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On the creation of a pharmaceutical safety system in the Russian Federation

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This article analyzes the formation and development of a pharmaceutical safety system in the Russian Federation, which was designed to protect the population and health organizations from threats arising in the production, distribution and consumption of pharmaceuticals. The most difficult period was 1991–1998, which was characterized by a sharp decline in the pharmaceutical industry's economic potential in connection with the transition to new, market-based management mechanisms and the lack of an adequate regulatory framework for pharmaceutical management. A second period began after the adoption in 1998 of the federal law *On Medicines*, in which for the first time the priority of state control and regulation of production, manufacturing, quality, efficiency, and safety of medicines was declared. However, opposition from the pharmaceutical industry and the inertia of state authorities in developing a regulatory legal framework detailing federal law provisions did not achieve positive results. Therefore, in 2009, the "Strategy for the development of the pharmaceutical industry of the Russian Federation for the period until 2020" was approved, marking the beginning of the modern period of improving the pharmaceutical safety system. The new federal law *On the distribution of Medicines* (2010) with the necessary set of normative legal acts and the "Strategy for the provision of medicines to the population of the Russian Federation for the period until 2025" (2013) set out a sequence of tasks for solving problems concerning the country's medicinal independence and providing the population with the necessary pharmaceutical products. In general, it is noted that the level of pharmaceutical safety has increased in Russia. The authors point out that the concept of "pharmaceutical safety" has undergone changes and currently presupposes not only a patient's personal safety when using medicines, but also the country's medicinal independence.

***Keywords**: history of health care, pharmaceutical safety, pharmaceutical industry, medicines, drug provision*

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For the Russian Federation as a social welfare state, "a policy aimed at creating conditions for the dignified life and free development of people"[1] and ensuring citizens' safety is a priority, as is creating the conditions necessary for meeting personal and social needs and implementing and

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[1] The Constitution of the Russian Federation, Article 7 // Official Internet portal for legal information. URL: http://www.pravo.gov.ru, 01.08.2014. Access date: February 13, 2018.

achieving the goals of the country's democratic and socio-economic development.

According to one of many definitions, "safety" refers to the conditions under which the vital interests of the individual, society and state are protected from potential and actual threats; it also refers to the absence of such threats [1]. "Pharmaceutical safety" is understood to mean the conditions under which the population and medical and pharmaceutical organizations are protected from the threats arising from the production, distribution and consumption of pharmaceuticals [2]. It follows that pharmaceutical safety is an integral measure in protecting the rights and freedoms of citizens in need of medical assistance, as well as health organizations that provide medical and pharmaceutical services.

The nature of medicines, being products designed simultaneously to meet vital health care needs and to provide economic profit, determines the specifics of the pharmaceutical safety sphere. On the one hand, it functions in the pharmaceuticals consumption system, and on the other hand, in the sphere of economic relations between industrial organizations and public health care in the production, promotion, distribution and use of pharmaceutical products [3].

The importance of pharmaceutical safety is demonstrated by the fact that at the end of 1918 (the most difficult period for the new republic), the decree of the Council of People's Commissars of the RSFSR "On the Nationalization of Pharmacies and Other Pharmacy Institutions" was adopted. The People's Commissariat of Health established a pharmaceutical department – the management body for the nationalized pharmacies. In addition to pharmacies, all the country's pharmaceutical enterprises were nationalized, and the General Directorate of Chemical and Pharmaceutical Factories was formed to manage them. These measures laid the foundation for the creation of a state system to manage the pharmaceutical industry [4].

The first five-year plans envisaged the development of a domestic pharmaceutical industry. In 1932, the country had about 1,700 urban and rural pharmacies. By early 1941, the USSR health system had 9,723 pharmacies, 109 pharmacy branches, 1,400 pharmacy stores, 270 pharmacy warehouses, 295 analytical monitoring laboratories, 149 galenical and pharmaceutical factories, 170 optical stores and repair centers for medical instruments and equipment and 13,864 rural pharmacy points [5].

