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# STRUCTURE ANALYSIS OF THE WORLDWIDE PHARMACEUTICAL MARKET AND PROSPECTS FOR ITS DEVELOPMENT IN KAZAKHSTAN

The pharmaceutical industry is one of the leading high-tech industries that significantly determines the innovative and strategic security of modern state. In this regard, it is necessary to take into account the issue of providing country with drugs in the framework of national security. A unified drug policy requires that development of Kazakhstan is carried out in one direction to ensure the country drug safety through establishment of its own pharmaceutical industry. This process is quite long, time-consuming and expensive. The purpose of work is to analyze pharmaceutical market in the Republic of Kazakhstan, the prospects for its development and the creation of domestic medicines that meet the needs of world standards. The paper considers the current state of country's pharmaceutical industry and the shortcomings of domestic pharmaceutical industry. The share of domestic drugs on the domestic market is little, wherein most of them made from imported raw materials. In order to improve the effectiveness of formation of own pharmaceutical industry, various strategies are being developed. One of them is the government support of domestic manufacturers, scientific organizations, universities and scientists.

Key words: pharmaceutical industry, pharmaceutical market of Kazakhstan.

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### Әлемдік фармацевтикалық нарықтың құрылымдық талдамы және оның ҚР-да даму перспективалары

Өздеріңізге белгілі, фармацевтика өнеркәсібі қазіргі заманғы мемлекеттің инновациялық және стратегиялық қауіпсіздігін айқындайтын жетекші жоғары технологиялық өндірістердің бірі болып табылады, сондықтан елімізді дәрілік заттармен қамтамасыз ету мәселесі ұлттық қауіпсіздік деңгейінде екендігін ескеру қажет. Бірыңғай дәрілік саясатына сәйкес, біздің мемлекетіміз дәрілік препараттардың қауіпсіздігін қамтамасыз ету үшін өзінің фармацевтикалық индустриясын дамыту арқылы бір бағытта қозғалуды талап етеді, бұл өз кезегінде жеткілікті ұзақ, еңбекқор және қымбат процесс.

Жұмыстың мақсаты – Қазақстан Республикасының фармацевтикалық нарығы, оның даму перспективаларын және әлемдік стандарттарға сай келетін отандық дәрі-дәрмектерді талдау.

Мақалада елдің фармацевтика өнеркәсібінің қазіргі жағдайы көрсетіліп, отандық фармацевтика өнеркәсібінің кемшіліктері қарастырылған. Ішкі нарықта отандық дәрідәрмектердің үлесі аз, олардың көпшілігі импорттық шикізаттан жасалады. Өз фармацевтикалық

саласын қалыптастырудың тиімділігін арттыру мақсатында отандық өндірушілерді мемлекеттік қолдау, ғылыми ұйымдар, университеттер мен ғалымдарды қолдау мәселелеріне үлкен көңіл бөлініп, әртүрлі стратегиялар әзірленуде.

Түйін сөздер: фармацевтика өнеркәсібі, Қазақстанның фармацевтикалық нарығы.

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### Анализ структуры мирового фармацевтического рынка и перспективы его развития в Казахстане

Фармацевтическая промышленность относится к числу ведущих высокотехнологичных отраслей, существенно определяющих инновационную и стратегическую безопасность современного государства. В связи с этим необходимо учитывать вопрос обеспечения страны лекарственными средствами в плоскости национальной безопасности. Единая лекарственная политика требует, чтобы развитие нашего государства осуществлялось в одном направлении по обеспечению лекарственной безопасности страны через становление собственной фармацевтической промышленности. Данный процесс является достаточно длительным, трудоемким и дорогостоящим.

Цель работы – анализ фармацевтического рынка Республики Казахстан, перспективы его развития и создания отечественных лекарственных препаратов, удовлетворяющих потребностям мировых стандартов.

В статье показано нынешнее состояние фармацевтической промышленности страны, рассмотрены недостатки отечественной фарминдустрии. Доля отечественных лекарственных средств на внутреннем рынке мала, при этом большая их часть изготавливается из импортного сырья. Для того чтобы повысить эффективность становления собственной фарминдустрии, разрабатываются различные стратегии, большое внимание в которых уделяется государственной поддержке отечественных производителей, поддержке научных организаций, вузов и ученых.

Ключевые слова: фармацевтическая промышленность, фармацевтический рынок Казахстана.

