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Analysis of The Development of Modern Pharmaceutical Industry.

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ABSTRACT

The modern pharmaceutical industry is an objective indicator of the socio-economic development of health care. Its evolution included the improvement of the technology of production of medicines, the change in the organizational forms of conducting the pharmaceutical business, the formation and improvement of regulatory standards in the production and distribution of pharmaceuticals. The subject of the study is the Russian pharmaceutical industry. The subject is a system of statistical and non-statistical indicators that characterize the investment attractiveness of Russia's pharmaceutical industry.
Keywords: pharmaceutical industry, regression model, investment attractiveness

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INTRODUCTION

The development of the world pharmaceutical industry at the beginning of the 21st century is characterized by a concentration of consumption, production and innovation in a relatively small number of countries with high income levels. The countries of North America and Europe, as well as Japan, account for 82% of global pharmaceutical sales (in value terms). Moreover, given the globalization of the world economy, noted by researchers of the pharmaceutical industry, it is now possible to speak not of the leading countries in the production of drugs, but of transnational pharmaceutical corporations (TNCs), called "Big Pharma".

"Big pharma" is the term for the world's largest pharmaceutical companies, such as AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Maxim, Merck, Monsanto, Pfizer, Roche and Tanabe. Over the past decade, European and American companies have dominated the Big Pharma. At the moment, there are 4 criteria that determine "Big pharma":

1. Sales of more than 2 billion dollars a year,
2. The presence of significant international operations and presence in 3 major markets (USA, Europe and Japan),
3. The coverage of several therapeutic classes with R & D and marketing efforts of implementation in at least five different therapeutic areas,
4. Access to fully integrated pharmaceutical activities, including internal R & D, production, clinical and regulatory research, and marketing and sales.

It should be noted that despite the worldwide presence of fares, R & D funds primarily come from US, Swiss and UK companies.

MATERIALS AND METHODS

According to international statistics, the pharmaceutical industry is the most knowledge-intensive and innovative sector of the world economy: the highest indicator of conditional-net production per employee, as well as the ratio of R & D expenses to sales. In 2012, 50 of the world's largest pharmaceutical companies spent $ 54.9 billion on R & D, or about 17% of total pharmaceutical sales.

At the same time, the average development time for a new drug, according to Pharmaceutical Research and Manufacturers of America (PhRMA), is 10-15 years. And if 20 years ago this process cost slightly more than 300 million dollars, today the cost of developing a new medicine has increased almost three-fold. The development of biotechnological drugs is even more expensive and can reach $ 1 billion. At the same time, experts say PhRMA, only 3 out of 10 drugs that hit the market, bring a profit greater or equal to the amount that was spent on their development.

This forces the industry to address the lower risks of the producers themselves and the life of cyclically managed projects with an emphasis on radically new methods of treatment. This is supported by the latest data on Kneller [1], Stevens et al [2], who reported that medicines are given priority to address regulatory issues, usually the public sector of origin, and that the drugs originally discovered by biotechnology companies and universities are most often classified as innovative. Medicines of this origin are also more often found in solving important needs of medicine.

In 2014, the demand and supply of the pharmaceutical market was strongly influenced by the consequences of the global financial crisis. Despite this, in the seventeen countries of the world known as "Pharmerging", the share of the world market has grown rapidly from 13% to 16% (including in China, Brazil, India, Russia, Mexico, Turkey, Poland, the Bolivarian Republic of Venezuela , Argentina, Indonesia, South Africa, Thailand, Romania, the Arab Republic of Egypt, Ukraine, Pakistan and Vietnam (in descending order of market size).

China is the fifth largest pharmaceutical market in the world in 2015 and the third in 2016 (after the US and Japan), with an annual growth rate of 26% in 2014.

At present, countries with double-digit growth rates are strategically attractive for many multinational pharmaceutical companies. The world consumption of medicines in value terms is very unevenly distributed. According to the World Health Organization (WHO), high-income countries account for 16% of the world's population and 78.5% of the total expenditure on medicines. On the other hand, low-income countries make up 17.6% of the world's population and only 1% of the total number of pharmaceutical expenditures. These differences occur not only because of per capita income and spending on medicines, but also because of the difference in the availability of medicines and in the nature of the pharmaceutical markets (and health) in these countries.

