REGISTRATION OF PHARMACEUTICAL PRODUCTS AND MEDICAL ITEMS IN KAZAKHSTAN AND LIABILITY FOR ITS ABSENCE

In this article, we will briefly describe the procedure, timing and list of documents for registration of pharmaceutical products ("PP") and medical items ("MI"), grounds for refusing to provide state registration services, as well as administrative and legal responsibility for implementation of unregistered of PP and MI.

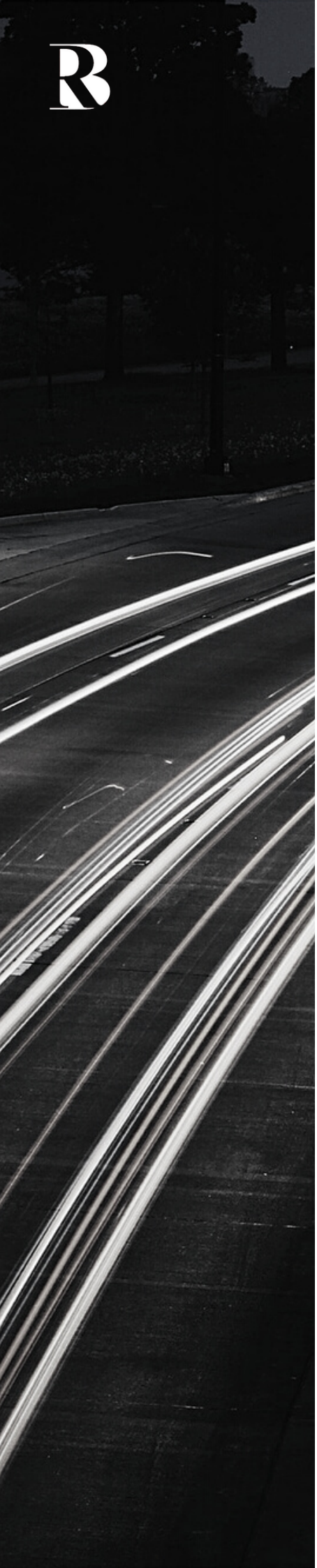
1. Carrying out expert examination of PP in the Ministry of Health of the Republic of Kazakhstan

Before the registration of PP, the PP is examined. The PP produced in the Republic of Kazakhstan, as well as imported into its territory, are subject to examination.

The examination of PP is carried out by the Republican State enterprise on the right of economic management "National center of expertise of pharmaceutical products, medical items and medical equipment" Committee quality control and safety of goods and services of the Ministry Healthcare of the Republic of Kazakhstan ("NCEPP").

In order to carry out such an examination, a person must submit in the NCEPP the following documents:

- application in the prescribed form for the examination of the PP;
- registration dossier in electronic form in the format of a cross-platform electronic document;
- list of documents to be submitted for examination manufacturers of the Republic of Kazakhstan;[1]
- list of documents provided in the general format technical document in the prescribed form;
- information confirming payment by the applicant for settlement account NCEPP amounts for the examination;



- PP samples, standard samples of chemical substances, standard samples of biological products, test strains of microorganisms, cell cultures, in quantities, sufficient for triple laboratory tests with residual shelf life of at least twelve months (except for cases that do not require laboratory tests), as well as specific reagents, consumables used in laboratory testing of medicinal the applicant provides funds within 5 (five) work days from the date of application.

The examination of PP is carried out within a period not exceeding two hundred ten calendar days in total and expedited the examination is carried out in a period not exceeding one hundred twenty calendar days.

After receiving an opinion on safety, quality and the effectiveness of PP as a positive result examination of PP, a person can register PP.

2. The State registration of PP and medical MI

The State registration of PP or MI also is carried out by the NCEPP. For the purposes of registration of PP and MI the applicant must submit an application to the NCEPP through the web portal "electronic government" when interacting with the Control System medicine provision of the Unified Information health care system of the Republic of Kazakhstan ("CSMP").

In order to register PP and MI devices, a person must submit the following documents to the NCEPP:

- an application for state registration of PP in the Republic of Kazakhstan in the forms established in the standard of public services, in the form of an electronic document certified by an Electronic Digital Signature (“EDS”) by the person who submitted the application;
- an electronic copy of the payment document confirming the payment of the registration fee, with the exception of payment through the "electronic government" payment gateway;
- an electronic copy of the conclusion of the NCEPP; information on state registration of a legal entity, certificate of state registration of the applicant as an individual entrepreneur

The term for the provision of public services on the portal is five working days.

3. Registration results for PP and MI.

In case of a positive decision on the registration of PP or MI, the following electronic documents are generated on the portal, signed by the EDS of the head of the state body:

- registration certificate;
- registered instructions (leaflet) on the medical use of PP or MI and general characteristics of PP in Kazakh and Russian languages;
- registered layouts of packages, labels, stickers on PP, MI in Kazakh and Russian languages.

After receiving the registration certificate, a person has the right to sell PP and MI on the territory of Kazakhstan.

4. Grounds for refusal to provide state service for registration of PP and MI

Below we provide the grounds for refusing to registration of PP and MI:

- negative conclusion of NCEPP, in connection with identification during their examination of inconsistencies declared indicators of quality, safety and efficiency in the order defined authorized body in the field health care;
- establishing the inaccuracy of documents submitted by a person to receive public service or data contained therein;
- inconsistency of the person or the submitted materials, objects, data and information necessary for the provision of public services with the relevant requirements;
- in relation to a person there is a court decision (decision) that has entered into legal force prohibiting activities or certain types of activities requiring a certain public service;

In case of refusal to register a PP or MI in the Republic of Kazakhstan, a refusal is generated on the portal in accordance with the established form.

5. Administrative and legal responsibility for the implementation unregistered PP and MI

When persons sell unregistered PP and MI, their actions violate:

- prohibition on the sale of unregistered PP, established in Article. 67 and 69 of the Code of the Republic of Kazakhstan "On people's health and health care system", according to which it is prohibited production and wholesale and retail sale of PP and MI that have not passed state registration in the Republic of Kazakhstan; and
- incurs liability under of the sanction of Article 426 of the Code administrative offenses of the Republic of Kazakhstan (“Code AO”) - "Violation of the rules of pharmaceutical activity and circulation of pharmaceutical products and medical devices” for illegal introduction into civil circulation of unregistered, PP and MI not approved for use.

It should be noted that the right to hear cases about administrative offenses and impose administrative penalties under Article 426 of the Code AO attributed to competence of territorial departments of the RSE "Committee quality control and safety of goods and services of the Ministry health care of the Republic of Kazakhstan".

If you have any questions regarding the above issues, please contact. We will be glad to help you.

Regards,
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