International Transaction Journal of Engineering, Management, & Applied Sciences & Technologies

http://TuEngr.com

PAPER ID: 10A19O

# DEVELOPMENT FEATURES OF PHARMACEUTICAL INDUSTRY AND ITS ROLE IN SECURING THE FUTURE DEVELOPMENT OF RUSSIAN ECONOMY

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ARTICLEINFO

*Article history*:
Received 29 May 2019
Received in revised form 01 October 2019
Accepted 11 October 2019
Available online 30 October 2019

*Keywords:*
Pharmaceutical industry;
National security,
Medical devices,
Innovative activities,
Medicines, Targeted state programs.

ABSTRACT

The article examines the factors of competitive potential and the risks of the development of the pharmaceutical industry in the modern Russian economy, its impact on the state of national security and the dynamics of the main macroeconomic indicators. The aim of the study is to identify tools to control the sources of competitive advantages of Russian pharmaceutical companies in order to increase their level of competitiveness in the domestic and foreign markets, enhance their innovative activities. The article uses the general scientific and specific methods to analyze the state of the pharmaceutical industry and the pharmaceutical industry as its component. the SWOT analysis identifies the strengths and weaknesses of the internal and external environment of Russian pharmaceutical companies, opportunities and development risks, and also formulate recommendations regarding the directions of strategic development of manufacturers of medicines and medical devices. Particular attention is paid to the analysis of the provisions of the state program "Development of the pharmaceutical and medical industry for 2013-2020" ("Pharma-2020") providing for the implementation of measures of state regulation of the pharmaceutical industry, including measures to stimulate investment and innovation activity, the adjustment of compliance control tools produced standards, the introduction of information and communication technologies in the process of monitoring the promotion of drugs NNYH funds on the market, the formation of integrated structures (pharmaceutical clusters) and innovation infrastructure.

**Disciplinary**: Multidisciplinary (Economic Sciences, State Law & Policy, Pharmaceutical Industrial Management).



## 1. INTRODUCTION

One of the features of the economy of a developed state in the modern world is the increasing importance of the pharmaceutical industry, the state of which largely determines the volume and efficiency of human capital sales, the level of risks of the national security system, and the dynamics of the main indicators of the state of the business sector and the national economy as a whole. The pharmaceutical industry has a significant impact on the direction and pace of innovation

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development, the effectiveness of which is a key factor in the competitiveness of drug manufacturers in the domestic and foreign markets, determines the composition of their key competencies and the dynamics of financial and economic indicators. In turn, the activity of scientific research in this area largely depends on the order of regulation of the processes of creation and commercialization of the results of intellectual activity, protection of rights of legal owners, determined by national legislation.

Pharmaceutical enterprises have a significant impact on aggregate demand, the structure of the market of production factors and final products, as well as the composition of technological infrastructure facilities. At the same time, an increase in the number and change in the age structure of the population, an increase in the proportion of elderly people is a potential source of growth for the pharmaceutical industry. According to expert estimates, in Russia the proportion of people over 60 by 2025 will be 24% (Overview of trends in the global and Russian pharmaceutical market, 2019).

The strategic importance and high rates of development of the pharmaceutical industry, on which cyclical fluctuations in the macroeconomic situation do not have a decisive influence due to inelastic demand for medicines, a strong dependence of health care, certain sectors of engineering, chemical industry, agriculture, biotechnology and other spheres of activity from its state indicate the need for increased attention from the government to numerous organizations that conduct research, develop, produce and implement medicines for the treatment of people and animals, the prevention of various diseases and disorders

The process of developing regulatory measures on the part of public authorities is complicated by the fact that producers and sellers are national and international organizations whose activities are governed by international and national legislation defining requirements for the development, patenting, standardization and certification of medicines and their promotion to the market. At the same time, public organizations and civil society have a significant impact on the activities of drug manufacturers.

The development of control measures for manufacturers to stimulate their innovative activity aimed at developing and producing medicines with improved therapeutic effects and minimal side effects requires an objective assessment of the state and development trends of the Russian pharmaceutical industry, taking into account the peculiarities of factors of the internal and external environment of manufacturers, and also high social significance of this type of activity, its high profitability and dynamism. This determines the choice of the research topic, its theoretical and practical significance.

## 2. METHOD

The theoretical basis of the research is the theory of management, the theory of state regulation of the economy, the concept of strategic planning, etc. To confirm the working hypothesis of the study, the system analysis method and elements of the structural-functional approach were used to identify the sources of sustainable development of the pharmaceutical industry in conjunction with the directions and dynamics main macroeconomic indicators, as well as general scientific and special methods, including ode content analysis and comparative analysis SWOT-analysis and others.

