

Russian pharmaceutical industry innovative development: present state and prospects

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Abstract. In the article the innovative development of the Russian Federation pharmaceutical industry is considered in the context of global trends and world pharmaceutical market development priority areas. The countries' patent activity in the sphere of medical technologies and pharmaceuticals is considered. The main technological and conceptual trends in the development of the Russian pharmaceutical market have been identified. The results obtained are aimed at the Russian pharmaceutical market innovative development in the context of global instability. The practical significance of the study lies in the fact that on its basis it is possible to develop tools aimed at increasing the level of innovation in the Russian pharmaceutical industry.

1 Introduction

The presently developed demographic situation in the Russian Federation is explained by the aging and high mortality rate of the population, as well as by an increase in the prevalence of chronic diseases. So, in 2020, about 30 years of life among men and 18.4 years among elderly women were lost due to blood circulatory system diseases. The mortality rate caused by socially significant chronic diseases is about 84.5%. At the same time, according to experts, timely use of innovative drugs could prevent fatal consequences in 45% of cases.

2 Problem statement

According to the data of the auditing company PricewaterhouseCoopers, on average in the world about 70-85% of the gross domestic product increase is achieved by means of innovative technologies [1]. The development of the pharmaceutical sector in the Russian Federation is also characterized by a continuous increase in the role of the innovation component, since the development of new drugs is the basis for increasing production efficiency and improving the quality of manufactured drugs. Increasing the life expectancy and population quality of life as well as strengthening its health are the state policy priorities, in connection with which the growth of innovative development of the

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pharmaceutical industry in the Russian Federation has both economic and social significance.

3 Purpose of the study

The purpose of the study is to analyze and assess the prospects for innovative development of the Russian Federation pharmaceutical industry

4 Research methods

In the course of the research, the following methods were used: methods of theoretical generalization and comparison, analysis and synthesis, methods of multivariate statistical analysis (to study the state of the pharmaceutical market in the Russian Federation).

5 Analysis of recent research and publications

The World Health Organization (WHO), the Pharmaceutical Safety Institute (PSI), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) deal with health issues, assessing the availability and affordability of drugs at the international level. The World Intellectual Property Organization (WIPO) and the European Patent Organization (EPO) are engaged in development in the field of patenting. Bykova E.A., Kotova O.E., Latkin A.P., Ovod A.I., Potapov A.A., Tolstopyatenko M.A., Tsyb S.A have made a significant contribution to the study of innovative processes in the Russian pharmaceutical industry. Berdnikova E.F., Voznyakov V.E., Kobylat A.O., Nekorysnov D.A., Sisterova A.A., Totskaya E.G., Khalapsina T.I. and Kuznetsova I.G were involved in the innovative development of healthcare.

6 Findings

Biotechnology, medicine and healthcare are global innovation trends and occupy the second position after information and communication technologies [2]. The pharmaceutical and biotechnology industries take a special place in the global economy, accounting for about 70% of the global healthcare market and occupy the third place in terms of capitalization among the leading industries, after the banking and oil and gas sectors. It should be noted that in 2019 the largest amounts of R&D expenditures were carried out in health care (Fig. 1). In addition, this industry is one of the most socially significant, due to which there is an increase in the life expectancy of the population and support for the state stable development.

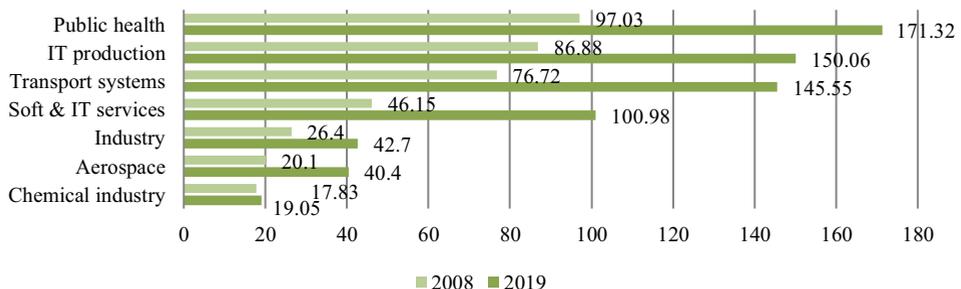


Fig. 1. Ranking of sectors in terms of R&D expenditures [3].

