
THE IMPACT OF THE NON-MARKET ENVIRONMENT ON THE OPERATION OF PHARMACEUTICAL COMPANIES IN SERBIA

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Abstract: Politics and economy represent two sides of the same medal. Poorly guides policy and insufficient reform prevent the achievement of desired economical results. Globalization and new technological discoveries facilitated communication between countries and intensified economic activity. However, their appearance has led to the complexity of the relationship and the necessity of adjusting to the new circumstances. Adaptability is a key virtue that domestic markets must possess in order to survive in a brutal international competition. To ensure economic growth in the country, political leaders have the task of creating an attractive economic environment for investment. Big investors are looking for countries that would be profitable to invest. When choosing a country, investors will first take into account the political stability of the country in order to reduce the risks of investing, but also taxes, permits and administrative and regulatory facilities offered by the state. The market itself is not strong enough to trigger economic growth, but must be supported by a non-market environment, such as the state apparatus, the regulatory system, stakeholders and other entities. The lack of protection of property rights and inadequate implementation of the law will negatively affect the inflow of investments (Zaric, Babic, 2014). Political and economic leaders should define the goals of the domestic economy, determine the limitations in achieving them and find proposals for their overcoming. Only effective synergy between the market and the non-market environment can achieve the desired progress. In the light of the transitional changes it is going through, it is important to consider the impact of institutional changes on the economic performance of the entities operating in Serbia. Political organization determines the institutional configuration and sets the rules on the basis of which a certain state functions, and the economic environment depends on political decisions. The pharmaceutical market is one of the fastest growing and profitable markets in the world. The pharmaceutical industry of Serbia, as an industry of strategic importance, belongs to the domain of state interests. In comparison to European and neighboring countries, the Serbian pharmaceutical market is considered undeveloped and highly regulated. At the time of the Socialist Federal Republic of Yugoslavia, Galenika covered a large percentage of domestic and foreign markets. By exporting drugs worldwide, it gained a great international reputation, but as a state-owned company it was often the target of financial exploitation of its managers. Today, it is one of the newly privatized companies. On the other hand, Hemofarm, which has been in the possession of the German pharmaceutical company for 11 years, has been continuously achieving success. This paper will analyze the existing regulatory framework in Serbia and the way in which it affects the business. On the concrete example of the business of the mentioned pharmaceutical companies, a positive, but also negative effect of the regulatory framework on their prosperity will be shown.

Keywords: reform, non-market environment, state regulation, pharmaceutical market

1. INTRODUCTION

The work of the theorists of institutionalism is highly important for transitional economies. Transition from a centralised economic and political system into a market oriented system requires the development of new institutions that will enable this process. In a joint section called *Why Nations Fail*, Daron Acemoglu and James Robinson point the determining role of institutions in developing the states all around the world. The failure of the states is caused by extractive institutions which are drawing extraordinary wealth in favour of a small elite. The authors point out that the existing political institutions are crucial for economic performance. Those institutions can be inclusive and guarantee rights and economic freedoms, or extractive, created with the intention of enriching a small part of population, while the rest is living in poverty (Acemoglu, Robinson, 2012). The main goal of post-communist countries is to create a regulatory environment that will ensure economic growth and development, as well as a complete transition to a market oriented economy. The countries of the Western Balkans have initiated a series of regulatory changes that are supported and stimulated by the International Monetary Fund and the World Bank, as well as the European Union for whose membership they compete. The guidelines of those institutions require a strong institutional infrastructure that would allow the implementation of new laws (Penev and Marušić, 2009). In order to improve business environment and reform the regulatory framework, the Republic of Serbia has adopted a Strategy that promotes economic and social development, domestic competitiveness, reducing administrative costs and procedures, analysing the efficiency of regulations, abolishing or amending inadequate regulations and establishing a good regulatory practice principle. The Council for regulatory reform of the economic system was established in order to monitor the effects of the Strategy. In 2010. this Council was replaced with the Office for regulatory reform and impact analysis that took over the Council's duties. The following goals were achieved: training of officials for the

analysis of the effects of regulations, meetings and discussions with the National Assembly services on the effects of the amendments on the laws for which they are proposed, a paper for analysis of the effects of regulations was created and study visits were organized in order to get acquainted with the work of newly founded bodies. (www.aler.rs)