The information base of the research is made up of information from the official federal bodies of state statistics of the Russian Federation and foreign countries, the Ministry of Economic Development of the Russian Federation, the Ministry of Industry and Trade of the Russian

Federation, and also data from international consulting organizations.

The paper uses the provisions of the Federal Target Program "Development of the pharmaceutical and medical industry of the Russian Federation for the period up to 2020 and beyond", approved by the Decree of the Government of the Russian Federation of February 17, 2011 No. 91 (expired on January 1, 2018) (Decree of the Government of the Russian Federation of February 17, 2011) the state program "Development of the pharmaceutical and medical industry for 2013–2020" ("Pharma-2020"), approved by Decree of the Government of the Russian Federation of April 15, 2014 N 305 (Decree of the Government of the Russian Federation of April 15, 2014).

## 3. RESULTS AND DISCUSSION

Understanding the importance of the pharmaceutical industry in the development of the modern economy and the need to develop control measures adapted to the peculiarities of its operation has led to the emergence of many studies, among which there are Russian works (Avrutskaya, 2015; Balashov, 2016; Vorobyova, 2017; Mamedyarov, 2016; Tretyakova, 2015; Kholn, 2017; Shilova, 2018 and others) and foreign (Roy, 2011; Kaplan, 2017; Scherer, 2010) Authors. The marketing agency DSM Group regularly analyzes the state of the Russian pharmaceutical market, which is followed by monthly analytical reviews.

Significant innovation potential, high technology determines the high rates of development of the pharmaceutical industry, which is accompanied by changes in the placement of assets in the economic space, the emergence of integrated entities (pharmaceutical clusters), acquiring the status of independent subjects of the international and national drug markets, the emergence of new segments in its structure, formation of qualitatively new technologies and tools for managing production and promotion of products, etc. In this connection, it is necessary to conduct further research on the development trends of the pharmaceutical industry in order to enhance the positive influence of its subjects on the state and dynamics of the main macroeconomic indicators, as well as the formation of practical recommendations for government bodies entrusted with the authority to regulate this sector of the Russian economy.

## 4. DYNAMICS OF THE RUSSIAN PHARMACEUTICAL MARKET

The pharmaceutical market in the modern Russian economy consists of two segments - commercial, or pharmacy, and the public procurement segment. The commercial segment includes the sale of drugs through the pharmacy chain for personal consumption, the public procurement segment includes the purchase of medicines by the Ministry of Health of the Russian Federation, regional departments and hospitals for privileged categories of patients. According to the Russian media holding Rosbiznesconsulting (RBC), "the share of the public sector of drugs in 2018 compared with 2017 decreased from 444 billion to 432 billion rubles, while the share of the commercial increased from 949 billion to 992 billion rubles. and has reached its maximum value in recent years - 69.7% of the total market " (Zvezdina & Grosheva, 2019). "Over the past five years, the growth of the pharmaceutical market has slowed six times. In 2018, its volume reached 1.7 trillion rubles, an increase of only 1.8% over last year, according to the calculations of the analytical company DSM Group. The year before, the market grew by 8.2%, and in five years it grew by about 16% annually "

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(Zvezdina & Grosheva, 2019). Dynamics of the Russian pharmaceutical market in the period from 2012 to 2018 reflected in fig. one.