During World War II, 4,800 pharmacies and pharmacy points and 51 pharmaceutical industry plants were destroyed. By 1943, the number of pharmacies had fallen to 6,221. Under difficult conditions, new pharmacies and pharmaceutical enterprises opened in the Urals, Western Siberia and Central Asia, where more than 200 new urban and rural pharmacies were constructed and 120 pharmaceutical plants and factories were set up. The dedicated work of many people, including specialists in the pharmaceutical field, contributed to 72.3% of the wounded and 90% of patients in general recovering [6, 7].

At the end of the war, the restoration of the pharmaceutical infrastructure and the pharmaceutical industry was proceeding at an accelerated pace. In 1945, the Main Pharmacy Directorate was formed within the USSR Ministry of Health, which managed the offices of Khimfarmtorg and Medinstrumenttorg, distributing medical products to the country's regions. Despite difficulties during the period of reconstruction, by the end of 1946, the number of the country's pharmacies exceeded the prewar level. During the first five postwar years, 2,900 pharmacies and more than 41,000 pharmacy points were opened, and more than 170 new medicines were produced.

The years from the end of the war to the beginning of the 1990s saw the creation of a powerful pharmaceutical industry in the USSR. By 1991, the country had produced 272 pharmaceutical substances, their volume reaching 17,000 tons per year. The demand met by the industrial production of these raw materials was 70 to 100 percent for the various groups of medicines produced. A considerable portion of the substances produced was exported to socialist countries. The assortment of medicines produced by the USSR chemical-pharmaceutical industry numbered about 2,000 items, including 150 cardiovascular medicines, 30 oncological preparations and more than 40 types of antibiotics [8].

However, by the mid-1980s, an increased number of production sites had led to stagnation in the pharmaceutical industry, obsolescence of technological equipment and diminished support

from the sciences for the pharmaceutical sector. Once again, the country faced the challenge of providing adequate medicines for the population. In 1985, the state plan for the production of medicines was fulfilled to a level of 52.1 percent, in 1989 to 46.7 percent and in 1990 to 39.1 percent. Government-approved directives for the construction of 37 medicinal factories remained unfulfilled. The bulk of medicines was produced at enterprises in socialist countries such as Hungary, East Germany, Poland, and Czechoslovakia. A period of medicine shortages began in the USSR. In 1989, the Soviet government began to allocate foreign exchange funds for large-scale purchases of imported medicines. However, it was almost impossible to reverse the negative trends in medicine supplies [9].

In the Soviet era, "medicinal safety" was understood as the safety in the use of medicines with minor side effects and the absence of habit-forming effects or serious addiction. By the time of the collapse of the USSR,[2] the concept of medicinal safety had changed significantly. It became obvious that ensuring pharmaceutical safety for the state was only possible if there was an effective system for protecting domestic health care from various factors impeding the necessary medicine production levels for the population. The building of such a system of pharmaceutical safety was possible only through state regulation of industrial medicine production and pharmaceutical activities.

The first period of the formation of the Russian pharmaceutical safety system began in 1991, immediately after the collapse of the USSR. The pharmaceutical industry's development in the Russian Federation took place against the backdrop of a number of problems related not only to the safe use of medicines, but also to the limited production capacity of the domestic pharmaceutical industry and health organizations. This situation resulted from the difficult conditions in which the Russian pharmaceutical industry found itself in the transition to a market economy. Among these conditions were the following:

– the emergence of private property as the main factor of the market economy and drastic restriction on the state's influence on health policy;

– the formation of the country's new economic principles for the pharmaceutical goods and services market;

– the emergence and intensification of competition both among organizations producing pharmaceuticals and medical products, and between wholesale and retail pharmaceutical organizations that provided these products to medical organizations and the public;

– the incompatibility of pharmaceutical industries' existing legal and regulatory frameworks with the new market management conditions.

