Prospective of Transformation of Current Models of the Global Pharmaceutical Market*

YURIY SOLODKOVSKYY, OLHA DOVZHENKO**

ABSTRACT. This article thoroughly analyzes the current state of the global pharmaceutical market, defines the key factors for its development and outlines the promising areas of transformation of existing business models of top companies. The forecasted data relating to the market development until 2015 have been investigated. The global, market, technological and organizational factors of transformation of modern model of the global pharmaceutical market have been identified.

KEY WORDS: The global pharmaceutical market, pharmaceutical industry, pharmaceutical companies, medications, generic drugs, blockbuster drugs, E7, blockbuster business model.

Introduction

The pharmaceutical market plays an important role in the economy of a county primarily as a measure of its innovation, on the one side, and of the population well-being, on the other side. It is the high-tech pharmaceutical industry which should be thanked to that many other areas of the economy being the suppliers of raw materials and equipment develop, namely: chemical, agricultural, medical glass, machine-building and instrument making and other industries, as well as service providers: software, financial, insurance, consulting etc. In modern environment, the pharmacy has become the most lucrative industry involving huge investment flows. This is because a person's health has always been (must be) a primary concern of both every individual and a society on the whole. The demand for effective and safe medications increases with increase in the global population and changes to environmental and climatic conditions of human existence.

The topicality of the subject selected is a result of that the basis of a successful, dynamic business is the understanding of basic characteristics and trends of the world market, ability to obtain and use accurate forecast information about its development, factors and assumptions of strategically possible transformations. The urgency of

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such study is driven by the need to improve the international competitiveness of domestic pharmaceutical industry, given global changes in the business environment, and to promote harmonious development of the Ukrainian market of pharmaceutical products.

The current base of knowledge on distinctive features of functioning the pharmaceutical market formed because of studies conducted by both Ukrainian and foreign scientists in the form of books, articles, monographs, etc. In particular, those who actively explore the industry are foreign scientists: Hlumskov V¹., Golubkov E²., Chapell S³, and domestic scientists: Hromovyk B⁴., Gasiuk G⁵., Levitska O., Mnushko⁶ Z., Dyhtiareva⁷ N., Chernykh V., Grytsenko⁸ I., Kovalenko S. and others. However, there is an objective need in further study of this field of knowledge, because the issue of integration of the Ukrainian pharmaceutical market in the world market, assessments of a level of competitiveness in terms of theory and methodology has not been examined fully. The variety of pharmaceutical products, the relevance to find new approaches to solving the problem of integration of the Ukrainian pharmaceutical market in the world space affected the choice of the theme for writing the paper.

The objective of our study is to determine the conditions, factors and parameters of the global pharmaceutical market functioning and to ground the directions of its transformation in the post-crisis development environment. Identification of the parameters of the global pharmaceutical market shall be the basis for development and implementation of international competition and business strategies of Ukrainian companies. While achieving the objective so set, the authors applied the following study methods: structural factor, qualitative and quantitative analyses, the method of scientific abstraction, synthesis, deduction and induction, the method of combining the logical and historical approaches to studies of economic phenomena, etc.

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Current state of the global pharmaceutical market

Today, the pharmaceutical market is one of the most dynamic sectors of the world economy. This is explained by increasing a capacity of the medicines market in the world, rapid expansion of the range of medicines and low elasticity of the demand for them. Experience shows that even in the downturn the pharmaceutical production than any other is less exposed to downturn risk. In 2009, the volume of the global pharmaceutical market grew by 7% and amounted to USD 808 billion; this growth was due to unfavorable epidemiological situation in most countries of the world. According to the 2010 results, the global pharmaceutical market volume grew by 5.2% and amounted to USD 865 billion (fig. 1).

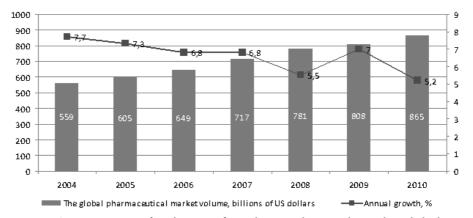


Fig.1. Dynamics of volumes of, and annual growth in the global pharmaceutical market in 2004-2010, billions of US dollars and %¹

It is possible to distinguish several significant factors that adversely affected the indicators of growth in the pharmaceutical market in 2010: American patents for a range of blockbuster drugs expired; decline in prices for medications in the Japanese pharmaceutical market second after the U.S. one, which led to that the CAGR indicator in the Japanese pharmaceutical market slowed to 0-2%; reduction in budgets for health care in Europe. Total sales of medications in the world's major pharmaceutical markets for 12 months — until January of 2011 amounted almost to USD 517 billion (fig. 2). The most active development of sales being 32% is shown by the pharmaceutical market of Venezuela, where drug consumption per capita is USD 194. A rapid growth rate is noted in the pharmaceutical markets of China, Argentina and Brazil (per