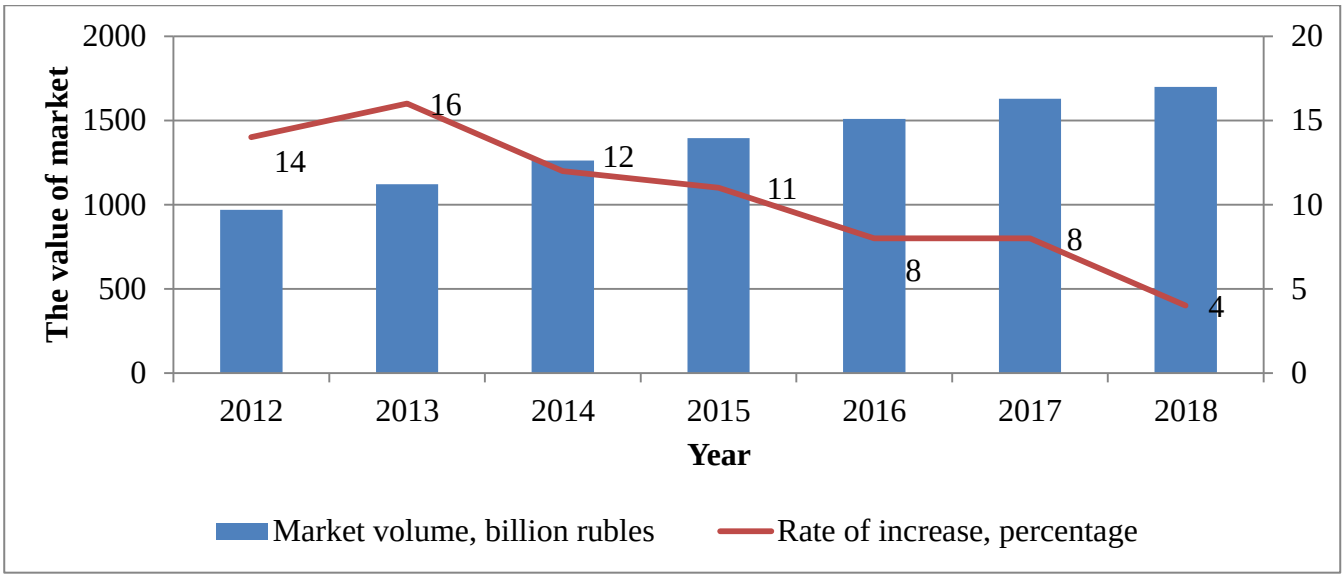


**Figure 1**: Dynamics of the Russian pharmaceutical market, 2012-2018 [ten]

The analysis of the presented indicators and their dynamics indicates that the increase in the market volume in nominal terms is explained by the inflation in Russia. In real terms, there is a negative trend prevailing in previous years, which indicates a slight increase in sales of medicines, which grew in physical terms by 1.5 percent. and amounted to 6.4 billion packs. The decrease in the share of OTC drugs and the growth of the market due to two price segments - “up to 50 rubles” and “over 500 rubles” represent two key market trends, which reflects the differentiation of consumer income (Pharmaceutical market of Russia: 2018).

The key factors hindering the growth of the Russian pharmaceutical market at the moment are: the fall in real incomes of the population, the lack of growth in budget expenditures on public procurement.

One of the significant shortcomings of the Russian pharmaceutical market is a significant proportion of imported products, which is a risk-forming factor for the national security system. This predetermined the need to develop and adopt the federal target program “Development of the pharmaceutical and medical industry of the Russian Federation for the period up to 2020 and beyond” (FTP “Pharma-2020”), which is part of the state program “Development of the pharmaceutical and medical industry for 2013–2020 years. " Funding amounts in accordance with the above programs are presented in Table 1.

**Table 1.** Funding volumes in accordance with the state program "Development of the pharmaceutical and medical industry for 2013-2020", mln. Rub (Pharmaceutical market of Russia: 2018).

| Directions of financing | Years | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019* | 2020* |
| Total funding | 15177 | 14654 | 16599 | 16330 | 11636 | 11220 | 11292 | 11278 |
| Development of | - | - | - | 5199 | 2244 | 7751 | 7896 | 7899 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| medicaments production | | | | | | | | |
| Development of medical device production | - | - | - | 1751 | 2246 | 3127 | 3129 | 3129 |
| Integrated development of the pharmaceutical and medical industries | - | - | - | - | - | 342 | 267 | 260 |
| The federal target program "Pharma - 2020" | 15177 | 14654 | 16599 | 9380 | 7146 | Completed early 31.12.2017 г. | | |

* forecast

During the period of implementation of the programs, the share of Russian drugs increased from 20 to 30 percent. market, which amounted to 295 billion rubles, while the market volume increased to 1.246 trillion rubles. In the list of essential drugs (VED), in 2018, domestic drugs accounted for 81.1 percent, while their share in government procurement is gradually increasing. The most significant indicators take place in the segments “7 high-cost nosologies” (in terms of money, 36.65 percent versus 10.2 percent in 2012), oncological diseases (32.94 percent versus 12.22 percent in 2012) , drugs for the treatment of HIV (29.66 percent. vs. 9.91 percent. in 2012) (From import to export, 2018). At the same time, it should be noted that according to the report of the Accounts Chamber of the Russian Federation on budget execution, in 2018, 62.9% of the planned expenditures were executed under this state program, which is the smallest indicator among all state programs. This government program should be replaced by the Pharma-2030 strategy, the draft of which was presented in 2018 by the Ministry of Industry and Trade of the Russian Federation, but was not adopted, since a number of its key provisions became objects of criticism. As the key areas for the development of the pharmaceutical industry, the project envisages an increase in the level of innovativeness of manufacturers with the support of states, as well as an increase in the export volume of Russian medicines by 2030 by 5 times, an increase in the production of medical products, which should replace imported products for all critical items.

