

## Determinants of Innovation Activity of Russian Pharmaceutical Manufacturers



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**Abstract.** The article presents the findings of an empirical study on the main determinants of innovation activity of Russian pharmaceutical manufacturers. We substantiate the application of two indicators that characterize innovation activity of pharmaceutical manufacturers: the first is the ratio of the number of the organization's proprietary intellectual property objects to those used under license; the second is the number of studies conducted by pharmaceutical manufacturers for original and reproduced medicines. Two-dimensional cluster analysis (the k-means clustering, excluding repetitions, using Euclidean distances) is used to classify enterprises as innovation-active. We highlight major factors influencing innovation activity of pharmaceutical manufacturers directly on the basis of the content analysis of Russian and foreign scientific works published on this topic. We analyze the selected determinants using statistical and econometric tools. The following statistical criteria are applied: Pearson's chi-squared test and Fisher's exact test for qualitative (dichotomous) indicators, as well as Student's t-test and

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the Mann – Whitney test to analyze quantitative indicators. Using discriminant analysis of the main determinants of innovation activity of Russian pharmaceutical enterprises we reveal the most significant determinants, primarily those that directly characterize the size of industrial enterprises. Additionally, we prove that widespread processes such as mergers and acquisitions of pharmaceutical manufacturers contribute to the possibility of accumulating resources necessary for innovation development of pharmaceutical manufacturers; however, these processes have certain negative effects associated with an increase in the oligopolization of pharmaceutical markets.

**Key words:** pharmaceutical industry, innovations, innovation activity determinants, cluster analysis.

### Introduction

Innovation development of pharmaceutical production is defined as one of the main directions of Russia's economic policy<sup>1</sup>; this becomes especially relevant when the socio-economic, scientific and technological ties with unfriendly countries are curtailed. This sphere of material production can become one of the main starting points of the planned structural transformation of the Russian economy<sup>2</sup> and its shift to a qualitatively new level of development, especially in the context of the new reality. External socio-economic effects are also of strategic importance, since the development of fundamental research in the medical and pharmaceutical industries directly contributes to improving the quality of life and increasing life expectancy<sup>3</sup>. In addition, the pharmaceutical industry in Russia is represented by slightly less than 1,400 manufacturers that create more than 80 thousand jobs<sup>4</sup>.

In this regard, it is of scientific and practical interest to assess the current level of innovation activity of leading Russian pharmaceutical manufacturers, as well as major factors (determinants) that promote such activity at present and evaluate longer-term trends. For the purposes of our study, the determinants of innovation activity are understood as main factors that are the driving force behind the development of innovation processes at enterprises or create conditions for such. These indicators are reflected in published scientific papers that describe innovation activity of enterprises in the manufacturing industry and material production in general, but they need to be adapted to the significant specifics of the pharmaceutical industry as a type of innovation activity. Such features are as follows: segmentation of the industry into the production of original drugs and generic drugs (reproduced drugs)<sup>5</sup>; the cycle of development of new drugs requiring substantial financial and time resources<sup>6</sup> (Tipanov, 2014); actually permissive

<sup>1</sup> See, for example: On approval of the state program of the Russian Federation "Development of the pharmaceutical and medical industry": RF Government Resolution 596, dated April 15, 2014; as of March 31, 2021.

<sup>2</sup> Romanova L. The Central Bank awaits the start of economic transformation in the coming months. What that transformation will be. *Vedomosti*. April 19, 2022. Available at: <https://www.vedomosti.ru/finance/articles/2022/04/18/918674-tsb-zhdet-starta> (accessed: April 29, 2022).

<sup>3</sup> See, for example: The pharmaceutical industry and global health. Available at: <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf> (accessed: April 21, 2022).

<sup>4</sup> INDSTAT 4 2022, ISIC Revision 4. Available at: <https://stat.unido.org/> (accessed: August 25, 2022).

<sup>5</sup> Moreover, the development and market launch of the latter does not imply any major discoveries or breakthrough development of science and technology, and, accordingly, does not contain an innovation component.