¹World pharmaceutical market 2010. [Electronic resource]. Access mode: http://www.publicagenda.org/chats/world-pharmaceutical-market

capita consumption ranges from USD 90 to USD 200). Growth rates for countries such as France, Italy, USA, Canada and Mexico are under 5%, and sales remain unchanged in Spain

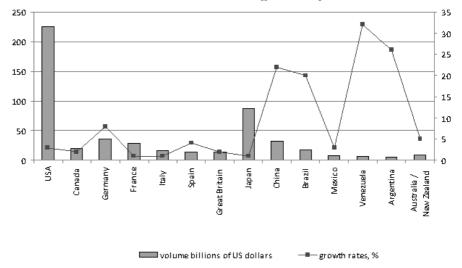


Fig.2. Total sales of medications in the major pharmaceutical markets in February of 2010 - January of 2011, billions of US dollars and $\%^1$

Despite the world's financial crisis, the global pharmaceutical market was able to maintain positive dynamics of growth, which averages 5-7% per year. However, it is worth to note two new market trends, which would exert significant influence on further development of the world's pharmaceutical industry and other related industries: first, the slowdown of growth rates from 8% to 4.5-5% in developed countries; secondly, territorial shift of major leading regions of pharmaceutical market from the developed countries to the BRIC countries. It is those countries with the growth indicators up to 15% that more largely determine the dynamics of the world market of pharmaceutical products. In addition, the world's financial crisis caused some redistribution of forces in the global pharmaceutical market. The analysts at «IMS Health» divide national markets in four large groups:

—developed pharmaceutical markets — USA, Canada, Germany,

Great Britain, France, Italy, Spain, Japan;

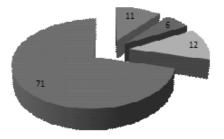
—developing pharmaceutical markets of Level 1 — China, Brazil, Mexico, Turkey, India, South Korea, Russia (E7 group);

¹Global Pharmaceutical Market Size & Growth by Region, 2010. [Electronic Resource]. Access mode:http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/? vgnextoid=e599410b6c718210VgnVCM100000ed152ca2RCRD&cpsextcurrchannel=1

—developing pharmaceutical markets of Level 2 — Ecuador, Peru, Chile, Colombia, Puerto Rico, Argentina, Venezuela, Vietnam, Philippines, Indonesia, Thailand, Pakistan, Algeria, Egypt, South Africa, Saudi Arabia, Lithuania, Bulgaria, Czech Republic, Hungary, Romania;

—others.

The direct correlation revealed between the demand for pharmaceutical products and macroeconomic indicators (GDP growth rate, consumer and government expenditures) somehow explains the new trends of the world market. As the financial crisis caused the greatest harm to developed countries with a high share of production in the services sector in GDP, this led to a significant reduction in consumer spending, in particular for products of the pharmaceutical industry. Therefore, we can say that the world's financial crisis gave rise to the formation of a new model of the global pharmaceutical market, which is characterized by a shift in emphasis from developed markets to the pharmaceutical markets of developing countries and by changes in commodity structure with emphasis on promising special-purpose markets and reduction in a share of general pharmacotherapeutic groups. In 2010, the aggregate share of the developed pharmaceutical markets was over 70% of the total global pharmaceuticals sales (Fig. 3).



■ Developing pharmaceutical markets of Level 1 ■ Developing pharmaceutical markets of Level 2

Others 📕 De veloped p harm aceutical markets

Fig.3. Shares of pharmaceutical market groups by sales in monetary terms in 2010,%²

Thus, the most promising markets in terms of an average annual growth rate are emerging markets of Levels 1 and 2. As it can be seen from fig.4, the contribution of developed pharmaceutical

² The global pharmaceutical market: state and trends. [Electronic resource]. Access mode: http://www.newchemistry.ru/letter.php?n id=7812&cat id=10&page id=2

¹ New world order in the pharmaceutical market. [Electronic resource]. Access mode: http://www.apteka.ua/article/16320

markets to the aggregate sales growth of the global market was 16% in 2010, and the developing pharmaceutical markets of Level 1 was 51%, despite the fact that they account for only 11% of the global pharmaceutical market volume. In 2010, the share of countries with the pharmaceutical markets of Level 2 accounted for 6% of global pharmaceutical sales and 22% of total global growth.