If the economy of a country tends to achieve the desired development, it is necessary that the market and the non-market environment be complementary and that they work together to achieve the goals. Coordination of economic and political goals is a prerequisite for the creation of sustainable development. Companies are facing non-market problems such as environmental issues, human rights protection, protection of intellectual property, NGO pressures, ethical questions and social responsibility. The significance of the non-market strategy is closely linked to control over the company's opportunities that can be controlled by the state or by the market. It turned out that the non-market strategies are more significant when the opportunities are under state control, like in the case of pharmaceutical industry or telecommunications which represent the industries of strategic importance for the state. Non-market strategy has the task to deliberate the opportunities under state control and to avoid its control over the company's opportunities (Baron, 2010).

2. BUSINESS AND INSTITUTIONAL ENVIRONMENT IN SERBIA

Every year the Foreign Investors Council publishes a *White Paper* which represents an overview of the economic situation as well as recommendations for improving the business climate in the country. The Report from 2016. says that Serbia has achieved significant economic performance in terms of GDP growth, export growth, reduction of unemployment, inflation reduction and foreign direct investment inflows. Encouraging comments were also given by the IMF, World Bank and European Union. In order to maintain a positive trend of growth it is necessary to focus on key development impediments such as the tax system, companies that are not privatized yet, the industry that should be revived and the public administration that requires reform and digitalization to facilitate business and ensure transparency. The Foreign Investors Council lists the key „development pillars“ that should be invested in order to stimulate growth and create a favorable economic climate. The mentioned pillars include transport, telecommunications and IT, real estate and construction, but also human capital (FIC, Bela knjiga 2016).

In the *Global Competitiveness Report* for 2016/2017, published by the World Economic Forum, Serbia ranks 90th out of 138 countries surveyed. Although such a score might be considered unfavorable, it certainly represents an improvement over the previous Report in which Serbia was ranked 94th. By observing the quality of institutions Serbia is ranked 115th and the most unfavorable segments are: protection of interests of minority owners (134th place out of 138), burden of government regulation (128th place), protection of intellectual property (127th place), protection of property rights (126th place), but also independence of the judiciary, corruption, organized crime and trust in politicians. (The Global Competitiveness Report, 2016-2017)

The achievements of the pharmaceutical industry depend on the level of autonomy in relation to the state. The state has different mechanisms of control over the pharmaceutical industry such as reduction or freezing of the prices, defining starting prices for new products and giving the approval for the price raise. In comparison to the EU and countries of the region, Serbian pharmaceutical market seems undeveloped. It is important to emphasize that the Serbian market is very regulated and that the state defines the conditions of sale. According to the Law on medicines and medical devices drug prices are defined by the state. By adopting the Drug pricing criteria regulation and Human drug pricing regulation the state has the power to create drug prices but also the wholesale and retail margins. Like in the neighboring countries, the state is the main drug buyer which creates a problem of irregular payments because of the permanent deficit of resources for medical care. (Lovreta, Stojković, 2014)

According to the Law on medicines and medical devices the main regulatory body of the pharmaceutical company is the Agency for medicines and medical devices of Serbia, established in 2004 with following competencies: issuing permits for drugs and termination of their validity, registration of medical devices in the Register, issuing permits for clinical trials, monitoring adverse reactions to medicines, issuing export and import permits, categorization of medicines and medical devices, collection of data on traffic and consumption, quality control, as well as the approval for public advertising. Supervision over the work of the Agency is performed by the competent ministry and the Agency itself is directly responsible to the government. The Law prescribes the types of medicines that can be produced or imported on the territory of the Republic of Serbia: biological, immunological, advanced therapy, blood and blood plasma drugs, radiopharmaceuticals, herbal remedies, traditional, homeopathic, veterinary, magistral and galenic drugs. The procedure for obtaining the licence for medical products involves the submission of complete or abbreviated documentation along with the necessary sample of the product. The competent ministry prescribes the form of the request for issuing the licence, the content of documentation as well as the method for obtaining a permit issues for a period of 5 years (www.paragraf.rs).