<sup>6</sup> See: The pharmaceutical industry and global health. Available at: <https://www.ifpma.org/wp-content/uploads/2017/02/IFPMA-Facts-And-Figures-2017.pdf> (accessed: April 21, 2022); World Preview 2021, Outlook to 2026. Available at: <https://www.evaluate.com/thought-leadership/pharma/evaluate-pharma-world-preview-2021-outlook-2026> (accessed: July 17, 2022); Pharmaceutical industry and global health: Facts and figures. Available at: [https://www.ifpma.org/wp-content/uploads/2016/01/2011\\_The-Pharmaceutical-Industry-and-Global-Health\\_RUS.pdf](https://www.ifpma.org/wp-content/uploads/2016/01/2011_The-Pharmaceutical-Industry-and-Global-Health_RUS.pdf) (accessed: July 17, 2022).

nature of the functioning of the industry and its strict state regulation at all stages; widespread use of patent protection of inventions, which is associated with the time-delayed transition to the growth phase within the life cycle of pharmaceutical products; advantages of large multinational corporations (MNCs) in pharmaceutical innovations.

The purpose of our study is to identify main features and determinants of innovation activity of pharmaceutical manufacturers by adapting existing theoretical and methodological developments and concepts to the specifics of pharmaceutical production; we also carry out quantitative assessment of the impact of the identified determinants on innovation activity at Russian enterprises specializing in pharmaceutical production.

#### Materials and methods

The results of a multi-stage study of major determinants of innovation activity of Russian pharmaceutical manufacturers are presented below. The research algorithm is shown in *Figure 1*.

So far, a sufficient number of empirical studies have been conducted with the aim of identifying main factors influencing innovation activity at industrial enterprises. Thus, T.A. Dubrova and A.A. Ermolina (Dubrova, Ermolina, 2019) put forward a model for innovation activity of manufacturing enterprises. Having tested various determinants, the authors point out the following ones that they consider most important and include in their own final model: the size of the enterprise, the size of the locality of the enterprise, presence of industrial clusters in the region, availability of high-speed Internet access, enterprise's export activities, predominance of employees with higher education among the staff of the enterprise.

I.A. Kuznetsov et al. (Kuznetsov et al., 2017) use the method of expert assessments. As a result, it is revealed that the greatest contribution to innovation activity at enterprises is made by such factors as labor resources in the field of innovation, financial support for innovation activity, profitability

Figure 1. Research algorithm

#### Stage 1: defining

- Setting the research goal, problem statement

#### Stage 2: informational

- Analyzing, assessing and systematizing the results of previous studies of the determinants of innovation activity
- Collecting statistical data on innovation activity of Russian pharmaceutical manufacturers, major determinants of this activity

#### Stage 3: analytical

- Classifying pharmaceutical manufacturers by the degree of their innovation activity (cluster analysis)
- Arranging the formed clusters into enlarged groups of enterprises with high and low innovation activity
- Statistical analysis of the impact of potential determinants on innovation activity of pharmaceutical manufacturers

#### Stage 4: final

- Verifying the obtained results (including with the use of discriminant analysis)
- Formulating main conclusions of the study

Source: own compilation.

of production, amount of capital investment, resource efficiency, introduction of new products, technologies, improvements or management techniques, technological potential and financial situation of the enterprise. Similarly, another study (Panyavina, Vanyatinskii, 2012) analyzes determinants of innovation activity of enterprises using expert assessments method; and, according to the authors, the most significant among the factors is the indicator of the state of the market and the position of the enterprise in this market. In the studies of S. Malik (Malik, 2020) and S. Krammer (Krammer, 2009), the macroeconomic determinants of innovation activity are given on the example of Asian and Eastern European countries, respectively.

A wide range of factors influencing innovation activity of pharmaceutical manufacturers has made it possible to systematize them (Tab. 1). The classification is based on a multilevel approach,

according to which all determinants are divided into country and global (macroeconomic); external determinants, which, in turn, are divided into sectoral and regional (mesoeconomic); as well as intracompany (microeconomic) determinants.