Based on the analytical agency DSM Group data, the volume of the Russian Federation pharmaceutical market in 2020 increased compared to 2008 by 3.8 times, which indicates a tendency for the drug market active development (Fig. 3). It should be noted that in 2017-2019 market growth slowed down significantly. So, in 2019, the market grew by less than once, which indicates a decrease in the population's income and consumption of non-priority drugs, such as vitamins, probiotics, dietary supplements, etc. [4].

The volume of the medicine drug market in 2020 amounted to 2,040 billion rubles, having increased by 10.7% compared to the previous year (Fig. 2). Also, there was an increase in medicine drug sales by 10.6% compared to 2019, which is associated with fluctuations in exchange rates and the presence of a rush for the purchase of drugs caused by an increase in drug prices and their shortages in the context of the COVID-19 pandemic, especially among elderly people with chronic diseases. Thus, in three months of 2020, drug consumption through pharmacies reached 1.5 billion packs, which is 13.2% more than in the same period in 2019.

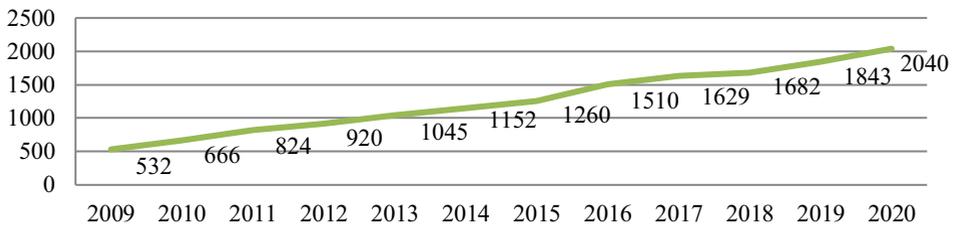


Fig. 2. Capacity of the Russian pharmaceutical market, billion rubles. Note: compiled by the author according to [4].

In 2008-2020 the share of Russian drugs increased in monetary and physical terms by 80% and 59%, respectively, which is associated with the state policy of import substitution and an increase in funding in the state segment for the purchase of expensive drugs (Fig. 3). Also an increase in sales of domestically produced drugs by 16.5% in 2020 compared to 2019 should be noted, which is lower by 10% than the imported drugs sales growth rate. These circumstances are largely associated with a drop in sales of drugs in the low price segment and a change in the sales structure in favor of Russian antiviral drugs, such as, for example, Arbidol (+ 353.9% in value terms and + 257.4% in physical terms) and Ingavirin (+ 110.9% in rubles and + 63.0% in packages), etc.

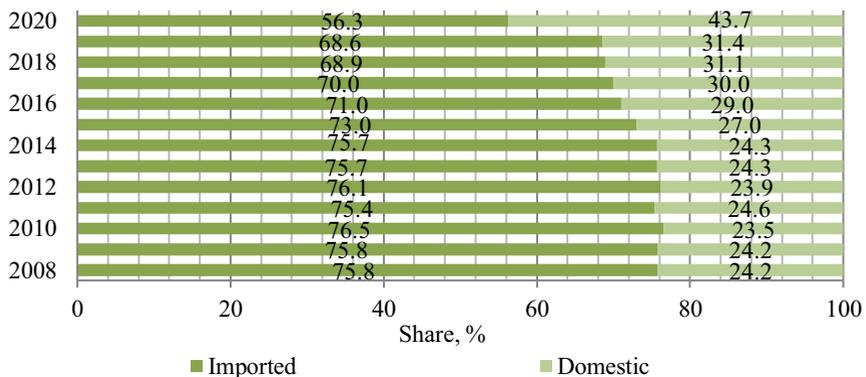


Fig. 3. Market structure in the context of national and imported drugs. Note: compiled by the author according to [4].