### Introduction

The importance of studying structure of pharmaceutical market and its segments is determined by two main factors: firstly, it has social significance in the economy (Evstratov 2016:32-37) and, secondly, it occurs as the source of the social development of society in any country in the world. High technology and science-intensive production of pharmaceutical products has an impact on development of other industries such as science, chemical production, mechanical engineering and etc (Wu 2016: 1-25). In addition, the level of development of pharmaceutical industry in the country is the key to functioning of health care system, ensuring preservation of work ability of the population, increase the quality of his life.

In economic terms, pharmaceutical market is a system of interacting agents of production and consumption of medicines based on the mechanism of market competition (Wu 2016: 1-25). The structure of the pharmaceutical market includes producers and consumers, distributors and

pharmacy chains (Pushkarev 2016:62-66). Analysis of distribution of an international pharmaceutical market in the world shows that North America, Europe and Japan in 2006 year occupied almost 84% of the world market (Evstratov 2016:72). Monopolization of pharmaceutical market affected the socio-economic growth of third world countries, which was an incentive for a number of countries to restructure it

The development of pharmaceutical market in developing countries is largely determined by trends in an internationalization of the world market (Kosyakova 2007:146-152), and therefore study of its various aspects is extremely urgent. Market growth in developing countries in year 2016 reached 12%, while on average the world market grows by 4.5% annually. Especially high growth is expected in China, Brazil, India and Russia.

The International pharmaceutical market is one of the most highly profitable and fast-growing in the world economy (Torres 2010:251). Despite the general decline in global economy of recent years, the pharmaceutical market continues to develop

dynamically (Evstratov 2016:920-923). According to the forecast of «IMS Health», its volume by 2020 year should increase to 1.5 trillion dollars. There are many factors contributing to growth of pharmaceutical market such as general increase in morbidity due to technical factors and the deterioration of ecological situation (IMS Institute – 2011), the trend of «population aging» in developed countries, and growth of income levels in developing countries (Dorovskoi 2014: 34-40). All these factors contribute to stimulate the use of expensive drugs.

To understand the processes of sustainable and effective development of the pharmaceutical market of Kazakhstan and its impact on the socio-economic development of developing countries, it requires a thorough analysis of its structure. There by, an important task is to analyze the state of international pharmaceutical market, identify problems and trends in its development, including developing countries.

The purpose of this article is to study the components of pharmaceutical market, their mutual position in the sphere of pharmaceutical products circulation. The following tasks were included: analysis of the state of international pharmaceutical market, identification of problems and trends in development of pharmaceutical

market, understanding the processes of effective functioning of the pharmaceutical market.

#### Results and discussion

Currently, for economy of the Republic of Kazakhstan the study of state of the world pharmaceutical market is becoming especially relevant in connection with implementation of the National Drug Policy as envisaged by the State Program «Densaulyk» for 2016-2019 ((Urbanets, 2017: 8).

According to «IMS Health», in year 2015 volume of the world pharmaceutical market was 1.1 trillion dollars (IMS Institute [Electronic resource]). We consider the structure of market of world manufacturers of pharmaceutical products and its composition. The main feature of current pharmaceutical industry in the US and Western Europe is concentration of production localization, especially research and development (R & D) studies of pharmaceutical products (Global Pharmaceutical Industry [Electronic resource]). The largest 20 companies of these countries make up the so-called «Big Pharma Group» with sales of over 500 billion dollars and R & D expenditures in excess of 70 billion dollars.

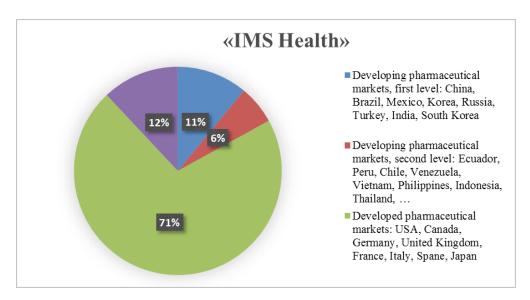


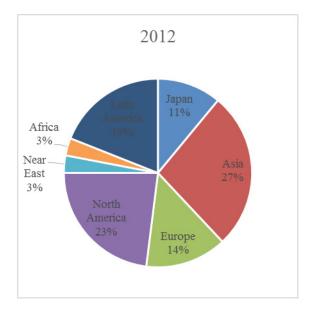
Figure 1 – Diagram of regional structure of international pharmaceutical market by the classification of «IMS Health», 2009 (Dorovskoi 2014: 34-40).

