

## Problems and Prospects of the Development of Import Substitution in Pharmaceutical Industry of the Russian Federation

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### Abstract

*At present, an effective system of import substitution represents a primary need of pharmaceutical industry in Russia, as there are a number of key issues requiring urgent solutions in the field of provision of medicine to population. The article proves the directions of the import substitution development in pharmaceutical industry not covered by the federal target program on the issue and scientific works of a number of researchers. The measures proposed in the paper take into account an actual state of the pharmaceutical market. The authors applied modern scientific apparatus and tools, a variety of research methods which include historical, economic, statistical, systematic, analytical and analogue methods, and others.*

**Keywords:** pharmaceutical industry, industrial plants, pharmaceutical production, problems of development, import substitution

### 1. Introduction

The pharmaceutical market is an important sector of economy of the state. This condition is characterized by the level of socio-economic development of the country. To ensure the health and prosperity of the nation, creation of custom pharmaceutical manufacturing sector is extremely important. The Government of the Russian Federation formed a strategy and state program for the future development of the pharmaceutical industry in Russia. As part of the program, a large-scale modernization of pharmaceutical production is planned, which involves conforming to international standards (GMP) [Vyugova, E.L., Meshkov, V.A., 2013; Semenov, A.M., 2014; Koroteev, A.V., 2011]. Currently, the level of Russian pharmaceutical industry is relatively low. Consumer needs in medicines of domestic manufacture are not fully covered. Meanwhile, to ensure national security of the state, the share of domestic products must be at least 30%. Import is a major factor of growth of the pharmaceutical market. Under these circumstances, pharmaceutical industry faces the task to create conditions for the import substitution of pharmaceutical and healthcare products based on advanced technology in accordance with international GMP standards.

Consequently, the problem of import substitution in the Russian pharmaceutical industry is extremely urgent that determined the choice of research topic.

The aim of the research was to examine the process of import substitution in pharmaceutical industry of the Russian Federation, and scientific justification of proposals on improving state support to pharmaceutical companies implementing import substitution projects in the context of economic globalization.

To attain this aim the following tasks had been set:

- To conduct a critical analysis of the current state policy of import substitution in the Russian Federation in the field of pharmaceutical production;
- To analyze and organize the results of domestic research in the field of import substitution in order to identify the most promising directions of development;
- To identify the major methodological and practical problems of formation and implementation of the import substitution policy in the pharmaceutical industry of the Russian Federation;

- To propose measures to stimulate economic and organizational support to the pharmaceutical enterprises that implement projects on production of import-substituting products.

## **2. Materials and Methods of the Research**

Fundamental works of Russian and foreign scientists on theoretical problems of import substitution policy, instruments of its implementation at pharmaceutical enterprises and in companies of other industries, as well as materials on mechanisms of its stimulation developed at the state level, compose methodological and theoretical basis of the research. Such authors as M. Smith, H. Sedlasek and others made a huge contribution to consideration of the import substitution specifics; pharmaceutical market research was introduced in papers of A.M. Biteryakova, T.G. Glembotskaya, M.P. Denisova, V.V. Dorofeeva, N.B. Dremova, E.E. Loskutova, E.A. Maksimkina and others. At the same time, a number of problems of the strategy of import substitution and stimulation of domestic manufacturers in the pharmaceutical industry are not well understood. Among the limited range of works on the subject, the works of A.I. Balashov, M.A. Getman, S.V. Kulagina and I.E. Nilva should be particularly noted.

The paper incorporates modern scientific apparatus and tools, a variety of research methods which include historical, economic, statistical, systematic, analytical and analogue methods, and others. The reason for choosing these methods is the need to achieve the three main principles of scientific knowledge: objectivity, consistency and reproducibility. The whole complex of the abovementioned methods in the present study allows implementing these principles. The economic analysis was based on a study of an array of domestic and foreign scientific literature, including monographs, articles, information and analytical publications of international organizations, as well as statistical information on the Russian pharmaceutical market. The authors examined strategies, concepts and long-term program for the development of pharmaceutical industry, adopted in Russia.

## **3. Results and Discussion**

There are two diametrically opposed views on the future development of import substitution. Thus, economic literature often describes the implementation of import substitution strategies as a catch-up policy [Vjugova, E.L., Meshkov, V.A., 2013]. This policy is typical of the "third world" as based on protectionism and contrary to the free market principle and competition. In this regard, implementation of the import substitution policy leads to stagnation and is not conducive to the production of quality products. Another point of view is based on the fact that import substitution is what contributes to the development of national industries, particularly in the areas of innovative products manufacturing.

Here are the factors defining the prospective of import substitution in pharmaceutical sector of RF: the current level of pharmaceutical production development, quality of products, the existence of potential markets, measures of state support of fair competition and so forth.