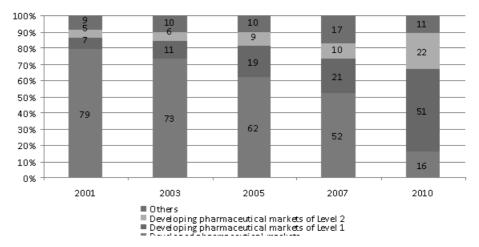


Fig.4. The contribution of pharmaceutical markets to an average annual increase in sales of pharmaceutical products in the world in 2001–2009, percentage (made by the authors according to the data in¹)

Conditions for further development of the global pharmaceutical market

According to forecast of «IMS Health», average annual growth rates of sales in the pharmaceutical markets of Level 1 by 2014 will amount to 13-16% (fig. 5). Sales in those markets would grow to USD 165-185 billion in 2014. Growth of medications sales in those pharmaceutical markets is due to several factors:

- —overall growth in morbidity through increasing the impact of man-caused factors and environmental degradation;
 - —trend of «population aging» in developed countries;
- —growth in population income levels in China, India, Russia, countries of Eastern Europe leads to the use of more expensive and qualitative medications;
- —rapid development of such relatively new areas as the segment of biologically active additives (BAA) and the segment of generic

¹ Leaders and outsiders of the global pharmaceutical market. [Electronic resource]. Access mode: http://www.aptekagal.com.ua/show_article.php?year=2011&month=3&num=12

drugs (cheap analogues of known medicines). Today, the share of generic drugs in the markets of U.S.A., Great Britain, Canada and Germany has already reached 30 %, and according to experts, it would continue to grow further on;

—increase in population in the world's certain regions;

—weakening of patent protection.¹

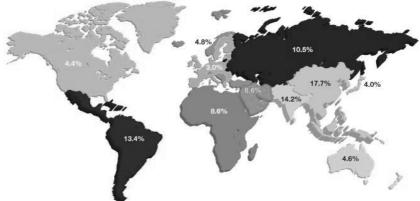


Fig.5. Forecast of annual growth in the global pharmaceutical market in 2011-2014, $\%^2$

North America will, however, remain the largest regional pharmaceutical market in the world (Fig. 6), but its development will slow significantly due to a vigorous growth in sales of cheaper generic drugs.

It is expected steady growth in the markets of Latin America; the largest growth dynamics is expected in Brazil and Mexico, which are among the developing pharmaceutical markets. In those countries new government guarantees of provision the population with medications are being formed. The company «IMS Health» predicts a maximum growth in the Venezuelan pharmaceutical market in the period of 2011–2013. It is expected an increase in pharmaceutical sales at 31–34%. Although that country has relatively unfavorable business climate in the pharmaceutical industry, weak legislation on intellectual property rights and political regime that restricts private entrepreneurship. On the other side, constant growth of the urban population is one of the important factors contributing to increasing the country's pharmaceutical market. It is the generic drug segment that is mostly

¹ Pharma 2020: The Vision — Which Path Will You Take? by PriceWaterhouseCoopers [Electronic resource]. Access mode: http://www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-vision-nath.ihtml

² Pharma 2020: The Vision — Which Path Will You Take? by PriceWaterhouseCoopers [Electronic resource]. Access mode: http://www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-vision-path.jhtml

developed in Venezuela. In general, Latin America has a significant potential as a market for distributing the drugs — inhibitors of angiotensin-converting enzyme and analgesics, which is associated with spreading the hypercholesterolemia in the region, which is a major factor of increasing the risk of cardiovascular diseases.¹

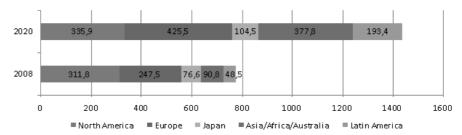


Fig.6. The global pharmaceutical market in 2008 and in 2020, billions of U.S. dollars (compiled by the authors according to the data in ²)

It is expected a slight growth in the leading markets (France, Germany, Italy, Spain, Great Britain) in Europe within the next 5 years. The situation would be determined by global economic forces, but a positive impact on sales would be inflicted by the region's aging population and growth in the demand for preventive services. The markets of countries in Central and Eastern Europe are forecasted to show certain growth.

Japan, one of the world's largest pharmaceutical markets, will continue to increase volumes by an average of 4-5% per year. The approval of new anticancer drugs, government programs of disease prevention, a two-year ban on increasing the prices for medications will foster the growth. The government's efforts to encourage the use of generic drugs have only limited impact on the market in Japan.