The discrepancy in the ratio of value and volume between imported and domestic drugs is primarily explained by low prices for the domestic products. Thus, the average cost of a domestic drug in 2020 was 152 rubles, which is 2.4 times lower than the cost of a foreign-made drug, which costs 367 rubles. [4]. The low cost of domestic drugs may be accounted for their low innovation level. Also, despite the almost equal quantity of domestic and foreign companies in the Russian pharmaceutical market (about 540 and 560, respectively), drugs of foreign origin are represented in the pharmacy segment more by 36%. These circumstances indicate that foreign companies are more likely to sell original drugs and branded generics. Russian-made drugs are produced in large volumes in the form of unbranded generics by several producers simultaneously.

According to the report of the Global Innovation Index (GII), in 2019 the Russian Federation occupied 46th position in terms of innovative development in the world. The calculation of this rating is carried out by calculating the average value between two sub-indices - innovation resources (related to human and scientific potential, infrastructure, development of the internal market and business processes) and innovation results (which is based on the technological progress level, innovative activity development, etc.). It should be noted that compared to 2013-2018, in 2019, there was an increase by 16 positions in the innovative potential of the Russian Federation and the value of the GII made 37.62. So, the leading positions in the GII in 2019 were taken by Switzerland, Sweden, and the USA [5]. Analysis in the context of the quality of innovation indicators among countries with a high level of income indicates that the leading positions are occupied by the United States, Japan, Germany and Switzerland. Whereas, among countries with an average income level, the leading performers are China, India and the Russian Federation (Fig. 4).

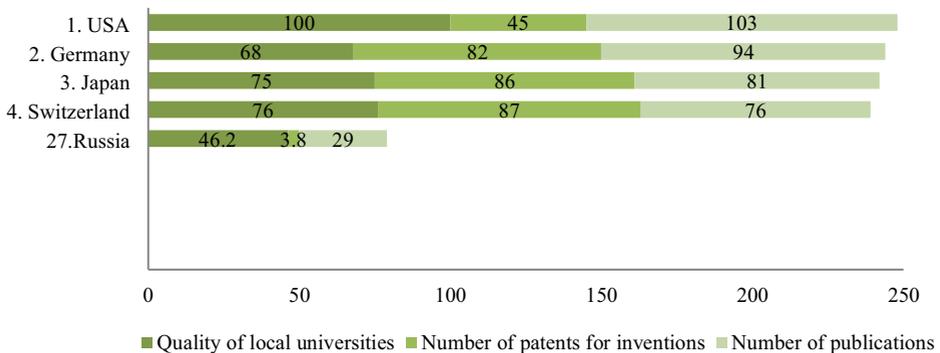


Fig. 4. Ranking of countries according to the innovation quality indicator, 2019 [1].

According to the report of the European Commission on Innovative Development, one of the main technological and conceptual trends in the development of the pharmaceutical market in the Russian Federation should be named as personalized medicine, defined by the Sechenov International Biomedical Summit - 2019, as the medicine of the future [6]. Thus, personalized medicine is an innovative concept in healthcare, which is associated with the selection of drugs according to the individual characteristics of patients, such as genetic characteristics, age, lifestyle, environment, etc.

An absolutely innovative model of healthcare 4P-medicine is spreading, which is based on the principles of focusing on the individual characteristics of the patient, in which the concepts of personalization are integrated (individual approach). These principles are prediction (studies of predisposition to the development of a disease), prevention (reducing the risk of developing a disease or the possibility of preventing it) and participation (involvement of the patient in the prevention of possible diseases and their treatment). The

purpose of this model is to determine risk factors and the presence of diseases before the appearance of a clinical picture, as well as to implement individual preventive measures. Also, it should be noted that according to the Russian Federation Ministry of Health data, in 2020, the state of health of about 53% of schoolchildren can be attributed to weakened, of which 66% of children aged 14 suffer from chronic diseases. The number of schoolchildren who cannot start systematic education exceeds 32%, which is 13% higher than in 2008. It should be noted that in 2020, only about 10% of school graduates can be classified as healthy. [6].

