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CONCEPT AND STAGES OF MEDICINAL PRODUCTS CIRCULATION IN THE REPUBLIC OF KAZAKHSTAN

Summary

The presented article describes the concept, principles, rules and stages of circulation of medicines in the Republic of Kazakhstan. We are talking about the procedure for conducting a coordinated policy in the field of circulation of medicines, taking into account mutual interest in ensuring guarantees of the safety, effectiveness and quality of medicines for the life and health of people, protecting the life and health of consumers of medicines, preventing actions misleading consumers. The impact of the current legislation of the Republic of Kazakhstan in the field of health care and pharmaceutical activities on legal relations arising during the passage of all stages of circulation of medicines was considered. The main problems in this area have been disclosed. The positive experience of some foreign countries with developed legislation in the field of health care and pharmaceutical activities is being studied.

Keywords: trade, business, circulation of medicines, pharmacovigilance, quality control, development of medicines, pharmacology, pharmacy, medical industry, safety, quality and effectiveness of the medicine, medical application of medicines.

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ҚАЗАҚСТАН РЕСПУБЛИКАСЫНДАҒЫ ДӘРІЛІК ЗАТТАРДЫҢ ТҮСІНІГІ ЖӘНЕ АЙНАЛЫМЫНЫҢ САТЫЛАРЫ

Аңдатпа

Ұсынылған мақалада Қазақстан Республикасындағы дәрілік заттардың айналымының түсінігі, принциптері, ережелері мен сатылары ашылған. Осында адамдардың өмірі мен денсаулығы үшін дәрілік заттардың қауіпсіздігінің, тиімділігінің және сапасының кепілдіктерін қамтамасыз етуде, тұтынушыларды адастыратын әрекеттерге жол бермеу үшін, адамдардың өмірі мен денсаулығын сақтауда өзара мүдделерді ескере отырып, дәрілік заттардың айналымы саласындағы келісілген саясатты іске асыру тәртібі туралы сөз болып отыр. Қазақстан Республикасының денсаулық сақтау және фармацевтикалық қызмет саласындағы қолданыстағы заңнамасының дәрілік заттар айналымының барлық сатыларында туындайтын құқықтық қатынастарға әсері қарастырылады. Бұл саладағы негізгі мәселелер анықталды. Денсаулық сақтау және фармацевтикалық қызмет саласындағы дамыған заңнамасы бар кейбір шет мемлекеттердің оң тәжірибесі зерттелуде.

Түйіндісөздер: саудақызметі, кәсіпкерлікқызмет, дәрілікзаттардыңайналымы, фармқадағалау, сапасын бақылау, дәрілік заттарын өңдіру, фармакология, фармация, медициналық өнеркәсіп, дәрілік заттың қауіпсіздігі, сапасы және тиімділігі, дәрілік заттарды медициналық қолдану.

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ПОНЯТИЕ И СТАДИИ ОБРАЩЕНИЯ ЛЕКАРСТВЕННЫХ СРЕДСТВ В РЕСПУБЛИКЕ КАЗАХСТАН

Аннотация

В представленной статье раскрывается понятие, принципы, правила и стадии обращения лекарственных средств в Республике Казахстан. Речь идет о порядке проведения скоординированной политики в сфере обращения лекарственных средств с учетом взаимной заинтересованности в обеспечении гарантий безопасности, эффективности и качества лекарственных средств для жизни и здоровья людей, охраны жизни и здоровья потребителей лекарственных средств, предупреждения действий, вводящих потребителей в заблуждение. Рассмотрено влияние действующего законодательства Республики Казахстан в области здравоохранения и фармацевтической деятельности на правоотношения, возникающие в ходе прохождения всех стадий обращения лекарственных средств. Раскрыты основные проблемы в этой сфере. Изучается положительный опыт некоторых зарубежных стран, имеющих развитое законодательство в сфере здравоохранения и фармацевтической деятельности.

Ключевые слова: торговая деятельность, предпринимательская деятельность, обращение лекарственных средств, фармаконадзор, контроль качества, разработка лекарственных средств, фармакология, фармация, медицинская промышленность, безопасность, качество и эффективность лекарственного средства, медицинское применение лекарственных средств.