The pharmaceutical business development in the countries of Africa and the Middle East will be promoted by improving the infrastructure in the health care sector and by creating the more effective regulatory environment. The South African Republic (SAR), Pakistan and Egypt shall be among the most dynamic markets in the region.

It is expected the emergence of new pharmaceutical market leaders, which would be China, India, Mexico, Brazil, South Korea and Turkey. Their growth would be primarily stimulated by significant governmental investment in the industry. For example,

² Pharma 2020: Supplying the future by PriceWaterhouseCoopers. [Electronic resource]. Access mode: http://www.pwc.com/en_GX/gx/pharma-life-sciences/pharma-2020/pharma-2020-supplying-the-future.jhtml

¹ New world order in the pharmaceutical market. [Electronic resource]. Access mode:http://www.apteka.ua/article/16320

the Chinese government intends to invest more than USD 120 billion in the health care system by the end of 2012. It is China where the largest pharmaceutical market growth rate is expected, which will be the third global pharmaceutical market by volume after U.S.A. and Japan already in 2013 (table 1).

Table 1. Top 20 Largest Pharmaceutical Markets in 2003, 2008, 2013 (Forecast)*

| Rating in 2003 | | Rating in 2008 | | Rating in 2013 | | |
|----------------|-----------------|----------------|-----------------|----------------|-----------------|--|
| 1 | USA | 1 | USA | 1 | USA | |
| 2 | Japan | 2 | Japan | 2 | Japan | |
| 3 | Germany | 3 | France | 3 | China | |
| 4 | France | 4 | Germany | 4 | Germany | |
| 5 | Italy | 5 | China | 5 | France | |
| 6 | Great Britain | 6 | Italy | 6 | Spain | |
| 7 | Spain | 7 | Great Britain | 7 | Italy | |
| 8 | Canada | 8 | Spain | 8 | Brazil | |
| 9 | China | 9 | Canada | 9 | Canada | |
| 10 | Brazil | 10 | Brazil | 10 | Great Britain | |
| 11 | Mexico | 11 | Mexico | 11 | Venezuela | |
| 12 | Australia | 12 | Turkey | 12 | Turkey | |
| 13 | India | 13 | India | 13 | India | |
| 14 | Poland | 14 | South Korea | 14 | Mexico | |
| 15 | the Netherlands | 15 | Australia | 15 | South Korea | |
| 16 | Belgium | 16 | Greece | 16 | Russia | |
| 17 | South Korea | 17 | Poland | 17 | Greece | |
| 18 | Turkey | 18 | the Netherlands | 18 | Poland | |
| 19 | Portugal | 19 | Belgium | 19 | Australia | |
| 20 | Greece | 20 | Russia | 20 | the Netherlands | |

^{*}Source: compiled by the authors according to the data in³

The activities in those promising markets would assist the pharmaceuticals manufacturers in coping with losses resulting from competition with unlicensed drug manufacturers. The medications with total sales of USD 137 billion may lose the patent protection within the next 3-4 years, including blockbusters such as Lipitor (Pfizer),

New structure of the global pharmaceutical market. [Electronic resource]. Access mode:http://www.provisor.com.ua/archive/2009/N15/nsmfr_159.php

Fulfilling the Promise of China. [Electronic resource]. Access mode: http://www.pharmafocu-sasia.com/strategy/promise of china.htm

³ Pharma's new world order. [Electronic resource]. Access mode: http://www.rsc.org/chemistryworld/News/2009/June/05060902.asp

Plavix (Bristol-Myers Squibb/Sanofi-Aventis) and Seretide (Glaxo SmithKline). A half of the global pharmaceutical market will be composed of cheaper generic analogues of those brands approximately by the end of 2015. It is expected that the peak of patent collapse in USA would be in 2012, when six in ten drugs being leaders in terms of sales in this market would face the threat. Some analytical calculations show that after unlicensed analogues have entered the market, the branded medications will lose about 90% of sales.

As early as by the end of 2012 generic versions of medicine Plavix (Bristol-Myers Squibb), medicine for treatment of schizophrenia Zyprexa[™] / Zypreksa[™] (olanzapine, «Eli Lillv&Co. Inc.») antibiotic Levaquin™ (levofloxacin, «Johnson&Johnson Pharmaceutical R&D») will enter the global pharmaceutical market. Loss of the patent protection for the most popular medications will negatively affect the profits of top companies in pharmaceutical markets (table 2). For example, the company Pfizer, which has headed the rating of most profitable companies in the global pharmaceutical market for many years, would predictably decline three points in 2015 due to loss of the patent protection for several of its blockbuster drugs, and Novartis would lead the rating of the most profitable companies as it has the smallest share of patented drugs in its range of products and has long been a leader in the production of generic drugs.

