



## IMPORT SUBSTITUTION IN THE RUSSIAN PHARMACEUTICAL INDUSTRY: CHALLENGES AND UNSOLVED ISSUES

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### ABSTRACT

**Background:** This article considers the specifics of import substitution in the Russian pharmaceutical market, discusses the state industrial policy, prospects, and trends in the development of the Russian pharmaceutical industry in the context of sectoral sanctions and the need to accelerate the process of import substitution. **Objective:** The study aims at revealing and analyzing the development of the pharmaceutical industry with due regard to the needs of the Russian market. **Methods:** The authors of the article analyzed the Strategy for the development of the pharmaceutical industry of the Russian Federation for the period until 2030. The study was based on statistical indicators of the Russian pharmaceutical industry and state policies forming an institutional framework for the substitution of drugs purchased from other states. **Results:** The study has highlighted the strategic importance of import substitution for the purposes of national security in the context of geopolitical instability. As a result, Russian pharmaceutical companies are rapidly localizing foreign production. The driving force of this process is state support and long-term strategic development programs. **Conclusion:** In modern conditions, import substitution is the result of the well-coordinated activities of all the parties involved. A key aspect of implementing such a policy is its consistency with ongoing institutional changes. The most promising approach is to build enterprises with the full production cycle of medicines.

**Keywords:** import substitution, production, pharmaceutical industry, strategy for developing the pharmaceutical industry.



## SUBSTITUIÇÃO DE IMPORTAÇÕES NA INDÚSTRIA FARMACÊUTICA RUSSA: DESAFIOS E QUESTÕES NÃO RESOLVIDAS

### RESUMO

**Antecedentes:** Este artigo considera as especificidades da substituição de importações no mercado farmacêutico russo, discute a política industrial estatal, perspectivas e tendências no desenvolvimento da indústria farmacêutica russa no contexto das sanções setoriais e a necessidade de acelerar o processo de substituição de importações. **Objetivo:** O estudo visa revelar e analisar o desenvolvimento da indústria farmacêutica tendo em conta as necessidades do mercado russo. **Métodos:** Os autores do artigo analisaram a Estratégia para o desenvolvimento da indústria farmacêutica da Federação Russa para o período até 2030. O estudo baseou-se em indicadores estatísticos da indústria farmacêutica russa e políticas estatais formando um marco institucional para a substituição de medicamentos adquiridos de outros estados. **Resultados:** O estudo destacou a importância estratégica da substituição de importações para fins de segurança nacional no contexto de instabilidade geopolítica. Como resultado, as empresas farmacêuticas russas estão localizando rapidamente a produção estrangeira. A força motriz desse processo é o apoio estatal e os programas de desenvolvimento estratégico de longo prazo. **Conclusão:** Nas condições modernas, a substituição de importações é o resultado de atividades bem coordenadas de todas as partes envolvidas. Um aspecto fundamental da implementação de tal política é sua consistência com as mudanças institucionais em andamento. A abordagem mais promissora é construir empreendimentos com o ciclo completo de produção de medicamentos.

**Palavras-chave:** substituição de importações, produção, indústria farmacêutica, estratégia de desenvolvimento da indústria farmacêutica.

### 1. INTRODUCTION

Import substitution is a strategic direction of the national security of the Russian Federation in the context of rapid geopolitical and geo-economic changes. Possible sectoral sanctions, the termination of imported technologies, the shortage of finished drug products, and supply chain disruptions in relation to pharmaceutical substances (raw materials for the production of drugs) threaten the sovereignty of the Russian Federation in the field of drug supply. This issue is aggravated by the COVID-19 pandemic, the possible market exit of European and American companies involved in the localization of pharmaceutical products and the supply of original drugs that have no Russian analogs. The expediency of creating export-oriented non-commodity sectors in the pharmaceutical industry through import substitution is supported at the highest level.