The influence of some determinants given in Table 1 seems to be very ambiguous. So, on the one hand, the size of the enterprise should have a positive impact on innovation activity due to the positive effect of scale, possibility of accumulating more significant financial resources and risk diversification; but the effectiveness of innovation due to the growth of management costs at large enterprises may decrease (Cohen, 2010). Similarly, it is logical to assume that a highly concentrated market allows a monopolist/oligopolist to accumulate more significant financial resources compared to a multitude of small producers, but at the same time the extinction or complete absence of competition obviously reduces the incentives

Table 1. Major determinants of innovation activity of industrial producers

Determinants of innovation activity of industrial producers		
External		Intracompany level (microeconomic determinants)
Country and global level (macroeconomic determinants)	Sectoral and regional level (mesoeconomic determinants)	
<p><b>General:</b></p> <ul style="list-style-type: none"> <li>• Dynamics of economic and financial cycles</li> <li>• Socio-economic development level in the country/region</li> <li>• Stability and predictability of the economic situation in the country</li> <li>• State support of enterprises, including availability of government contracts*</li> <li>• Development of institutions in the country (including financial, state, etc.)</li> <li>• Inflow of foreign direct investment and the country's general involvement globalization processes</li> </ul> <p><b>Specific (innovation-related):</b></p> <ul style="list-style-type: none"> <li>• Level of national scientific and technological development</li> <li>• Extent of intellectual property protection</li> <li>• State innovation policy</li> </ul>	<ul style="list-style-type: none"> <li>• Type of economic activity</li> <li>• Geographical location</li> <li>• Concentration level of the market and its conjuncture</li> <li>• Development level of innovation infrastructure in the region</li> <li>• Stability and predictability of the economic situation in the region</li> </ul>	<ul style="list-style-type: none"> <li>• Age of the organization</li> <li>• Enterprise's size and its affiliation with a large corporate structure</li> <li>• Organization's access to high-speed Internet and its use</li> <li>• Export activities of the enterprise</li> <li>• Level of employees' qualifications</li> <li>• Financial situation of the organization, including its financial stability</li> <li>• General technical level and rate of equipment renewal and organization's intangible assets</li> <li>• Product renewal rate</li> <li>• Other internal features of the organization (ownership form, organizational structure, etc.)</li> </ul>
<p>* This refers to state support in general, and not only the targeted areas related to enterprises' innovation activity (respectively, this indicator is attributed to the general macroeconomic determinants).                      Compiled according to: Avdonina, 2011; Gernego et al., 2019; Davidson et al., 2018; Dubrova, Ermolina, 2019; Ibatullova, 2008; Karakulina, 2020; Panyavina, Vanyatinskii, 2012; Razumova et al., 2017; Alam et al., 2019; Cohen, 2010; Krammer, 2009; Kuznetsov et al., 2017; Malik, 2020; Zakic et al., 2008).</p>		

for innovation activity among pharmaceutical manufacturers (Lambertini, Orsini, 2000; Ornaghi, 2009).

The causal relationship between the export and innovation activity of industrial enterprises is also ambiguous. At the theoretical level, it is noted that the dependence here should be two-sided: innovation activity provides favorable conditions for the company to enter foreign markets, but for enterprises already included in international trade, the world market, in turn, dictates the need for continuous improvement of exported products. However, the results of statistical analysis of the data on British small and medium-sized enterprises show that, with a high degree of probability, it is innovation activity (and only with regard to product innovations; this dependence is not confirmed for process innovations) that is the determinant of export activity, and not vice versa (Higon, Driffield, 2010). A specific feature of the global pharmaceutical industry is the dominance of large MNCs often called Big Pharma, and the patterns of their functioning and development differ from those observed when considering small and medium-sized enterprises. Major MNCs largely determine competition in the global pharmaceutical industry and also possess significant advantages in the course of research and market launch of innovative medicines and other pharmaceutical products (Szmelter, 2018).

Based on the above analysis of previous empirical studies (see Tab. 1) and the information availability of indicators, we consider the following potential determinants of innovation activity of Russian enterprises that are manufacturers of medical and pharmaceutical products:

- age of the organization, years;
- number of employees, people;
- state support for the enterprise;
- placement of state orders at the enterprise;
- book value of intangible assets of the organization, thousand rubles;

- share of intangible assets in the total value of the organization's assets, %;
- commissioning rate of new noncurrent assets in the organization, %<sup>7</sup>;
- total value of the organization's assets, thousand rubles;
- the enterprise's remaining in the production growth phase<sup>8</sup>;
- financial stability of the company<sup>9</sup>;
- volume of the enterprise's revenue, thousand rubles;
- volume of gross profit of the organization, thousand rubles<sup>10</sup>;
- profitability of the main activity of the organization, %.