Table 2. Forecast of Changes in Profitability of Top Companies in the Global Pharmaceutical
Market (2008 and 2015 (Forecast), Millions of us Dollars*

| Top companies | Profit of top companies | | Forecast of changes | Rating of top companies | |
|----------------------|-------------------------|--------|---------------------|-------------------------|------|
| iii the market | 2008 | 2015 | in profit, % | 2008 | 2015 |
| Pfizer | 48,639 | 34,075 | -30 | 1 | 3 |
| Sanofi-aventis | 43,177 | 36,186 | -16 | 2 | 2 |
| Novartis | 40,529 | 45,714 | +13 | 3 | 1 |
| AstraZeneca | 31,522 | 16,878 | -40 | 4 | 8 |
| Merck & Co | 29,724 | 24,428 | -18 | 5 | 4 |
| GlaxoSmithKline | 22,858 | 20,294 | -11 | 6 | 6 |
| Wyeth | 22,367 | 20,537 | -8 | 7 | 5 |
| Bristol-Myers Squibb | 21,603 | 16,364 | -24 | 8 | 9 |
| Schering-Plough | 20,595 | 20,216 | -2 | 9 | 7 |
| Eli Lilly | 20,275 | 15,286 | -25 | 10 | 10 |

^{*}Source: compiled by the authors according to the data in 1

 $^{^1}$ New structure of the global pharmaceutical market. [Electronic resource]. Access mode: $\label{eq:http://www.provisor.com.ua/archive/2009/N15/nsmfr} 159.php$

The results of patent protection expiry will be undoubtedly partially offset by a new wave of promising innovations that will allow meeting the demand of patients and significantly altering the treatment paradigm in several key therapeutic areas, including diabetes prevention, treatment of melanoma, multiple sclerosis, breast cancer and hepatitis C. In addition, according to the forecasts of «IMS Health», in 2011-2013 it will be agreed, patented and introduced to the market five new products being the potential blockbuster drugs, which annual sales will make more than USD 1 billion. Those among them may become thrombolytic Brilinta[™] (ticagrelor, «AstraZeneca plc.»), anticoagulant apixaban from the companies «Pfizer» and «Bristol-Myers Squibb Co.», a medication for treating breast cancer iniparyb («Sanofi-Aventis S.A.») and a viricide telaprevir for hepatitis C treatment from «Vertex Pharmaceuticals Inc.». It is worth to note that according to the Pharmaceutical Research and Manufacturers of America (PhRMA), the average time for developing a new medication is 10-15 years. In addition, if the process cost a little over USD 300 million 20 years ago, today the cost of developing a new medication has increased almost three-fold. The development of biotechnology drugs is much more expensive and may reach USD 1 billion. Thus, only 3 of 10 medications that enter the market generate the revenues to cover the cost of its development and are beneficial for the developer.

It should be noted that the basis of modern pharmaceutical industry activity is a business model that does not ensure the stable economic development. It does not allow companies to quickly produce innovative drugs that are required in the global market. It would be impossible without a fundamental change in the nature of the industry to maximally use the opportunities offered to it. In particular, now pharmaceutical companies are facing such key objectives following from the industry's main weaknesses (fig.7): intensification of research and updating of innovative development model, involvement of significant additional financial resources, introduction of new sales methods and international marketing activities, organization of collaboration with regulators to unify and simplify the global legal regulatory business environment, improvement of the industry reputation in the eyes of consumers and the market regulators, etc.

The world market for pharmaceuticals belongs to the monopolistic competition market type. As a result of global «division of labor» in the industry of pharmaceuticals production, of 50 largest pharmaceutical companies occupying over 80% of the market, 20 companies are in the United States territory (39.2% of the global pharmaceutical market), 18 companies in Europe (33.3% of the market), 11 companies in Japan (7.8% of the market) and 1 in Israel (table 3).

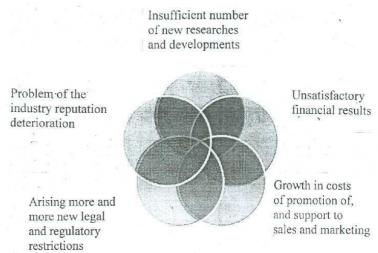


Fig.7. Problems of pharmaceutical companies (made by the authors based on materials in¹)

The competition between multinational pharmaceutical firms continues today not around the prices for medications, but around the wide use of achievements of scientific and technological progress in the pharmaceutical industry. The leading position of the firms in the global market is linked to the widespread use of achievements of genetic and cell engineering, biotechnology, allows the firms to develop and produce the medicines with significantly improved pharmaceutical properties, good tolerance and high stability.

