

MAIN STATE INDUSTRIAL POLICY MEASURES FOR THE PHARMACEUTICAL INDUSTRY OF THE RUSSIAN FEDERATION

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Due to the changes in the modern world, it is necessary to develop the domestic pharmaceutical industry, which is a task especially important in the context of implementation of the import substitution policy. The article classifies the main measures the state industrial policy has for the pharmaceutical industry; these measures cover informational and consulting aspects, research and technical parts, innovations and economic matters. Practical actions and their possible consequences are considered for each group of the industrial policy measures: encouragement of domestic consumption, regulation of imports, stimulation and support of exports, stimulation of technological development, public-private partnerships, support of the development of intersectoral territorial production complexes (clusters), direct state support of investment activities, tax incentives for investors.

Keywords: pharmaceutical industry, competition support, industrial policy, innovation, consumer welfare.

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ОСНОВНЫЕ МЕРЫ ГОСУДАРСТВЕННОЙ ПРОМЫШЛЕННОЙ ПОЛИТИКИ В ФАРМАЦЕВТИЧЕСКОЙ ОТРАСЛИ РОССИЙСКОЙ ФЕДЕРАЦИИ

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Ввиду изменений в современном мире необходимо развитие отечественной фармацевтической отрасли, что особенно актуально при проведении политики импортозамещения. В работе классифицированы основные меры промышленной политики государства в фармацевтической отрасли: информационно-консультационные, научно-технические, инновационные и экономические. Для каждой группы мер промышленной политики рассмотрены практические действия и их возможные последствия: стимулирование внутреннего потребления, регулирование импорта, стимулирование и поддержка экспорта, стимулирование технологического развития, государственно-частное партнерство, поддержка развития межотраслевых территориально-производственных комплексов (кластеров), прямая государственная поддержка инвестиций, налоговые инвестиционные стимулы.

Ключевые слова: фармацевтическая отрасль, поддержка конкуренции, промышленная политика, инновации, благосостояние потребителя

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Russian Pharmaceutical Industry

Pharmaceutical companies have always found production of drugs an investment appealing sector of the Russian economy, since Russian market is one of the largest markets for medicines worldwide and it continues to grow. June 2021 through June 2022, the size of the commercial drugs market of the country was about 1.3 trillion rubles. In rubles, it has increased by 29.2% first six months of 2022 over first six months of 2021 [1]. Pharmaceutical industry is strategically important: health of the population hinges on timely provision of high-quality drugs and cannot be critically dependent on imports. Over the past 9 years, 62 integrated pharmaceutical production complexes have been opened in Russia and 16 factories launched; there are over 500 pharmaceutical companies currently in business that stably produce drugs with sanctions in the background, but this is not enough to foster competition, it is necessary to pursue an industrial policy aimed at developing the pharmaceutical market [2]. In Russia, foreign companies, such as OTCPharm, Bayer, Stada, GlaxoSmithKline, Sanofi, remain the leading players, and they specialize not only in sales

and promotion but also in the development and production of pharmaceuticals [3].

Given the current political and epidemiological conditions and the fact that foreign pharmaceutical companies are superior to their Russian national counterparts, it can be said that industrial policy is an important practical tool for the Russian economy. During the initial adaptation, import substitution efforts proved to be insufficiently effective and rather costly [4].

This article defines the industrial policy measures that have to do with informational and consulting aspects, research and technical parts, innovations and economic factors.

Industrial policy measures

The industrial policy measures being implemented in Russia (and within its pharmaceutical industry in particular) were developed with the current political and epidemiological circumstances in mind (see Table) [5, 6].

In addition to the above industrial policy measures, it is necessary to pursue a staffing policy, since economic sustainability of pharmaceutical companies depends on

Table. Industrial policy measures and tools of state support. (According to: Kalinin A. Developing a balanced industrial policy: structuring goals, objectives, tools. Questions of Economics. 2012; (4): 132–146.)

#	Industrial policy measures	Tools of state support
1	Encouragement of consumption of domestic drugs	State purchasing of products from domestic producers
2	Regulation of drug imports	Non-tariff regulation of imports, technological barriers
3	Drug exports stimulation and support	Tax incentives for the exports, simplified customs procedures
4	Stimulation of technological development	Provision of resources to support innovations and technological development
5	Public private partnerships	Joint ventures
6	Support of development of intersectoral territorial production complexes (clusters)	Organizational and financial support of organization and development of clusters Organization of cooperation between educational and research institutions, producers and industry bodies
7	Direct support of investments by the government	Interest rate or cost subsidies, milder deposit requirements, other preferences
8	Tax incentives for investments	Privileges

competitive human resources. Their skills, professional training and qualifications ensure improvement of the production efficiency. The demand for highly qualified personnel has long exceeded supply thereof, and the labor market has been seeing a significant shortage of the respective labor resources [7].

Regulations allow sales of drugs in foreign packaging in the Russian Federation until December 31, 2023, subject to the availability of labeling in Russian [8]. In addition, drug suppliers are required to give a 6-month advance notice of their plans to leave the pharmaceutical market [9].