The Decree of the Chairman of the Government of the Russian Federation M. Mishustin of December 29, 2021 "On Amendments to the State Program of the Russian Federation 'Development of the Pharmaceutical and Medical Industries'"



approved plans for the development of the pharmaceutical industry for the period until 2030. This document establishes the strategic priority of the state policy in the field of drug safety, i.e. import independence. In particular, the Russian pharmaceutical industry should substitute 90% of strategically important drugs with its own full production cycle by 2030 (Government of the Russian Federation, 2021).

The pharmaceutical industry can be called the No. 1 industry for import substitution due to its impact on socio-economic indicators and the multiplier effect. In this regard, the study aimed at determining and analyzing import substitution in the pharmaceutical industry becomes relevant in theoretical, methodological, and practical aspects. One of the most important conditions for ensuring an effective import substitution policy should be a well-coordinated state industrial policy. State support is required to solve a number of regulatory and legal conflicts, without which enterprises will not be able to develop dynamically.

## 2. LITERATURE REVIEW

The topic under study is developed. Both Russian and foreign scientists have addressed the issues of import substitution. In the Russian scientific community, the theoretical and methodological aspects of import substitution are studied by A.P. Ovchinnikov (2020), A.S. Kuznetsova (2020), B.B. Doskaliyeva, D.A. Torzhanova, A.V. (2020), Litvinova, N.S. Talalaeva, M.V. Parfenova (2019), etc.

A significant contribution to understanding the processes and issues of import substitution in the pharmaceutical industry was made by N.V. Krivenko, D.S. Epaneshnikova (2020), M.S. Oborin (2021), S.V. Bushnev, N.V. Zagorodniy, A.V. Burtsev, M.V. Stogov, E.N. Ovchinnikov and A.V. Gubin (2020). Summarizing their research, we should note that scientific and technological progress, geopolitical instability, and international sanctions have initiated a conceptual transformation of state policy aimed at localizing production in order to manufacture competitive innovative products to meet domestic needs and create export potential. Thus, S.N. Khobotov (2020) and A.S. Alekanov (2021) studied the specifics of the national model of import substitution.