In 2008-2019 the number of students who are assigned to a special medical group for health reasons increased by 21% and amounted to 25% in 2019. However, in some cases, this figure is about 40% and, according to experts, by 2021 it will reach 50%. The largest specific indicators are disorders of the visual organs, the endocrine and nervous systems, as well as the functions of digestion and blood circulation.

According to the Federal Compulsory Health Insurance Fund, in 2020, among the elderly population, the loss due to premature death from diseases of the blood circulatory system is more than 30 years of life among men aged 50-60 years, and 18.4 years among women. Moreover, in 84.5% of cases, death was caused by socially significant chronic non-infectious diseases - cardiovascular (48%), oncology (21%), diabetes mellitus (15.5%), lung diseases (12%). It should be noted that when carrying out preventive measures for these diseases on a population-wide scale, the effectiveness is provided by more than 50% [6].

Among Russian companies involved in personalized medicine, the leading role is played by Generium, the only biotechnological research center in the Russian Federation that has its own technology park producing innovative drugs in accordance with international GMP standards. The share of innovative drugs produced by the company in 2019 amounted to 32% of the Russian pharmaceutical market; the company also develops tests for antibodies to COVID-19 and express-tests for its presence. In 2019, Generium began construction of a plant for the production of drugs for the treatment of orphan, cardiovascular and pulmonological diseases. The cost of this investment project is 3.9 billion rubles.

In 2020, the priority direction for the development of the Russian pharmaceutical market was defined as the creation of a centers network for personalized medicine until 2024. The organizations on the basis of which the centers will appear are Rospotrebnadzor, the National Research Center Kurchatov Institute and the Institute of Molecular Biology named after V.A. Engelhardt of the Russian Academy of Sciences. For the financing of the project it is planned to allocate 11.3 billion rubles. [7]. It is also planned to create an All-Russian Genomic Center, where it will be possible to store the genetic data of the population in order to further develop the medicine of the future.

The shift to personalized medicine is a worldwide trend. So, in 2015, the Health Precision Medicine Initiative project was created in the United States, funding for which reached an average of 215 mln US Dollars per year. The orientation of this project is aimed at studying the influence of genetic factors and their characteristics on the activity of the human body. The main strategy of the largest pharmaceutical companies is based on activities in the field of introducing a personalized approach to the development of innovative drugs and medical technologies. Leaders in this area are Big Pharma representatives such as Roche, Novartis and Pfizer. According to the University of Tufts Medical Research Center, from 12 to 50% of scientific research of drug companies is directed to personalized medicine [8].

Another important area of innovative development is the introduction of a patient-centered healthcare model. The result of the implementation of this model is patient satisfaction with all aspects of medical care, from the professionalism of doctors to the

creation of a comfortable environment in the hospital / polyclinic. For example, the elements of patient-centered medicine are improving the material and technical equipment of hospitals, developing a culture of communication with patients, creating an online registry, electronic queues for an appointment with a doctor, providing patient services in one window, reducing the waiting time in the emergency department, increasing the hours for visiting patients, providing emergency patients with disposable linen and personal hygiene products, introducing a hospital patient escort service for moving the patient to medical manipulations, removing restrictions on visiting intensive care patients, etc. Thus, a patient-centered approach will take into account the individual preferences and needs of patients in the process of providing medical care. According to experts, it is necessary to build medicine "... convenient not for doctors, but for patients" [9].

The digitalization of medicine and the pharmaceutical industry is the next technological trend in the development of the Russian Federation pharmaceutical market. Key segments of "digital" healthcare, such as mobile medicine, telemedicine, innovative products (sensors, applications, etc.), will provide a unique service for patients, adopted to their specific needs. Also, pharmaceutical companies will be able to track the effect of drugs on the patient, thereby optimizing its composition and minimizing adverse reactions, thereby creating more effective drugs. The first stage in the digitalization of medicine was digital pharmacies. So, in 2020, due to the introduction of COVID-19 quarantine restrictions, the pharmaceutical retail industry rapidly transformed into online sales. The COVID-19 pandemic has become the driver for digitalization, due to which about 30% of drug retail companies will have to leave the market or redirect themselves to new realities. At the same time, according to experts, in 2020 the share of online drug sales increased by 10-12% against the indicator of 2019 - 6% [10].