Pharmaceutical workers and citizens had to deal with real threats that hindered both professional work and the satisfaction of demand for medicines. Among these were the domestic pharmaceutical industry's insufficient production capacity; an uncontrolled increase in the number of pharmacies and a reduction in state and municipal pharmacies' market share; the appearance of counterfeit, inferior and contraband medicines on the pharmaceutical market; volatility in the prices of pharmaceutical products and other factors [10]. These threats necessitated the development and adoption of comprehensive measures to establish a pharmaceutical safety system in the country.

The basis for enforcing the rights and freedoms of citizens and monitoring the consumption of medicines in society, as well as developing and maintaining Russia's "drug independence", is a powerful pharmaceutical industry and a network of organizations engaged in medical research [11].

From 1991 to 2000, the pharmaceutical industry in Russia was in a downturn. This was due to the fact that the largest industrial, scientific and raw material production capacities for the USSR's pharmaceutical industry were situated outside contemporary Russia, on the territory of a number of sovereign states – Ukraine, Belarus, Armenia, Azerbaijan, the Baltic countries and Central Asia. In addition, in the transition to the market economy, many Russian pharmaceutical enterprises failed in the competitive environment and closed, and imported medicines of inconsistent quality and effectiveness flooded the domestic market.

During these years, the consumption level of medicines produced in Russia fell to 50 to 60 percent. This situation demonstrated

[2] The USSR ceased to exist in 1991.

the increasing obsolescence of the Russian pharmaceutical industry, not only compared with the economically developed countries of the West, but also with the developing nations of Southeast Asia. Domestically made active pharmaceutical ingredients, which are the basis of the pharmaceutical industry, only comprised about 35 percent. The resulting deficit was met by supplies from China and India. The share of imported active pharmaceutical ingredients in the domestic market reached 70 percent. From 1991 to 1998, the production volume of active pharmaceutical ingredients in the Russian Federation decreased to less than a 20th of its former size. The country's direct dependence on foreign suppliers of pharmaceutical ingredients was a serious threat to socio-economic development plans.

Among the system-wide problems of the Russian pharmaceutical industry, the following were of particular significance:

– the impossibility of supplying the pharmaceutical market with a full range of essential medicines completely produced within the Russian Federation;

– a significant development lag in innovative designs and technologies for the creation and production of medicines;

– the inadequate provision of the medical services of the armed forces and the All-Russian Disaster Medicine Service with specific medications (radio-protective agents, antidotes, general prophylaxis substances, especially for dangerous infections) for rendering medical assistance to people in radioactive, chemical and biological emergencies [12, 13].

Until 1998, the state, following the principles of a market economy, was virtually uninvolved in the formation of the pharmaceutical segment of the national health care system. The absence of uniform rules for the development of new medicines, their industrial production, preclinical and clinical trials, quality control, efficacy and safety, as well as rules for the sale of pharmaceutical products, led to the dominance of the pharmaceutical industry's economic benefits over social obligations and the weakening of the state's attention to pharmaceutical safety. An indication of this trend was the disappearance of inexpensive medicines (not exceeding 50 rubles per package) from available retail pharmaceutical products. These medicines formed the most affordable price segment of the market and had the lowest levels of trade overlaps and profitability. In these years, there was a significant volatile increase in the number of pharmaceutical organizations, both wholesale (distribution) and retail, which resulted from the opening of private pharmaceutical companies, pharmacies and pharmacy chains. A characteristic feature of that period in the development of the pharmaceutical market's distribution network was the absence of a legislative framework regulating pharmaceutical activities. Frequently, pharmacy workers had to follow the normative legal documents developed in the USSR, which held the development of a system for providing medicine to the population to the principles of a market economy.