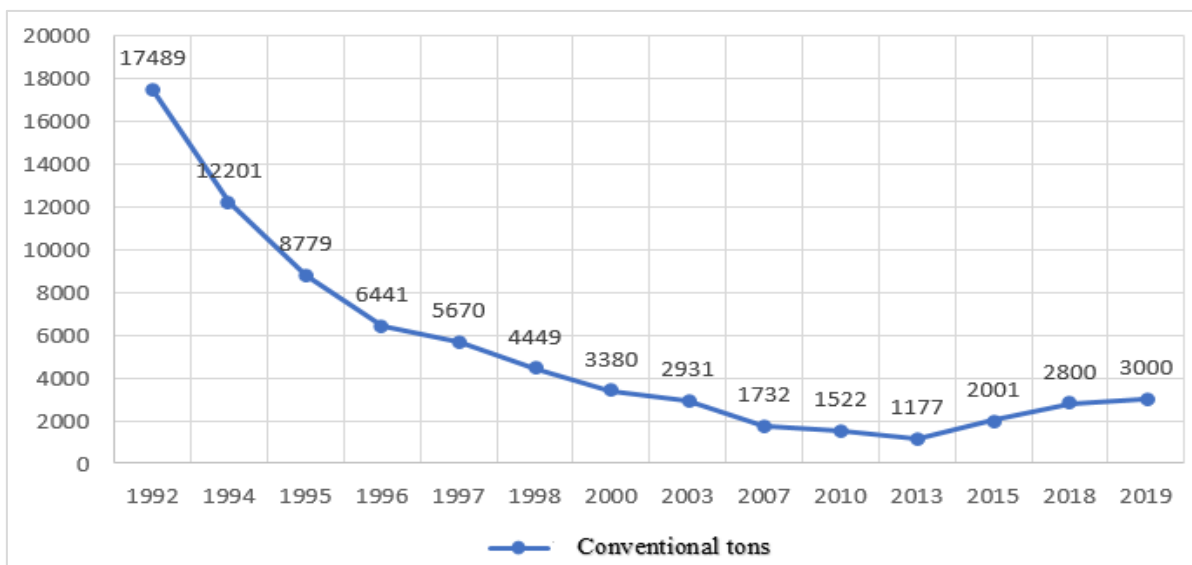
### 3. RESULTS

#### THE SPECIFICS OF INDUSTRIAL POLICY IN THE PHARMACEUTICAL INDUSTRY OF THE RUSSIAN FEDERATION

The Russian market of pharmaceutical products is a complex multi-level and multifunctional formation, whose development is interconnected with trends in the country's socio-economic development. Modern issues of the pharmaceutical industry are associated with market reforms at the turn of the 1980s–1990s, which radically changed the economic and social situation in the country. The pharmaceutical industry and the system of providing medicines to citizens were not ready to transform under the new economic paradigm, which caused a shortage of medicines aggravated by the economic crisis of the 1990s. The state failed to satisfy domestic demand through its own production. On the contrary, there were trends to reduce production and reorient it to cheaper imported products from India and China. By 1999, the production of pharmaceutical substances had decreased by 80% from 17,489 to 3,464 conventional tons (Figure 1), the volume of production of finished drugs was cut down by 50% (Manturov, 2018).

The Russian market had been suffering from a shortage of medicines until the 2000s when the state came to the aid of manufacturers. The first steps to improve the situation were to create conditions for the localization of foreign production within the country, in particular, companies from Eastern Europe. Until the 1990s, they had been part of the Council for Mutual Economic Assistance and focused on meeting the needs of the domestic market of the USSR. As a result of this policy and the restoration of the living standards of the population, there was a rapid growth in market capacity at the level of 15-20% per year from 2000 to 2008.





**Figure 1.** The production of pharmaceutical substances from 1992 to 2019, in conventional tons

Until 2008, the goal of the state industrial policy had been to eliminate imbalances in supply and demand caused by the transformation of the national economy. As a result, these processes established the import share at the level of 75-80%. To overcome negative consequences, the Government of the Russian Federation developed the "Strategy for development of the pharmaceutical and medical industry of the Russian Federation for the period until 2020" (Pharma 2020) in 2009. The key element was to form a comprehensive legislative framework for the period from 2009 to 2012.

The further vector of development is determined by the Decree of the President of the Russian Federation No. 598 of May 7, 2012 "On Improving the State Policy in the Sphere of Healthcare" (President of the Russian Federation, 2012). Accordingly, the production of domestic drugs according to the list of vital and essential drugs should be estimated at 90% by 2018. The PHARMA 2020 program set a goal to localize 50% of drugs used in the country by 2020, which formed the import substitution policy.

It is generally accepted that import substitution in the Russian Federation started in May 2014, when the President of the Russian Federation formed the "List of Instructions on Additional Measures to Stimulate Economic Growth". This instruction is a response to the imposition of international sanctions on Russia, in particular those aimed at the pharmaceutical sector. On its basis, the Government of the Russian Federation formed "Plan for promoting import substitution in the industry" on September 30, 2014 No. 1936-r. On March 31, 2015, the Ministry of Industry and Trade of the Russian Federation approved an action plan for import substitution in the

pharmaceutical industry of the Russian Federation (Ministry of Industry and Trade of the Russian Federation, 2015).

## THE ISSUES OF IMPORT SUBSTITUTION IN THE PHARMACEUTICAL MARKET

The main goal of developing the pharmaceutical market is to improve the quality of life of the population, which is related to the formation of the necessary competences to ensure import independence. It is impossible to achieve these goals without solving the fundamental problems of the industry.

After analyzing the main causes of all problems in the pharmaceutical industry, we classified them into three main groups: market-related, administrative, and problems associated with the specifics of production (Table 1).