The most important trend of world pharmaceutical market is change in geographical structure of demand (Danzon, 2012: 35-71). At present, developing countries are making an increasing

contribution to its development. Figure 1 shows the regional structure of the world pharmaceutical market in the 2009 year classification (Dorovskoi, 2014:34-40). According to «IMS Health», volume of world pharmaceutical market in 2015 year was 1.1 trillion dollars (Dorovskoi 2014: 34-40).

It is necessary to characterize the regional structure of pharmaceutical market in 2012 year and

for the future until 2020 year. Figure 2 shows the structure of the world pharmaceutical market for 2012 and for the future until 2020 (Evstratov 2016: 24-31).



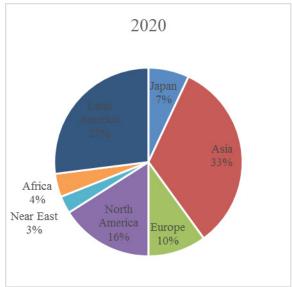


Figure 2 – Diagram of the regional structure of the world pharmaceutical market in 2012 and 2020.

In domestic pharmaceutical industry of Kazakhstan there are significant limitations such as small share of native drugs in the domestic market, manufacture of drugs with low added value and where in most of them are made from imported raw materials.

According to the Center of industry analysis of «Industry Development Institute of Kazakhstan», in 2016 year the volume of produced domestic pharmaceutical products amounted to 42.4 billion tenge, which is 33.3% more than the corresponding period of 2015. The main producers of domestic pharmaceutical products were the enterprises of the South-Kazakhstan region (41.5%), the Almaty region (24.2%) and Almaty city (22%). Significant growth was due to an increase in the output of products at the enterprises of «HimPharm», LLP «Abdi Ibrahim Global Pharm», LLP «VivaPharm» (Development of the pharmaceutical industry in the Republic of Kazakhstan [Electronic resource)

Recently, the share of foreign drugs was high in the market of Kazakhstan, but due to intensive development of domestic producer this trend may be changed. Social policy remains the same. The healthcare budget is growing. Growth for the reporting period was due to an increase in volume of production of basic medicines in physical terms 1.6 times till 17.7 million kg (Development of the pharmaceutical industry in the Republic of Kazakhstan [Electronic resource). The growth of the output is observed at the following enterprises: «Him Pharm», LLP «Abdilbrahim Global Pharm», LLP «Viva Pharm», LLP «Eikospharm».

conducted analysis of the pharmaceutical market reveals a number of characteristic trends and problems in modern pharmaceutical industry (J. Kohler [Electronic resource]). Among the main problems development are: 1) contradictions that lead to the restructuring of the world pharmaceutical market, which indicates the most likely directions for the development of the world pharmaceutical market and the industry in line with the adjustment of company strategies (Henry 2001: 209-210). Therefore, more and more companies are planning to transfer administrative functions (44%), research and development (43%) and sales departments (51%) to developing countries (Mossialos 2004: 1-37). The second problem can be attributed to a decrease in the efficiency of research and development works and a significant increase in the expense of companies of «Big Pharma» (Mrazek and Mossialos 2004:114-130, Wu 2016:1-25). Expenditures on research and development work worldwide increased by more than 80%, and new medicines began to register 43% less. Accordingly, the cost of developing one original medicinal product increases, which has become a key problem of the world pharmaceutical market (Kalganov 2017: 213-216).

The formation of its competitive pharmaceutical industry is a long, laborious and costly process. Creation of conditions for import substitution of pharmaceutical and medical products based on modern technologies in accordance with international standards GMP (Good Manufacturing Practice) is one of the main tasks for the development of pharmaceutical industry of the Republic of Kazakhstan. It also is important to take into account that from January 1, 2016 year on the territory of the Customs Union a single market of medicines began to operate.

However, one must take into account that the issue of providing country with medicines lies in plane of national security (Vogler 2012: 44-51). The country needs to have its own medicines, especially those that are included in the list of vital drugs. That is why the head of state sets the task of developing our own pharmaceutical production, training personnel for the industry, supporting large investors in this field, close cooperation with the EurAsEC countries (Urbanets, 2017: 8).

