

## РАЗВИТИЕ ФАРМАЦЕВТИЧЕСКОЙ ПРОМЫШЛЕННОСТИ РФ КАК ИНСТРУМЕНТ ОБЕСПЕЧЕНИЯ ЛЕКАРСТВЕННОЙ БЕЗОПАСНОСТИ СТРАНЫ

Лекарственная безопасность является ключевым аспектом национальной безопасности, включающим обеспечение доступности, качества и эффективности лекарственных средств. В данной статье анализируется развитие фармацевтической промышленности в России и ее влияние на лекарственную безопасность. Особое внимание уделяется проблемам, вызванным санкциями и специальной военной операцией (СВО), а также способам их преодоления.

В статье анализируются действующие меры государственной поддержки фармацевтической отрасли в России. Рассматриваются различные финансовые, регуляторные, научные и инфраструктурные меры, направленные на развитие отечественного производства лекарственных средств, повышение их конкурентоспособности и обеспечение лекарственной безопасности страны. Обсуждаются ключевые нормативные акты, регулирующие поддержку фармацевтической отрасли,

*Ключевые слова:* государственная поддержка; фармацевтическая отрасль; лекарственная безопасность; импортозамещение; программы развития; «Фарма-2030».

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## THE DEVELOPMENT OF THE RUSSIAN PHARMACEUTICAL INDUSTRY AS A TOOL FOR ENSURING THE COUNTRY'S DRUG SECURITY

The article analyzes government support measures aimed at developing the Russian pharmaceutical industry as a tool for ensuring the country's drug security. It examines financial incentives, regulatory measures, scientific-educational, and infrastructural programs designed to promote the growth of domestic drug production. The article provides an overview of key regulatory acts, such as the Federal Law «On Circulation of Medicines» and government decrees that regulate this sphere. Additionally, it reviews current programs, including «Pharma-2030» and the «National Technology Initiative» (NTI), aimed at achieving strategic goals for import substitution and increasing the share of domestic pharmaceutical products in domestic and foreign markets. The main focus is on analyzing the effectiveness of these measures and their impact on ensuring drug security in Russia.

*Keywords:* development of the pharmaceutical industry; drug security; government support; regulatory acts; Pharma-2030; import substitution; National Technology Initiative (NTI); Russian drug market.

Drug security is a fundamental aspect of national security and healthcare, encompassing the availability, quality, and effectiveness of medicines. This article analyzes the development of the pharmaceutical industry in Russia and its impact on drug security. Special attention is given to the problems caused by sanctions and the special military operation (SMO), as well as ways to overcome them.

Drug security includes the following key elements:

1. **Availability:** Ensuring uninterrupted access for the population to vital and essential medicines is a primary task. This includes both geographical and price availability.

2. **Quality and Safety of Drugs:** Control over the quality of produced and imported drugs, regulation of production standards, certification, and compliance with international norms.

3. **Effective Regulation:** The presence of strict regulatory mechanisms that control the development, production, distribution, and sale of drugs. Legislation must counteract counterfeit and substandard drugs.

4. **Scientific Research:** Support and development of pharmaceutical research and innovations; the ability to develop domestic technologies and drugs to reduce dependence on imports.

5. **State Support Program:** Inclusion of mechanisms for subsidizing and supporting strategically important drugs and pharmaceutical enterprises.

6. **Public Awareness:** Educating and informing the public about the correct and safe use of medicines, as well as potential risks.

These elements are closely interconnected and require a comprehensive approach to ensure the country's drug security, which in turn strengthens the overall health of the nation and improves the quality of life of the population.

The Russian pharmaceutical industry has undergone significant transformations. During the Soviet period, production was centralized and state-owned. The post-Soviet period is characterized by the transition to a market economy and privatization. Currently, there is a growth of private pharmaceutical companies and significant state investments in the industry.

Sanctions and military conflicts have significantly affected Russia's drug security. New challenges require adaptation and strengthening of internal mechanisms to ensure medical and pharmaceutical stability.

Primarily, sanctions restrict access to foreign technologies and drugs, increasing dependency on domestic production and potentially leading to shortages of essential medications. Additionally, supply chain disruptions affect the logistics of drug deliveries.

All of this leads to an increase in drug prices due to the rising cost of imported components, making medications less accessible to the population. The complex geopolitical situation generates economic instability, inflation, and a decrease in the purchasing power of the population, further complicating access to necessary medications. Additionally, international cooperation and knowledge exchange, which are crucial for maintaining quality standards in drug production, become more difficult.

Russia has achieved significant success in the development of pharmaceutical drugs. Some key achievements include:

### 1. COVID-19 Vaccines:

- Sputnik V: The first registered COVID-19 vaccine based on an adenoviral vector, developed by the Gamaleya Institute.
- EpiVacCorona: A peptide-based vaccine developed by the Vector Institute of Virology and Biotechnology.
- CoviVac: An inactivated virus vaccine developed by the Chumakov Center.

### 2. Antiviral Drugs:

- Arbidol: A broad-spectrum antiviral drug used for the treatment and prevention of various viral infections.
- Kagocel: A drug that stimulates the production of interferons, used for the prevention and treatment of influenza and other viral infections.

3. Insulins and Insulin Analogues: On October 17, 2023, the Russian Ministry of Health issued a permit for the clinical trial of an innovative drug by the biotech company BIOCAD to prevent the development of type 1 diabetes. The drug could potentially halt the increasing need for insulin therapy in patients. Investments in development and research amount to approximately 1 billion rubles<sup>1</sup>. The company GEROFARM will begin testing an innovative insulin in June 2024. It has already received permission from the Russian Ministry of Health to conduct the first phase of clinical trials. The essence of the new insulin's development is that it only needs to be used once a week, which will improve patient adherence to therapy and enhance disease management quality<sup>2</sup>.