A significant segment of the pharmaceutical company is the protection of intellectual property. The Kingdom of Serbia was one of the founding member of the Paris Convention for the protection of industrial property in 1883. In 1920, the Kingdom of Serbs, Croats and Slovenes established the Industrial property protection administration. The Administration later became the Institute which has registered 54 934 patents, 1 474 small patents, 71 121 trademarks and 11 084 industrial designs by now. Since 1992, Serbia has been a member of the World Intellectual Property Protection Organization (WIPO), and since 2010 the member of European Patent Organization. Since 2012, Serbia has been developing cooperation with the European Union Intellectual Property Office (EUIPO) on the inclusion of Serbian stamps and designs in their systems. (www.zis.gov.rs)

3. PHARMACEUTICAL INDUSTRY OF SERBIA

In most countries in Europe the state is the largest buyer of drugs and medical products which results with a high degree of regulation of this market. As the largest buyer, the state is in a position to determine the prices of medicines. On the other hand, in the United States, the main influence on the formation of drug prices has the market so it can be considered to be the main cause of the high lucrativeness of the US pharmaceutical market (Lovreta, Stojković, 2014). The pharmaceutical market of the United States takes the first place, both by product consumption and investment in research and development. The value of the market is 339 694 billion dollars, followed by Japan with 94 billion, China 86 billion and Germany with 45 billion dollars (worldatlas.com). The US Food and Drugs Administration approved the entry of 46 new drugs in 2017, and it was estimated that the members of the Association of Pharmaceutical Researchers and Producers invested around 60 billion dollars in research and development (investingnews.com). The US market creates favorable conditions for the development and trade of pharmaceutical product with the smallest amount of market barriers. The power of the market is reflected in the developed system of intellectual property protection that rewards and stimulates innovation, as well as scientifically oriented regulatory system that supports the development of the industry (trade.gov). Pharmaceutical companies in the US have been building strong relationship with the government. For example, during the US trade negotiations in 1990s, pharmaceutical companies supplied government with confidential information about potential losses caused by foreign plagiarism. Consequently, the government adopted stricter intellectual property rules, which was favorable for pharmaceutical companies to protect their invention as long as possible (Bach, 2010). In addition to the largest producers from the US and Europe a significant share of the world pharmaceutical market is occupied by developing countries from the Asian or Latin American continent. Continuous legislative reform, enhanced intellectual property protection and an improved regulatory environment contribute to the efficient development of these markets. However, most developing countries remain a risky investment ground. Companies entering a foreign market face numerous challenges such as a specific regulatory environment that often lacks transparency, barriers set by the authorities, lack of adequate intellectual property protection and rigorous pricing policies. The challenges of entering the pharmaceutical market are not specific to developing countries, but also to the most developed, such as the United States. Companies that want to operate on the US market must overcome challenges such as regulatory approval, patent approval, patent application, compulsory licencing, regulatory data protection, pricing policy and tariffs (trade.gov).

Statistics show that Hemofarm has a market share of around 17% in the pharmaceutical market of Serbia while Galenika, with its former 65% share in the market of the Social Federalist Republic of Yugoslavia, has fallen to only 10% of the market share of Serbia (novosti.rs). In addition, Hemofarm is the largest exporter of pharmaceutical products with a share of 79% in total export of these products from the Serbian market. Since 2006 Hemofarm has been the part of the STADA group, a renowned German pharmaceutical company (hemofarm.com).

With only 43 employees, in 1945 the Directorate for medical production decided to establish the state pharmaceutical company called Galenika. In the beginning, the production was based on the import of a large number of raw materials which stimulated the development of scientific research with the aim of improving the company's performance and productivity. A significant incentive was the decision of the United Nations Agency for Assistance and Reconstruction to transfer the production of penicillin to Yugoslavia. The demand for penicillin was largely outweighed by the offer and Galenika embarked on a reconstruction of the plant to enable the satisfaction of the existing demand. The expansion of the product range and the intensifying business resulted in an increase in drug exports. Recognizing the importance of scientific research, Galenika sought to develop its own research capacity. In accordance with the Law on organization of scientific work the company established a Development laboratory for scientific research in organic and pharmaceutical chemistry. High quality of products and a constant tendency to perfect the production soon provided Galenika a significant reputation in the World (ICN Galenika, Pola veka razvoja, 1995).