The importance of India has grown as a producer and exporter of medicines. India has become a net exporter of drugs, while several high-income countries are net importers (for example, the United States and Japan). China is also the largest exporter, but it is still a net importer, probably because it still needs large volumes of branded medicines.

India and China have become major exporters of medicinal preparations, especially generic and bulk active ingredients, their domestic policy is becoming increasingly influential on pharmaceutical policy worldwide. In the US, for example, the Food and Drug Administration (FDA) considers the growing globalization of pharmaceutical production as the main risk to industrial safety, since "the vast majority of medicines [in the US] contain import ingredients, most of which are imported from India and China".

Quality assurance in low- and middle-income countries is a major problem because of their limited regulatory capacity.

Pharmaceutical research and development (R & D), high-income countries manage spending in the public and private sectors. In 2015, for example, 97% of medical R & D occurred in high-income countries: pharmaceutical companies spent about $ 80 billion on R & D in high-income countries and only about $ 1.6 billion in low- and the average level [47]. According to the statistics of the Organization for Economic Cooperation and Development (OECD), the US government spent an amount equal to 0.22% of gross domestic product (GDP) for health-related R & D, of which the pharmaceutical industry accounted for an amount equal to 0.3% Of GDP. In a number of other high-income countries (Japan, France and Germany), the pharmaceutical industry has spent significantly more. As a result of the dominance of both private and public investment in pharmaceutical R & D into five pharmaceutically developed countries (USA, UK, Japan, Germany and France), a significant part of the new patents in the world pharmaceutical market.

The effect of the dominance of high-income countries in R & D reflects the allocation of funds for research. A significant part of pharmaceutical R & D is carried out by a relatively small number of international companies that are directly focused on the discovery and development of new chemicals that can become "blockbuster" drugs. Blockbuster products are highly effective newest medicines, patent sale of which can reach global sales of more than $ 1 billion a year and significantly bring profit to the company-creator. The blockbuster business model led economic and business strategies into research pharmaceutical companies. This dynamic allows us to understand that companies have concentrated in high-income countries - where their products can be sold at a high price, with patent protection, more patients. However, this business model does not involve spending on the development of a new medicine that can be sold to poor patients in poor countries at low prices, where most patients lack a list of medications from health insurance and they must purchase drugs for their money.

In 2014, the pharmaceutical industry faces the expiration of patents for 10 blockbuster drugs that previously had a global sales volume of about $ 50 billion per year. All large companies are trying to come up with new strategies to deal with the problem of a sharp drop in sales revenue. Many pharmaceutical companies are turning to emerging markets: in countries with large populations and potential market growth. This change creates both problems and opportunities, especially for middle-income countries.

Speaking about the world pharmaceutical market, it is necessary to recognize that production has various forms in different countries. Not all manufacturers undergo a full cycle of production activities:

1. development of active ingredients of medicines,
2. production and delivery of dosage forms,

3. packing of tablets, capsules, or liquids in containers and boxes, checked and ready for sale to consumers.

Production in low-income countries and many middle-income countries (including Russia) usually includes only the last two stages, the import of active ingredients along with other materials needed for production. Even middle-income countries that produce some active ingredients are mainly targeted at small molecules, that is, relatively simple drugs.

The combination of several approaches to assessing the investment attractiveness of Russia's pharmaceutical industry will provide the most comprehensive picture of the industry's situation for investors. In the mixed methodology, we propose to use the regression model and the method of expert assessments. A distinctive feature of the study is that in the course of the work it is possible to find out how current the investment flows in the pharmaceutical sector correspond to the expectations of investors.