A detailed study for a more extended analysis<sup>11</sup> was conducted for 85 Russian pharmaceutical manufacturers (the sample includes enterprises whose main activity is under Code 21 according to OKVED-2 (Russian National Classifier of Types of Economic Activity)<sup>12</sup>). The sample was formed

<sup>7</sup> Calculated as the ratio of the value of new noncurrent assets to the total value of noncurrent assets of the enterprise in the reporting period. Source: Blank I.A. (2007). *Financial Management*. Kiev: Nika-Center Elga. Pp. 191–192.

<sup>8</sup> Estimated as a simultaneous increase in fixed assets, inventories and revenues of the organization. Source: Kostrova A.A. (2018). *Financial Reporting Analysis according to Russian and International Standards*. Yaroslavl: Yaroslavl State University. P. 56.

<sup>9</sup> Its presence is characterized by the fulfillment of the condition of excess of current assets to noncurrent over the ratio of borrowed funds of the organization to its own funds. Source: Kostrova A.A. (2018). *Financial Reporting Analysis according to Russian and International Standards*. Yaroslavl: Yaroslavl State University. P. 57.

<sup>10</sup> Other types of profit include, among other things, the results of noncore activities of the organization.

<sup>11</sup> We have previously conducted a pilot study, the main purpose of which was to identify the main indicators characterizing innovation activity of Russian pharmaceutical manufacturers, and to carry out analytical assessment of the state of innovation activity of pharmaceutical enterprises (Berkovich, Volin, 2021). The study, based on data from 50 Russian pharmaceutical manufacturers, showed that most of them have insufficient innovation activity.

<sup>12</sup> Production of drugs and materials used for medical purposes. Source: OK 029-2014 (KDES Ed. 2). Russian National Classifier of Types of Economic Activity (approved by Rosstandart Order 14-st, dated January 31, 2014: as of July 26, 2022).

according to the principle of quality, completeness and availability of statistical data<sup>13</sup>. This explains its slight shift relative to the general population in favor of pharmaceutical manufacturers that are larger in terms of production and sales volumes. However, further on we show that such a shift is justified, since it is for larger pharmaceutical manufacturers that the issues of innovation activity are most relevant (Zabolotskii, Markov, 2010). It is important to note that since import substitution as such is characterized by the development and introduction of generics to the market and, in fact, does not involve any major discoveries and inventions, then the activity of developing generics objectively cannot be called innovation activity (Zabolotskii, Markov, 2010). We select two indicators as the main features of pharmaceutical manufacturers' innovation activity:

- ratio of the number (units) of clinical trials conducted by manufacturers for original drugs and generic drugs (reproduced drugs);
- ratio (within the organizations' portfolio) of the number (units) of own intellectual property objects representing the results of innovation activities to the number (units) of objects, used by manufacturers under license.

The first indicator is of particular interest, since the policy of import substitution is recognized as one of the most relevant areas of state regulation of the pharmaceutical industry<sup>14</sup>. Thus, the proposed approach to assessing innovation activity of pharmaceutical manufacturers by two criteria allows assessing innovation activity both from the point of view of the innovation process itself (conducting research) and in relation to its final

<sup>13</sup> State Register of Drugs. Available at: <https://grls.rosminzdrav.ru/GRLS.aspx> (accessed: January 23, 2022); SPARK system of Interfax International Information Group. Available at: <https://spark-interfax.ru/> (accessed: January 23, 2022).

<sup>14</sup> See, for example: On approval of the state program of the Russian Federation "Development of the pharmaceutical and medical industry": RF Government Resolution 596, dated April 15, 2014: as of March 31, 2021.

results (possession of intellectual property objects as the results of innovation activity).

To distribute enterprises according to the degree of their innovation activity, a two-dimensional cluster analysis with the help of the k-means method, excluding repetitions (Euclidean distances were used in the calculations) was applied, regarding the two characteristics of innovation activity of Russian pharmaceutical manufacturers indicated above. We chose the statistical analysis methods proceeding from the nature of the distribution of the indicators under consideration (normal, in which case parametric methods were used, or different from normal, in which case nonparametric methods were used). The hypothesis about the nature of the distribution of indicators was tested using special statistical criteria (the Kolmogorov – Smirnov, Lilliefors and Shapiro – Wilk tests). For the statistical analysis of quantitative determinants, Student's t-test was used, as well as its nonparametric analogue, the Mann – Whitney U test. Categorical data comparison was carried out using Pearson's  $\chi^2$  test and Fisher's exact test. The most significant main determinants of innovation activity of Russian pharmaceutical manufacturers were selected with the help of discriminant analysis.

