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STATE REGULATION OF PHARMACEUTICAL ACTIVITIES OF THE REPUBLIC OF UZBEKISTAN

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ABSTRACT

The article discusses the state regulation of pharmaceutical activities in the Republic of Uzbekistan. Pharmaceuticals are considered high-tech and science-intensive production processes due to the fact that it is the level of provision of the population with medicines that is the main indicator of the social development of society. The regulatory framework, state support and development prospects of the domestic pharmaceutical industry are analyzed, and state programs aimed at the development of this industry in the country are considered. The main factors that hinder the production of efficient and safe pharmaceutical products that are competitive in the external and internal markets are highlighted.

KEYWORDS: *Government Regulation, Pharmaceutical Activities, National Economy, Government Support, Government Programs, Government Control, International Standards.*

INTRODUCTION

The pharmaceutical market is a rapidly growing sector of the global economy. The market has grown significantly over the past two decades, with global revenue of $1.27 trillion in 2020.

Pharmaceutics is considered to be a high-tech and science-intensive production process due to the fact that it is the level of provision of the population with medicines that is the main indicator of the social development of society and an indicator of well-being. Based on the high social significance of the pharmaceutical market, both throughout the world and in the country, pharmaceutical activities are controlled and regulated by the state.

State regulation is defined as “the impact of the state, represented by state bodies, on economic objects and processes and the persons participating in them. State regulation is carried out in order to give processes an organized character, streamline the actions of economic entities, ensure compliance with laws, state and public interests” **[1].**

Due to the specifics of the industry, the state should act here as a key institution, which has a serious managerial responsibility for its effective functioning in the interests of consumers. Ensuring the safety of medicines, effectively controlling the volume and quality of spending on medicines, maintaining incentives for research and development, and ensuring a constant flow of new innovative drugs to the market are the main directions of state regulation.

LITERATURE REVIEW

The definition of state regulation of the economy and the evaluation of its effectiveness were carried out by such scientists as A. Smith, F. Hayek, M. Friedman, V. Oyken, E. Lindal, G. Myrdal, J. Keynes, A. Pigou, J. Gelbraith, R. Lucas and others.

So, according to the Austrian economist F.A. Hayek, the state should only play the role of a "night

watchman" without interfering in economic processes. Together with F. Hayek [**2]**, the neoclassical economist M. Friedman **[3]** develops the ideas of economic neoliberalism in relation to the conditions of the second half of the 20th - early 21st centuries. In their opinion, the state should not only support, but create the conditions necessary for the effective functioning of the market and entrepreneurship. They consider the main conditions to be the protection of law and order, the protection of property rights, the cultivation and protection of competition, a healthy, non-inflationary monetary circulation, and a tax policy that stimulates entrepreneurship. The economy is considered by them as an equilibrium and relatively harmonious system that leads to the well-being of society, and any state intervention in the actions of market forces causes them great damage.

According to A. Smith, the absence of government intervention is the optimal mode of functioning of a market economic system. His ideas of economic liberalism were first fully substantiated in the "Study on the Nature and Causes of the Wealth of Nations". He argued that the best option for the state is to adhere to a laissez-faire policy. **[4]**

The German scientist Walter Eucken (1891-1950) argued that the state should not be allowed to plan and regulate the economic process, but at the same time it is necessary for the formation of elements of the economic order. The word "order" he denoted generally recognized legal and economic norms, phenomena and conditions. **[5]**

J.M. Keynes in his book "The General Theory of Employment, Interest and Money" he revealed the reasons for the limited, reduced effectiveness of the mechanism of free competition and the deepest crisis of overproduction in 1929-1933, proving the objective need for the stateization of an unbalanced economy. In his main scientific work, John. Keynes proceeded from the fact that the free market system is devoid of an internal mechanism that ensures macroeconomic equilibrium. **[6]**

The research methodology includes a quantitative and qualitative assessment of the state regulation of the pharmaceutical industry, the identification and analysis of factors influencing research activities in the pharmaceutical industry of the republic.