Also, one of the most important factors in the development of the Russian Federation pharmaceutical market is biopharmaceuticals and biomedical technologies. So, in 2020, 62% of the biotechnology market was concentrated in the United States. According to the estimates of the American consulting company Frost & Sullivan, the volume of the global biotechnology market is growing by about 10% per year and by 2025 it will reach trillion US Dollars. At the same time, the market for biopharmaceutical drugs in 2020 was estimated at 336 bln US Dollars [8]. Biotechnology stimulates transition from standardized treatment to personalized medicine, taking into account the genetic characteristics, the patient's lifestyle and the characteristics of the environment, which is especially important in the treatment of rare and complex diseases.

It should be noted that the share of the Russian Federation in the biotechnology market is less than 0.1%, biotechnological drugs occupy no more than 5% of the Russian pharmaceutical market, which indicates the need to develop this component of the Russian pharmaceutical market by creating a legislative framework and state support for the industry. Thus, in 2018, Law No. 323-FZ "On Amendments to Certain Legislative Acts of the Russian Federation on the Circulation of Biomedical Cell Products" was adopted and an action plan for "Development of Biotechnology and Genetic Engineering" for 2018-2020 was approved. In 2019, the volume of production of products based on industrial biotechnology amounted to 14.1 bln rubles, while in 2024 this figure is planned to be increased by 3.5 bln rubles.

According to the analytical report of DSM Group, in 2018-2019 the number of manufactured innovative drugs increased by 3.4%, indicating a development in the field of biotechnology [4]. Thus, in St. Petersburg, the Bayer corporation organized the production of medicinal products, which are used in diagnostics and computed tomography, at the facilities of the Russian manufacturer Polisan. The Ultravist brand became the first original X-ray-contrast agent located in the Russian Federation. Also in 2019, the Russian company Vertex put into operation an innovative production complex in St. Petersburg at the site of

the SEZ "Novoorlovskaya". Total investments in this project amounted to about 7.3 bln rubles. In addition, in 2019 in the Chechen Republic on the territory of the SEZ "Grozny" it is planned to create a plant for the production of drugs for tuberculosis and diabetes mellitus. According to experts' forecasts, in 2028 the volume of investments in the Grozny SEZ will amount to about 14.2 bln rubles. These circumstances indicate a positive trend in the development of biotechnology and the Russian Federation pharmaceutical market in the context of innovations, as well as a focus on a new model of the healthcare system.

To assess the current results of R&D, it is necessary to analyze the number of patents granted and patent applications, thanks to which it is possible not only to introduce innovations based on the results of R&D, but also to commercialize them (Fig. 5).

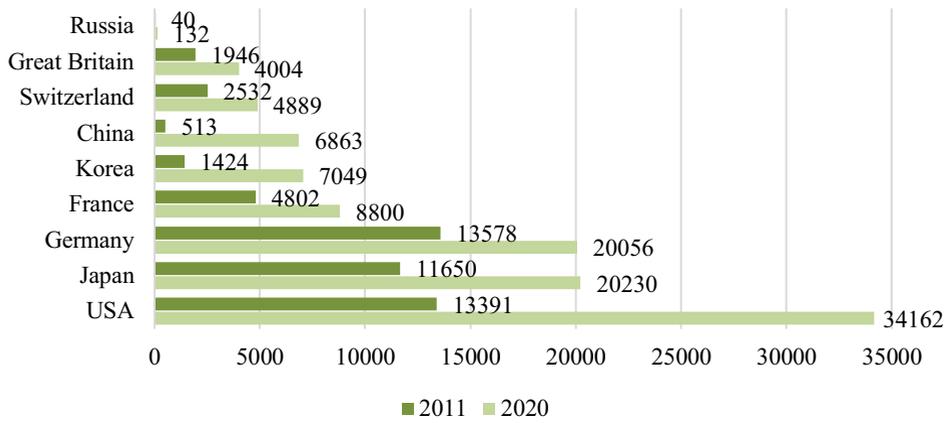


Fig. 5. Number of patents granted by country, 2011-2020. Note: compiled by the author according to [11].