## Results

Figure 2 shows two scatter plots. The first one represents the number of clinical bioequivalence studies conducted to confirm the pharmaceutical equivalence of a generic to an original drug, which do not include an innovation component, as well as clinical studies of phases I–IV necessary to market a new drug (phases I–III) or optimize the use of an already registered drug (phase IV)<sup>15</sup>. The information base of our research includes the data on the number of authorized studies with the "Ongoing" status in the Register of Permits for

<sup>15</sup> General considerations for clinical studies: Guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) No. E8 (R1), dated May 8, 2019.

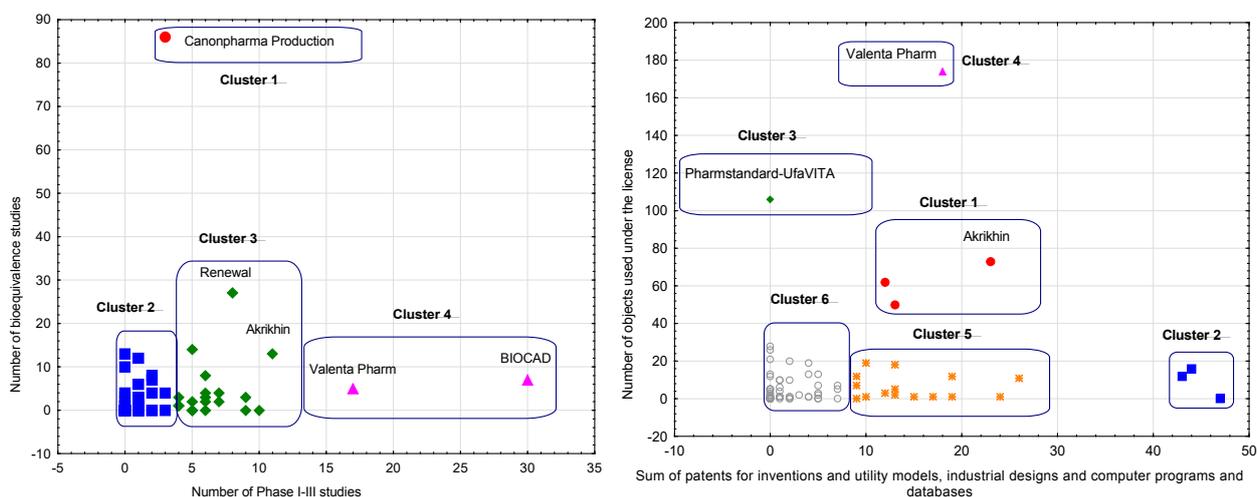
Clinical Trials<sup>16</sup> as of January 2022. The second scatter plot shows the spread of the number of patents for own inventions and the use of licenses for third-party developments for pharmaceutical manufacturers included in the study.

In general, the concentration of pharmaceutical manufacturers in the lower left corner of the scatter charts confirms the low innovation activity of most of them. According to the results of the analysis of the ratio of research conducted by enterprises, all pharmaceutical manufacturers are arranged into four groups, depending on the degree of their innovation activity determined by the ratio of the number of studies of original and reproduced drugs (generics). Due to the small number of the first and fourth groups for further analysis, they are combined, respectively, with the second (aggregated group of enterprises with low innovation activity) and third (aggregated group of enterprises with

high innovation activity) groups. According to the results of the analysis of the ratio of own to licensed intellectual property objects in the organizations' portfolio, all the pharmaceutical manufacturers under consideration are grouped into six clusters. Enterprises included in clusters 3 and 6 have low and very low innovation activity. For further analysis, they will be combined into an aggregated group of enterprises with low innovation activity. Enterprises grouped into clusters 1, 2, 4 and 5 have on average a greater number of their own innovation developments and, as a result, are characterized by a higher degree of innovation activity. For further analysis, they will be combined into an aggregated group of enterprises with high innovation activity.

Further, we analyze the influence of the proposed determinants of innovation activity on the inclusion of an organization in one of the previously identified aggregated groups. Table

Figure 2. Segmentation of Russian pharmaceutical manufacturers by the degree of their innovation activity using the cluster analysis method



Compiled according to: State Register of Drugs. Available at: <https://grls.rosminzdrav.ru/GRLS.aspx> (accessed: January 23, 2022).