RESULTS AND DISCUSSION

In the course of the analysis of the activity of the branch, the actual tendencies of its development and the factors influencing its investment attractiveness were revealed. As a result, six factors were singled out, which direct investors focus on when choosing the pharmaceutical industry as an investment:

1. The share of innovative products in the medicinal portfolio of the industry (the implementation of innovations is a leading factor in the prospects for the development of the industry);
2. share of investment in R & D (this factor shows the investor how much the industry is ready for self-development);
3. public expenditure on health (the investor estimates state support for the development of the industry, which reduces the risk of investment);
4. the volume of the pharmaceutical market;
5. number of firms in the industry;
6. The refinancing rate (affects the adoption of investment decisions, as the higher the rate, the more expensive the investments are estimated)

Description of variables and hypotheses:

Firms: - number of firms from the field for the reporting year (pcs.) The more firms in the field, the more in- vestments

Gsh - public expenditure on health care for the reporting year (million dollars). The more the state spends on healthcare development, the more investors invest in pharma-ral

Innov_medical - the share of innovative medicinal products from the total number of new drugs released on the market (%). The greater the share of innovative drugs, the more investment is poured into the industry

R & D_invest - share of investment in R & D (%). The greater the proportion of the company's revenue spent on R & D, the more investment the industry receives.

Vol_market - The volume of the pharmaceutical market (million USD) The more the volume of the pharmaceutical market, the more attractive it is to investment

R - Refinancing rate for the reporting year .The refinancing rate affects the amount of investment in the pharmaceutical industry

The construction of a multifactorial regression model will help to assess the significance of the selected factors that have the greatest impact on the amount of investment in the pharmaceutical sector:

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$$R = \sum c_i X_i$$

,

where c - regression coefficients,
X - values of regression factors.

The statistical significance of factor indices is determined by calculation. As an explanatory variable, the gross investment in the pharmaceutical industry was taken, as regressors - indicators that affect the investment flow of the pharmaceutical industry from 2010 to 2018.

A regression model was constructed, which was improved to improve the quality of the model. This model describes the logarithmically linear dependence of investments in the pharma industry on a number of indicators presented in Table 1:

INVEST = C (1) * R & D_invest + C (2) * Innov_medical + C (3) * Firms + C (4) * Gsh + C (5) * R + C (6) * Vol_market + C (7) that the coefficients C (l) - C (7) are positive.

Table 1: Results of the regression model

Variable	Coefficient	Std. Error	t-Statistic	Prob.
Gsh	0.768718	0.030990	24.80520	0.0016
Innov_medical	21.12531	7.697975	2.744269	0.1111
Firms	-8.743326	0.590643	-14.80307	0.0045
R&D_invest	118.5800	12.91729	9.179947	0.0117
R	-18.21537	19.80358	-0.919802	0.4548
Vol_market	-0.005742	0.000611	-9.402654	0.0111
C	6383.669	561.3690	11.37161	0.0076
R-squared	0.999578	Mean dependent var		3268.556
Adjusted R-squared	0.998311	S.D. dependent var		1261.620
S.E. of regression	51.84703	Akaike info criterion		10.78595
Sum squared resid	5376.229	Schwarz criterion		10.93935
Log likelihood	-41.53678	Hannan-Quinn criter.		10.45492
F-statistic	789.1590	Durbin-Watson stat		1.918559
Prob(F-statistic)	0.001266			

The table shows that, in general, regression is significant (F-statistic = 789.1590). The coefficient of determination R-squared = 0.999578 shows the inclusion of significant factors in the regression model, and also indicates that the form of the relationship in question reflects the real relationship between the variables included in the model.

According to Durbin-Watson statistics, the model is considered qualitative and can be used (no autocorrelation of the residues) if the value of this criterion does not exceed 2. In the constructed model, the value of the Durbin-Watson criterion is 1.918559.

The quality of the found regression coefficients can be checked with the help of t-statistics at a certain level of significance (as acceptable we take 90% confidence interval). If the significance level does not exceed 0.1, then it can be argued that the equation and its coefficients are statistically significant. Statistical significance of factors is determined by the values of Prob. At the same time, the lower the value of this indicator, the greater the impact of the factor on the score. Note that five of six indicators are significant, which confirms the correctness of the choice of indicators.

