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Registration of pharmaceuticals and medical products in Kazakhstan

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Unfortunately, pharmaceuticals and medical products that are not duly certified and registered are illegally circulate on the market of Kazakhstan. Such illegal pharmaceuticals and medical products violate consumer rights and rights and commercial interests of trademark and patent owners. In this article we review possible violations and administrative-legal responsibility for sale of unregistered pharmaceuticals and medical products. At the same time, we shall not highlight civil liability of those importing original goods of a producer without his consent in violation of patent rights and unfair competition as we reviewed it earlier . Opinions, recommendations and approach of this article can be used by the right owners as an additional tool for dealing with violations and we hope that this article shall help diligent companies to avoid accidental offences, in particular, so-called violations of "out of ignorance".

Presently everyone has a right to freely transfer pharmaceuticals and medical products across the border and within the country, both for personal use and for commercial purposes. If pharmaceuticals and medical products are imported for gaining commercial profit, then an individual introducing them into the circulation (and the import is already means introduction) shall take into account the rules according to which the country registers, sells, advertises, and also needs to know what kind of responsibility may arise in case of violations related to illegal circulation of

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unregistered pharmaceuticals and medical products.

The legislation of the Republic of Kazakhstan provides for regulation of issues related to registration of pharmaceuticals and medical products and responsibility thereof:

- The Code of the Republic of Kazakhstan On Public Health and Healthcare System (Article 71);
- Annex No. 6 to the Order No. 293 of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated of April 28, 2015;
- Order No. 227 of the Minister of Healthcare and Social Development of the Republic of Kazakhstan dated April 16, 2015 On Approval of the Rules for Labeling Pharmaceuticals, Medical Products and Medical Equipment;
- The Code of the Republic of Kazakhstan on Administrative Offences (Article 426).

In addition, a number of decisions and rules governing the procedure for registration, labeling of pharmaceuticals and medical products intended for circulation on the market of the Eurasian Economic Union (EEU) had been adopted within the framework of the Eurasian Economic Union (EEU). One of such decisions is the Decision No. 78 dated November 3, 2016 of the Council of the Eurasian Economic Commission on the Rules for Registration and Examination of Pharmaceuticals for Medical Use (hereinafter referred to as the "Rules").

Pursuant to the Rules when registering pharmaceuticals and medical products that are subject to registration in the framework of the EEU, the following approaches are used:

- a procedure of mutual recognition of registration, first in the reference state (that is, the EEU member state, which prepares report on safety, efficacy and quality of a pharmaceutical on the basis of examination) and then in any state selected and requested by the applicant;

- a decentralized procedure, in accordance with which a pharmaceutical is registered at once by several member states of the EEU, where an application for registration of a pharmaceutical has been submitted with a choice of reference state;

- registration only pursuant to national rules (for the market of one state).

When pharmaceuticals of one producer, for example are issued and registered both in Russia and in Kazakhstan, separately in each state. This option is provided for in Article 2.b of the Rules, which says: «Until December 31, 2020, at the applicant's option a pharmaceutical may be registered either in accordance with the Rules or in accordance with the legislation of a member state. At the same time, pharmaceuticals registered in accordance with the legislation of a member state shall be admitted to circulation only in the territory of a member state whose authorized body issued a registration certificate.».

Consequently, individuals planning to register a pharmaceutical and/or medical product are entitled to select independently a registration procedure either in accordance with the Rules or in accordance with the national legislation of a member state. When selecting the latter, a pharmaceutical can be registered upon applicant's request consistently in several member states in accordance with the mutual recognition procedure or simultaneously in several member states in accordance with the decentralized registration procedure.

What is the procedure for registration of pharmaceuticals and medical products in Kazakhstan?

In Kazakhstan, the state has a monopoly on the examination and registration of pharmaceuticals and medical products. The executive body is the Pharmacy Committee of the Ministry of Healthcare of the Republic of Kazakhstan (hereinafter – the Pharmacy Committee) and the National Center for Examination of Pharmaceuticals, Medical Products and Medical Devices of the Ministry of Healthcare of the Republic of Kazakhstan (hereinafter - NCEP). Further detailed review of registration procedure for pharmaceuticals and medical products:

1. Examination of pharmaceutical and medical product by NCEP

Examination of pharmaceuticals and medical products in the NCEP. NCEP conducts the following: 1.1. Evaluates conditions of production and quality assurance system by visiting producer of pharmaceuticals or medical products;

1.2. Examines registration file and samples of pharmaceuticals and medical products, typical samples of pharmaceutical substances (active

pharmaceutical substances) and their impurities, in quantities sufficient for triple analysis, specific reagents and consumables, in exceptional cases and on return basis.

2. Obtaining positive results of examination or grounded refusal;

3. Filing of application, examination decision and payment of fee;

3. Filing (1) an application on behalf of the developer, producer of a pharmaceutical or medical product, or from their authorized representative, (2) the expert opinion and (3) payment of fee (fee is 11 MCR, which for today makes KZT 27775). Documents are filed through http://www.elicense.kz/ (which is preferable) or by hand through the office of the Pharmacy Committee.

4. Recording of information with the Registry of Pharmaceuticals and Medical Products;

Recording a pharmaceutical or medical product for a certain term with the State Registry of Pharmaceuticals and Medical Products (hereinafter - the Registry). This Registry is available in digital version and is open for public use. Any interested party can check availability of registration and appropriate permission to use a pharmaceutical or medical product.

