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Scientific article

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Scientific-industrial cluster opportunities to implement import substitution programs for biotechnology enterprises

Abstract: The article presents an analysis of the main trends in the development of the global and Russian biotechnology market. It is shown that currently one of the key biotechnology areas is biomedicine and biopharmaceuticals. An analysis of Russian foreign economic activity in recent years has led to a conclusion about the significant dependence of some domestic industries on imported products. In particular, the article presents the results of the analysis of equipment and materials procurement by Biocad CJSC, which allowed us to conclude that the domestic biotechnology industry is highly dependent on imported technologies, equipment, and materials. The purpose of the article is to identify ways to improve the effectiveness of import substitution programs in the biotechnology industry. The methodological bases of the research are the methods of industrial economics, theory of innovation and strategic management, as well as methods of system analysis of economic phenomena and processes. The article defines the relationship of concepts in the implementation of import substitution programs. It is also proved that the most important participant in the implementation of projects in the field of import substitution can become scientific and industrial clusters. The possibilities of participation of scientific and industrial clusters in the implementation of import substitution programs in the biotechnology sphere, as well as their role in providing the required level of import independence of domestic biotechnology enterprises are considered.

Keywords: scientific-industrial cluster, biotechnology industry, biotechnology enterprise, import dependence, import substitution, import outstripping.

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Научная статья

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Возможности научно-промышленного кластера при реализации программ по импортозамещению для биотехнологических предприятий

Аннотация: В статье представлен анализ основных тенденций развития мирового и российского рынка биотехнологий. Показано, что в настоящее время одним из ключевых биотехнологических направлений является биомедицина и биофармацевтика. Результаты анализа внешнеэкономической деятельности РФ за последние годы позволили сделать вывод о существенной зависимости отдельных отраслей отечественной промышленности от импортной продукции. В частности, в статье приведены результаты анализа закупок оборудования и материалов ЗАО «БИОКАД», что позволило сделать вывод о высокой степени зависимости отечественной биотехнологической промышленности от импорта технологий, оборудования, материалов. Целью статьи является определение способов повышения эффективности программ по импортозамещению в биотехнологической промышленности. Методологической базой исследования являются методы экономики промышленности, теория инновационного и стратегического менеджмента, а также методы системного анализа экономических явлений и процессов. В статье определена связь понятий при реализации программ импортозамещения. Также доказано, что важнейшим участником реализации проектов в области импортозамещения могут стать научно-промышленные кластеры. Рассмотрены возможности участия научно-промышленных

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кластеров в реализации программ импортозамещения в биотехнологической сфере, а также их роль в обеспечении требуемого уровня импортонезависимости отечественных биотехнологических предприятий.

Ключевые слова: научно-промышленный кластер, биотехнологическая промышленность, биотехнологическое предприятие, импортозависимость, импортонезависимость, импортозамещение, импортоопережение.

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Introduction

Currently, one of the main areas of innovative development of the Russian economy is biotechnology, which provides modernization of industrial enterprises, taking into account new global challenges and priorities, determining the need to solve various kinds of technological problems. The biotechnology sphere has a significant impact on various sectors and fields of knowledge, among which we can mention food production, pharmaceuticals and medicine, genomics and others. High value of biotechnology and biotechnological products is determined primarily by the possibility of their use for solving problems associated with the treatment of various diseases and improving the quality of life in general, protecting the natural environment and ensuring energy conservation. Thus, the development and application of biotechnology and biotechnology products can improve the quality of food, create new types of medicines, obtain new types of biofuels, and form new properties in living organisms, cells and systems in order to use them to solve various practical problems.