<sup>16</sup> State Register of Drugs. Available at: <https://grls.rosminzdrav.ru/GRLS.aspx> (accessed: January 23, 2022).

2 presents the results of statistical analysis of previously selected categorical determinants that presumably influence innovation activity of organizations (state support, placement of state orders at the enterprise, the enterprise being in the growth phase, financial stability).

We see that none of the categorical factors is a statistically significant determinant of innovation activity of Russian pharmaceutical manufacturers. We should note that there was no statistically significant relationship between the two areas of state regulation (in the form of both subsidies and placement of state orders) and the increase in innovation activity of pharmaceutical manufacturers in Russia. This may indicate, in particular, the insufficient effectiveness of state support for innovation development of the Russian pharmaceutical industry, or insufficient orientation of state regulation to directly support innovation activities of Russian pharmaceutical manufacturers.

At the next stage of the study we conduct statistical analysis of the quantitative determinants of innovation activity of Russian pharmaceutical manufacturers (namely, the age of the organization, number of employees, amount of assets, revenue, gross profit of the organization and its intangible

assets, share of the latter in the total value of the organization’s assets, commissioning rate of new noncurrent assets; Tab. 3). The results of analyzing the geometric mean growth rates of the main indicators characterizing the size of the enterprise (asset value, revenue and gross profit) are also presented here in order to trace the possible impact of the rate and direction of their dynamics on the company’s innovation activity<sup>17</sup>.

Descriptive statistics indicators provide a quantitative reflection of the difference between the factors under consideration, broken down by previously formed groups of pharmaceutical manufacturers according to the levels of their innovation activity.

The results of the statistical analysis confirm the statistical relationship between the enterprise’s innovation activity and the size of the company expressed by four indicators: the number of employees, value of all assets, revenue and gross profit. Obviously, the larger the company, the more resources it can accumulate for innovation development; and the increasing volume of its gross profit expands opportunities for innovation. At the same time, we should emphasize that these conclusions turned out unfit for the indicators

Table 2. Statistical analysis of Russian pharmaceutical enterprises’ innovation activity determinants (categorical indicators)

Determinant name	Enterprises’ innovation activity	
	On clinical trials	On intellectual property objects
State support for enterprises (Yes/No)	Differences are statistically insignificant	Differences are statistically insignificant
State orders placement (Yes/No)	Differences are statistically insignificant	Differences are statistically insignificant
The enterprise is in the growth phase (Yes/No)	Differences are statistically insignificant	Differences are statistically insignificant
Financially stable enterprise (Yes/No)	Differences are statistically insignificant	Differences are statistically insignificant
* Determinants are given as of the end of the reporting year 2020. Source: own compilation.		

<sup>17</sup> The period for calculating the geometric mean chain growth rates from 2018 to 2020 is chosen in connection with the general principles of accounting statements of enterprises, which ensure the comparability of indicators. Source: On the forms of accounting statements of organizations: RF Ministry of Finance Order 66n, dated July 2, 2010, with amendments and supplements, entered into force with regard to reporting statements for 2020.

Table 3. Statistical analysis of the determinants of innovation activity of Russian pharmaceutical manufacturers (quantitative indicators)

Determinant name	Enterprises' innovation activity	
	On clinical trials	On intellectual property objects
Organization's age, years	Differences are statistically insignificant	Differences are statistically significant*
Number of employees, persons	Differences are statistically significant**	Differences are statistically significant**
Intangible assets, thousand rubles	Differences are statistically significant**	Differences are statistically significant**
Share of intangible assets in the total value of the organization's assets, %	Differences are statistically significant**	Differences are statistically significant**
Acquisition of noncurrent assets, thousand rubles	Differences are statistically significant*	Differences are statistically significant**
Balance sheet assets, thousand rubles	Differences are statistically significant**	Differences are statistically significant*
Average geometric growth rate of assets (2018–2020), %	Differences are statistically insignificant	Differences are statistically insignificant
Revenue, thousand rubles	Differences are statistically significant**	Differences are statistically significant**
Gross profit, thousand rubles	Differences are statistically significant**	Differences are statistically significant**
Profitability, %	Differences are statistically significant*	Differences are statistically significant*
Commissioning rate of new noncurrent assets, %	Differences are statistically insignificant	Differences are statistically insignificant
Average geometric growth rate of revenue (2018–2020), %	Differences are statistically insignificant	Differences are statistically insignificant
Average geometric growth rate of gross profit (2018–2020), %	Differences are statistically insignificant	Differences are statistically insignificant
* – statistically significant differences at a 95% level ** – statistically significant difference at a 99% level Source: own compilation.		

of revenue growth, gross profit and the size of assets. Thus, the presence of a factor of long-term return on financial investments in innovations in pharmaceutical production is confirmed (Tipanov, 2014; DiMasi et al., 2016).