**Table 1.** The classification of problems related to the development of the Russian pharmaceutical industry

	Challenge	Feature
Market-related	High proportion of counterfeit drugs	Volume of counterfeit products, according to various estimates, reaches 5-10%
	Imported raw materials	About 90% of substances are imported from Asian countries. The Russian manufacturers are dependent on imported medicines
	Production of generic drugs	86% of drugs in the Russian market are generic drugs. The low-level production of substances within the main pharmacotherapeutic groups
	Entry barriers	High capital expenses
	No Russian manufacturers in the global market	Less than 10% of all the drugs produced in Russia are exported in other countries
	Tense competitive climate	Large number of foreign companies in the pharmaceutical industry. The need for strong advantages for successful competition
Specifics of the industry	Low innovation activity	Enterprises spend about 2-5% of all expenses on innovations, therefore they lack their own scientific and technical base for the development of new drugs
	Outdated technologies	Lack of investment in the purchase of innovative technologies. Focus on the use of Indian and Chinese equipment
	Long drug development cycle	The full cycle of developing a new drug lasts until five years, the cycle of "updating" an already created drug is until three years
Administrative	Complex algorithm of new drug registration	Complicated and lengthy registration processes for new types of products
	No public-private partnerships	No mechanism for attracting investments through public-private partnerships
	Lack of legal framework for the sale of drugs via the Internet	No regulations governing the sale of prescription drugs via the Internet
	Regulation of intellectual property rights	No legal framework to protect the intellectual property rights of foreign manufacturers
	Lack of a comprehensive innovation support system	No effective mechanisms to support production innovations and innovation clusters



It is worth mentioning market entry barriers due to high competition in the industry and government regulation, the need for high capital investments from enterprises' funds. At the same time, the most profitable drugs are under patent protection, therefore new market players are forced to focus on low-margin products or violate intellectual property rights. Another factor hindering the production of innovative drugs in Russia is the long research and development cycle of new biologically active molecules (Litvinova et al., 2019).

The analysis has demonstrated that the listed factors are fundamental in ensuring high import dependence of pharmaceutical products at the present stage of development. The low share of self-produced drugs and dependence on foreign raw materials was the reason behind the import substitution policy. The causes are as follows: direct financing by providing preferential loans and subsidizing production; providing tax preferences to manufacturers engaged in the localization of foreign drugs for the full production cycle; stimulating investments through special investment contracts; creating a system of preferences for the public procurement of domestic drugs; forming scientific-technological clusters; establishing links between production and the scientific community. However, the measures taken by the state are not systemic. Being a response to certain decrees and orders of the Government of the Russian Federation, they aim at meeting the needs of the domestic market and creating a high-tech export potential. For example, manufacturers can be supported by the reimbursement of costs of clinical trials at all levels, creating chains for the production of substances, developing innovative biologically active chemicals, subsidizing interest rates, and registering Russian drugs in foreign countries.

The further development of the pharmaceutical industry is connected with pricing issues, a high share of imported substances, compulsory licensing, support for full-cycle manufacturers, dialogue between government agencies and the pharmaceutical market (from raw material producers to distributors). This dialogue should adapt the economy to changes in supply and demand, thereby creating a competitive pharmaceutical market and national economy as a whole.

#### 4. DISCUSSION

The current development of the Russian pharmaceutical industry is at the bifurcation point, i.e. a crossroads that will determine the future of the industry. However, market participants do not understand what steps to take in order to solve the existing



problems. Russian experts interpret the goals and objectives of the import substitution policy in different ways, thereby creating an array of various strategies. They express the need for a transition from the production of generic to original drugs, the localized production of active pharmaceutical ingredients, the creation of export potential, and other measures of direct and indirect support, which can be contradicting but still effective in ensuring import dependence.

Thus, M.S. Oborin believed that pharmaceutical companies had stable development trends despite international instability. The main role in the process of import substitution should be played by quality control mechanisms for the production of medicines (Oborin, 2021). S.N. Khobotova (2020) emphasized the positive impact of import substitution and proposed to increase the international competitiveness of the industry in order to solve the problems of the PHARMA 2030 program. A.S. Alekanov (2021) claimed that the problems were caused by insufficient budget funding compared to European countries.