MAIN PART

After gaining independence, large-scale reforms were carried out in the republic in all sectors and sectors of the economy. These changes also affected the pharmaceutical industry. During the first years of independence, a solid legal and regulatory framework was developed for the sustainable and dynamic development of pharmaceutical activities. In 1993, the state-joint-stock concern "Uzpharmprom" was formed in the republic. **[7]** The main objectives of the concern were the following:

- Organization of development and production of drugs, implementation of measures to meet the needs of the population, medical institutions in medicines, biological products, other medical and sanitary-hygienic products;
- Interaction with republican and local government authorities and administration on issues of complex development of the pharmaceutical industry, improvement of the territorial location of enterprises in this industry, environmental policy;
- Implementation, together with the Ministry of Health, other ministries and departments, of a unified scientific and technical policy in the field of creating medicines and technologies for their production;
- Development and consistent implementation of a program to reduce the import of medicines by increasing their own production, improving and expanding scientific, technical and economic cooperation with foreign partners.

State regulation of the pharmaceutical market is implemented through the adoption of laws and regulations that establish norms and rules in the field of drug circulation, as well as through state supervision and control over their implementation. In order to effectively operate pharmaceutical activities and provide the population of the country with high-quality medicines and medical products, the following legislative acts regulating pharmaceutical activities in the republic were adopted:

1. Law of the Republic of Uzbekistan "On Certification of Products and Services" (December 28, 1993)
2. Law of the Republic of Uzbekistan "On Protection of Consumer Rights" (April 26, 1996)
3. Law of the Republic of Uzbekistan "On Standardization" (August 29, 1996)
4. Law of the Republic of Uzbekistan "On Metrology" (August 29, 1996)
5. Law of the Republic of Uzbekistan "On the protection of the health of citizens" (August 29, 1996)
6. Law of the Republic of Uzbekistan "On Medicines and Pharmaceutical Activities" (April 25, 1997)
7. Law of the Republic of Uzbekistan "On Advertising" (December 25, 1998)
8. Law of the Republic of Uzbekistan "On Narcotic Drugs and Psychotropic Substances" (August 19, 1999)
9. Law of the Republic of Uzbekistan "On Licensing Certain Types of Activities" (May 25, 2000)

The Government of the Republic of Uzbekistan considers healthcare as an integral part of the national development program aimed at creating a society where all citizens lead a healthy lifestyle. Medicines are an important element in the prevention, diagnosis and treatment of diseases, and therefore providing the population with safe and effective medicines is one of the important tasks of public health. In this regard, on May 30, 1999, the national drug policy of the Republic of Uzbekistan was approved. The main goal of which is: ensuring the availability of effective, high-quality and safe medicines for the population, their rational prescription and proper use. The main objectives of the state drug policy are as follows: **[8]**

- ❖ Ensuring the availability of effective, high-quality and safe medicines for the population;
- ❖ Creation of a unified state system for quality control and registration of medicines;
- ❖ Development of the domestic pharmaceutical industry, creation of jobs in the pharmaceutical sector;
- ❖ Ensuring the rational use of medicines;
- ❖ Improving the professional training of pharmaceutical personnel.

Modernization of the pharmaceutical industry is one of the priorities in the country. Reforming the pharmaceutical industry is designed to help ensure the country's drug safety, modernize the pharmaceutical sector, create new science-intensive and high-tech industries, increase the export of pharmaceutical goods and services, stimulate advanced scientific and technological developments and minimize dependence on foreign markets. In this regard, the regulatory and legal framework is constantly being improved, in the period 2017-2021. 44 documents aimed at reforming the pharmaceutical sector were adopted. For example, by Decree of the President of the Republic of Uzbekistan dated December 30, 2019 No. PP-4554 “On additional measures to deepen reforms in the pharmaceutical industry of the Republic of Uzbekistan”, the concept for the

development of the pharmaceutical industry of the Republic of Uzbekistan in 2020-2024 was approved (hereinafter referred to as the Concept). **[9]** According to the Concept , Uzbekistan plans to increase the share of domestically produced pharmaceutical products in the domestic market up to 50% in value terms by 2025, and the range of domestic products from the current 2,500 to 4,000 items, as well as develop projects jointly with pharmaceutical enterprises in India and Russia , Ukraine, China, Hungary, Bulgaria and Slovakia.