The key competitive advantages of leading multinational

pharmaceutical firms include²:

—a wide network of dealers and distributors;

- —the existence of a network of factories in different countries;
- —relatively low prices for medications being the analogues from other firms due to availability of factories and wide dealers network;
 - —a trademark common for all factories;
- —the only advertising company for all manufacturing factories and distributors;
 - —a wide range and mix of products;
 - —availability of own research laboratories;
 - —output targeted at different market segments;
 - —a guarantee of safety to use the drugs of a firm;
 - —development of new types of medications;
 - —the firms' goodwill (presence in the market for many years).

¹ The global pharmaceutical market will double by 2020 and reach USD 1.3 billion. [Electronic resource]. Access mode:http://optica.in.ua/se/news/index.php?action=show&nid=4169
² Nigel MacLennan, *Brand Planning for the Pharmaceutical Industry* (P.: Gover House, 2004).

Table 3. The World's Largest Pharmaceutical Companies in 2010, Millions of U.S. Dollars*

| | | | 2010 | | | |
|----------------------|----------------------|-------------------|-----------------|----------------------------------|-----------------|--|
| Company's name | Country of origin | Top drugs | Rating position | Profit, millions of U.S. dollars | Market share, % | |
| Pfizer | USA | Lipitor, Lyrica | 1 | 45,4 | 6,6 | |
| Sanofi-Aventis | France | Lovenox, Plavix | 2 | 40,9 | 6,0 | |
| Novartis | Switzerland | Diovan, Gleevec | 3 | 38,5 | 5,8 | |
| GlaxoSmithKline | Great Britain | Seretide, Valtrex | 4 | 36,7 | 5,6 | |
| AstraZeneca | Great Britain | Nexium, Crestor | 5 | 31,9 | 4,9 | |
| Merck & Co. | USA | Singulair, Cozaar | 6 | 26,9 | 4,4 | |
| Johnson & Johnson | USA | Remicade, Topamax | 7 | 22,5 | 3,3 | |
| Eli Lilly & Co. | USA | Zyprexa, Cymbalta | 8 | 20,6 | 3,1 | |
| Bristol-Myers Squibb | USA | Plavix | 9 | 18,8 | 2,6 | |
| Abbott Laboratories | USA | Humira | 10 | 16,5 | 2,3 | |
| Takeda Chem. Ind. | Japan | Pioglitazone | 11 | 14,2 | 2,2 | |
| Boehringer-Ingelheim | Germany | Spiriva | 12 | 14,0 | 2,2 | |
| Teva Pharma | Israel | Copaxone | 13 | 13,8 | 2,1 | |
| Bayer Schering | Germany | YAZ | 14 | 13,3 | 1,9 | |
| Astellas | Japan | Prograf | 15 | 10,5 | 1,5 | |

^{*}Source: (compiled by the author according to the data in^1)

At the same time, the market participants realize that the cost of the majority of pharmaceuticals is unreasonably high today. The economic crisis has revealed additional challenges to the entire

 $^{^1}$ TOP-50-Pharmaceutical-companies-Pharm-Exec The Pharm Exec. [Electronic resource]. Access mode: http://www.scribd.com/doc/21016515/

industry and each of its companies. Today, the manufacturers have to adapt their strategies and tactics to the new conditions of the world business environment: to re-evaluate business models; to use any opportunities in the emerging markets to boost the potential benefits of their medications; to determine how to maximize the share of their business in new markets with the highest growth rates. By 2008, only 1/3 of all new products entered the market countries. the E7 Now many companies GlaxoSmithKline, Sanofi-Aventis, etc.) consider those markets as a priority. Despite the fact that all pharmaceutical markets in E7 have many similar features, each of the group countries has unique characteristics and areas of development need to be taken into account in the new business models of pharmaceutical companies. example, China, India and Korea have been always characterized by prevailing importance of traditional medicine and very different population density across the countries' regions, which makes access to these markets and maximum consumers reach difficult, primarily in rural areas. Brazil and Mexico are the markets with many local manufacturing firms focusing on patients who are unable to afford more expensive foreign drugs. The market in Russia is characterized by availability of strong domestic production and uneven location of solvent population over the country's large territory. The market in Turkey is the most traditional as it is close by the key characteristics to the markets of some European countries (particularly, Greece).