The second development period of the pharmaceutical industry and the Russian pharmaceutical safety system began in June 1998 after the adoption of the federal law *On Medicines*.[3] For the first time, the law established the dominant role of the state in the control of industrial production and pharmacy preparation of medicines in order to ensure their effectiveness, safety and quality. The state's regulatory functions concerning pharmaceutical products included the following:

– the registration of medicinal products under unified state rules;

– the development of requirements and organization of licensing for industrial medicine production and pharmaceutical activities;

– the provision of continuous professional education through periodic accreditation and certification of pharmaceutical workers;

– the implementation of viable monitoring of the effectiveness, safety and quality of medicines at all stages of their life cycle;

– the introduction of a socially oriented methodology for medicine pricing into pharmaceutical practice.[4]

The responsibility for state registration of medicines was assigned to the Russian Ministry

[3] On Medicines: the federal law of June 22, 1998, № 86-FZ // Collection of legislation of the Russian Federation, No. 26, June 29, 1998, art. 3006. It has ceased to be in force as of September 1, 2010, in connection with the adoption of the federal law of April 12, 2010, No. 61-FZ.

[4] On Medicines: the federal law of June 22, 1998, № 86-FZ.

of Health. Registration was to be carried out after obtaining positive results from preclinical and clinical trials and verifying, on their basis, the data of the accompanying regulatory documents.

The procedure for licensing in the distribution of medicinal products was assigned to the Federal Service for Surveillance in Health Care (Roszdravnadzor) and consisted of establishing the license applicant's compliance with the licensing requirements for managers and staff of the pharmaceutical organization and its premises, as well as observing the technological processes involved in the licensed activity. In addition, licensing tasks included preventing, identifying and stopping violations by legal entities and individual entrepreneurs of the statutory provisions and conditions for carrying out pharmaceutical activities.

Accreditation and certification of specialists involved in the distribution of medicinal products was to be carried out at regular intervals (at least once every five years) in certain secondary and higher education organizations using standardized curricula. The aim was to create a system of continuous training and regular verification of employees' qualifications in accordance with their positions and level of professional education.

Aiming to secure state control over the quality and safety of medicines in civil circulation, a network of independent analytical monitoring laboratories and quality control and certification centers for medicines was established. Their tasks included supervision of pharmaceutical activities in their territories of responsibility and quality control of pharmaceutical products provided to the population by wholesale and retail pharmaceutical organizations [14].

To curb price increases for medicines, the federal law *On Medicines* introduced a system of state registration of maximum selling prices for medicines included in the List of Vital and Essential Medicines (List of VEM). The State Register of Maximum Selling Prices for Manufacturers of Vital and Essential Medicines was introduced to ensure that this goal was met. The list is approved annually by the Russian government. It includes medicines that provide for priority health care needs in the prevention and treatment of diseases prevalent in the Russian population's morbidity rates.

The main result of this period in the pharmaceutical safety system's formation was the establishment of the state's leading role in regulating the economic and social relations related to the circulation of medicinal products.

However, the introduction of a state monopoly on regulatory oversight in the provision of medicines to the population was not actively supported by the Ministry of Health or other interested federal executive bodies. Their lack of support was reflected in the delays of various ministries and departments in the adoption of necessary regulatory legal documents in which the requirements of federal laws and the mechanisms for their implementation were detailed. Meanwhile, the pharmaceutical industry, pursuing its commercial interests, continued to provide an economically profitable assortment of pharmaceutical products, some manufactured domestically and others imported.

Having assessed the nation's pharmaceutical industry at the end of 2007, the Russian government decided to determine an appropriate strategy for the development of the domestic pharmaceutical industry. The Russian Ministry of Industry and Trade implemented this strategy. In October 2009, the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the Period up to 2020 was adopted (Pharma-2020 Strategy).[5] It is at this point that the modern development period of Russia's pharmaceutical industry and pharmaceutical safety system began.