The term conversion is quite common both in law and in doctrine and judicial practice, while it is given a different interpretation everywhere. Today, in the literature on entrepreneurial activity, the circulation of goods means transportation, storage, sale of goods[1, С.5[illegible]6] or, in general, trading activities[2, С.22].

The circulation of medicines in the Code of the Republic of Kazakhstan On public health and health care system(further in the textthe Code of the Republic of Kazakhstan On Health) refers to activities that include the processes of development, preclinical (non-clinical) studies, trials, clinical studies, expertise, registration, pharmacovigilance, quality control, production, manufacture, storage, transportation, import and export, issue, sale, transfer, use, destruction of medicines[3]. In the Agreement on Unified Princi-

ples and Rules of Circulation of Medicines within the Framework of the Eurasian Economic Union, circulation refers to activities that include certain processes[4].

Thus, circulation of medicines is considered as a generalized concept, which includes all stages of the movement of medicines - from development (including obtaining a patent and a trademark) to human consumption or destruction if it is impossible to use it for its intended purpose.

The isolation and study of specific stages of the movement of medicines is important, since this allows for more thorough legal regulation of the circulation of medicines.

Consider in more detail the stages of circulation of medicines provided for by law.

The first stage of circulation of medicines established by the legislator is their development. Article 235 of the Code of the Republic of Kazakhstan On Health states that the development of medicines includes the search and/or creation of new active substances or new combinations thereof, the subsequent study of pharmacological properties, pharmaceutical development, preclinical (non-clinical) and clinical research, as well as the development of technologies for the industrial production of medicines. The scientific development of medicines is engaged in such sciences as chemistry, pharmacology, pharmacy. In this case, law regulates relations arising in the process of developing medicines, securing, among other things, the legal status of their participants, establishes the procedure for interaction of the state with the participants in these relations.

Due to the fact that the state seeks to provide the population with affordable and high-quality medicines, in 2020 the Comprehensive Plan for the Development of the Pharmaceutical and Medical Industry for 2020-2025 was approved [5]. The main objective of this strategy is to stimulate the development and production of innovative medicines. The first stage of the strategy is the localization of the production and development of medicines in the territory of the Republic of Kazakhstan, the purpose of which is to create a modern pharmaceutical production and development of medicines in the territory of the Republic of Kazakhstan. The Code of the Republic of Kazakhstan On Health establishes that financial support for the development of medicines is carried out at the expense of the republican budget; medicinal products developers products; medicinal products manufacturers when performing research works under the contract between the developer of medicinal products and the manufacturer of medicinal products; other sources not prohibited by the legislation of the Republic of Kazakhstan.

The developer of medicinal products can be any organization that has rights to the results of preclinical studies of the medicinal product, clinical studies of the medicinal product and (or) to the technology of production of the medicinal product. The situation is completely different with the development of narcotic drugs, psychotropic substances and their precursors. The development of narcotic drugs and psychotropic substances, as well as precursors of narcotic drugs and psychotropic substances, is subject to a state monopoly. The development of new narcotic drugs and psychotropic substances is carried out only in accordance with the state order and is entrusted to state unitary enterprises and state research institutions in the presence of a license for this type of activity. This norm is justified by the fact that, having certain physicochemical properties that can cause significant harm to human health, narcotic drugs, psychotropic substances and their precursors are under additional state control.

The Code of the Republic of Kazakhstan On Health provides that the rights of a developer of a medcine are protected by civil law. This norm is a reference. In this case, we are talking about the rights to the results of intellectual activity and the means of individualization.

The developer, in order to obtain evidence of the safety, quality and effectiveness of the drug, conducts its preclinical study, which is the second stage of drug circulation. Information obtained as a result of preclinical research can be an object of intellectual rights as a secret of production. The exclusive right to the secret of production is valid as long as the confidentiality of the information constituting its content is maintained. From the moment of loss of confidentiality of the relevant information, the exclusive right to the secret of production ends with all copyright holders.

The Code of the Republic of Kazakhstan On Health prohibits the use for commercial purposes of information on the results of preclinical studies of medicines and clinical trials of medicinal products for human use, submitted by the applicant for state registration of a medicinal product, without its consent for six years from the date of state registration of a reference medicinal product in the Republic of Kazakhstan. If the generic manufacturer decides to register a drug product earlier than six years from the date of release of the reference drug, it will need to

conduct an independent clinical trial of the drug product.