Note that according to research by Global Market Insights, the global biotechnology market in 2020 was about \$497 billion (\$399.4 billion in 2017) (Official Website of Global Market Insights. Biotechnology Market Size By Application (Biopharmacy, Bioindustries, Bioservices, Bioagriculture, Bioinformatics), By Technology (Fermentation, Tissue Engineering and Regeneration, PCR Technology, Nanobiotechnology, Chromatography, DNA Sequencing, Cell Based Assay), COVID19 Impact Analysis, Regional Outlook, Application Potential, Competitive Market Share & Forecast, 2021–2027. Available at: <https://www.gminsights.com/industry-analysis/biotechnology-market>) and according to forecast estimates, its average annual growth rate is estimated at 9.4% from 2021 to 2027, and the total volume in 2027 should exceed \$952 billion (ibid.). One of the key biotechnology areas is biomedicine and biopharmaceuticals. By 2027, according to the forecast of Global Market Insights, the biopharmaceutical segment will increase by 9.2%, which may be due, on the one hand, to the growth of diseases and the emergence of new problems affecting health, on the other hand, to increased efficiency and safety of biopharmaceutical products. This leads to an increase in the investment appeal of this sector of the economy, which has a positive impact on the development of innovative processes in the field of biomedicine and biopharmaceuticals (Glazkova, Dulasova, 2018; Dulasova, Rogova, 2012). In particular, investment in the biotechnology sector at the global level exceeded \$13 billion in 2020 (Official Website of Global Market Insights. Available at: <https://www.gminsights.com/industry-analysis/biotechnology-market>). Agilent Technologies, Bio-Rad Laboratories, Perkin-Elmer, Abbott Laboratories, Amgen, Danaher, F. Hoffmann-La Roche, Illumina, Merck, Qiagen, Thermo Fisher Scientific, and others are among the largest international biotechnology companies.

Somewhat different data are provided by the research company Abercade (Review of the biotechnology market in Russia and in the world. Barriers and prospects for development. Available at: <http://biotech2030.ru/wp-content/uploads/2019/09/Orlova-N-V.pdf>), which estimated the global biotechnology market in 2018 at \$0.6 trillion, and determined the share of the Russian Federation at 0.6% according to the research data. According to the data cited by the experts of the above research company, the biotechnology market in Russia is mainly represented by biomedicine and agricultural biotechnology, and it is also characterized by a significant dominance of imports (in 2018 about 82% of the total market volume). Different spheres of the Russian biotechnology market are characterized by different degrees of import dependence. Thus, if in the field of biomedicine from 2015 to 2018 there was a slight reduction in the share

of imports from 78% to 76%, in such sectors as agricultural biotechnology, industrial and food biotechnology, the value of this indicator remained almost unchanged during this period and is currently quite high (85–90%).

The problem of dependence on imported goods and services is quite urgent for domestic enterprises in various industries. Despite the implementation since 2014–2015 of a set of measures related to import substitution in the most important industries, the share of imports in the biotechnology sphere, as well as in other key sectors of the economy, with some positive trends remains quite high. The greatest dependence on imports is observed at enterprises of high-tech types of economic activity.

The analysis of RF foreign economic activity in recent years allows us to speak about the presence of multidirectional tendencies in this sphere. Thus, with a significant reduction in imports as a whole in 2015–2016 (up to \$182 billion). (In 2017–2019, there was an increase to \$244.3bn, and in 2020, primarily due to the introduction of various kinds of economic restrictions and a certain break in logistics chains, imports fell again by 5.2%. However, in the first half of 2021 there was already an increase in imports to the RF by about 29% as compared to the same period of the previous year. At present, Russia's share in world imports is 1.32%. Considering the structure of Russian imports, it should be noted that such category as “machinery and equipment” dominates in it. Whereas in 2020 the proportion of machinery and equipment in total imports was at 47.6% or \$110.3bn (in 2019 – 46.2%), in the first half of 2021 imports of said products increased by 38.9% (including land vehicles – by 69.2%, ships – 4.9 times, industrial, construction and computing equipment – by 26.9% and electrical equipment – by 29.7%). Traditionally in this category of import (“machinery and equipment”) there are such components as electronics, vehicles, household appliances, optics, as well as investment imports, etc. In the total volume of imported machinery and equipment products, a significant share falls precisely on investment imports, which in 2019 accounted for 53.4% of its total volume (\$59.1 billion), and in 2020 – 56.4% (\$61.2 billion). The structure of investment imports, in turn, includes such elements as industrial equipment and computers (whose share in 2020 was 45.5%), electrical equipment (24.8%), motor vehicles (5%), aircraft equipment (11.8%), medical equipment (10%), marine transport (2.6%), etc. There have been no significant changes in the structure of consumer goods imports into the Russian Federation in recent years. However, a slight reduction has affected, for example, pharmaceutical products, the share of which decreased from 15.3% (\$10.4 billion) to 11.9% (\$7.4 billion) from 2019 to 2020, and in the first half of 2021 was 12.5% (\$4.4 billion) (Official site of the Ministry of Economic Development of the Russian Federation. Results of foreign economic activity of the Russian Federation in 2020 and the first half of 2021. Available at: https://www.economy.gov.ru/material/file/abo3f167412ee7cbc60d8caf776bab70/itogi_ved_v_2020g_i_1_polugodie_2021.pdf).