We should highlight the opinion of M.S. Oboronin, A.M. Chernyshev, A.M. Zobov, and E.A. Fedorenko, who marked the exceptional success of the PHARMA 2020 program and innovation-oriented pharmaceutical industry with an export focus. In our opinion, Russia has introduced many programs that describe goals and priorities for developing the industry, including PHARMA 2020, but all of them are not fully implemented. Despite having a positive impact on various aspects of the drug production chain, it failed to solve the fundamental problem (import independence). According to Decree of the President of the Russian Federation No. 598 of May 7, 2012 "On the Improvement of Public Health Policy", 90% of the production of Russian drugs should have been localized in conformity with the list of vital and essential drugs by 2018. By 2022, only 6% of such medicines had been produced in the full production cycle. Under the PHARMA 2020 program, over 50% of medicines in value terms should have been localized by 2020, but the actual figure was only 40% (Table 2).

**Table 2.** The results of the "Pharma 2020" program

Year	2011		2020	
	Fact	Plan	Plan	Fact
Indicators/planned and actual values				
Share of domestic drugs in the market, in %	24.60%	50.00%		40.00%
Market size of pharmaceutical products, in billion rubles	824 billion rubles	1,498 billion rubles		2,040 billion rubles
Share of organizations implementing technological innovations, in %	21%	50.00%		about 40%
Share of the pharmaceutical industry in GDP, in %	0.32%	0.60%		about 0.4%





The current geopolitical situation and no effect of previously approved programs necessitate a comprehensive solution to problems of the pharmaceutical industry, radically changing the state policy of import substitution. It is necessary to focus on solving social issues, connect the development of the pharmaceutical industry with the tasks of the healthcare system and the implementation of Decree of the President of the Russian Federation of May 21, 2020 No. 474 "On the national development goals of the Russian Federation for the period until 2030". This sets national goals for increasing the life expectancy of the nation (President of the Russian Federation, 2020).

We need to solve pricing challenges. In our opinion, the main barrier to the development of the Russian pharmaceutical market is the reduced availability of medicines for the population. This trend shows a decline in product sales in quantitative terms. According to DSM Group, the capacity of the Russian pharmaceutical market increased by 15% in 2020, if compared to 2019, in monetary terms and decreased by 4% in terms of packages. In 2021, the average price of a medical package increased by 14.1%. For the first half of 2021, the 25 most popular pharmaceuticals in Russia became 25% more expensive (Lebedeva, 2021). Thus, prices for medicines rise and their availability decreases, which encourages the population to buy cheaper drugs (lower-quality generic products).

There are many reasons for such dynamics but the Decree of the Government of the Russian Federation of October 31, 2020 No. 1771 "On approval of state regulation of the maximum selling prices for medicines" (Government of the Russian Federation, 2020). This document allows pharmaceutical companies to raise selling prices for scarce medicines.

To solve this issue, it is necessary to establish preferences for full-cycle manufacturers. The cost of medicines is 80% determined by the prices of raw materials. Earlier, experts proposed similar solutions to the Ministry of Industry and Trade but they were not supported due to the small number of companies operating in the full production cycle.

In this regard, it is necessary to localize the production of pharmaceutical substances. Import independence cannot be achieved without the production of pharmaceutical substances from the list of vital and essential drugs in the territory of Russia. Their production is a guarantee of the country's drug safety but manufacturers prefer to buy them from India and China, instead of localizing production. In Russia,



47 companies have patents for the production of active pharmaceutical ingredients, but only five of them produce original drugs and vaccines. It is economically unprofitable for pharmacists to organize the production of substances for generic drugs in Russia due to high barriers to entry and small volumes of required raw materials.

