal force on 19 April 201, with the exception of certain provisions to come into force later.[1]

For the purposes of the Law implementation, amendments were introduced into a number of codes and laws of the Republic of Kazakhstan (including the Labor Code, Code on Public Health and Healthcare System (hereinafter, the "Code"), Criminal Code, Code on Administrative Violations, etc.).

This Information Memorandum offers a brief analysis of some key innovations introduced by the Law.

1. Conceptual Framework

The conceptual framework of the Law has been substantially amended in order to bring it in line with the international standards. Some definitions of the concepts existing in the current legislation have been concretized, with the Law also introducing radically new concepts such as "long-term contract for the supply of medicines and medical equipment," "long-term contract for storage and transportation of medicines and medical equipment," "certification of experts in healthcare field," "tobacco sponsorship," etc.

2. Long-Term Contract

The Code's version previously in effect contained a concept of supply and storage contracts, which was common for civil law contracts. By newly introducing the concepts of the "long-term contract for the supply of medicines and medical equipment" and "long-term contract for storage and transportation of medicines and medical equipment" the legislator imparts thereto the characteristics differentiating them from the usual civil law supply and storage contracts.

The conceptual content of the said contracts now came to include a provision regarding the obligatory party to the contract – a unified distributor whose products must comply with the good manufacturing practice (GDP) and international standards and have a certificate of origin for domestic circulation in accordance with the RK legislation. Additional focus is made on the contract term.

[1] For example, the provisions regarding attestation of healthcare experts are to come into force on 9 October 2015, those regarding consumption of tobacco – on 9 April 2017, and those regarding healthcare activities compliance with good practice standards – on 1 January 2018.

Despite introduction of the long-term contract concept, the Law does not provide for any regulation of its conclusion conditions, except for those mentioned above. Probably, these issues will have to be additionally governed by further subordinate legislation.

3. Pharmaceuticals Inspectorate

The Law introduces a new institute of "pharmaceuticals inspection as to compliance with good pharmaceutical practices" to be carried out by the structural subdivision of the Ministry of Healthcare and Social Development of the Republic of Kazakhstan – "pharmaceutical inspectorate in the field of medicines circulation."

Pharmaceutical inspection is conducted based on an application submitted to the authorized agency by a person engaged in the circulation of medicines, medical products and medical equipment and requesting to conduct a pharmaceutical inspection of such person's facilities, i. e., on a voluntary basis.

In case the pharmaceutical inspection yields a positive result, the inspected facilities are issued a certificate of compliance with good pharmaceutical practices. The Law's amendments set forth that during the effective term of such certificate, pharmaceutical inspections are to be conducted at least once in 3 years.

4. Medical Products Advertising

The Law clarifies the requirements to placement and dissemination of the advertising of medicines, medical products and medical equipment ("medical products") by way of the following:

- Adding new prohibitions applying to the advertising of medical products being placed and disseminated (for example, the Law now expressly prohibits advertising information to be placed on industrial products and prescription blanks);

- Adding exceptions to the previously established prohibitions (for example, placement and dissemination of medical products advertising is now allowed at medical and pharmaceutical conferences, congresses, symposia and other scientific meetings).

The legislator also introduces a requirement that medical products advertising is to contain a full (including the relevant medicine use limitations) and authentic information, which, if omitted, may entail inappropriate use of medicines or unjustified risk for consumers. In our view, this wording of the established legislative requirement is very ambiguous. We would deem it expedient to request clarifications from the authorized agency as to what it is going to actually mean by such information, after the amendments come into force.

5. Medical Products Registration

The Law adds specifics to the medical products registration procedure, including as follows:

- The list of medical products subject to and exempt from registration is expanded;

- A provision envisaging the issuance of a certificate of pharmaceutical product (CPP) by the authorized agency for registration of domestic medical products abroad is added;

- A clarification that in the framework of medical products registration the expedited procedure applies not to the registration as a whole, but to the expert review of medical products, is added.

6. Healthcare Experts Certification

The current legislation provides for the procedure for passing qualification exams and the requirements for assigning the qualification category to persons, including those invited to perform professional medical activities at the National Healthcare Holding and its subsidiaries, as well as at the Nazarbayev University or its medical organizations.

The Law introduces certification of healthcare experts held in order to determine the preparedness of persons having secondary (technical and vocational), postsecondary and higher medical education and having completed re-training and/or acquiring postgraduate education, to the performance of medical activities and to their admission to clinical practice (work with patients), issuing to them an expert certificate.

The certification is held based on evaluation of the vocational training level and confirmation of appropriate healthcare experts' qualification to be conducted by the organizations performing the said evaluation and confirmation and accredited by the authorized agency in accordance with the procedure established thereby.

7. Medical Examinations

Beside the preliminary and periodical employee examinations, the Law additionally provides for mandatory pre-shift medical examinations (in order to identify or confirm the absence or presence of an employee's disease and determine the employee's health status, temporary incapacity for work and professional fitness for work during the upcoming shift).

If previously only employers engaged in the sphere of production and economic activities were obligated to deny admission to employees not passing the mandatory types of medical examinations (preliminary and periodical), at present, such obligation is imposed on any employer regardless of its nature of activities. Furthermore, employers must also deny admission to those employees who have not passed preventive medical examinations in the framework of the guaranteed scope of free medical aid. The procedure for preventive medical examinations is determined by the authorized agency; however, so far, this procedure does not reflect the process of employers' interaction with healthcare organizations performing the preventive medical examinations.[2] Accordingly, the mechanism for complying with the new requirements of the Law relating to medical examinations has not yet been legislatively determined, which may in practice give rise to difficulties and disputes.

8. Preventive Measures and Restrictions on Tobacco and Alcohol Consumption

The amendments prohibiting sponsorship of tobacco and tobacco products and the advertising of alcohol-imitating products are to come into legal force on 9 April 2017.

The Code on Administrative Violations has also undergone amendments related to the liability for violations of legislation dealing with the sale and/or consumption of tobacco products.

[2] Order No. 685 of the Acting Minister of Health of the Republic of Kazakhstan "On Approval of the Rules for Conducting Preventive Medical Examinations for the Targeted Groups of Population" dated 10 November 2009.

Should you have any further questions, please do not hesitate to contact us. We would be happy to provide you with the required advice.

Best regards,

AEQUITAS Law Firm