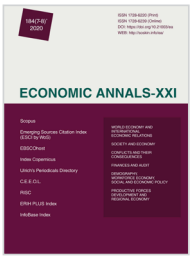

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Irina Belova
PhD (Economics),
Associate Professor,
Peoples' Friendship University of Russia (RUDN University)
6 Miklukho-Maklay Str., Moscow, 117198, Russia
ibelova03@yandex.ru
ORCID ID: https://orcid.org/0000-0002-0397-9790

Maria Dyatlova
PhD Student (Economics),
Peoples' Friendship University of Russia (RUDN University)
6 Miklukho-Maklay Str., Moscow, 117198, Russia
masha_dyatlova@mail.ru
ORCID ID: https://orcid.org/0000-0002-2982-6477

World medical devices market: current trends and their realization in Russia

Abstract
The goal of our study is to search and analyse the main trends in the medical devices (MD) market and their presence in the Russian medical devices market. Using the main indicators of the medical devices market, such as: the dynamics of the export and import volumes of the world and Russian medical devices market, the volume and dynamics of the Russian medical devices market, as well as the main directions that could contribute to the development of this market, we achieve the delivered goal.
We used the theory and methodologic foundations in the field of evolutionary and institutional economics, methods of comparative, systemic, structural, logic analysis, and the economic and statistical method. Let us single out a number of scientists and researchers, as well as analytical companies, whose works formed the information basis for supplementing and creating a more complete picture of the medical device market in our study, namely: M. V. Silva-Vega (2018), V. A. Vilensky (2013), E. V. Miklashova (2015), and companies Evaluate (2020) and Emergo (2020).
Currently, leading positions in the international market of medical devices are held by manufacturing companies, global giants such as Medtronic, Johnson & Johnson, Thermo Fisher Scientific, Philips, GE Healthcare, Fresenius, Abbott Laboratories, Cardinal Health, Siemens Healthineers, Stryker. It should be noted that, according to experts, the share of foreign companies in the Russian market of medical equipment reaches 80%. However, the Russian medical industry, as the basis of the medical devices market, is recognized among priority areas for the development in the Russian economy, since it has significant growth potential, including in international markets. Leading domestic companies in Russia are Electron, Geppik, Amiko, MTL, Ural Optical and Mechanical Plant, and Izhevsk Mechanical Plant.
Based on the results of the world and Russian markets of medical devices analysis, determining the main potentials and directions of the medical devices markets development, trends in the world market of medical devices were identified. These trends can be divided according to several criteria. A geographical criterion: the highest growth rate of the market will remain in the USA and European countries, the Asian market, as well as the countries of South America and the Middle East, will become promising in terms of development rate. A market sector criterion: the largest growth is observed in the sector of laboratory diagnostics, cardiology, traumatology, as well as in the low-margin segments (masks, gloves, etc.). A state priority criterion: an increase in state funding for the development of high-tech equipment, innovations, simplification of the registration process for medical devices. A global social development criterion: the emergence of new dangerous infections, an aging population, increased requirements for the quality of medical services, a change in the categories of diseases, a constant deterioration of the ecological situation. The coronavirus pandemic broke out in 2020 gives increased attention and relevance to this issue, and served as a factor in a sharp increase in demand for personal protective equipment, ventilators, test kits, etc., which is also reflected in our research.

Keywords: Medical Devices Market; Medical Devices Industry; Trends; Turnover of Medical Devices; Competitiveness; Medical Products; Medical Equipment
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Бєлова І. М.
кандидат економічних наук, доцент кафедри міжнародних економічних відносин,
Російський університет дружби народів, Москва, Російська Федерація
Дятлова М. І.
аспірант кафедри міжнародних економічних відносин,
Російський університет дружби народів, Москва, Російська Федерація