Global prospectives of pharmaceutical industry transformation

According to the estimates of experts at the company «PriceWaterhouseCoopers», the following changes shall take place: a main focus on business results, the formation of a system of continuous monitoring of health care services, an increased in the share of drugs for disease prevention, the introduction of a dynamic innovation model of development, optimization of testing and licensing procedures, strengthening of international collaboration in the regulatory sphere, the disappearance of the blockbuster sales model, etc. (fig.8).

In our opinion, the major pharmaceutical industry transformations will take place along the lines: patents formulization; changes in a pricing model; implementation of a system for compensation and diversification of risks between the following key market players — pharmaceutical companies, insurance companies, distributors and regulators of markets. Top companies will also seek to prove their

highest efficiency and capacity to rapidly develop and introduce new medications to the market.

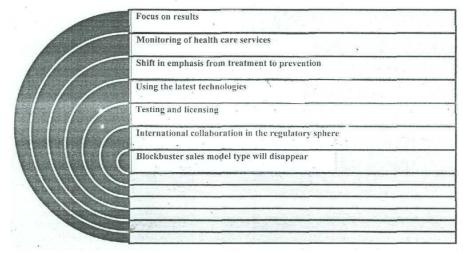


Fig.8. Prospective lines of the global pharmaceutical industry development (made by the authors according to the materials in ¹)

Market experts and representatives of the health care consider a possibility to develop and implement additional services to their customers. First of all, it concerns the implementation of a system for monitoring of compliance of actions by patients with regard to taking medications with doctor recommendations. Such initiative is explained by the fact that, for example, in USA 20% of patients totally ignores the recommendations of doctors without any reasons and 60% do not adhere to them completely. This affects the safety and results of therapy, and pharmaceutical companies lose the revenues and reputation as manufacturers of quality products. Pharmaceutical companies are planning to introduce new methods of monitoring of patients compliance as an additional service to them, insurance companies and pharmaceutical market operators. The results of such monitoring can be used in clinical trials as well.

The preventive health care also opens some opportunities of the pharmaceutical industry, unused today. In the countries that are members of the Organization for Economic Cooperation and Development, it is scheduled to increase a share of expenditures for disease prevention up to 30% of the total health care expenditure for the next five years. According to WHO, those predictable are about

¹ Pharma 2020: The Vision — Which Path Will You Take? by PriceWaterhouseCoopers. [Electronic resource]. Access mode: http://www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-vision-path.jhtml

80% of cases of the cardiovascular system diseases, stroke and diabetes, and 40% of cases of oncopathology, which confirms the promising outlook of «preventive medications» development and introduction them to the market. The pharmaceutical industry, when realize the saving of means for disease prevention among healthy people instead of treating a patient, will form a health-improving administration with the best programs, monitoring of compliance of medications with health state of patients, vaccination and other extra services. Today, 245 monovalent vaccines and 11 combined ones are being studied in clinical trials. Their contribution to the pharmaceutical market in 2015 will amount to USD 42 billion.

Technological transformations will also assist in updating the business strategies of pharmaceutical companies. The use of genetic tests in conjunction with the medications for genetic therapy has made the research process more focused, less long and, in experts' opinion, predicted. Further studies of the human genome will open a world of new possibilities in molecular science and will allow to differently impact the human body. New technologies would be used to better understand diseases. They will become a link to harmonizing the genetic and clinical data.

The current approach involves submitting an application for getting a permit for marketing a drug only at the end of early phase of clinical trials. It will be replaced by the licensing process, which will cover the entire life cycle of a product. Regulatory agencies will be continuously provided with the results of small accurately planned researches. Even today, some national and regional regulatory agencies began to collaborate with using data on the safety and efficacy of medications. Maybe by 2020 there would appear a single

global regulatory system, which will be managed by national or federal agencies, as well as be responsible for ensuring the new medications meet the needs of patients in a particular region.¹

A new industry being pharmacogenomics emerges at the junction of traditional pharmacology and biotechnology, which aim is to create personalized medications — «the most effective medication for a given patient at the given time.» Medicine personalization based on modern biotechnology developments with parallel production of medications will lead to complete disappearance of the blockbuster business model and to fundamental changes in the system for distribution of the pharmaceutical industry products.