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The second stage in assessing the investment attractiveness of the pharmaceutical industry of the Russian Federation is the ranking of indicators by the method of expert assessments. This stage involves performing a comparison of each indicator-factor level of its significance for analysis, in accordance with the expectations of the investor. Since this indicator is special for each investor (perhaps as a level of significance to consider the risk of this or that factor), we use the universal indicators determined by the Fishburn rule:

$$r_i = \frac{2(N - i + 1)}{(N + 1) * N},$$

where N - is the number of factors in the model,

i - is the ordinal number of the factor.

To use the Fishburn formula, we arrange all the indicators in descending order of significance in such a way that the rule is fulfilled:

$$r_1 \geq r_2 \geq \cdots \geq r_N$$

1. Public expenditure on health in the reporting year (million dollars) 0.768718 - according to the Fishburn - 0.16666666667
2. The number of industry firms for the reporting year (pcs) -8.743326, according to the Fishburn 0.138888889
3. The volume of the pharmaceutical market (million dollars) -0.005742, according to the Fishburn 0.11111111
4. Share of investment in R & D (%) 118.5800, according to the Fishburn 0.083333
5. The share of innovative medicinal products from the total number of new drugs introduced on the market (%) 21.12531, according to the Fishburn 0.0555555556
6. Refinancing rate,% -11.21537, according to the Fishburn 0,02777778

The obtained values of factors and level of significance can be the basis for assessing the investment attractiveness of the pharmaceutical industry. Fig. 1.

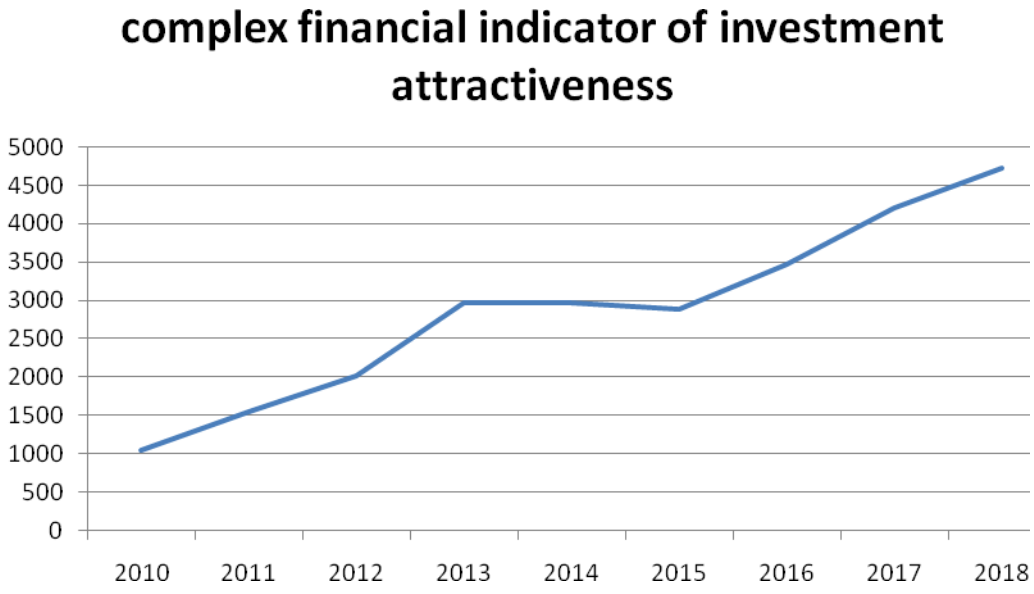

Fig 1: Complex financial indicator of investment attractiveness of the pharmaceutical industry

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CONCLUSION

The result showed that with an increase in public spending by 100 thousand dollars, the volume of investments into the industry will increase by 7.7%; with an increase in the share of proceeds for R & D investment by 0.01%, investment in the industry will increase by 118.58% (that is, more than 1.1 times); an increase in the share of innovative medicines in the industry's food portfolio by 0.01% will increase investment by 21.13%.

It follows from this that an increase in the investment attractiveness of the domestic pharmaceutical industry is possible only with an increase in the costs of R & D, the introduction of more and more innovative medicines on the market, and increased government support in the health sector.

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