Pharmacists, pharmacy network workers have always been in demand. This category of graduates has never had problems with employment. Now the question arises in the specialists for pharmaceutical production, which the developing pharmaceutical industry needs, and the demand for these specialists will grow with appearance of new and expansion of old pharmaceuticals. The presence of specialists will contribute to the development of our own pharmaceutical production on the basis of domestic raw materials, and consequently, cheap drugs.

In Russia, the development of the pharmaceutical industry in the context of crisis and sanctions at the state level has also been given great importance. The government adopted the state program «Strategy for the development of the Russian pharmaceutical industry»((Urbanets, 2017: 8). A major role in this strategy is given to the state stimulation of innovative projects for the development of medicines from domestic pharmaceutical raw materials, the support of scientific organizations, universities and scientists. The result of this policy will be the provision of national security through the innovative development of the domestic pharmaceutical industry, focused on import substitution.

For a long time, the Government of the Republic of Kazakhstan discussed the possibility of creating a single distributor of medicines and medical products. In February 2009, it was decided to create a similar agency in the structure of «National Welfare Fund» Samruk-Kazyna» (Development of the pharmaceutical industry in the Republic of Kazakhstan [Electronic resource]). By the Government Decree of the Republic of Kazakhstan No. 516 of May 25, 2013, the rights to own and use a wholly owned interest in the limited liability company SK-Pharmacy were transferred to the Ministry of Health of the Republic of Kazakhstan. The Single distributor system was created with the aim of providing the population with medicines within the guaranteed volume of free medical assistance, increasing the stability and competitiveness of the pharmaceutical industry in the Republic of Kazakhstan, and developing the pharmaceutical industry by consolidating state purchases of medicines. Since 2011, in accordance with the Government Decree of the Republic of Kazakhstan dated October 30, 2009 No. 1729 LLP «SK-Pharmacy» is the organizer of procurement medical equipment purchased from the republican budget, and for further transfer to health organizations on the terms of financial leasing.

In the Republic of Kazakhstan, the state has a significant influence on the formation of the domestic pharmaceutical market through the provision of a guaranteed volume of free medical care. The support of domestic producers is being carried out within the framework of the existing programs for the development of manufacturing industry. The activity on registration, certification, assurance of quality control of medicines, medical products and medical equipment, as well as their advertising, has been regulated. The National Information Drug Center was established. State regulation of prices for medicines purchased from the budget was introduced. Moreover, in connection with the transition to a free-floating exchange rate regime from August 20, 2015, the issue of changing prices for medicines and their accessibility to the population has become acute. Consequently, memorandums are held in all regions of the republic to contain prices for medicines and medical products.

The increase in government purchases and the provision of a guaranteed volume of free medical care in Kazakhstan served as the main factors for the growth of the pharmaceutical industry according to the results of January-June last year. Purchase of pharmaceutical products within the framework of guaranteed volume of free medical care from 2009 to 2015 increased by 2.9 times. Among other things, for the period from 2010 to 2015 the share

of pharmaceutical products purchased through the «Unified Distributor» within the guaranteed volume of free medical care increased, on average, by 3 times – from 35.8 to 107.5 billion tenge. In 2016, within the framework of guaranteed volume of free medical care, through the LLP «SK-Pharmacy» it is planned to purchase 1034 products for about 101.9 billion tenge.

The share of domestic producers in the structure of the purchase of the «Unified Distributor» is about 75% in physical terms. Several years ago, the guaranteed level of free medical care did not exceed 6%.

It is extremely necessary to attract foreign investors to the pharmaceutical industry. The inflow of investments will facilitate the acceleration of the development of pharmaceutical enterprises, improvement of the quality of human resources, creation of new workplaces, attraction of advanced technologies and stimulation of their distribution, and also implementation of import substitution policies (Leopold 2012: 50-60).

For this purpose, hard work has to be undertaken in order to attract large world pharmaceutical leaders to the market of Kazakhstan, such as Pfizer (USA) with the project on the production of vaccines in the Almaty region, Sanofi (France) with a project for the production of tablet form of drugs in the Karaganda region. For example, the British transnational pharmaceutical company HIKMA (founded in Jordan in 1978) is interested in organizing its own production of drugs for the treatment of diabetes mellitus, diseases of the central nervous system and antibiotics in Almaty. It is planned to attract about 11 billion tenge in the form of investments and creation of about 300 new workplaces.

Regarding already existing foreign investors in the pharmaceutical industry of the Republic of Kazakhstan, work is continuing on expanding and modernizing existing production facilities, as well as creating new production sites within the framework of the Industrialization Maps for 2015-2019.