Thus, the Code of the Republic of Kazakhstan On Health implements a mechanism for protecting the exclusive right to the secret of production. Despite the fact that the above-mentioned law specifies the term for maintaining confidentiality of information obtained as a result of preclinical studies of medicines and clinical trials of medicinal products for human use, it does not provide for liability for violation of the norms prohibiting the use of information about the study of medicinal products. It seems logical not to establish the norms of special responsibility.

The legislator indicated that it should be referred to preclinical studies of the drug - biological, microbiological, immunological, toxicological, pharmacological, physical, chemical and other studies of the drug by applying scientific methods of assessment. In this regard, under preclinical research it is necessary to understand the scientific study of the drug by applying various scientific methods of assessments before the stage of making a decision on the production of the drug. The legislator establishes the procedure for organizing and conducting a preclinical study with indication of the types of legal entities that can carry out the study, and the procedure for monitoring the preclinical study.

The third stage of drug circulation is clinical trials. If a preclinical study is carried out with respect to a medicinal product in its broad sense, then a clinical study is carried out with respect to the medicinal product, which is carried out for their state registration. Which means the study of the diagnostic, therapeutic, preventive, pharmacological properties of the medicinal product in the process of its use in humans, including processes of absorption, distribution, modification and elimination, through the use of scientific assessment methods for the purpose of obtaining safety evidence, quality and efficacy of the medicinal product, data on adverse reactions of the human body to the use of the medicinal product and on the effect of its interaction with other medicinal products and (or) food products. In accordance with the Code of the Republic of Kazakhstan On Health, state registration is the mandatory stage of the introduction of drugs into civil circulation and another stage of their circulation.

What is the state registration of drugs? In civil law, there is state registration of law, transactions, issue of securities, registration of business entities, certain types of property. According to V.S. Ema, state registration of actions, events and rights, making them publicly reliable, is a means of public control over civil turnover in order to ensure the most complete protection of the most important property and personal rights, benefits and freedoms of subjects. For all participants in the turnover, this means that only actions and events registered in accordance with the requirements of the law are legal facts that give rise to civil law consequences, and that only registered rights are considered existing[6, C. 362].

Depending on the subject of registration, civil registration has its own characteristics. State registration creates guarantees of proper fulfillment by the parties of obligations and, therefore, contributes to the strengthening and stability of civil turnover in general. So state registration of the right is the only evidence of the existence of a registered right to real estate, which can only be challenged in court.

State registration of business entities, according to V.F. Popondopulo, is an integral part of state regulation and control over the economy. State registration allows you to keep records of entrepreneurs, controls the most important corporate processes. State registration is the final stage in the process of creating an entrepreneur.

The legislator provides for the registration of certain types of movable property, the use of which is prohibited without registration. It seems that such registration is carried out in order to ensure state registration of objects of civil law, detection of crimes and suppression of offenses.

The purpose of state registration of goods, including medicines, is to prevent products and goods that are not provided with a sufficient degree of protection against harmful effects on a potential consumer from entering the commodity markets. State registration of goods is necessary to assess the effectiveness of measures to prevent harmful effects of goods on human health during their manufacture, circulation and use, as well as during their disposal or destruction[7, C.602].

The legislator provides for state registration of substances and products. Certain types of first-time manufactured and intended for sale in the territory of the Republic of Kazakhstan or first-time imported into the territory of the Republic of Kazakhstan and intended for sale in the territory of the Republic of Kazakhstan food products, materials and products are subject to state registration.

The drug registration mechanism is used in

almost all countries of the world. In the United States, the relevant legislation appeared in the 30s of the last century, in Europe - in the 60s. In Russia, mandatory registration of medicines was introduced back in the 19th century. According to lawyers, state registration of medicines is a legal fact that is the only basis for introducing a drug into civil circulation in the territory of the Republic of Kazakhstan.