The understanding of the importance of the issues related to reducing the dependence of various industries on supplies of imported equipment, components and materials is reflected both in the definition of the main tasks in the formation of “economic conditions for the development and introduction of modern technologies, stimulation of innovative development”, given in the Decree of the President of the Russian Federation “On the Strategy of economic security of the Russian Federation for the period up to 2030” (Presidential Decree “On the Economic Security Strategy of the Russian Federation for the period up to 2030” № 208 of May 13, 2017. Available at: <https://www.garant.ru/products/ipo/prime/doc/71572608/>) № 208 of May 13, 2017, and in determining the target indicators of the State Program of the Russian Federation “Development of industry and increasing its competitiveness” (Decree of the Government of the Russian Federation of April 15, 2014 № 328 “On the approval of the state program of the Russian Federation “Development of industry and increasing its competitiveness”. Available at: <https://programs.gov.ru/Portal/programs/reportIndicators?gpId=16&year=2019>), as well as the development of action plans for import substitution in various sectors of the economy.

As follows from the data published on the results of the December 10, 2019 meeting of the Government Commission on Import Substitution (Medvedev), as well as the transcript of the annual report of the Government in the State Duma for May 12, 2021 (Annual Report of the Government in the State Duma. Available at: <http://government.ru/news/42158/#mvm>) for the period from 2015 to 2018, more than 1.6 trillion

rubles were allocated for the implementation of the import substitution program in various industries, and in 2021 more than 330 billion rubles are planned to be allocated for this purpose.

However, despite the fact that some planned values of key indicators related to import substitution in accordance with the State Program of the Russian Federation “Industry Development and Improvement of its Competitiveness” were achieved (for example, the actual value of the indicator “the number of manufactured and sold import-substituting means of production” was 840 units in 2019 (the planned value of this indicator – 403 units), the actual value of the indicator “share of import of main technological equipment, e.g., the share of imports of the main technological equipment, e.g., the number of import substituting means of production” was 840 units in 2019 (the planned value of this indicator – 403 units). Thus, one of the industries, for which the need to solve the problems of overcoming import dependence is the most urgent, is the machine-tool industry, characterized by a high share of import in consumption (77% in 2019) (Strategy for the development of the machine tool industry for the period up to 2035 (approved by the Decree of the Government of the Russian Federation from November 5, 2020 № 2869-r). Available at: <http://static.government.ru/media/files/pdf>).

Also, despite the implementation of various measures of state support of import substitution, as already mentioned above, the biotechnology sector of the economy is characterized by a significant degree of dependence on import of technology, equipment and materials. For example, the analysis of the structure of purchases of equipment and materials by CJSC BIOCAD (Official website of BIOCAD. Available at: <https://biocad.ru/>), which is one of the major Russian biotechnology companies whose activities are related to the implementation of the full cycle of creation of drugs intended for therapy of autoimmune, cancer, infectious and other diseases, shows that imported products prevail in almost all categories of purchased materials. In particular, the share of imports in the categories “technological and engineering equipment” is 95%, “laboratory and auxiliary equipment” – 71%, “R&D materials” – 97% (Figure 1).