The main objectives of the Pharma-2020 Strategy were as follows:

– an increase in accessibility of the most popular Russian-made medicines for citizens and their provision to the domestic health care system;

– the creation of conditions for increasing the competitiveness of the pharmaceutical industry in Russia by harmonizing Russian and international standards for the industrial production of medicines;

[5] On the approval of the Strategy for the Development of the Pharmaceutical Industry of the Russian Federation for the Period up to 2020: Order of the Ministry of Industry and Trade of the Russian Federation of October 23, 2009, No. 965. URL: http://www.consultant.ru/. Access date: February 17, 2018.

– the development and implementation of economic incentives for the creation of new medicines and their industrial production;

– the protection of Russian entities in the pharmaceutical market from unscrupulous forms of competition and the creation of equal rights of market access for domestic and foreign producers;

– comprehensive technological modernization of the scientific base and production of Russian pharmaceutical enterprises;

– stricter measures to ensure the quality of medicines and their components in general circulation;

– improved professional training for pharmaceutical workers engaged in the creation and industrial production of medicines meeting international quality standards.

The schedule of completion of these goals is divided into three periods. The first period (2009–2012) called for large-scale deployment in Russia of enterprises and organizations in the complete cycle development and production of medicines. The goal was to create a modern production and research base in Russia that meets the international GMP requirements[6] and is capable of producing the necessary types and volumes of pharmaceutical substances and medicines. The second period (2013–2017) was focused on creating a modern industrial production system for generic pharmaceuticals and their adoption, which was to increase access to expensive imported original drugs by the use of their generic counterparts. The goal of the third (current) period (2018–2020) is the introduction of state measures to develop the Russian pharmaceutical industry's competitive advantages and its transition to a contemporary model. Using domestic industrial production, a policy of import substitution is planned for medicines that are patented and in the highest demand on the international pharmaceutical market.

The Pharma-2020 Strategy also set out the desired results of its practical implementation:

– by 2020, increase the share of domestic pharmaceutical products in the total volume of consumption to 50 percent in monetary terms;

– update the nomenclature of medicinal products and increase the share of original Russian-produced preparations to 60 percent in monetary terms;

– introduce Russian pharmaceutical products onto the international market and increase the volume of exports from 6 billion rubles (2008 indicator) to 48 billion rubles by 2020;

– create production facilities for releasing strategically important medicines[7];

– give preference to Russian enterprises that produce pharmaceutical products in order to ensure industrial production of at least 50 percent of medicines in monetary terms, including at least 85 percent of strategically significant items.

By 2010, the provisions of the federal law *On Medicines* had become inconsistent with the development of the Russian pharmaceutical industry and the trends in the international pharmaceutical market. Given this situation, a new federal law on the circulation of medicines was developed and approved with the participation of the Russian Ministry of Health, the scientific community and the pharmaceutical community.[8] The scope of its regulation was expanded to include additional procedures for testing, production standardization, manufacture, storage, transportation, import and export, advertising, release, sale and disposal. The new federal law updated the national requirements and approaches to the development and maintenance of the State Pharmacopoeia of the Russian Federation, labeling of medicines, pharmaceutical activities, state pricing regulation, monitoring of medicines' effectiveness and safety, system for monitoring the supply of medicines through the distribution network from the producer to the final consumer and other areas. The government ministries and agencies concerned responded promptly to the new federal law and within a

[6] Good Manufacturing Practice.

[7] In order to ensure the economic and physical availability of medicines for the treatment of the most common diseases, the Russian government approved the List of Strategically Important Medicines to be Produced on the Territory of the Russian Federation (On approval of the list of strategically important medicines: 07/06/2010 No. 1141-p // Collection of Legislation of the Russian Federation, July 19, 2010, No. 29, Article 394), which included 57 international non-patented types of medicines.

[8] On the Distribution of Medicines: Federal Law No. 61-FZ of April 12, 2010 // Collection of Legislation of the Russian Federation, April 19, 2010, No. 16, art. 1815.

year completely revised and approved more than 30 by-laws setting out the requirements.