Світовий ринок медичних виробів: сучасні тренди та їх реалізація в Росії

Анотація
Мета нашого дослідження – пошук й аналіз основних трендів світового ринку медичних виробів і їх присутність на російському ринку. Використання основних показників ринку медичних виробів (МВ), таких як: динаміка обсягів експорту й імпорту світового та російського ринку МВ, обсяг і динаміка російського ринку МВ, а також основні напрями, які могли би сприяти розвитку цього ринку, дозволять у повній мірі досягти поставленої мети.
Для підготовки даного дослідження були використані теоретичні та методологічні напрацювання в області еволюційної, інституціональної економіки, методи порівняльного, системного, структурного, логічного аналізу й економіко-статистичний метод. Виділимо вчених і дослідників, а також аналітичні агентства, праці яких склали інформаційну основу для доповнення й створення більш повної картини ринку медичних виробів: В. А. Віленський (2013), Е. В. Міклашова (2015), М. В. Сільва-Вега (2018), а також компанії Evaluate (2020) й Emergo (2020).
Російська медична галузь як основа індустрії медичних виробів визнана одним із найбільш пріоритетних напрямів розвитку економіки Росії, оскільки вона володіє значним потенціалом зростання, у тому числі на міжнародних ринках.
За результатами проведеного аналізу світового та російського ринків МВ, визначення основних потенціалів і напрямів розвитку ринків МВ, були означені тренди світового ринку МВ, які можна розділити за кількома ознаками. За географічною ознакою: найбільший темп зростання ринку зберігається в США та країнах Європи, перспективним щодо темпу розвитку стане Азіатський ринок, а також країни Південної Америки й Близького Сходу. За секторами ринку: найбільше зростання спостерігається в секторі лабораторної діагностики, кардіології, травматології, а також у низькомаржинальних сегментах (маски, рукавички і т.д.). За державним пріоритетом: збільшення фінансування державою розробок високотехнологічного обладнання, інновацій, спрощення процесу реєстрації медичних виробів. За загальносвітовими соціальними ознаками: поява нових небезпечних інфекцій, старіння населення, підвищення вимог до якості медичних послуг, зміна категорій хвороб, постійне погіршення екологічної ситуації. Підвищену увагу й актуальність даній проблематиці надає вибух у 2020 році пандемії коронавірусу, яка послужила чинником різкого зростання попиту на засоби індивідуального захисту, апарати ШВЛ, комплекти для проведення аналізів і т.д., що також знайшло відображення в статті.
Ключові слова: ринок медичних виробів; виробництво медичних виробів; оборот медичних виробів; конкурентоспроможність; медична продукція; медичне обладнання.

Белова И. Н.
кандидат экономических наук,
доцент кафедры международных экономических отношений,
Российский университет дружбы народов, Москва, Российская Федерация
Дятлова М. И.
аспирант кафедры международных экономических отношений,
Российский университет дружбы народов, Москва, Российская Федерация

Мировой рынок медицинских изделий:
современные тренды и их реализация в России

Аннотация
Цель нашего исследования – поиск и анализ основных трендов мирового рынка медицинских изделий и их присутствие на российском рынке. Использование основных показателей рынка медицинских изделий (МИ), таких как: динамика объемов экспорта и импорта мирового и российского рынка МИ, объем и динамика российского рынка МИ, а также основные направления, которые могли бы способствовать развитию этого рынка, позволят в полной мере достигнуть поставленной цели.
Для подготовки данного исследования были использованы существующие теоретические и методологические наработки в области эволюционной, институциональной экономики, методы сравнительного, системного, структурного, логического анализа и экономико-статистический метод. Выделим ученых и исследователей, а также аналитические агентства, труды которых составили информационную основу для дополнения и создания более полной картины рынка медицинских изделий: В. А. Виленский (2013), Е. В. Миклашова (2015), М. В. Сильва-Вега (2018), а также компании Evaluate (2020) и Emergo (2020).
Российская медицинская отрасль как основа индустрии медицинских изделий признана одним из наиболее приоритетных направлений развития экономики России, так как обладает значительным