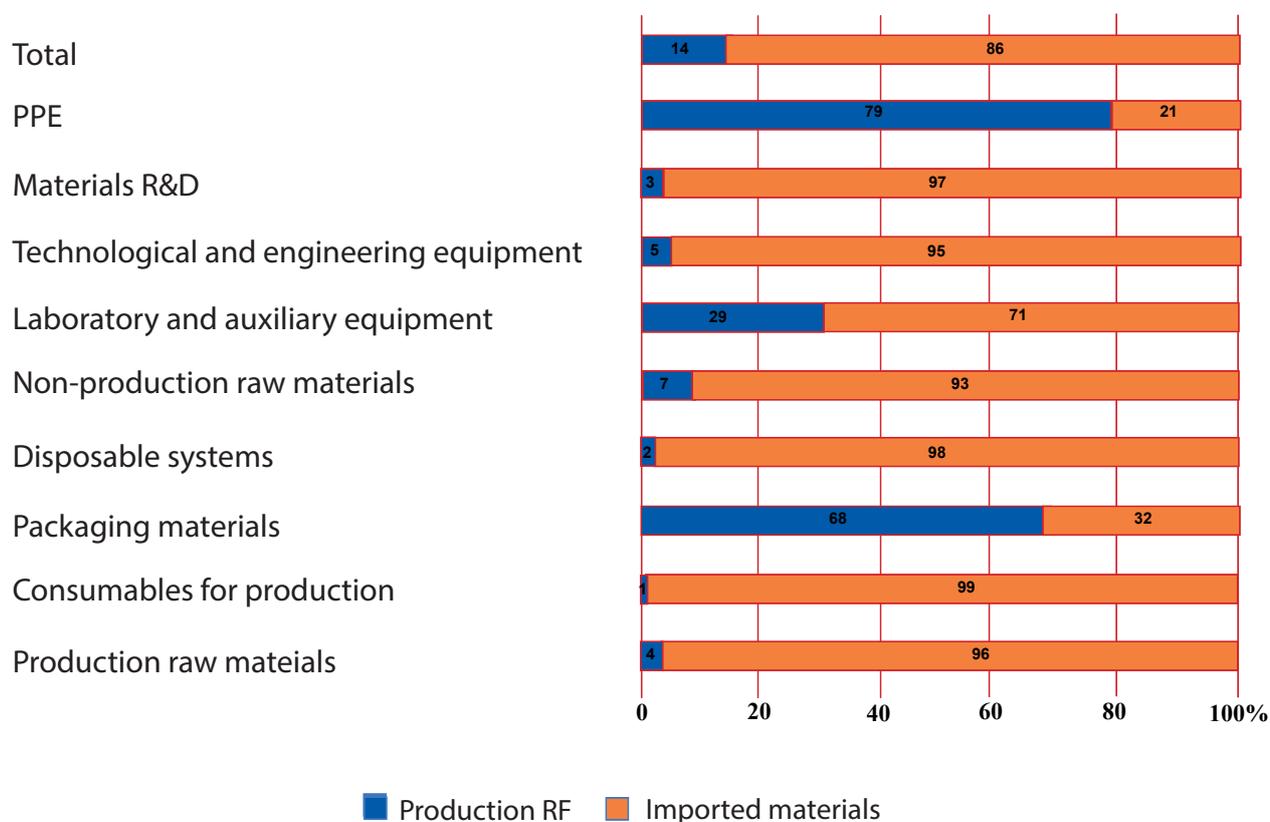


Figure 1 – Distribution of purchases of equipment and materials in Biocad in 2021, %.

Рисунок 1 – Распределение закупок оборудования и материалов в ЗАО «БИОКАД» в 2021 г., %

The problems associated with high dependence on imports, especially in the field of biomedicine and biopharmaceuticals, given the importance of this sector of the economy in terms of its impact on human health and improving the quality of life in general, require the search for effective methods of solution. At the same time, in most cases, individual enterprises cannot overcome these problems on their own. It seems that prompt reduction of the degree of dependence of the domestic biotechnology industry on imported technologies, equipment, materials, as well as increasing the level of its competitiveness is possible through the consolidation of efforts of all participants in the process of creating biotechnology and biotechnology products, which can be implemented through the formation of biotechnology scientific and industrial clusters that will integrate resources of biotechnology industry enterprises and ensure coordination of the adoption of. At the same time, due to the presence of certain difficulties in the transportation of pharmaceutical substances, biotechnological equipment, components and other elements, if the integration of biotech enterprises and partner organizations is ensured, the effect of territorial localization of biotechnology production can be used.