Statistically significant is also the relationship between the absolute and relative number of intangible assets on the balance sheet of the organization and its innovation activity. This means that, on the one hand, the presence of such assets can be used in the organization's innovation activities, and, on the other hand, the results of such activities lead to the emergence of corresponding copyrights, the valuation of which is reflected on the balance sheet of the innovation organization.

Another important determinant of innovation activity of pharmaceutical enterprises, which has statistically confirmed its influence, is the number of noncurrent assets and the annual costs of the organization for their acquisition. Noncurrent assets include, in particular, specific experimental equipment used in the development of new or improved medicines; and their timely updating can contribute to the emergence of innovations in the company's production processes.

The impact of profitability on the company's innovation activity turned out to be somewhat less significant, and the influence of such determinants as the age of the organization and the amount of fixed assets on its balance sheet, taking into account

the statistical analysis carried out, seems rather doubtful, although it is impractical to exclude it completely.

**Discussion.** The results of the analysis of the most significant determinants of innovation activity of Russian pharmaceutical manufacturers indicate the decisive importance of those that somehow characterize the size of a particular enterprise and the scale of its activities. This conclusion is also confirmed by the results of the discriminant analysis we conducted, according to which, in accordance with the results of the step-by-step method with inclusion, the greatest contribution to the differences between the aggregates of organizations included in the analysis on the basis of the presence or absence of innovation activity is made by such factors as the amount of revenue and the amount of intangible assets of the organization; these factors help to assess innovation activity by the number of clinical trials of medicines conducted by the organization; the number of employees of the organization is another factor that helps to assess innovation activity by the nature of intellectual property objects in the portfolio of a

particular organization (*Tab. 4*). Obviously, these factors somehow characterize the size of the organization, as well as the availability of financial, intellectual and other resources necessary for the implementation of innovation activity.

At the same time, the steady average growth trend showed by Russian pharmaceutical manufacturers included in the analysis, regardless of their level of innovation activity, may be due to the fact that the global pharmaceutical industry as a whole is characterized by a high degree of intensity of mergers and acquisitions (Evstratov, 2018); however, consolidation processes have not been widespread among Russian pharmaceutical manufacturers so far, although there exist some examples of these processes<sup>18</sup>. Obviously, given the high risks and long-term returns on investments in pharmaceutical innovations, only powerful corporations are able to accumulate a sufficient amount of financial, intellectual and other resources to maintain a high level of innovation activity. Thus, mergers and acquisitions of manufacturers within the Russian pharmaceutical industry at the present stage seem rather a favorable trend, if in the end they do not

Table 4. Results of the discriminant analysis of the main determinants of innovation activity of Russian pharmaceutical manufacturers\*\*\*

Modeling results	Enterprises' innovation activity			
	On clinical trials		On intellectual property objects	
Method	Step-by-step analysis with inclusion			
Number of steps	3		2	
Factors	Name	F-criteria for inclusion (p-value)	Name	F-criteria for inclusion (p-value)
	Revenue, thousand rubles	<0.001**	Number of employees, persons	<0.001**
	Intangible assets, thousand rubles	0.014*		
* – statistically significant differences at a 95% level ** – statistically significant difference at a 99% level *** The analysis was conducted for the determinants, for which a statistically significant influence on innovation activity of enterprises had been previously revealed (Tables 2 and 3). Source: own compilation.				

<sup>18</sup> See, for example: On the merger of Binnopharm and Obolenskoye, led by Sistema, in 2019: Labykin A. (2019). "Sistema" gathers pharmacists. *Ekspert*, 8, 32–35.

lead to high oligopolization or even monopolization of the market. Otherwise, excessive concentration of market power of individual producers may lead to a decrease in incentives for innovation development (Deangelis, 2016; Ornaghi, 2009).