In order to stimulate the integrated development of the pharmaceutical industry in the Republic, the Decree of the President of the Republic of Uzbekistan dated January 28, 2020 No. PP-4574 "On the creation of an innovative scientific and production pharmaceutical cluster" was approved pharma park ". **[10]** The main goal of which is the transition of the pharmaceutical industry to an innovative development model, as well as the organization of stable activities of the pharmaceutical industry, aimed at ensuring a high level of quality and effectiveness of pharmacotherapy and prevention of diseases of the population, and ultimately contributing to an increase in the duration and improvement of the quality of human life.

The state also initiates the creation of free economic zones Nukus-farm, Andijan-farm, Kosonsoy-farm, Bustonlik-farm, Parkent-farm, Zomin-farm, and Boysun-farm", "Sirdaryo-farm". The adoption of the Decree, first of all, will contribute to the development of the pharmaceutical industry, support for manufacturers of medicines and medical products, and saturation of the domestic market of medicines with high-quality locally produced drugs. **[11]**

The Government of the Republic of Uzbekistan has taken preferential taxation measures, in particular, drug manufacturers are exempted from paying all taxes for a period of 5 years. Companies implementing projects for the creation of new industries and the reconstruction of existing ones are exempt from paying all customs duties when importing technological equipment.

The state regulates the activities of production and distribution entities, using mechanisms such as licensing of pharmaceutical activities and the production of medicines, registration of medicines and regulation of prices for pharmaceutical products. In addition, state control over the circulation of medicines is carried out by checking compliance with the rules of preclinical and clinical trials, laboratory practice, organization of production and quality control of medicines, wholesale trade in medicines, dispensing medicines, storage and destruction of medicines. **[12]**

Insufficient organization of work on the implementation of international standards at domestic enterprises, including the requirements of good manufacturing practice (GMP), good pharmacovigilance practice (GVP) and ISO 13485, which regulate the quality and safety management system at pharmaceutical enterprises, limits the ability to produce effective and safe pharmaceutical products. Products that are competitive in the foreign and domestic markets. The transition of the pharmaceutical industry to GMP standards will lead toto the formation of a market for high-quality drugs, the improvement of the pharmaceutical industry as a whole and the movement to the world level in terms of the quality and range of manufactured drugs. **[13-15]**

CONCLUSIONS AND OFFERS

In conclusion, it should be noted that the pharmaceutical market provides the population of the country with socially significant products, therefore, state regulation of the pharmaceutical market is aimed primarily at ensuring the rights of citizens to effective and safe medicinal products. It is state regulation that contributes to the dynamic development of the industry, provides a favorable investment climate for the implementation of all projects, and the tax policy of the republic stimulates the development of the domestic pharmaceutical industry. **[16-18]**

Based on the above, the author makes the following recommendations:

- In the field of drug circulation, the state should act as a regulator and organizer of the pharmaceutical market, while using a wide range of both administrative and economic regulatory measures;
- The system of state regulation of the pharmaceutical industry, first of all, should be aimed at improving the quality of life of the population;
- Fiscal policy should lower entry barriers for new companies, especially biotech companies with high innovation potential;
- Active participation of institutions that support the effective implementation of government regulatory measures, but at the same time do not create unnecessary administrative barriers and are sufficiently transparent for business and the public. Also, the development of new bills to optimize and facilitate these processes for all parties.

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