Circulability of Medicines in Russia: Historical and Legal Retrospective

V I Panfilova[1], E V Safronova[2], V B Turkutyukov[3]

[1]The Far Eastern State Transport University, Khabarovsk, Russian Federation
[2]Belgorod State University, Belgorod, Russian Federation
[3]Pacific State Medical University, Vladivostok, Russian Federation

E-mail: vitaflamma@gmail.com, belvp46@mail.ru, vyach.12593@mail.ru

Abstract. The article analyzes legal aspects of circulability of medicines in Russia. The medicines may be freely alienated or may pass from one person to another, if they have not been withdrawn from circulation or restricted in the circulation. These medicines are freely available for purchase without a prescription. The kinds of the medicines, whose circulation shall not be admitted / withdrawn from circulation, shall be directly pointed out in the law. With kinds of the medicines, which may only be possessed by definite participants in the circulation, or whose being in the circulation shall be admitted by a special permit / with a restricted circulation capacity, it is impossible to carry out any actions, except for the cases expressly provided for by regulatory acts, for example, for scientific purposes. Throughout the history of Russia, one can observe periods of recession and a rise in the production and manufacture of medicines. Due to the absence of sufficient medicines, there are could be freely alienated, withdrawn from circulation or restricted circulation capacity.

1. Introduction

Historical and legal aspects of the regulation of circulation of medicines are as multifactorial, interrelated and interdependent as in other areas of health. State regulation of public life has a complex structure and covers the diverse relationships of various area.

The issues of state regulation in the sphere of circulation of medicines include to targeted state influence on the organization of this activity by issuing regulations that define the relevant rules and regulations, permits and prohibitions, reporting and control. State regulation is carried out by registration of medicines, licensing, certification of specialists, development control, research, expert examination, quality control, manufacturing, storage, transportation, export, import, advertising, release, use, disposal of expired drugs; price controls and more.

There are three criteria that characterize the use of medicines.

1. Targeted use. The use of medicines only for the purpose of diagnosis, prevention, treatment of disease.

2. Social value. Medicines are socially significant, since not only health, but also the lives of national directly depend on their availability and the possibility of acquiring the required medicines.

3. Legal aspect. A system of measures and means of ensuring proper control over medicines on the territory of Russia.

2. Legal retrospective of circulability of medicines in Russia

According to Art. 5 of the Civil Code of the RSFSR of 1922 [1], every citizen of the RSFSR and the USSR had the right to acquire and dispose of property with the restrictions specified in the law, to make transactions and enter into obligations. This law pays great attention to the right of private property in terms of its limitations [2]. Art. 54 of the Civil Code of the RSFSR listed all types of property that could have been the subject of private property, such as household goods, household items and personal consumption, goods whose sale was not prohibited, and all property not withdrawn from private circulation. In accordance with Art. 23 Civil Code RSFSR, the latter were potent poisons. Such property could be subject to civil law only to the extent established by law, for example, under Art. 56 Civil Code RSFSR potent poisons could be in private possession with the permission of the relevant authorities.

For personal use, individuals could send and receive packages from drugs from abroad without the permission of the People's Commissariat of Foreign Trade, provided that they pay customs duties if they are not exempted [3]. It was allowed to take the combined medicines and patented medical devices sent, provided the consignee submitted the prescription to the Soviet doctor. The simplest medical products like boric acid, quinine, iodine, manganese-sour potassium, aspirin, soda, herbs, salicylic soda, glycerin and etc., were given away without a prescription of doctors.

At the same time, another limitation was established – the frequency of delivery of parcels and the uniformity of the objects in them. If a destination was set for sale, and not for personal use, then the general rules regarding the passage of goods from abroad were applied to the parcel only with the special permission of the People's Commissariat for Foreign Trade with payment of the duty.

In the preamble of the Fundamentals of Civil Legislation of the USSR [4] in 1961 it was stated that personal property is derived from socialist property and serves as one of the means to meet the needs of citizens. They set the limits of personal property of citizens, where belonged the property intended to meet their material needs, including personal items, which include drugs [5].

According to Art. 129 of the Civil Code of the Russian Federation all things are divided into three groups: freely convertible (allowed in circulation), limited in circulation and withdrawn from circulation [6].

During almost the entire history of the RSFSR, one can observe periods of decline and a rise in the production and manufacture of drugs. Due to their shortage in sufficient quantity to meet the needs of the population, drugs could be freely circulated or restricted in circulation at different times. It also depended on the level of scientific knowledge, which determined the degree and nature of the harmful effects on the human body.

In the first years of Soviet power, retailing directly to consumers from places of trade without registering them in the provincial health departments [7] was not allowed potent medicinal plants in unground form, not marked in the pharmacy tax by the sign of the cross, and substances from non-potent chemical and other plant and mineral.

Simple drugs were dispensed from pharmacies by prescription and on the notes of doctors and the verbal requirements of individuals [8]. They were attached to the labels indicating the name of the pharmacy, the content of drugs and its price.

Medicines were subject to state registration, as well as fixed in certain lists. During the New Economic Policy years, several different lists of drugs can be distinguished, which were periodically changed and supplemented.