In 2014, the volume of medicines production has increased compared to 2013 by 2.4%, and amounted to 185.4 billion rubles. Forty one government contracts for the development of technology and organization of production of vital and essential medicines were executed. New pharmaceutical manufactures were opened: JSC "Berlin-Pharma" plant for the production of drugs used in cardiology, neurology, gastroenterology and other branches of medicine; LLC "FORT" plant producing drugs for the infectious and somatic diseases treatment; a shop for the production of biologically active substances on the territory of technopolis "Generium"; Teva Pharmaceutical Industries plant in Yaroslavl, etc.

However, the pharmaceutical import dependence of Russia is currently a major nationwide problem. Thus, according to "DSM Group" rating agency, the share of imported medicines on the market is 75.2% in monetary terms and 43% in value terms [CJSC "DSM Group", 2013]. At the same time the consumption of ready-made medicines and medical products of Russian production is annually reduced by 1-2 per cent. Only 16.4% of items included into the list of vital and essential drugs, approved by the Decree of the Government of the Russian Federation, are produced by domestic manufacturers, only 36.5% of names are manufactured by foreign producers, while the remaining 47.1% of drugs – by both Russian and foreign pharmaceutical enterprises [Andrianov, V.D., Gorst, M.Y., Toropylin, Y.A., & Shvareva, N.V., 2012].

Development problems of pharmaceutical and medical industry are solved within the framework of federal programs. Although, these programs are generally aimed at knowledge generation and technology development. Some results are of a very high level, not inferior to the world level. Frequently, the results are not in demand because of the lack of effective institutional arrangements for the involvement of scientific research into industrial production. The technological level of the production facilities of the pharmaceutical and medical industry of the Russian Federation does not meet the modern standards of production. All of this leads to domestic producers of medicines being not competitive,

not only in comparison with the world leaders - manufacturers of pharmaceutical products - but also with generic companies.

Thus, despite the positive effect of the implementation of the state policy in the sphere of public health, domestic production of pharmaceutical and medical industry is replaced by the import one. This trend reduces the competitiveness of domestic pharmaceutical and medical industries, and negatively affects the growth of the Russian economy as a whole.

The problem of the development of pharmaceutical industry in the country can possibly be solved on the basis of two approaches. The first approach emphasizes the use of institutional and financial instruments by federal authorities competent in the field of pharmaceutical manufacturing. This solution relates to financial constraints. In addition, a duplication of program activities in the area of concern, the lack of coordination of actions of these bodies and others are likely to occur. The second approach is based on the use of program-target method. This method is characterized by a clear statement of goals and objectives in the problem solution and a reasonable list of activities in this area. The program-target method is expected to overcome the technical backwardness of the Russian pharmaceutical industry and bring it to an innovative path of development. The program-target approach also requires timely financing in planned volume while, in the global political and economic crisis, such a scenario is very unlikely. In this connection, preference is given to program-target method with a specific financing scheme where initial phase of the launch of the innovation cycle is carried out at the expense of the federal budget, and in the future, with the commercialization of results, follow-up research and development will be financed by the pharmaceutical companies themselves.

As part of this approach the Federal target program "Development of the Pharmaceutical and Medical Industry of the Russian Federation for the period up to 2020 and beyond" was developed. Its implementation will allow not only to technically re-equip pharmaceutical enterprises of the country, but also to increase the growth rate of innovation in the field of competitive medicines. As a result, the pharmaceutical industry will be able to compete successfully both on the domestic and foreign pharmaceutical markets.

The basis of the program events includes a mechanism of state-private partnership in the joint financing of research, development and innovation manufacture of pharmaceutical products in Russia.

The trends for development and activities of the program are given in Table 1 [The federal target program, 2010].

**Table 1:** Areas of development and activities of the federal target program "Development of the Pharmaceutical and Medical Industry of the Russian Federation for the period up to 2020 and beyond"

Areas	Activities
1	2
Technical re-equipment of enterprises of the pharmaceutical industry and research capacity improvement	<ul style="list-style-type: none"> <li>renewal, technical re-equipment of pharmaceutical companies producing drugs, turnover of which is restricted by the legislation, as well as some vaccines to meet national security concerns</li> <li>renewal, technical re-equipment, the construction of new production sites that produce medical products;</li> <li>material and technical base improvement of enterprises investigating and developing innovative medicines, medical devices and other medical products.</li> </ul>
Production of strategically important medicines	<ul style="list-style-type: none"> <li>competitive work on conclusion of public contracts for the development of technologies for the production of medicines included in the list of strategically important drugs and the list of vital and essential medicines</li> </ul>
Market promotion of innovative products	<ul style="list-style-type: none"> <li>creation of scientific research resource for the development of innovative pharmaceutical products;</li> <li>development of a mechanism to finance innovative projects in the field of medicines;</li> <li>promotion of the growth of innovative small and medium-sized businesses;</li> <li>export improvement of new medicines</li> </ul>
Staffing for launch of innovative pharmaceutical industry development model	<ul style="list-style-type: none"> <li>creation of research centers for the development of innovative medicines;</li> <li>creation of innovative educational infrastructure;</li> <li>development of new educational programs across the spectrum of medical and pharmaceutical specialties</li> </ul>
Information infrastructure improvement	<ul style="list-style-type: none"> <li>development of a system for predicting and monitoring the development of the pharmaceutical and medical industries;</li> <li>creation of a system to demonstrate the achievements and support to market products of the domestic pharmaceutical and medical industries;</li> <li>scientific, methodological and analytical support for the transition of the pharmaceutical and medical industry to innovative development model</li> </ul>

Therefore, the federal target program reflects the main ways of development of pharmaceutical industry in the country.