The Code of the Republic of Kazakhstan On Health contains a definition of state registration of medicines. State registration of medicinal products means the procedure for obtaining a permit for circulation of medicinal products or medical devices in the territory of the Republic of Kazakhstan and entering a medicinal product or medical device for a certain period into the State Register of Medicinal Products and Medical Devices.

State registration of medicinal products for human use is carried out by the Ministry of Health of the Republic of Kazakhstan based on the results of expert examination of medicinal products and ethical examination of the possibility of conducting a clinical trial of a medicinal product for human use[8].

The purpose of the expert examination of medicinal products is to issue a permit to conduct a clinical trial of a medicinal product, as well as to study the proposed methods for monitoring the quality of the medicinal product and the quality of the presented samples of the medicinal product using these methods and to study the ratio of expected benefit to possible risk of using the medicinal product, carried out after conducting its clinical trial.

An ethical examination is carried out in order to issue an opinion on the ethical validity of the possibility of conducting a clinical trial of a medicinal product for human use by an ethics board established in accordance with the procedure established by the authorized executive body[9].The conclusion of the expert committee based on the results of the expert examination of medicines is the basis for making a decision on the state registration of medicines or on the refusal of state registration.

The document confirming the fact of state registration of the medicinal product is the marketing authorization. The list of medicines that have passed the state registration is contained in the state register of medicines, the presence of which for the subjects of circulation on the pharmaceutical market is an additional guarantor of the quality of the goods, since the purpose of the modern registration of medicines is to assess the ratio of benefit and risk for the drug to resolve the issue of its marketing.

Quality control of medicines by the legislator stands out as an independent stage of circulation of medicines. Quality is the compliance of the properties of the product with a certain set of requirements that determine the ability of the product to meet the needs of the buyer [10].In the Code of the Republic of Kazakhstan On Health, the quality of a medicinal product is understood as the compliance of the medicinal product with the requirements of the pharmacopoeial article or in the absence of regulatory documentation or regulatory document. In order to obtain a high-quality and effective drug by the end user, their quality control is carried out at all stages of production, storage, transportation, sale. There are two types of quality control: state and quality control in organizations engaged in the production and sale of medicines.

State quality control of medicines is carried out by the Ministry of Healthof the Republic of Kazakhstan, and quality control is carried out by manufacturers of medicines and subjects of pharmaceutical activity independently.

The purpose of control at the production stage is to prevent the use or sale of products that do not meet the quality requirements.

The legislator refers to the stages of circulation of medicines standardization. Standardization refers to activities aimed at achieving the optimal degree of streamlining of the characteristics of health processes, technologies and services by developing, implementing and ensuring compliance with standards, requirements, norms, instructions, rules. Standardization is one of the most important elements of technical regulation.

The Rules of right Manufacturing Practice establish the requirements for the organization of production and quality control of medicines. The rules apply to all types of medicines and establish general requirements for the organization of their production and quality control, as well as special requirements for the organization of the production of certain types of medicines.

The production of medicines in the Republic of Kazakhstan is carried out by manufacturers of medicines licensed for the production of medicines.

Along with production, the legislator distinguishes such a stage of circulation as the manufacture of drugs. Manufacturing is carried out by pharmacy organizations, individual entrepreneurs

licensed for pharmaceutical activities, according to prescriptions for medicines or according to the requirements of medical organizations. In the manufacture of medicinal products, pharmaceutical substances are used, respectively included in the state register of medicinal products for human use in accordance with the established procedure. At the same time, the manufacture of drugs not registered in the Republic of Kazakhstan is not allowed.

Thus, it can be said that the production of drugs is carried out in large quantities for further turnover, and the production takes place in individual quantities for a particular consumer, patient.

Medicines, with the exception of those manufactured by pharmacy organizations, individual entrepreneurs licensed for pharmaceutical activities, must enter the consumer market after labeling. Labeling is the final stage in the manufacture of medicinal products. In the legal dictionary, labeling refers to information applied by the manufacturer directly to specific goods, containers, labels or dockets, etc.; identification symbols applied to the packaging of each cargo item (box, cage, bag, etc.) containing the data necessary for proper transportation and delivery of the cargo to the recipient [11].

Marking means information in the form of inscriptions, digital, color and legend, applied to products, packaging, label or docket to ensure identification and acceleration of processing during handling, transportation and storage.