During the pandemic, the Russian pharmaceutical industry realized its dependence on the substances supplied by China. After a number of Chinese pharmaceutical companies were closed during the quarantine, supply chains were broken, which caused shortages. In 2021, deliveries resumed but a new problem arose due to amendments to the Chinese environmental legislation. The production of pharmaceutical substances requires expensive environmental protection measures.

Facing their shortage during the COVID-19 pandemic, the state took a number of measures to subsidize the Russian pharmaceutical industry by providing tax preferences to full-cycle manufacturers. Currently, the Government of the Russian Federation also prepares the necessary legislative acts.

The localized production of pharmaceutical substances is of critical importance for the national system of drug supply, in contrast to the production of finished products from imported raw materials. For its import substitution, it is necessary to simplify registration procedures, eliminate regulatory barriers, create an institution for the protection of intellectual property rights, and speed up the state registration of drugs that have foreign analogs registered in the country.

To create favorable conditions for import substitution, the Government of the Russian Federation adopted the "Strategy for development of the pharmaceutical industry of the Russian Federation for the period until 2030" on December 29, 2021. It aims at import substitution and the creation of competences in the production of Russian innovative products while highlighting the following priorities of state policy: import independence, ensuring the necessary growth in the production capacity of the pharmaceutical industry, developing the institute for monitoring the quality of medicines, creating and improving conditions for the development of innovative medicines (Doskalieva & Torzhanova, 2020; Government of the Russian Federation, 2021; Kuznetsova, 2020).

In addition to import substitution, the state program should have increased the production of domestic drugs two times to 1.5 trillion rubles and their export to 311 billion rubles by 2030. Special attention is paid to the localization of strategically important drugs in the full production cycle until 90%. The state policy of import



substitution is characterized by the following features: the support of manufacturers to create competence in the production of innovative drugs, regardless of other market participants (consumers, distributors, etc.). However, ignoring the needs and interests of other participants in the process will lead to a misunderstanding of the goals and objectives of import substitution, which will affect the effectiveness of the above-mentioned state program. This viewpoint is shared by A.M. Chernysheva, A.M. Zobova, and E.A. Fedorenko (2021).

From the analysis of the PHARMA 2030 program, it follows that only enterprises with a full production cycle are competitive in the pharmaceutical market. The formation of such enterprises is inextricably linked with the innovation process. However, the innovative potential of the Russian pharmaceutical industry is concentrated in the hands of foreign manufacturers, which is a consequence of the country's socio-economic development since the 1990s. It is more important to create a subsystem of enterprise management: the strategic adaptive management of development potential, the creation and use of opportunities for the effective functioning, development, and formation of fundamentally new approaches to methodological tools.

The pharmaceutical industry should be regarded as an integral targeted system of a public-private partnership, whose formation and functioning should involve all participants in the chain of creation of a pharmaceutical product from institutes developing innovative drugs to end users. The strategic development of the pharmaceutical complex will allow the most complete harmonization of the economic interests of the parties associated with its activities.

## 5. CONCLUSION

The case of import substitution in the Russian pharmaceutical industry is rather ambiguous. On the one hand, the Russian pharmaceutical industry is rapidly implementing an import substitution policy, and the state actively supports these activities. On the other hand, the development of the pharmaceutical industry is not connected with the priorities of the healthcare system and other industry development programs. One of the most important conditions for ensuring the effective implementation of the import substitution policy is its consistency with ongoing institutional changes and the subsequent definition of constructs that determine the desired implementation scenario. Without the help of the state, it is impossible to solve



regulatory and legal conflicts, without which the industry will not be able to develop dynamically.

Due to geopolitical instability, only enterprises that manufacture pharmaceutical products according to the full production cycle remain competitive. The local production of pharmaceutical substances is more important for ensuring the proper functioning of the healthcare system than the domestic production of finished products from imported raw materials. For the needs of import substitution, it is necessary to simplify registration procedures, eliminate regulatory barriers, and speed up the procedure for registering medicines.

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