Results

In recent years, Russia has been actively implementing a cluster policy, under which a number of innovative territorial clusters have been created, including in the biotechnology sphere (Zharkov, Patlasov, 2014), and measures have been implemented to support them (Dli, Zaenkovski, Tukaev, 2017). Such biotechnology clusters were created as the “Cluster of Pharmaceuticals, Biotechnology and Biomedicine” (Kaluga Region), “Pushchino Biotechnological Innovative Territorial Cluster” (Moscow Region), “Innovative Cluster of Information and Biopharmaceutical Technologies” (Novosibirsk Region).

However, the existing biotechnology clusters are practically not focused on solving the problems of import substitution. At the same time, to ensure strategic competitive advantages in the biotechnology sector it is necessary to solve the problem not of import substitution, but of import substitution, i.e. to develop and implement domestic technologies and equipment whose characteristics are superior to similar characteristics of foreign analogues. Figure 2 shows the relationship of concepts in the implementation of import substitution programs.

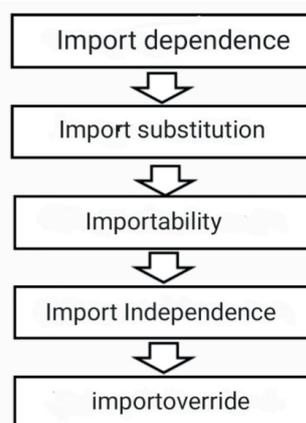


Figure 2 – Relationship of concepts in the implementation of import substitution programs

Рисунок 2 – Связь понятий при реализации программ импортозамещения

The concepts of “import dependence”, “import-independence” and others, presented in Figure 2, are often used in scientific articles and policy documents (Kalinin et al., 2021; Vazhenin et al., Sokolova, Kolotyryn, Skvortsova, 2017). (Order of the Ministry of Industry and Trade of the Russian Federation № 656 of March 31, 2015. “On approval of the sectoral plan of measures for import substitution in the pharmaceutical industry of the Russian Federation”. Available at: <http://base.garant.ru/70937974/>; Action Plan on Import Substitution in the Pharmaceutical Industry of the Russian Federation until 2024. (approved by order of Russian Ministry of Industry and Trade № 2681 of July 20, 2021) Available at: https://minpromtorg.gov.ru/docs/#!plan_meropriyatiy_po_importozameshheniyu_v_farmaceuticheskoy_promyshlennosti_rossiyskoy_federacii_do_2024_goda). Let us consider these concepts in terms of their relationship.

Usually under import dependence we understand the existing or potential threat to the national economic system or its components in the case of a significant change in the terms of supply of imported products. Examples of such changes are not only options of complete cessation of foreign supplies (products, raw materials, materials, technologies, spare parts, etc.), but also increase of terms of delivery and prices for imported products due to a variety of reasons.

It is obvious that in the conditions of globalization and international integration it is impossible and unreasonable to provide complete absence of import dependence. In this connection this concept should be considered from the point of view of the theory of risks, according to which the possible negative consequences from foreign supplies can be estimated as the product of the probability of an unfavorable situation by the possible damage that this situation will cause, for the socio-economic development of the country. In this context, the reduction of import dependence should not be a “global” task of functioning of the economy as a whole – it is necessary to implement only those measures which will reduce (or exclude) the dependence on import of enterprises of key (in terms of various aspects) types of economic activity. In substantiating these measures it is also necessary to take into account:

- risks of organizing the production of domestic counterparts in the country;
- a certain negative impact of imports on the socio-economic indicators of the country’s development in terms of formation of a part of the added value of products used or/and produced abroad.