In contrast to the trademark indicating the belonging of the goods to a certain manufacturer, the marking contains information required by the consumer: data on the type of the product, its purpose, quantity, procedure of use, precautions for use, date of manufacture [12, С.84].

Marking in accordance with the Law of the Republic of Kazakhstan On Protection of Consumer Rights is one of the ways to communicate the necessary information to the consumer[13]. Labeling will allow monitoring the movement of medicines from the manufacturer to the end user, which is a positive point, since it will protect the consumer from falsified, poor-quality and counterfeit medicines.

One of the important stages of circulation is the stage of storage of medicines, which is carried out by all subjects performing circulation of medicines. Violation of storage standards leads to unsuitability of the drug product. Therefore, it is so important to comply with the rules for the storage of medicines approved by the relevant authorized executive body of the Republic of Kazakhstan. At the same time, the storage of narcotic drugs, psychotropic drugs, radiopharmaceutical drugs is carried out according to special, more stringent requirements.

The legislator distinguishes a separate stage of circulation of medicines - their transportation. At the same time, this issue is practically not regulated.In law. In addition, it seems controversial to attribute transportation to the stage of circulation of medicines.

Medicines, like any other product, enter the consumer market as a result of production in the Republic of Kazakhstan or by import into the Republic of Kazakhstan. The peculiarity of medicines is that they can be imported into the Republic of Kazakhstan for certain purposes established in the Code of the Republic of Kazakhstan on Health.

The quality of medicines imported into the Republic of Kazakhstan must be confirmed by the manufacturer's certificate. For the import of medicines, both registered and unregistered, permission is required to provide medical care for the vital indications of a particular patient. However, in practice, permission is only required for the import of an unregistered drug.

The previous legislation on medicines did not contain a mechanism for the acquisition and authorized use by persons suffering from rare diseases, necessary for their treatment of medicines that have not passed state registration in the Republic of Kazakhstan. When adopting the Code of the Republic of Kazakhstan On Health, the legislator provided for the possibility of the patient receiving a drug absent from the Republic of Kazakhstan for vital reasons. However, obtaining permission to import an already registered drug into the Republic of Kazakhstan complicates the process of availability of the medicine to the patient.

It seems correct to require permission to import only an unregistered medicinal product, since the Code of the Republic of Kazakhstan on Health allows the import of a medicinal product, which is included in the state register of medicines.

The export of medicines from the Republic of Kazakhstan is carried out without the application of restrictions established by customs legislation and (or) legislation of the Republic of Kazakhstan on state regulation of foreign trade activities.

The Code of the Republic of Kazakhstan On Health established the priority of state regulation of the safety, quality and effectiveness of medicines during their circulation.

The main goal of state regulation can be called the receipt by the end consumer of high-quality goods and the exclusion of the process of self-medication, which sometimes leads to death. Therefore, it is completely justified that the state regulates the advertising of medicines. Article 56 of the Code of the Republic of Kazakhstan On Health provides for requirements for advertising in the field of health, as well as information on medicinal products, on the methods of its distribution.

Information disseminated in any way, in any form and using any means, addressed to an indefinite circle of persons and aimed at drawing attention to the object of advertising, forming or maintaining interest in it and its promotion in the market is called advertising [14].

However, not all information that meets the listed criteria and is required to be placed by law or placed by virtue of a business practice can be qualified as advertising, since the provision of such information is necessary to inform consumers.

The requirements for advertising of medicines are enshrined in the Law On Advertising, which establishes the main criteria for its admissibility. A mandatory requirement for advertising medicines is its support with a warning about the presence of contraindications to their use and use, the need to familiarize themselves with the instructions for use or receive advice from specialists.

There are two directly opposing opinions on the need to regulate medicines advertising. The first is the requirement of a sharp legislative restriction on advertising of medicines. The second is the idea of completely freeing advertising of medicines from restrictions, including for prescription drugs[15, C.13].