In addition to the global development trends inherent in the Russian pharmaceutical industry, the dynamics of its indicators are determined by a number of specific factors, including changes in the regulatory framework. In 2019, a new method of determining the price of drugs from the list of vital and essential drugs (VED) is introduced, while the list of countries for determining the reference price is expanded to include an additional 12 countries, which, along with the mandatory re-registration of drugs from this list should lead to lower prices. At the same time, the opposite trend in the price level is being implemented, which is due to the introduction of mandatory labeling of all drugs from January 1, 2020, which will lead to an increase in production costs. The adoption of a law regulating the distant sale of non-prescription drugs will result in an outflow of buyers from the retail market of drugs to the online space, which is a necessary prerequisite for companies to use information and communication technologies more widely and change marketing strategies. According to expert estimates, a decrease in the share of OTC drugs in favor of prescription drugs and a decrease in the share of generics in favor of original drugs is predicted, which is a result of the trend towards an increase in the share of innovative and original drugs in 2018. Such a trend is a form of realization of a high level of innovative activity of leading manufacturers.

The peculiarity of the Russian pharmaceutical market is the composition of factors of investment

attractiveness of manufacturers, among which an important role is played by preferences for participation in government procurement and manufacturers' tenders that have their own or joint production with national companies in the Russian Federation. According to the Ministry of Industry and Trade of the Russian Federation, in the period from 2011 to 2017. private and public investments in the pharmaceutical industry exceeded 150 billion rubles, which led to the opening of 30 production sites, as well as ensure in 2013-2016. high rates of growth in the production of medicines and medical devices (Digitalization strategy as a way to organize interaction with end users, 2018). According to expert estimates, companies specializing in the production of medicines for such therapeutic sectors as diabetes, oncology, thrombotic diseases, blood fibrinolytic activity, etc., have the greatest investment attractiveness. Investment in the development of new drug promotion programs as a unique value proposition is expected interaction with consumers based on the use of information and communication technologies That is the source of formation of competitive advantages in the domestic and global markets.

A SWOT analysis of the Russian pharmaceutical industry shows that its strengths are: the presence of state support and budget financing of state programs; implementation of import substitution strategy; high profitability of enterprises, which largely neutralizes the cost of inflation; the presence of highly qualified personnel, which is determined by the system of training specialists by educational organizations. As weaknesses it should be noted: the orientation of domestic companies to the production of generic pharmaceutical products (generics), due to the need for significant investment in the development of new and effective medicines, problems of compliance of domestic products to GMP standards (Good Manufacturing Practice - good manufacturing practice), and also the considerable duration of such investment projects in the presence of high competition with foreign manufacturers; low level of innovation; dependence on imports of primary substances.

The possibilities of domestic pharmaceuticals are: increasing life expectancy and the proportion of older people in the population structure; development of cooperation with the participation of foreign manufacturers; expired drug substitution options. Among the risks to the operation of the pharmaceutical industry enterprises are the following: the structure of domestic demand, in which the demand for low-performing, obsolete cheap drugs prevails; the specifics of the compulsory health insurance system, which does not provide for reimbursement of expenses for the purchase of medicines; relatively low (compared to world levels) level of drug consumption per capita; the intensification of competition with foreign manufacturers; the prevalence of counterfeit products.

## 5. CONCLUSIONS

The identified risks of the development of the pharmaceutical industry pose threats to the effective functioning of the national security system of the Russian state and are an obstacle to the realization of the trajectory of sustainable economic development. In this regard, it seems necessary to comprehensively study the experience of the functioning of foreign pharmaceutical companies in order to use it to develop a development strategy in the face of growing uncertainty of the external environment and macroeconomic instability Increased competitiveness determines the growing role of investment in basic and applied research, without which there is no possibility of accumulating and realizing the innovative potential. In this regard, it is necessary to determine the strategic guidelines for the development of the pharmaceutical industry within the framework of state programs at the

federal level and to develop tools for their implementation in conjunction with the rationale for the drug doctrine of Russia.

The condition for the implementation of the strategic goals of the pharmaceutical industry development is the formation of an appropriate institutional environment that ensures the creation and commercialization of intellectual property. Creation of innovation infrastructure facilities (business incubators, databases, etc.) and integrated entities (pharmaceutical clusters) with the participation of the state, business structures, research and educational organizations is a prerequisite for the initiation and dissemination of open innovation, the use of public-private partnership tools, the realization of the potential of contradictory relations of cooperation and competition. Special investment contracts, concessional and leasing loans act as instruments of state support for the pharmaceutical industry.

The study allows us to conclude that there is a significant competitive potential accumulated by manufacturers of drugs and medical devices. Realization of competitive potential will ensure increased availability of highly effective innovative medicines for the population and increase the level of security of the Russian state.

## 6. DATA AND MATERIALS AVAILABILITY

Relevant information is available by contacting the corresponding author.

## 7. ACKNOWLEDGEMENT

The work is performed according to the Russian Government Program of Competitive Growth of Kazan Federal University.

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