Import substitution is understood as a process that includes the implementation of a set of measures to reduce the dependence of the economy and social sphere on the risks associated with import supplies. These activities are usually included in the state, sectoral or regional programs on import substitution and involve the impact both on the likelihood of the problem (e.g., the choice of suppliers from friendly countries, the organization of domestic production, the use of analogues, etc.) and the damage from its occurrence (for example, insurance against supply disruption, creation of insurance stocks of products and spare parts, etc.). Obviously, the priority of activities in the field of import substitution is determined by the degree of criticality of the “substituted” foreign products for the implementation of production processes and the importance of these processes for socio-economic development of the country.

The implementation of the import substitution program should make it possible to increase the “import resistance” of industries and the economy as a whole, i.e. to ensure their development along the planned trajectories in conditions of possible challenges under the influence of international factors. As a result, the state and economic entities should have at their disposal the resources and capabilities to prevent critical deviations of socio-economic indicators of the country and individual Subjects of the Russian Federation from the planned targets in case of intentional or objective negative actions of foreign partners. First of all, it is necessary to prevent deviations of indicators that determine the national security of the country.

Import substitution measures in a number of cases are aimed at solving current problems and do not always directly contribute to the technological development of the country based on innovation. To ensure the technological superiority of Russia in the strategic perspective it is advisable in solving import substitution problems to pay special attention to projects aimed at creating competitive technologies and products that are superior in characteristics both to existing and currently developed foreign analogues. This approach, often referred to as “import substitution” (Kalinin et al., 2021; Vazhenin et al., Sokolova, Kolotyryn, Skvortsova, 2017), allows us to concentrate resources on breakthrough solutions and to ensure in the long term for the Russian Federation the so-called “import-independence”, i.e. the property of the country, reflecting the ability, without threats to the main indicators of socio-economic development in the required cases and in a given time, to move from foreign supplies to the organization of the production of domestic products or services of adequate quality.

An example of import substitution in terms of new technologies is the production of a vaccine against coronavirus “Sputnik V” or “Gam-CovID-Vac”, created in the Federal State Budgetary Institution “National Research Center for Epidemiology and Microbiology named after honorary academician N. F. Gamaleya”. The given vaccine, according to researches, is remarkable for high efficiency, low cost of one injection, and also for simple enough logistics and conditions of storage (temperature of storage of a preparation at the level of +2...+8 degrees Celsius) that does not demand essential investments into formation of an infrastructure for its transportation.

It seems that the most important participant in the implementation of projects in the field of import substitution, as mentioned above, can become scientific and industrial clusters.

Figure 3 shows the participation of the scientific-industrial cluster (SIC) in the implementation of import substitution programs, where BTE are biotechnology enterprises.

At present, despite the considerable research and production and technological potential possessed by some biotechnology enterprises (BTEs), it seems quite difficult for them to ensure independence from imports of equipment, components, technology, raw materials and materials on their own. This task is also complicated by the presence of various interconnections with other participants in the development and production of biotechnological products. In this regard, scientific-industrial biotechnology clusters, as a consolidating link in the biotechnology industry, can ensure the coordination and coherence of all biotechnology enterprises and their partners in creating samples of equipment, components, technologies, materials necessary for the production of final biotechnology products and able to replace foreign analogues.