In this regard, it is understandable that attempts have been repeatedly made to ban advertising of medicines. The initiators of the bill proposed to stop the self-medication of citizens flourishing in our country, from which doctors warn, but which provokes advertising of medicines. Many experts note that self-medication by the lack of advertising cannot be avoided. Some believe that banning advertising will harm health care, human health, physician and public awareness, since a rebuilt system will stop working when only the medicine that is registered, certified and there is responsibility for the information contained in the advertising is advertised. Since advertising of medicines is regulated by law, its distribution is under state control, which allows you to track unreliable, false advertising. In the event of a ban on advertising, as noted, uncontrolled information will increase, primarily on the Internet, which is fraught with misuse of drugs by the consumer. This can lead to a decrease in inexpensive drugs. Therefore, with the ban on advertising of medicines, the problem of self-medication will not disappear.

According to ethical standards adopted in the EU countries, the purpose of advertising medicines is to promote their more rational use, provide objective information and not exaggerate their therapeutic value. The ethical criteria of WHO define the goals of advertising activities as promoting the introduction of drugs into practice and increasing the level of awareness of specialists and the population [15, C.14].

In the United States, advertising of all medicines is allowed. In the Republic of Azerbaijan, first banned advertising of medicines, and then again allowed, making an informed exception - while maintaining the ban on advertising of drugs on prescription of a doctor. Germany prohibits advertising of prescription drugs aimed at the end consumer, but they are allowed to be advertised in media intended for health care professionals. In the UK, advertising of both over-the-counter and prescription medicines must meet the general requirements for advertising drugs to the end consumer. In Denmark, the issue of advertising of medicines is regulated in great detail by national legislation. All advertising information should be accurate, relevant and sufficiently detailed, which allows the recipient to form his own opinion on the therapeutic value of the drug [16].

Taking into account the experience of foreign countries, it seems advisable to leave advertising of over-the-counter drugs, while banning advertising of prescription drugs. Advertising of over-the-counter medicines should be informational in order for the consumer to navigate the choice of a wide range of medicines. Since prescription drugs can have a significant impact on human health and are sold only on a prescribed prescription, information about the existence of certain prescription drugs, their actions should be communicated directly to medical workers, bypassing the consumer.

One of the stages of circulation of medicines is their vacation, while the legislator does not define this term. On the one hand, the analysis of the term "requirement of a medical organization" - a document of the established form, which was discharged by a medical worker who has the right to do so, and contains in writing an instruction

from a pharmacy organization on the issue of a drug or on its manufacture and on leave to ensure the medical process in a medical organization, allows the vacation to understand the meaning of "issue". On the other hand, leave is considered as a synonym for the word "implementation", which, in turn, is a separate stage in the circulation of medicines.

A more detailed study of these concepts is carried out in the paragraph on the licensing of pharmaceutical activities in the consumer market of medicines.

Wholesale is traditionally one of the key links in the economic complex, performing important functions of the relationship between production and consumption [17, С.162].In accordance with the Code of the Republic of Kazakhstan on Health, only two entities of economic activity can carry out wholesale trade in medicines: manufacturers of medicines and organizations of wholesale trade in medicines in any organizational and legal form. At the same time, for wholesale organizations, it is necessary to have a pharmaceutical license with the type of activity "wholesale trade in medicines", and manufacturers of medicines carry out wholesale sales within the framework of activities for the production of medicines, which is also subject to licensing.

The wholesale of medicines is carried out in accordance with the rules of good distribution practice and the rules of good practice for the storage and transportation of medicines approved by the relevant authorized executive authorities. Civil law relations of wholesale purchase and sale are formalized by the supply contract. However, the legislator, in addition to specifying specific suppliers under this contract, also establishes specific buyers of medicines. Since, as previously mentioned, there are drugs with a regulated mark-up, when concluding a supply agreement for such drugs, their prices should not exceed the registered maximum selling prices for drugs. In addition, the sale of drugs included in the list of VEDs for which the maximum selling price is not registered by drug manufacturers is not allowed.

The above makes it possible to argue that the wholesale of medicines is a separate stage of their circulation, designated by the legislator as an implementation, which in turn can be both wholesale and retail.

In the circulation of medicines, such a stage as their transfer is distinguished. The transfer of medicines is a free transaction. It can also be argued that pharmacy organizations do not have the right to carry out the "transfer" stage of medicines. Although in the case of a social service, the provision of necessary medicines in accordance with the standards of medical care on the prescription of doctors, it is precisely the transfer of medicines to a certain category of citizens who have the right to receive the above-mentioned service.