Thus, after the adoption of the current federal law *On the Distribution of Medicines*, the unified rules governing the work of all those involved in the pharmaceutical market were clarified and largely tightened, and strategic development fields for the pharmaceutical sector's industrial potential in the state economy were determined, making it possible to form an effective pharmaceutical security system.

However, in addition to a strategically developed pharmaceutical industry, the country's pharmaceutical safety depends to a large extent on the effectiveness of a drug supply system with effective barriers against the introduction of poor-quality, falsified and counterfeit medicines. In such a system state social assistance measures should be implemented for certain categories of citizens, in a timely manner, so as to fully meet the needs of health care organizations and the public.

The state's constant attention to pharmaceutical safety is demonstrated by the Strategy of Medicinal Provision for the Population of the Russian Federation for the Period up to 2025 (Strategy-2025),[9] developed and adopted in 2013. The adoption of this document was necessary due to the nature of Russia's socio-economic development. The strategy's main goal is to determine the optimal system for the provision of medicines in the country's health care system, balanced with the financial resources of the state. To achieve the goals of Strategy-2025, the following main tasks needed to be solved:

– provide for the rational prescription and use of medicines based on standardized medical care, making drug therapy decisions by taking into account patients' personal data, optimizing the criteria for inclusion of drugs in the List of Vital and Essential Medicines and introducing the electronic prescription of medicines with the possibility of their integration with decision support systems in the field of rational pharmacotherapy;

– introduce effective medicine reimbursement models for outpatient treatment through the system of drug insurance;

– refine the price regulation system by introducing a pricing model with a weighted average (reference) price for medicines from one group and the subsequent transition from the registration of restricted producer prices to the formation of reference market prices;

– optimize the procedure for the distribution of medicinal products through the creation of a state system for standardizing quality control using certified state standard samples and regular updates to the State Pharmacopoeia;

– increase the availability of essential medicines through the review and optimization of the prescription and non-prescription drug-dispensing procedure, the creation of a single information reference system with current methods of treatment and categorized pharmaceutical products and the development of international contacts and information exchange on drug provision for the general population;

– raise the awareness of medical specialists and the public of drug supply issues by identifying scientific and practical priorities in the development of a methodology for assessing health technologies (taking into account drug components) and the criteria for making decisions on their inclusion in regulatory legal acts governing the volume and quality of medical care.

The practical implementation of Strategy-2025 was planned in three stages. The first (2013) was preparatory and included the study of foreign experience in the implementation of medicine supply systems, the development of mechanisms for their correlation with the program of compulsory medicine insurance, comparative studies of the socio-economic efficiency of medical technologies and calculations for the creation of medicine provision models for citizens at different financial security levels and development of the necessary legislative and regulatory framework for the implementation of the strategy. In the second stage (2014–2015), the implementation of pilot projects to improve the disbursement system for medicines began. This stage was intended to develop models for the reimbursement of the cost of medicines for outpatient treatment in several regions of

[9] On the approval of the Strategy of Medicinal Provision for the Population of the Russian Federation for the Period up to 2025 and the plan for its implementation: Order No. 66 of the Ministry of Health of the Russian Federation of February 13, 2013. URL: http://www.consultant.ru. Access date: 2/24/2018.

Russia, and following their implementation, to adjust the state medicinal product supply system, including price regulation mechanisms. The third stage (2016–2025), which is currently being implemented, is introducing contemporary models for the provision of medicines to the population on a national scale and involves the use of new economic mechanisms, the permanent monitoring of its functioning, the use of modern organizational regulatory models and optimal control for the effective distribution of pharmaceutical goods and services.

As a result of the implementation of all the measures stipulated in Strategy-2025, there should be an increase in the population's satisfaction with the accessibility and quality of medicinal assistance. The use of original domestic and generic medicines, the improved quality of medical care, increased life expectancy and longer working life (including for those suffering from severe chronic diseases) and the strengthening of state control over the quality of pharmaceutical goods in general circulation in Russia are all intended to contribute to the improvement and accessibility of medicinal assistance.