5. Granting of registration certificate for pharmaceutical and medical product.

After receiving a registration certificate, individuals importing pharmaceuticals or medical products can offer and promote them within legal framework in the territory of Kazakhstan.

What risks face people who import pharmaceuticals and medical products without registration?

When third parties sell unregistered pharmaceuticals and medical products, their actions can be considered as:

- violating the ban on the sale of unregistered pharmaceuticals (Articles 67 and 69 of the Code of the Republic of Kazakhstan On Public Health and Healthcare System dated September 18, 2009) according to which it is prohibited to produce, offer for wholesale and retail sale of pharmaceuticals and medical products that are not

duly registered in the Republic of Kazakhstan; and;

- falling under the provisions and sanctions of Article 426 of the Code of Administrative Offences of the Republic of Kazakhstan (Administrative Code) – "Violation of the rules of pharmaceutical activity and the sphere of circulation of pharmaceuticals and medical products" for illegal introduction of unregistered pharmaceuticals and medical products into civil circulation (Article 426/3 of the Code of Administrative Offences of the Republic of Kazakhstan):

  Pursuant to Article 426.1 "Violation of the rules for registration and re-registration, production, and quality control, testing (research), importation, procurement, transportation, storage, labeling, sale, application (use), provision, destruction and advertising of pharmaceuticals and medical products if had not entailed harm to human health" entails a fine for individuals in amount of 70 MCR, for executive officers in amount of 100 MCR, for small businesses in amount of 130 MCR, for medium businesses in amount of 200 MCR, for large-scale businesses in amount of 1000 MRR. The Head or his deputies of the Pharmacy Committee or its territorial subdivisions are entitled to impose fines on such cases and within the limits of their authority.

  The violation provided for by Article 426 of the Administrative Code, repeated within a year after the imposition of administrative fine entails the suspension of a license for pharmaceutical activity for a period of up to six months and is subject to consideration by the court.

Further we shall consider in details Article 426.3 of the Administrative Code: "3. Production, purchase, transportation, storage, sale, application (use), advertising of unregistered, not allowed for use pharmaceuticals and medical products if had not entailed harm to human health…- entail the following:

A) Fine:

Subjects of offence:

- Individuals - 100 MCR - 252 500 тенге;
- Executive officers - 150 MCR-378 750 KZT;
- Objects of small business - 200 MCR -505 000 KZT;

- Objects of medium business - 300 MCR- 757 500 KZT;
- Objects of large-scale business -1500 MCR- 3 787 500 KZT.

Amount as of today 1 monthly calculation ratio (MCR) -2 525 KZT.

Б) suspension of business activity with seizure pharmaceuticals and equivalent products, products of therapeutic and preventive nutrition and food additives, cosmetics, which represent direct objects of an administrative offence and income obtained in the result of an administrative offence.

Pursuant to Article 426.4 of the Administrative Code if the above violations caused harm to human health, if these violations do not contain features of a criminal offence, responsibility increases up to the prohibition of business activity.

Presently authorized bodies involved in bringing to administrative responsibility in relation to Article 426.2.3.4. of the Administrative Code are territorial divisions (departments) of the Pharmacy Committee, with further consideration of the case by the court.

In order to bring to administrative responsibility individuals introducing into circulation unregistered pharmaceuticals and medical products, it is necessary:

- Application of the complainant filed with the authorized body;
- Availability of body of evidence (confirmation of the absence of registration of pharmaceuticals, evidence of introduction and storage of unregistered pharmaceuticals);
- Possible participation in administrative proceedings as a complainant and provision of testimony.

Please note that as complainant can be recognized any individual or legal entity which suffered physical, property or moral damage by an administrative offence. The legislation of the Republic of Kazakhstan does not clearly define which body or executive officer can recognize an individual or legal entity as a complainant of an administrative offence. In contrast to the criminal procedure legislation, the Administrative Code does not establish a special procedural order for recognizing an individual as a complainant. However, within the meaning of a number of provisions of the Administrative Code it is obvious that the recognition of an

individual as a complainant related to administrative offence is carried out by a judge, a body or an executive officer in charge of the administrative case.

The administrative case may be initiated also in the result of unscheduled inspection by an authorized body in order to identify pharmaceuticals without proper registration. Further, in accordance with the provisions of Administrative Code, the authorized body initiates administrative proceedings, drafts a report on administrative offence and transfers the case to the specialized district or equivalent administrative court. According to Article 684.1 of the Administrative Code such courts deal with the bringing to responsibility of individuals and entities whose actions include production, procurement, transportation, storage, sale, application (use) and advertising of unregistered, unauthorized pharmaceuticals and medical products, if they had not entailed harm to human health.

Anyone who introduces or plans to introduce unregistered pharmaceuticals or medical products into civil circulation in Kazakhstan should understand the importance of compliance with registration procedure. In addition to administrative fines, there is a possibility of suspension of business activity and seizure of pharmaceuticals and medical products, such individuals may suffer not only losses and also may undermine business reputation both among consumers and partners.

Every producer of pharmaceuticals and medical products should be sure that his products may be distributed in accordance with the rules and regulations of the legislation of a country where they are sold. Therefore, we recommend to check and to identify unregistered pharmaceuticals and medical products on a timely manner in order to prevent negative legal consequences in future.

1 https://ru.bolotovip.com/uslugi/parallelnii-import/

2 The costs associated with the examination of drugs and medical products during their state registration are borne by the applicants.

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