It should be said that despite the rather strict rules established for the sale of medicines, including for the end consumer, attempts have been repeatedly made to organize sales of medicines in stores and retail chains. The main argument in this case is two criteria: increasing the availability of drugs and developing competition in the drug market.

For the sale of medicines, pharmacy organizations must obtain licenses for pharmaceutical activities, contain a minimum range of medicines and comply with all the requirements of regulatory documents adopted in this area. The legislator initially established special requirements for the place of sale of medicines, given their ability to influence the human body. Changing the rules for the sale of medicines will lead to a violation of order in the pharmaceutical market, to an increase in the number of low-quality medicines.

Thus, for the sale of medicines in grocery stores and retail chains, compliance with the licensing requirements for the retail sale of medicines is required. The above entities will have to obtain licenses for the sale of medicines. To obtain high-quality goods by the end consumer, compliance with the established rules for the storage of medicines is required. To exclude self-medication, there must be specialists with a pharmaceutical education in the department with medicines so that they can carry out a full and reliable consultation.

Use of the medicinal product (i.e. application, use by a person) as the stage of his appeal by the legislator is not directly regulated. However, as previously mentioned, drugs are prescription and over-the-counter, the conclusion follows: without a doctor's prescription, a person should not use any drug. Thus, by establishing certain requirements for the prescription and sale of medicines, the legislator indirectly regulates their use.

The state, in an effort to reduce the amount of low-quality medicines that are dangerous to health, regulates, including the process of destroying such drugs. Destruction refers to actions that make it impossible to use the destroyed object for its intended purpose, as well as access to

it by humans and animals. Article 250 of the Code of the Republic of Kazakhstan On Health regulates the grounds and procedure for the destruction of medicines and medical devices. The main principle of the destruction of medicines is that the destruction should be carried out by the owner of the medicine, regardless of whose fault it is poor quality (for example, it became unusable as a result of violation of storage standards, low-quality goods came under a supply contract, etc.).

The study of the issue of circulation of medicines showed that the drug goes through many certain stages of circulation, which can be conditionally divided into groups.

The first group is the stages of circulation before the appearance of the medicine on the RK market (development, preclinical and clinical studies, expertise, state registration, standardization, quality control, production, manufacture, import into the RK), i.e. a stage where the drug is created as an object of civil law. It should also include those not named by the legislator of the stage of obtaining a patent for a medicinal product and obtaining a certificate of trademark for a medicinal product. These stages are not mandatory, but in the modern world, patent protection and trademark registration are to a certain extent a guarantee of the quality of the drug product. The second group is the stages of circulation, ensuring the promotion of the drug to the commodity market (storage, transportation, export from the Republic of Kazakhstan, advertising). And finally, it is possible to distinguish the stages of circulation of medicines (distribution, sale, transfer and use), when the drug enters the commodity market and becomes the subject of transactions. A separate stage of drug destruction has a peculiarity: drug destruction can occur at any stage of its circulation.

It should be noted that the legal regulation of the circulation of medicines, for the most part, is carried out by administrative methods, in particular, binding prescriptions. Civil law regulation at the stages of the first group is carried out in order to protect the exclusive rights of persons to the results of their intellectual activity.

Since the appearance of the medicine on the market, the stages of its circulation are regulated mainly by the method of legal equality of the parties. If all stages of the first group are aimed at the emergence of a drug, then the stages of the following groups are aimed at the promotion, preservation of high-quality and effective drugs for use for their intended purpose - human use. We can say that such stages as storage, transportation, export from the Republic of Kazakhstan, advertising are concomitant stages for the release, sale and transfer of medicines to the end consumer. The most interesting in this work is the study of the main stages of circulation of medicines, where they are transferred to a retail buyer. Since the legal regulation of the entire process of the emergence of a drug and the preservation of its properties is aimed at providing the population of the Republic of Kazakhstan with affordable medicines, a study of the turnover of medicines in the consumer market of the Republic of Kazakhstan will be carried out in the future, by which a set of transactions on the transfer of the drug from one participant in legal relations to another should be understood.

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