In 2020, the total number of patents in the world amounted to 133,715 pcs, means an increase of 115.3% compared to 2011. It should be noted that the growth rates of this indicator in China, Korea and the Russian Federation are higher than those of the leading countries, which indicates an increase in scientific-technical capacities of these countries and the future positive trend. At the same time, in terms of the number of patents granted, the performance indicators of the Russian Federation are 259 times less than those of the United States, which indicates the need to intensify innovation in the most significant technical areas. According to the European Patent Organization, in 2020, the top 10 technical spheres accounted for about 55% of the total quantity of European patent applications filed (Table 1).

Table 1. Number of patent applications filed by area, 2020. Note: compiled by the author according to [11].

Area	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Medical technologies	10628	10502	10782	11234	12531	12382	13134	13707	13935	14295
Digital communication	8261	9809	9398	10427	11051	10967	11853	11853	13978	14122
Computer Technics	8194	8540	9158	9787	10359	10772	11348	11589	12859	13097
Electric machines, energy	8693	9746	10138	10387	9794	9900	10239	10668	11297	11346
Transport	6448	7002	7443	7926	8108	8559	8536	9039	9540	9020
Pharmaceuticals	6081	6309	5568	5369	6055	5849	6534	7371	7797	8589

Measuring instruments	6448	6633	6779	7156	7739	7460	7999	8711	9048	8582
Biotechnology	5870	5539	5269	5754	5724	5477	6013	6689	6814	7246
Special machines	4120	4348	4489	4732	5152	5543	5750	6344	6419	6261
Organic chemistry	6935	6588	6215	6283	6447	6195	6464	6199	5993	5905

Medical technology is the most urgent area for patenting as it encompasses medical instruments for the diagnosis, treatment and surgery of diseases and vaccinations. Technologies related to this area include - prosthetics, surgical robots, computed tomography, cardioaccelerators, etc. The change in the structure of research activity towards medical technologies is associated with the formation of demand for a new quality of life, including the possibility of compensating for the lost function of the body, organ or its parts, primarily due to aging processes. Thus, according to experts, by 2030 the demand for innovative materials is expected to increase, primarily in the field of orthopedics and cardiology. In connection with the increase in the life expectancy of the population, the demand for lifelong use drugs aimed at maintaining the body's performance and products for monitoring health will increase. So, in 2020, about 30% of the world's population suffered from hypertension, 13% from oncology and 7% from diabetes, being forced to take drugs on an ongoing basis.

It should also be noted that the introduction to the market of an innovative device, equipment and tool for the detection or prevention of diseases is in average 4 times cheaper than the introduction of a new drug, which is due to the long duration of high-cost clinical trials of the drug. Moreover, the COVID-19 pandemic became the impetus for the development of the medical technology market. As a result, the demand for medical technologies in 2019 increased by 41.3% compared to 2018, in particular for artificial ventilation and lung oxygenation devices, respirators, non-contact thermometers, oxygen saturation measuring devices, etc. In 2011-2020 the total number of patent applications in the area of medical technology in the world increased by 34.5%. The leaders in the number of patents in this industry in 2020 are the countries of Europe, the USA and Japan (Table 2).

Table 2. Ranking of countries by number of patent applications filed by area, 2020. Note: The EPO membership includes 38 member states including 27 EU states. compiled by the author based on [11].