The availability of medicines for citizens, regardless of where they live, is one of the indicators of pharmaceutical safety and is determined by the availability of a sufficient number of pharmacy organizations. In terms of this indicator, Russia is one of the leading countries in the world. Prior to 1991, on average one pharmacy served about 9,000 citizens, but now this number has decreased to 2,000. According to the Federal Service for Surveillance in Health Care, as of September 2015, 25,631 organizations were licensed for pharmaceutical activities in Russia, and the retail pharmaceutical market segment amounted to 74,057 establishments: 25,043 pharmacies, 26,895 pharmacy points, 260 pharmacy kiosks and 1,870 individual entrepreneurs, as well as 19,989 first aid-obstetrics points, outpatient and general practice offices that sell retail medicines.[10]

Nonetheless, a sufficient number of pharmacy organizations alone will not provide a full solution to the problem of medicinal safety for citizens because of such reasons as fluctuations in demand, pricing policy and storage costs for pharmacy supplies. Thus, in order to eliminate discrepancies between the pharmacies' capabilities and the needs of citizens, the federal law *On the Distribution of Medicine*s stipulates that "pharmacy organizations licensed for pharmaceutical activities are obliged to provide a minimum assortment of medicines required for the provision of medical assistance established by the authorized federal executive body".[11] Such an assortment was first established by the decree of the Russian government of December 30, 2014 No. 2782-p for 2015 and is updated and approved annually. Offering a minimal assortment of medicines is a licensing requirement for pharmacy organizations' right to carry out pharmaceutical activities.

The powerful distribution network in Russia ensures the availability of pharmaceutical products, but at the same time it creates conditions for permanent threats associated with the introduction of poor-quality, falsified and counterfeit medicines onto the pharmaceutical market [15]. In the area of pharmaceutical safety, a key role is assigned to medicine wholesalers, pharmacy organizations and the Federal Service for Surveillance in Health Care. Thanks to the control system for the distribution of medicines in Russia, significant volumes of medicinal products that threaten public health are withdrawn from the retail sector of the pharmaceutical market annually [16] (see table).

The total number of medicines withdrawn from circulation in 2015 amounted to 2.186 billion and in 2016 to 2.619 billion packs; that is, the volume of recalled medicinal preparations increased by about 20 percent. The numbers cited testify to attempts to obtain a profit on the pharmaceutical market through the sale of medications that may be harmful to the population's health.

In order to protect citizens from poor-quality, falsified and counterfeit medicines that have been introduced onto the domestic pharmaceutical

[10] Federal Service for Surveillance in Health Care: in three years the number of pharmacy organizations in the Russian Federation has increased by more than 1.5 times // Official website of the Federal Service for Control in the Sphere of Health. URL: http://www.roszdravnadzor.ru/spec/news/285. Access date: 2/18/2018.

[11] On the Approval of the List of Strategically Important Medicinal Products: the order of the Government of the Russian Federation of July 6, 2010, No. 1141-p // Collection of Legislation of the Russian Federation, July 19, 2010, No. 29, art. 394.

Withdrawals of poor-quality, falsified and counterfeit medicines from general circulation, 2015–2016.

Criterion	Number of lots, units.		Dynamics, %
	2015	2016	
Low-grade m.	701	533	-24
Falsified m.	27	11	-59
Counterfeit m.	33	29	-12
Recalled by manufacturer	952	1365	+43
Total lots	1713	1938	+13

Note. "m." = medicines. "-" = decrease, "+" = increase.

market, and provide them with reliable information about the medicines' producers and journeys through the distribution network, a pilot project on the labeling of distributed medicines was launched in Russia on January 1, 2018.[12] By the end of 2018, individual stamps, in the form of a QR code, will be applied to all consumer packs of Russian manufactured and imported medicinal preparations. The QR code will provide information about the authenticity, the date of manufacture, the manufacturer and batch number and unique product number, as well as the package's process through the distribution network. This information can be accessed using a special smartphone application, distributed free of charge. The system will track more than..5 billion packs of medicine annually, and place under constant monitoring thousands of industrial pharmaceutical companies, up to 2,500 medicine wholesalers and up to 350,000 medical and pharmacy organizations.[13]