Within the framework of the first industrialization program, a lot of investments were made in the domestic industry. Along with the arrival of foreign investors in the pharmaceutical market of Kazakhstan, a new stage in the development of the industry has began. So, 51% of the shares of «Him Pharm» was acquired by the well-known European company «Polpharma». The largest domestic pharmaceutical company currently has three certificates of compliance with GMP standards, which indicates a great deal of done work to improve the quality of production of pharmaceutical

products for its possible implementation, not only on the domestic, but also on external markets.

With the arrival of foreign partners in Kazakhstan, there are production sites certified according to international GMP standards. At present, 12 production sites of 8 domestic pharmaceutical companies have received GMP certificates. It should be noted that most of them are enterprises with foreign participation. The availability of GMP certificates for certain production facilities should help to increase the output of manufactured products and help to more freely promote domestic drugs to foreign markets. The Turkish investor in the Almaty Pharmaceutical Factory, LLP «Nobel» which became one of the leading domestic manufacturers of pharmaceutical products. Moreover, the enterprise has confirmed compliance with GMP standards at its two production sites. The Russian investor, the company «Pharm standard», invests 15 million dollars to the Karaganda pharmaceutical complex (Development of the pharmaceutical industry in the Republic of Kazakhstan [Electronic resource). In 2015 year, the plant completed the reconstruction and expanded the production according to GMP standards within the Industrialization Map. Another major pharmaceutical company in Turkey is Abdi Ibrahim Ilaç San.ve Tic. A.S acquired 60% of shares from LLP «Global Farm». The cost of the project is 60 million dollars.

Currently, 63 pharmaceutical industry facilities in the Republic of Kazakhstan have implemented international GxP (Good Practice) standards, including laboratory practice (GLP), clinical practice (GCP), production practice (GMP), distribution practice (GDP), pharmacy practice (GPP) and pharmacovigilance practice (GVP). These standards set the requirements for the production, transportation, storage and sale of pharmaceuticals. Such large domestic pharmaceutical manufacturers as «Nobel», «Him Pharm», LLP «Viva Pharm», LLP «Eikos», LLP «FitOleum» and others have already implemented GxP standarts.

As a result, these investments should contribute to an increase in volume of production of domestic production. The domestic pharmaceutical industry needs modern personnel solutions and large financial injections in order to develop itself (Stargardt 2006: 235-47). Such measures are implemented by domestic pharmaceutical companies. This is demonstrated by the proposed investment projects that participate in the Industrialization Map for 2015-2019 years (15 investment projects with the creation of about 2200 workplaces and attracting over 64.7 billion tenge) (Development of the pharmaceutical

industry in the Republic of Kazakhstan [Electronic resource).

Currently, in order to develop the manufacturing industry, as well as the pharmaceutical industry in particular, a lot of initiatives are being carried out by the state. Within the framework of the state program of industrial-innovative development for 2015-2019 there are various tools to support business, including pharmaceutical industry. Such programs as the Business Road Map 2020, Exporter 2020, Employment 2020, Industrialization Map for 2015-2019 years, the productivity 2020 program are aimed at increasing the competitiveness of domestic enterprises through stimulation of production, export, personnel and technological potential of enterprises.

Within the framework of the Industrialization Map in the Pharmaceutical Industry for 2010-2015, launched 28 projects, attracted investments worth about 50.5 billion tenge. For 2016-2019 it is planned to commission about 12 investment projects involving about 53.7 billion tenge.

Thus, as a result of structure study of the world pharmaceutical market, it was concluded that the once stable and localized production of world pharmaceutical market is losing stability, there is a shift in favor of the developing countries, the work of a group of the largest companies of Western Europe and the USA that make up «BigPharma»is less promising (Outlook to 2020 [Electronic resource).

Thus, the further development of pharmaceutical market of Kazakhstan will make it possible to become independent of world manufacturers of pharmaceutical products, to adjust the economic course, to influence the development of other industries, which will lead to an increase in the rates of social development. For the world pharmaceutical market, the development trends are: high level of concentration of production capacities (Creese 2011:1-35); increase in costs for research and development; the activation of developing countries and third world countries in the reconstruction of the world pharmaceutical market with a view to overcome the superiority of transnational companies (Marinoso 2011:737-56); the desire of transnational companies to interact with partners and the formation of cluster-type structures.

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