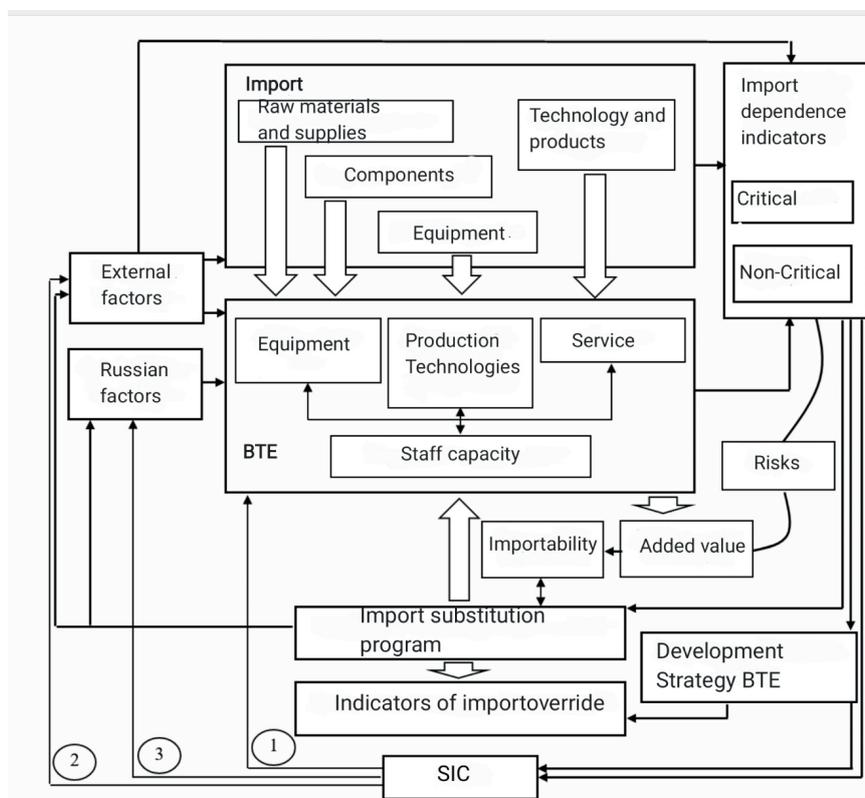


Figure 3 – Participation of scientific-industrial cluster (SIC) in the implementation of import substitution programs

Рисунок 3 – Участие научно-промышленного кластера (НПК) в реализации программ импортозамещения

Analysis and consideration of the characteristics of imported equipment, components and materials, as well as determination of the degree of criticality of their impact on the production and technological processes and characteristics of the final biotechnological products, which can be identified when calculating import dependency indicators and taken into account in the development of industry import substitution programs, will not only make products similar to products of foreign manufacturers, but also surpass it in certain characteristics and ensure technological superiority.

The results of the calculation and analysis of import dependence indicators are advisable to take into account when developing development strategies for biotechnology enterprises as well as scientific-industrial biotechnology clusters, which, on the one hand, will make it possible to increase the efficiency of the realization of the potential of enterprises as well as to determine priority areas of industry development in order to ensure import substitution on relevant positions in the biotechnology sphere.

The figure shows that SICs can support BTEs directly (arrow “1”). For example, the management structures of the cluster can coordinate the processes of innovative technology transfer, equipment maintenance, and the coordination of educational programs of universities and secondary vocational education institutions with biotechnology companies as part of import substitution programs.

Arrow “2” shows that consolidated actions of SIC participants can significantly reduce the negative impact of external factors and realize the emerging opportunities. Such factors include a drop in demand for certain types of biotechnological products, limited access to global markets for modern equipment and technology, etc.

Similarly, the potential of SICs makes it possible to organize extensive interaction with Russian partners (arrow “3”) engaged in various economic activities to ensure the required level of import independence of domestic biotechnology enterprises.

Conclusions

It appears that in order to determine the role and place of each member of the scientific-industrial cluster in the implementation of the import substitution program (and, subsequently, its transformation into an import substitution program) it is necessary to evaluate its contribution to the provision of the integral indicator of import substitution. This indicator can be determined by analogy with the indicators given in (Kokhno, Kokhno, 2021; Kolotov, 2018).

Given that in some cases the dependence of the indicators presented in Figure 3 on external and internal factors affecting the biotech RPC when developing an import substitution program is not formalized enough, it is advisable to use artificial intelligence methods to assess the degree of influence of import substitution program measures on the target indicators (Dli, Bulygina, Sokolov, 2020; Borisov et al, 2020; Glimarov, Dli, Kruglov, 2004; Puchkov, Kireyenkova, 2020; Bulygina, Emelyanov, Yashin, 2020).

Given the high degree of dependence of the domestic biotechnology industry on imported technologies, equipment, and materials, the proposed structure of interaction between the scientific and industrial cluster and biotechnology enterprises in the implementation of import substitution programs will increase the efficiency of these programs through the rational use of the potential of industry enterprises, and in the long term will ensure import substitution on various items in the biotechnology sphere.

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