Moreover, the topic of import substitution in pharmaceutical industry constantly attracts scientific personnel [Dissertation and abstract scientific library]. Analysis of scientific works of the last decade has allowed establishing an applied nature of work on this issue. The most representative works are presented in Table 2.

**Table 2:** Scientific works on the development of pharmaceutical industry in Russia

Name	Author	Year	Main results
1	2	3	4
Marketing analysis of import substitution strategy realization by Russian pharmaceutical manufacturers	I.E. Nilva	2004	<ul style="list-style-type: none"> <li>– classification features allowing to allocate import-substituting products and develop an information database to assess the import substitution process in the pharmaceutical market of the country, are justified;</li> <li>– rating criteria and methodology for Russian companies in pharmaceutical industry and import substitution implementation strategy are developed</li> </ul>
Improvement of innovation management system in the pharmaceutical industry	E. Yu. Blinova	2010	<ul style="list-style-type: none"> <li>– guidelines for assessing the value of innovative medicines and socio-economic effectiveness of innovation in pharmaceutical industry of the country are developed</li> </ul>
Methodical bases of business activity in the field of import substitution in the pharmaceutical market of Russia	A.V. Koroteev	2011	<ul style="list-style-type: none"> <li>– a rating method for the attractiveness of domestic segment of pharmaceutical market in the field of import substitution is developed</li> </ul>
The policy of import substitution in the development of pharmaceutical industry in Russia	A.M. Semenov	2014	<ul style="list-style-type: none"> <li>– a multi-criteria method for determining product niches for import substitution is proposed;</li> <li>– specific product groups crucial for the production of domestic manufacturers are determined;</li> <li>– government support import-substituting industries in the pharmaceutical industry are offered</li> </ul>

A review of the import substitution program and the research works showed that they cover very important aspects of this process, however, despite that, some problems are not involved in federal programs or researches.

For example, in our view, in terms of training, it is advisable not only to train employees abroad but also to attract foreign specialists (especially with GMP experience), making it a national priority. Pharmaceutical companies should be encouraged to undergo certification to Good Manufacturing Practice (GMP), as its absence is a major barrier to export.

Due to the fact that consumers prefer, when possible, imported pharmaceutical products, then guaranteed domestic pharmaceutical production market channels should be provided. There is also a problem of attracting foreign investment in the pharmaceutical industry.

Beside certainly important production of vital and essential medicines, the production of original drugs, which is now extremely inadequate, must be included in the plans for development.

A pressing problem also appears in constant rise of prices for medicines of domestic production, which requires the development of an effective system of control over price increases.

Material and technical base of pharmaceutical companies today is very worn out. In this regard, it is necessary to take measures for the development of domestic production of technological equipment for the pharmaceutical industry.

Thus, in our opinion, we can formulate the main measures to support domestic enterprises-producers of finished drugs and substances:

1. To provide allowance for producers participating in public procurement competitions.
2. To de-register substances with the simultaneous strengthening of measures for quality control of finished medicines.
3. To encourage domestic production of equipment for the pharmaceutical industry, in particular, to compensate interest on state loans and preferential loans for companies involved in customization of pharmaceutical production with new domestic equipment. The same credit procedure is also necessary to be established for producers of finished drugs and substances that organize production in accordance with GMP standards.
4. To grant the preferences when exporting domestic drugs and substances.
5. To monitor the growth of prices for domestic products, in particular, for a transitional period to the import substitution, the limits may be set on the selling price of all domestic medicines, having developed an appropriate methodology that would take into account interests of both producers and consumers of pharmaceutical products.
6. To attract foreign investments in the country's pharmaceutical industry. To provide guaranteed markets, joint

ventures and attract strategic investors, pharmaceutical manufacturing companies need long-term orders guaranteed by the state and guaranteed return on investment costs for all parties. As a possibility to provide guarantees for innovative projects we can propose long-term «offtake» contracts with producers to purchase drugs, medical products, manufactured in the framework of investment projects or joint ventures.

#### 4. Conclusion

Thus, the analysis of provisions of the federal target program for the development, including the pharmaceutical industry, and a number of scientific papers on the subject revealed that, in general, the main path of development is identified. However, some problems were reflected neither in any policy document nor in numerous applied researches on the issue of import substitution. Therefore, additional measures were formed to support domestic producers of medicines and substances. Proposal formulated in this study may be useful for the executive authorities of the Russian Federation that regulate the development of the pharmaceutical industry and support of domestic producers, as well as managers and specialists of pharmaceutical companies in the market analysis and the development of enterprise development strategies.

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