In this regard, we can state that there is some dilemma that has not been solved to date and is of interest for future research on pharmaceutical production; the dilemma is related to the consequences of pharmaceutical markets oligopolization that inevitably follows the processes of mergers and acquisitions and to the need for consolidation of pharmaceutical manufacturers to increase the ability to accumulate financial, logistical, labor and other resources required for their innovation development. In this situation, an alternative to mergers and acquisitions may be to stimulate scientific and technological cooperation between independent Russian and foreign pharmaceutical manufacturers, primarily those representing friendly countries (India, China, etc.), including the use of advantages of industrial clusters (Ornaghi, 2009).

### Conclusion

In our study, the generalization and systematization of the main determinants of innovation activity of industrial enterprises was carried out, a list of the main determinants directly influencing innovation activity of pharmaceutical manufacturers was formed, taking into account the specifics of this type of activity; and a quantitative analysis was carried out, followed by identifying the most significant factors based on cluster and discriminant analysis, calculation of the Mann – Whitney U test or Student's t-test for quantitative indicators and Pearson's  $\chi^2$  test or Fisher's exact test for categorical indicators. As a result, we identify the most significant determinants of innovation activity of Russian pharmaceutical manufacturers.

At the information stage of the study, a multilevel structuring was carried out, as a result of which we prove that the main determinants

of innovation activity of pharmaceutical manufacturers include intracompany (at the microlevel), sectoral and regional (at the mesolevel), as well as national and global (at the macrolevel), which can also be divided into general and specific or innovation.

Based on the econometric and statistical analysis, the most significant determinants of innovation activity of Russian pharmaceutical manufacturers are indicators characterizing the size of the organization (the number of employees; book value of its intangible assets and their share; book value of non-current assets; amount of all assets of the organization, as well as its revenue and gross profit). This conclusion regarding the impact of the size of the organization on its innovation activity is also confirmed by the results of the discriminatory analysis. We also find out that a significant factor in innovation activity of Russian pharmaceutical manufacturers is the degree of renewal of the organization's fixed assets (analyzed according to the annual spending of pharmaceutical manufacturers on the acquisition of noncurrent assets), which on the one hand may include special experimental equipment used for the development of new drugs, and, on the other hand, the constant updating of equipment increases the potential for production innovation. Also, the impact of profitability of core activities on innovation activity of organizations is somewhat less strong. In addition, our calculations show the insufficient effectiveness of state support for innovation development of pharmaceutical manufacturers, or its insufficient focus on this aspect of the work of pharmaceutical enterprises. The dynamic assessment of the main determinants shows the absence of short-term effects of innovation activity of organizations in relation to their growth, but does not exclude the presence of longer-term effects, which confirms the long-term return on investment in pharmaceutical innovations.

In general, we can draw an analytically substantiated conclusion that innovation activity of Russian pharmaceutical manufacturers currently seems insufficient, which may be due to some shortage of internal resources for long-term investments in the development of innovations. At the same time, major pharmaceutical manufacturers are the most innovation-active ones in Russia, i.e. innovation development is more relevant for those organizations that are able to accumulate sufficient financial, scientific, technological, human and other resources necessary to address such tasks. Potentially, this problem can be solved by the processes of mergers and acquisitions of drug manufacturers that have become a global trend by now, but with some exceptions that have not sufficiently affected the Russian pharmaceutical industry. However, when creating prerequisites for such processes, it is obviously necessary to take into account the balance of interests not only of producers, but also of consumers, who may experience negative effects associated with increased oligopolization and even monopolization of drug markets. A possible alternative to such processes is the

expansion of the cluster approach that has already proven effective; this allows creating complete chains of innovation processes through more flexible forms of scientific and technological cooperation, as well as stimulating the creation of production chains (including various stages of R&D) with foreign pharmaceutical manufacturers (primarily those originating from friendly countries).

Scientific and practical significance of our research consists in the use of our own multistage research algorithm, which expands the understanding of the combination of general and special features in the development of forecasts and programs for innovation development of the country and individual economic sectors, substantiates the expediency of using complex complementary mathematical tools in identifying sectoral determinants, and adds to the tools for evaluating the effectiveness of public policy in the field of innovation. The results of the analysis can be applied in making decisions, including strategic ones, regarding innovation development of individual pharmaceutical enterprises and the industry as a whole.

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