A historic milestone in Galenika's business occurred in 1990 when negotiations on cooperation with *ICN Pharmaceuticals* began. At the end of the year, the signing of the Agreement on the establishment of the joint company called ICN Galenika came to an end. As for capital input, a mixed company was made up of 75% of

the ICN role and 25% of Galenika's role and the value of the new company has been estimated at 360 million dollars. (ICN Galenika, Pola veka razvoja, 1995). New joint company recorded significant business success in the first three years of its operation and the value of production and sales increased from 170 millions in 1989 to 325 million dollars in 1992. Partnership with ICN resulted in expanding business to the markets of the United States, Canada, Mexico, Spain, France, Germany, China, Japan and Australia. In 1997, the most famous economic magazine *Wall Street Journal* analyzed the 1000 largest US companies for the effectiveness of using company's funds. In the pharmaceutical industry the first place was occupied by the ICN as well as the 15th place among the other 1000 companies. (The world of ICN, 1998)

Today, Galenika operates under the name „Galenika joint stock company for the production of medicines, dentals, antibiotics, pharmaceutical raw materials, parapharmaceutics, veterinary products and additives“. Galenika maintains a tradition of respecting social responsibility and balancing between economic and social goals. The principle of corporate social responsibility is included in company's business strategy and covers a wide range of issues such as the preservation of safety and health of workers, continuous education and training of employees, taking care of young people, protecting children, environmental protection, developing of science and education system and respecting the ethic criteria. Care for employees is regulated by the Collective Agreement, an act that guarantees health and safety at work, provides ongoing health control for employees, education and business improvement as well as participation in decision making. Regular wages, clearly defined working hours, organized transportation, the possibility of continuous learning and promotion are some of the characteristics of the company that employees are extremely satisfied with. The employees of the Institute for research and development monitor international pharmaceutical trends and work on the development of new products (galenika.rs). In October 2017, a news story was published about the sale of Galenika to *Aelius*, a Luxembourg company which is the part of the largest Brazilian pharmaceutical company called *EMS S/A Brazil*. Along with the formal, purchase price of 16 million euros, the buyer also accepted the payment of 25 million euros in the name of bank debts (B92.net). Galenika is one of the symbols of the greatness and power of the former Socialist Federal Republic of Yugoslavia, but also a symbol of the long-term transition of the Republic of Serbia. After several decades of social and state ownership, Galenika became a private company. During its long history of business it had numerous ups and downs but it was still considered as a reputable company that maintained the quality of its products. The positive economic performance that company has achieved has often been annihilated by the irresponsible behavior of its executives, as well as the state itself which has often avoided paying off debts to Galenika. One of the largest state gigants was destroyed by the state itself. The future will show whether privately owned Galenika will succeed in regaining the former glory.

In 1960, Hemofarm was founded and headed by Nikola Gerdec, the first director and one of the founders. Four years later, the company broke into the first foreign market and began exporting its products to Iran. The last decade of the twentieth century brought about major changes in the company. In 1990, from a status of a socially owned company, Hemofarm became a shareholding company. The same year company opens its own research and development laboratory. The following year, the company opened the first foreign company in Germany, called *Hemofarm GmbH*, which became the center of foreign trade activities. In spite of the war events, Hemofarm, like Galenika, continued with a positive trend of development and in 1992 it opened a representative office in Moscow and the following year it started with the production of veterinary and phytosanitary products (hemofarm.com). Previous year, 2017, brought major changes both for Hemofarm and for the entire STADA group. Two large investment funds, *Bain Capital* and *Cinven*, acquired STADA group by purchasing 63% of shares for 5,4 billion euros (blic.rs). Investment funds have committed themselves to not be laying off employees in the next four years and that the production and business program will continue with current business strategy (politika.rs).