1. Admitted to further trade within the country [9].
2. Prohibited to further trade within the country [10].
3. Allowed for the sale of manual sales from pharmacies, without medical prescriptions [7].
4. Drugs having mainly economic or technical use [11].
5. Finished medicines for the prescription of doctors [12].
6. Over-the-counter finished medicines.

Based on the above, the drugs that were fixed in the above lists as numbers 3, 4 and 6 were free to circulation. There were a limited number of them, about 40-80 items, mainly produced in the territory of the RSFSR.

With the development of the chemical and pharmaceutical industry, the number of manufactured products increased, and new drugs were released into circulation in the country. Some alcohol tinctures and poisonous and dangerous drugs have become fully revolving.

Drugs could be dispensed not only by pharmacies, but also by pharmacies and kiosks (a small retail network). Over their presence in pharmacies and holidays, the population was constantly monitored [13]. Thus, pharmaceutical items of the first category could sell ready-made drugs according to prescriptions and without them, according to the nomenclature corresponding to the assortment minimum of drugs for self-supporting pharmacies of groups VII-VIII. The chemist's shops of the second category dispensed drugs without a prescription, according to the "List of drugs and medical products sold to the public without a doctor's prescription. By 1982, the list of drugs allowed to leave without a doctor's prescription included 328 items.

All potent and complex drugs in the RSFSR, in 1917–1991, were mostly limited in circulation, regardless of historical conditions. Those of them that contained in their composition potent or poisonous substances were designated in the pharmacy tax by the sign of the cross, and complex drugs were dispensed exclusively according to the prescriptions of the doctors registered in the health department [9]. The design and supply of such drugs was clearly regulated by special rules, regulations and instructions. There was also a list of drugs withdrawn from circulation, which included some narcotic drugs.

Thus, drugs could be released, both by prescription and without a doctor's prescription. The list of drugs permitted for dispensing without a prescription of a doctor was approved by the People's Commissariat of Health of RSFSR, and after 1946 - by the USSR Ministry of Health. They were available in all pharmacies. All other drugs were sold only by prescription [14]. A wide list of freely circulated drugs and forms in the RSFSR was constantly updated with new names and forms of drugs, limiting it only to the freedom to receive.

3. Results

Medicinal products as diagnostic, therapeutic, prophylactic and rehabilitation chemical and pharmaceutical products are a fundamental component of the health care system in terms of providing the state with quality medicinal care for citizens in order to guarantee health protection and free medical care. Medicinal are usually referred to as things that can freely apply, and to things that are limited in turnover [15].

The criterion for the classification of medicines by turnover is the scientific data, practical knowledge of the effects of drugs on the human body, as well as their total amount in circulation. It was determined that the lack of proper nomenclature and systematics of drugs, especially in the field of potent, poisonous and narcotic drugs, led to legislative consolidation of limited in circulation funds as freely alienable.

4. Conclusions

Active vital activity, viability, life expectancy of the country's population has a direct and direct connection with the health of the nation, the state of which is significantly affected by the circulation of medicines. Of particular importance is their quality and availability, depending on the production and manufacturing process, regulated by the state through the adoption of legal norms covering various aspects: from the preparation of medicinal raw materials to the use of finished dosage forms and tools, both in hospitals and in individual use. The pharmaceutical market has significant specificity. The consumer is offered a product that has the potential to cause harm to health or life, both if it is used improperly and when all precautions are taken. Accurate correlation of the drug to the list of freely circulated, restricted or prohibited in circulation will lead to a decrease in the possibility of causing harm to the lives and health of citizens.

References

[1] 1922 On the introduction of the Civil Code of the RSFSR *Collection of Legislations of the RSFSR* **71** Art 904
[2] Novitskaya T E 2002 Civil Code of the RSFSR Zertsalo-M **75**
[3] 1922 On the procedure for admission of postal parcels delivered from abroad *Collection of Legislations of the RSFSR* **35**, Art 418
[4] 1961 On approval of the Fundamentals of Civil Legislation of the USSR and Union Republics *Bulletin of the Supreme Soviet of the USSR* **50** Art 525
[5] 1964 Civil Code of the RSFSR *Bulletin of the Supreme Soviet of the RSFSR*. **24** Art 407
[6] Sergeev U D, Farber E V Medicinal products as objects of civil rights Homepage http://xn7sbbaj7auwnffhk.xn-p1ai/article/5406
[7] 1922 Instructions on the right to open and manufacture trade in medicines *Collection of Legalizations* **41** Art 488
[8] 1926 Rules for dispensing drugs from pharmacies *Bulletin of the National Commissariat of Health* **5** 58-59
[9] 1924 Circular No 53 *Bulletin of the National Commissariat of Hea*lth **5**
[10] 1924 Circular No 54 *Bulletin of the National Commissariat of Health* **5**
[11] 1925 About non-pharmacy retail trade in medicines *Bulletin of the National Commissariat of Health* **11** 5-6
[12] 1928 About ready-made medicines Health issues **15** 91-92
[13] On measures to further improve the drug supply of the population and medical institutions Homepage http://www.consultant.ru
[14] Somina S 1988 Rules for dispensing drugs from pharmacies 1-6
[15] Panfilova V I, Turkutyukov V B, Strelnikova N V 2018 State legal regulation of production and use of immunobiological drugs in Russia Adv*ances in Economics, Business and Management Research* **47** 535-538