### 4. Immunomodulators and Drugs for Autoimmune Diseases:

- Polyoxidonium: An immunomodulator used in the complex therapy of chronic and acute infectious diseases.
- The drug Bursanatal, created by scientists from the Ural State University of Economics, has been recognized as one of the main domestic developments of 2023. Bursanatal helps fight breast and uterine cancer. The drug is patented, and clinical trials have shown that at the maximum effective concentration, the chance of destroying cancer cells is 80–92%<sup>3</sup>.

It is worth noting the flagship of the pharmaceutical industry in the Irkutsk region — Pharmasyntez LLC. This leading Russian manufacturer of socially significant medicines plays an important role in the state import substitution project, investing in local production and innovative research. Since 1997, Pharmasyntez has expanded its production capacity and opened several factories across Russia, including in St. Petersburg, Irkutsk, Tyumen, and other cities<sup>4</sup>. The enterprise is known for developing unique drugs such as Saterex® for the treatment of type II diabetes and Perchlozone® for the treatment of tuberculosis. Overall, Pharmasyntez produces more than 300 drugs in various forms.

These achievements demonstrate that Russia is actively working on the development of biotechnology and biopharmaceuticals, aiming to reduce its dependence on imported drugs.

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<sup>1</sup> <https://pharmmedprom.ru/news/v-rossii-nachinayut-ispitaniya-lekarstva-dlya-ostanovki-razvitiya-diabeta-1-tipa>.

<sup>2</sup> <https://spbdnevnik.ru/news/2024-05-23/v-peterburge-nachnut-ispitaniya-innovatsionnogo-insulina>.

<sup>3</sup> <https://oblgazeta.ru/pressreleases/2023/12/29470/?ysclid=lxwriectvu9748492487>.

<sup>4</sup> <https://pharmasyntez.com>.

However, there remains a significant list of drug groups that are difficult to substitute in Russia. These include genetically engineered drugs and biopharmaceuticals, the production of which requires advanced technologies, specialized equipment, and world-class scientific research (e.g., monoclonal antibodies, recombinant proteins, cell and gene therapies); drugs for the treatment of rare diseases, which are often economically unviable to produce without government support (e.g., medications for cystic fibrosis, rare types of cancer, genetic diseases, and others); oncological drugs, which require complex synthesis and quality control technologies; antibiotic drugs that are resistant to multiple drug resistance; antidepressants and drugs for the treatment of mental disorders; and medications for the treatment of HIV/AIDS.

Substituting these drugs with domestic equivalents requires significant efforts, investments in technology and research, as well as international cooperation and the exchange of experience and knowledge. Without these factors, the production of complex and high-quality drugs in the domestic market remains a challenging task.

Existing state support measures for the pharmaceutical industry are summarized in Table 1.

Table 1

State Support Measures for the Pharmaceutical Industry in Russia

Direction	State Support Instruments
Financial Support	- Subsidies and grants for pharmaceutical R&D and new production facilities.
	- Preferential loans for pharmaceutical companies, development of priority projects.
	- Tax benefits for enterprises engaged in drug development and production.
Regulatory Measures	- Accelerated registration of drugs that are priorities for state support.
	- Program for replacing imported drugs with domestic equivalents.
Scientific and Educational Support	- Support for educational institutions training pharmaceutical specialists.
	- State grants and subsidies for conducting pharmaceutical R&D.
Infrastructure Support	- Creation of pharmaceutical clusters, formation of infrastructure for pharmaceutical production deployment.
	- Support for technology parks and business incubators for pharmaceutical enterprises.

The regulatory framework for supporting the pharmaceutical industry in Russia includes various legislative acts and programs aimed at enhancing national drug security, summarized in Table 2.

Table 2

Regulatory Framework for Supporting the Pharmaceutical Industry in Russia

Group	Regulatory Act Number, Title	Content
Federal Laws	Federal Law No. 61-FZ of April 12, 2010 "On Circulation of Medicines"	Regulates the entire lifecycle of medicines.

Group	Regulatory Act Number, Title	Content
	Federal Law No. 178-FZ of July 22, 2010 "On State Support of Small and Medium Enterprises in the Russian Federation"	Includes measures for pharmaceutical companies.
Government Decrees	Government Decree No. 434 of April 23, 2018 "On Providing Subsidies to Drug Manufacturers to Compensate Part of Production Costs"	-
	Government Decree No. 2393 of December 31, 2020 "On Approval of the State Support Program for Pharmaceutical Industry Clusters"	-
Programs	Pharma-2030	Long-term program for the development of the Russian pharmaceutical industry until 2030.
	National Technology Initiative (NTI)	Program supporting the development of high-tech industries, including pharmaceuticals.
	"Roadmap" for Import Substitution in Pharmaceuticals	Aimed at reducing dependency on imported drugs and components.

As seen, programs are being developed to subsidize and support domestic manufacturers to stimulate the growth of internal drug production. Emphasis is placed on the development of import-substitution technologies to reduce dependency on external supplies; investments are attracted to build new production capacities and modernize existing enterprises; funding for pharmaceutical R&D is increased.

Overall, completely meeting the country's drug needs through domestic production remains an ambitious but very challenging goal. Government support and investments in the sector contribute to the growth of production, the improvement of quality, and the accessibility of drugs, which in turn strengthens national security.

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