To summarize all current features of the global pharmaceutical market, it should be noted such of its main features and trends that define the future of the industry (fig.9): the market's high

¹ The global pharmaceutical market will double by 2020 and reach USD 1.3 billion. [Electronic resource]. Access mode:http://optica.in.ua/se/news/index.php?action=show&nid=4169

saturation, a reduction in the expenditures for public health care as a result of reform of national health care systems; strengthening the role of health care state regulation in general and the pharmaceutical industry in particular; an increase in the expenditures for scientific research and research design works; an increase in production efficiency and optimization of cost structure; consolidation of pharmaceutical companies; creation of strategic alliances and making of agreements between them on joint development of drugs, development of drugs with the dedicated action mechanism; extensive development of biotechnology, genetic engineering; generation of personalized medications under the principle «the most effective drugs for a given patient now»; increasing the production and sale of generic drugs; diversification of activities of pharmaceutical companies (production of drugs for veterinary medicine, production and sale of medical equipment, participation in solving the matters of health care arrangement, etc.); extensive use of benchmarking in a company operation; increasing the expenditures of pharmaceutical companies for promotion of drugs in traditional and new regional markets

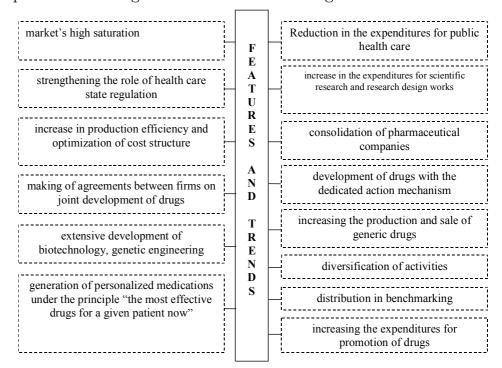


Fig. 9. Current features and trends of the global pharmaceutical market development (made by the authors according to the materials in¹)

The pharmaceutical market within coming years will continue to generate changes that will be developing in three main strategic directions:

—main points of the pharmaceutical market growth are the development of segments of biologically active additives (BAA) and generic drugs, transition from the chemical technology dominant today in the production of drugs to biotechnology as well as to pharmaceutical herbal products, which share in the market according to the WHO forecasts will exceed 60% of total medications volume in the largest ten years;

—enhancement of contradictions between the interests of the pharmaceutical industry of the West, which is mainly focused on the profit and profitable developments for the treatment of non-communicable diseases that spread in developed countries, and the needs of people of the poorest and developing countries in drugs against specific infectious diseases;

—competition between multinational pharmaceutical companies will completely forsake the pricing and assortment areas arrange around wide practical use of the latest achievements of scientific and technological progress in the pharmaceutical industry, primarily of the achievements of genetic, and cell engineering, biotechnology, etc.

The said transformations of the global pharmaceutical market, which are taking place lately and forecasted for the next 5-7 years, will undoubtedly lead to a significant change in the modern model of the market. Having recognized such outlook, top companies of the world market even today make deals with small and medium-sized firms in the E7 group on the production of generic drugs, which allows them to save operational and marketing resources and redistribute them to open research centers and clinical sites in India, China, Singapore in order to intensify the generation of new original medications and technologies.

Conclusions

The recent global financial crisis was a catalyst for many processes that had slowly evolved in many global markets of goods and services, particularly in the pharmaceutical one. The future of the global pharmaceutical market looks pretty optimistic as its constant growth is forecasted (the market volume will reach USD 1.3 billion by 2020). At that, the regional structure of the market

¹ Hlumskov V., "Global pharmaceutical market: state and trends," *Expert* (2010). [in Russian].

will change as the E7 countries (Brazil, China, India, Indonesia, Mexico, Russia and Turkey) became the fastest growing ones. It is those markets that will determine the priorities for operation of pharmaceutical companies toward abandonment of business models such as «blockbuster drugs» and transition to production of «generic drugs», which shall be performed mainly under a contract with local firms of regional markets. The major resources of transnational top companies in the industry will be mainly applied to R&D, in particular, to the development of products of genetic and cell engineering and biotechnology, introduction of new services designated to maximally harmonize the collaboration between pharmaceutical companies and the health care system, etc.

Given the identified parameters of transformation of the global pharmaceutical market and competitive advantages of Ukrainian pharmaceutical companies, the strategy most relevant for them, in our opinion, would be the one on increasing the production of generic drugs to sale them in the domestic market with the parallel involvement of direct foreign investment in countries with weak domestic production and rising demand (developing pharmaceutical markets of Level 2 — Ecuador, Peru, Chile, Colombia, Puerto Rico, Argentina, Venezuela, Vietnam, Philippines, Indonesia, Thailand, Pakistan, Algeria, Egypt, South Africa, Saudi Arabia, Lithuania, Bulgaria, Czech Republic, Hungary, Romania, etc.). In addition, an important strategic objective is the realization of collaboration with powerful multinational companies towards the production of generic drugs and conducting the joint R&D.

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