As of December 2017, the domestic pharmaceutical industry had significant intermediate results from the implementation of strategic development goals. For example, more than 900 medicinal product manufacturers operate in Russia. This has increased total share of domestic pharmaceutical products consumed to 43 percent in monetary terms, as well as having increased the share of original medicines produced in Russia in monetary terms to 40 percent.

Since May 2017, Russia, as a member state of the Eurasian Economic Union, has enacted the Rules of Good Manufacturing Practices of the Eurasian Economic Union, establishing the principles used in the production of pharmaceutical substances and medicines in various forms.[14] By early 2017, the volume of Russian pharmaceutical product exports had not increased sufficiently, due to stiff competition in the global pharmaceutical market. The Rules of Good Manufacturing Practices of the Eurasian Economic Union will provide for increased exports of Russian medicines and enable mutually beneficial volumes to eventually be reached.

From 2007 to December 2017, the value of the Russian pharmaceutical market increased from 310 billion rubles to 1,052 billion rubles (an increase of 340 percent). At the same time, the share of domestically produced medicines increased from 20 percent to 42 percent in monetary terms.

Of the 57 strategically important medicines in Russia, the production of 47 medicinal preparations is localized, amounting to 82 percent of the established nomenclature items.

[12] On conducting an experiment on marking with control (identification) symbols and monitoring the turnover of certain types of medicinal products for medical application: Resolution of the Government of the Russian Federation of January 24, 2017, № 62 // Official Internet portal of legal information. Access code: http://www.pravo.gov.ru, January 30, 2017. Access date: February 5, 2018.

[13] The system of medicinal products' labeling // The official website of the Federal Service for Control in the Sphere of Health. URL: http://www.roszdravnadzor.ru/marking. Access date: February 18, 2018.

[14] On the Approval of the Rules for Good Manufacturing Practices of the Eurasian Economic Union: Decision of the Council of the Eurasian Economic Commission No. 77 of March 11, 2016 // Official site of the Eurasian Economic Union. URL: http://www.eaeunion.org. Access date: 2/17/2018.

Measures to stimulate the production of Russian pharmaceutical substances have increased, in monetary terms, the production of finished medicines created on their basis up to 40 percent and the production of strategically important medicines up to 78 percent. They also contributed to the fact that by the beginning of 2018, Russia was producing 4.2 percent (468 international non-proprietary items) of medicines included in the List of Vital and Essential Medicines.[15]

About two years remain before the end of the Pharma-2020 Strategy. The dynamics for the implementation of its main parameters allow the assertion that the goals will be reached and that there will be a competitive pharmaceutical industry in Russia that can fully provide its population and health organizations with the necessary and sufficient assortment of pharmaceutical products.

In conclusion, a state system of pharmaceutical safety has been formed and is developing in Russia. Analysis of the regulatory framework governing the pharmaceutical industry and the distribution of medicines, interim results and prospects for the implementation of strategic approaches for the development of industrial production of medicines and the system of providing medicines to the population and health care organizations all attest to the state's leading role in the formation of a socially oriented medicinal policy aimed at preserving and strengthening the health of Russian citizens. In addition, the notion of "pharmaceutical safety" has undergone changes: at present, it applies to not only citizens' personal safety but also the country's independence with respect to medicines, which corresponds to the current stage of its social and economic development.

[15] Ministry of Industry and Trade of Russia forms priorities for the development of the pharmaceutical industry // The official website of the Ministry of Industry and Trade of the Russian Federation. URL: http://minpromtorg.gov.ru/press-centre/news. Access date: February 19, 2018.

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