Hemofarm operates as a joint-stock company with 2 500 employees, exports products to three continents and owns five factories. An additional success and image of the company is achieved by its positioning as a socially responsible company. Hemofarm has introduced the practice of replacing plain paper with recyclables which enabled savings of 10% and, more importantly, this procedure reduced air pollution by 74%. Also, by building the modern boiler rooms the company regulates the release of negative substances into the air and through the system for wastewater treatment prevents pollution of water flows. The water necessary for production activities is procured from its own wells. Only in 2016 the company invested around 620 000 euros for various projects in order to protect the environment.

The Centre for research and development is engaged in development of new products for the entire STADA group, the transfer of new products into the production process as well as their registration in the markets in the region. In the 25 years of work of the Center 250 new product were placed on the market. The regulatory team of this Centre has enabled the obtaining of 1500 licences for the release of medicines into seventeen markets into the World. The Centre has fulfilled 104% of the envisaged program for 2016. Sixty nine new products were released to markets across South-East Europe, as well as 159 licences for registration of medicines and medical

devices. Through the Centre for corporate communication Hemofarm is in contact with all stakeholders, such as patients, product users, local communities, government, NGOs and regulatory bodies (hemofarm.com). The Hemofarm foundation, founded in 1993, aims at improving the health situation in Serbia, improving the quality of life through the development of a responsible social community. So far, the Foundation has conducted 1700 actions through which provided assistance to hospitals, municipalities, schools and sport associations. In 2016, the company had 113 actions in which 400 000 euros was invested. Special attention was drawn to the action in cooperation with numerous institutions, called „The most important call in life“ which pointed to the huge problem of patients requiring organ transplantation. This action had a strong response in the public and many citizens signed a statement on the donation of their organs after death (hemofarm.com). Another significant contribution to social welfare is a program called „Active society“. The goal of the program is to involve civil society in community development, help the health system and develop empathy and care for other citizens. By providing financial support, Hemofarm strives to assist the development of health care, local communities, socially vulnerable parts of the population and to implement programs in the field of environmental protection, culture and sports (fondacijahemofarm.org.rs). In 2016, Hemofarm adopted the Safety and security policy in which it commits to implement the environmental standards ISO 14001:2015, as well as the standards for the management of health and safety at work OHSAS 18001:2007. In accordance with this document Hemofarm is obliged to carry out activities in accordance with the stated standards as well as with other domestic and international regulations. Responsible business will strive to eliminate all potential hazards to the health and safety of people and the environment, reduce waste and harmful substances and save natural resources and energy (hemofarm.com).

4. CONCLUSION

On the examples of privatized Hemofarm and ICN Galenika in the 1990s we have seen that market mechanisms and private ownership are achieving better performance than state-owned enterprises such as Galenika so far. As an industry of strategic importance, the pharmaceutical industry must be under state control but it does not mean that the state should fully control its business. An example of the free pharmaceutical market of the United States shows that this industry records the highest profits and permanent growth. As a dynamic industry, it requires a certain degree of autonomy to develop smoothly. Nevertheless, the development of the industry is constantly under the watchful eye of the public. Given the fact that it is in the public interest to find new drugs and prolong the life expectancy, the population, the media, interest groups and NGOs closely monitor the evolution of the pharmaceutical industry. The announcement of the potential integration of the two big companies, *Bayer* and *Monsanto*, has found a fierce resistance among Europeans and Americans who believe that such integration would harm the quality of food and medicines. In addition, US authorities are postponing the acceptance of Bayer's bid in fear that new joint company will endanger competition in the country (politika.rs). An important segment of business of almost every company, especially pharmaceutical, is the orientation towards socially responsible business. In line with global trends and demands, both Galenika and Hemofarm are devoting special attention to environmental protection, employee care, humanitarian actions and investment in human capital. In accordance with the new mantra of experts around the world – *lifelong learning*, the domestic companies are trying to further educate and perfect their employees through seminars and trainings.

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