Country	Medical technology			Pharmaceuticals		
	Applications	Share. %	Rate of growth 2019-2020	Applications	Share. %	Rate of growth 2019-2020
USA	5 519	39	0.6	3 359	39	13.6
Germany	1 210	8	-5.3	631	7	8.0
Japan	1 011	7	1.2	428	5	-0.2
France	677	5	17.5	575	7	21.8
Switzerland	676	5	-13.1	479	6	2.4
Netherlands	709	5	-9.2	232	3	14.9
Great Britain	436	3	1.6	290	3	-4.0
China	414	3	34.4	289	3	-11.6
Korea	338	2	13.0	247	3	1.6
EPO member countries	7212	50	8.5	4875	58	36.2
Others	1553	11	10.3	675	8	-6.3
TOTAL	14295	100	-	8584	100	-

The leading positions were taken by the American companies Johnson & Johnson and Medtronic, the number of applications of which amounted to 781 pcs and 567 pcs

respectively. It should be noted the positive dynamics of the growth rate of patent applications in the field of medical devices in China and Korea, whose indicators exceeded the rate of the USA by 33.8% and 12.4%, Germany - 29.1% and 7.7%, Japan - 33.2 % and 11.8%, respectively. Analyzing patenting in the field of pharmaceuticals, the prevalence of applications from the following companies should be noted, they are French company Inserm - 118 pcs. and American companies Merck & Co - 99 pcs. and Johnson & Johnson - 92 pcs. [11]. These circumstances indicate the predominance of research activity in the field of medical technology and pharmaceuticals in Europe and the United States. To assess the results of countries' patent activities, it is reasonable to analyze the number of patents granted to them (Table 3). The USA, Germany and Japan remain the leaders in the number of patented medical technologies and pharmaceuticals. At the same time, the growth rate of the number of patented medical devices in 2011-2020 in China and Korea exceeds the indicators of the United States by 10 and 8 times, granted patents for drugs by 8 and 4 times, respectively. Also, it should be noted that in Korea out of 100% of filed patent applications for technologies in the field of medicine, 78.7% are patented, which is comparable to the figure in Japan and is 0.8% higher than the US data. In the field of pharmaceuticals, China is the most efficient, with the share of issued patents exceeding those of the United States and Germany by 21.5% and 26.2%, respectively. The gap between Japan and China in 2020 was 11.1%, decreasing compared to 2011 by 27.7%. These circumstances indicate the presence of the innovative potential of China and Korea and the strengthening of their positions in the future.

Table 3. Ranking of countries by number of issued patents by area, 2020. Compiled by the author based on [11].

Country	Medical technology			Pharmaceuticals		
	Patents granted	Rate of growth 2011-2020. %	Share of patents granted in the filed	Patents granted	Rate of growth 2011-2020. %	Share of patents granted in the filed
USA	4 300	143.1	77.9	1 325	110.7	39.4
Germany	1 062	76.4	87.8	219	7.9	34.7
Japan	796	59.8	78.7	308	59.6	72.0
France	370	102.2	54.7	177	45.1	30.8
Switzerland	517	83.3	76.5	156	48.6	32.6
Netherlands	517	392.4	72.9	78	69.6	33.6
Great Britain	284	123.6	65.1	140	79.5	48.3
China	199	1430.8	48.1	176	877.8	60.9
Korea	266	1166.7	78.7	145	437.0	58.7

The indicators of the Russian Federation are not presented in the reports of the European Patent Organization, therefore, it is not possible to assess the position of the Russian Federation in this rating. However, according to Rospatent, in 2021, 25.2% of the submitted applications for inventions and utility models for combating COVID-19 were granted [12].

7 Conclusion

The global innovation trends are analyzed, it is determined that the pharmaceutical and biotechnology industries are among the most socially significant, capital-intensive and high-tech industries. The tendency of the drugs market growth in the Russian Federation as well as an increase in the share of Russian drugs in monetary terms were noted. The

position of the Russian Federation in the GII is analyzed. The analysis of the main technological and conceptual trends in the pharmaceutical market development was conducted, the basis of which is 4P-medicine healthcare model. The patent activities of countries in the field of medical technologies and pharmaceuticals are considered. The decrease in the growth rate of innovation activity in Europe, the USA and Japan and its growth in China and Japan have been determined.

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