Stimulation of domestic consumption was analyzed in one of the studies investigating group buying of medicines in low- and middle-income countries [10]. The authors of that study looked into the structure of pharmaceutical markets in India (Kerala state), the Philippines, Senegal, Serbia, South Africa (states of KwaZulu-Natal, Northern, Western and Eastern Capes), Tunisia and Zambia. The data covered purchases of 40 drugs from 16 therapeutic areas (most of them — generics) made in 2015 through 2017. The results of the study allowed identification of two consistent patterns. First, the increased demand for drugs produced in low- and middle-income regions reinforces the position of their producers as awardees of the public procurement contracts. Secondly, centralized buying means purchasing of large amounts, which, for governments, translates into volume discounts. Thus, centralized bulk orders of pharmaceuticals in the public sector drive the prices down [10]. It is possible to stimulate national consumption of domestically produced drugs under the following conditions: population of the country has access to all necessary drugs; producers have sufficient capacities and human resources; and supporting them does not cause critical damage to the economy as a whole.

Otherwise, reducing the prices requires regulation of imports of drugs. For example, in the US, purchases of prescription drugs account for 10% of the total healthcare spending: in 2016, the prescription drug sales there amounted to over \$448 billion. A study by the Kaiser Family Foundation established that in 2019, the average spending by Medicare beneficiaries on various hematologic drugs was as follows: venetoclax — \$8712/year, imatinib — \$8983/year, acalabrutinib — \$10,175/year, midostaurin — \$11,830/year, lenalidomide — \$14,461/year. Both consumers and policy makers have underscored the significant differences in cost of drugs in the US and other industrialized countries. Many of these drugs are new, there are yet no generics and biosimilar medicines that could put pressure on their prices. In order to drive the said consumer prices down, it was proposed to allow additional large-scale imports of drugs

from the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, EU member states and member states of the European Economic Area [11].

In Europe, the US and other countries with strict patent laws, competing producers are not allowed to produce generic drugs or biosimilar medicines even if they are made only for export to a country where the respective patents are invalid, have been obtained or have expired. This situation encourages producers of generics to systematically grow their capacities in potential export markets and not in Europe or the US, while the patents still have to expire. European market is expected to gain from non-renewal of patents in other countries, the respective benefits taking the form of additional exports worth about \$1 billion per year and about 25000 new jobs [12]. In Russia, holder of a pharmaceutical patent is protected legally as per the international standards. However, in some cases, patent law conflicts such factors as the security of the state, protection of life and health of the citizens, public welfare and technological progress. In this connection, the state implements mechanisms to regulate such conflicts, such as limitation of effect of the patent law in the form of compulsory licensing [13].

In recent years, as part of implementation of the European Union's industrial policy there was established a public-private partnership called Innovative Medicines Initiative (IMI), which seeks to actively develop innovative drugs. The objectives of IMI are to accelerate the development of more effective and safer drugs by designing reliable and validated study patterns, to eliminate the poorly predictable preclinical models, to develop new biomarkers and drug targets and to create tools and methods enabling prediction of adverse reactions to drugs. With around €5 billion in funding, IMI can boost drug development in Europe by 2024. Currently, the initiative supports 86 consortiums comprised of 593 research groups that are members of the European Federation of Pharmaceutical Industries and Associations (EFPIA), as well as 1214 academic partnership groups and 249 other partnership groups. IMI is engaged in all types of pharmaceutical research, including development of biomarkers, drugs against infectious diseases and diseases of the central nervous system [14].

In Russia, pharmaceutical clusters have been created since 2010 as part of implementation of the industrial policy [15]. One of the main exporters working with the Kaluga pharmaceutical cluster is Liston, a vendor that supplies medical products to 35 countries and operates in more than 50 countries. The cluster also cooperates with Eurobiomed, Bavaria and MediconValley. The export revenue of residents of the Kaluga region's pharmaceutical, biotechnological and biomedical cluster

is expected to double by 2024 and amount to \$160 million while employing 11.3 thousand people, but the real foreign policy situation may adjust the estimated export figures: the trade with the European and American companies shrinks and new trade relations between Russia and countries of the East and South Asia evolve [16, 17]. Therefore, it is important to mention the Chinese and Korean experience of implementation of the industrial policy measures. Some of the key measures in China are beneficial lending, tax cuts, subsidies and relaxed requirements for companies wishing to enter the market. The industrial policy can improve the efficiency of resource allocation and promote industrial development [18]. South Korea has adopted the Western model of industrial policy measures, which include, for example, barriers to imports [19].

Seeking to stimulate research and development of the new drugs, the government of the Russian Federation will provide subsidies to pharmaceutical companies. There are two main subsidies allocation strategies: subsidies for innovative resources and subsidies for innovative products. For companies, subsidies mean better profits, and for the state — stimulation of innovations by the companies and improvement of the social welfare [20].

There are also tax incentives supporting investments into the pharmaceutical industry in Russia. For example, the

government of Moscow issued a decree that decreases the income tax from 20 to 16.5% for pharmaceutical facilities that received the status of an industrial pharmaceutical production complex. These support measures ensure creation of highly paid jobs and the further development of industrial production [21].

CONCLUSION

In today's difficult economic and foreign policy conditions, additional analysis and implementation of industrial policy measures enable expansion of the possibilities available to the domestic pharmaceutical production facilities. From the perspectives of both the pharmaceutical companies and the state, the most appealing industrial policy measures are those design to support of development of intersectoral territorial production complexes (clusters), stimulate and support exports. Organization of pharmaceutical clusters translated into new cooperation ties with 35 countries and the possible creation of 11.3 thousand jobs. Exports to the Southeastern part of the globe, China, Republic of Korea, will support expansion of the production capacities of domestic pharmaceutical companies. Implementation of comprehensive industrial policy measures enable creation of the best prerequisites for development of the pharmaceutical industry, which is socially significant.

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