потенциалом роста, в том числе на международных рынках. По результатам проведенного анализа мирового и российского рынков МИ, определения основных потенциалов и направлений развития рынков МИ, были обозначены тренды мирового рынка МИ, которые можно разделить по нескольким признакам. По географическому признаку: наибольший темп роста рынка сохраняется в США и странах Европы, перспективным по темпу развития станет Азиатский рынок, а также страны Южной Америки и Ближнего Востока. По секторам рынка: наибольший рост наблюдается в секторе лабораторной диагностики, кардиологии, травматологии, а также в низкомаржинальных сегментах (маски, перчатки и т.д.). По государственным приоритетам: увеличение финансирования государством разработок высокотехнологического оборудования, инноваций, упрощение процесса регистрации медицинских изделий. По общемировым социальным признакам: появление новых опасных инфекций, старение населения, повышение требований к качеству медицинских услуг, изменение категорий болезней, постоянное ухудшение экологической ситуации. Повышенное внимание и актуальность данной проблематике придает разразившаяся в 2020 году пандемия коронавируса, послужившая фактором резкого роста спроса на средства индивидуальной защиты, аппараты ИВЛ, комплекты для проведения анализов и т.д., что также нашло отражение в статье.
Ключевые слова: рынок медицинских изделий; производство медицинских изделий; оборот медицинских изделий; конкурентоспособность; медицинская продукция; медицинское оборудование.

1. Introduction and Brief Literature Review

The role of the healthcare sector in the socio-economic policy of a modern state is among the key ones. Just like the pharmaceutical industry, the production of medical devices is one of the most important in the field of healthcare.

The MD category includes a fairly wide list of products that are very diverse in their structure, production technology and technological level, functional purpose and capabilities, and methods of application. The Russian Federal Law «On the Basics of Health Protection of Citizens in the Russian Federation» dated November 21, 2011 N 323-FL (as amended on December 29, 2015), determines that «medical devices are any tools, apparatus, devices, equipment, materials and other products, used for medical purposes separately or in combination with each other.» Currently, leading positions in the international market of medical devices are held by manufacturing companies, global giants such as Medtronic, Johnson & Johnson, Thermo Fisher Scientific, Philips, GE Healthcare, Fresenius, Abbott Laboratories, Cardinal Health, Siemens Healthineers, Stryker (Monique, 2019).

It should be noted that, according to experts, the share of foreign companies in the Russian market of medical equipment reaches 80% (Re-port.ru, 2020). However, despite the predominance of foreign companies, the Russian market has huge growth prospects. The latter is due to growing demand, sanctions against Russia and government policy priorities. The government is interested in the development of this industry and directs high investments in priority market segments and companies - manufacturers of high-tech products (Strategy for the development of the medical industry of the Russian Federation for the period up to 2030: draft Federal Law).

According to analysts of the consulting company, the global MD market, subject to an average annual growth rate of 5.2%, will grow to USD 529.8 billion by 2022 (Muir & Kearns, 2017). The growth rate of this industry may turn out to be even higher, subject to the dynamic development of modern technologies, primarily in the fields of medicine, electronics, biochemistry and materials science, since the production of medical devices and equipment is one of the key consumers of innovations. For any company focused on the production and sale of medical devices, it is important not only to determine the most relevant sectors and types of medical devices, but also in which direction the market is changing, which medical devices and in which market will be more in demand for medical devices in the next (1-2 years), but also in the medium and long term (5-10 years or more), the markets of developing or developed countries will show more active growth, as the priorities for consumers change from year to year. This article is focused on defining further prospects. To this end, the current state of the global medical device market, the specifics of the situation in connection with the pandemic, and what experts say about trends in the medical device market have been determined.

2. The purpose of this study is to identify the prospects for the development of the market for medical devices in the Russian Federation in the context of modern trends in the world medical devices market.

3. Results

3.1. World market of Medical Devices

According to the data received from the Evaluate Company, by 2022 the global sales of medical devices may reach USD 529.8 billion and continue to grow due to a sharp increase in demand for medical devices (Digest Medical Devices, 2016). At the moment, the market has already reached USD 513 billion (Gromov, 2020; Batirov, 2017). Several prerequisites for significant growth can be named, namely: the development of modern technologies, the creation of high-tech equipment (the main growth is observed in the field of biochemistry, electronics, and medicine), and the coronavirus pandemic (Figure 1).

The growth of the medical device industry can be justified by the growth of consumption not only in developed countries, such as Japan, the USA, Germany, but also in developing countries (Brazil, China, Russia, India, etc.). It should be noted that in developing countries (excluding the Russian Federation), in the period from 2013 to 2020 the growth of global medical devices market was within 7-10%, while in the developed countries 4-6% (Akimov, 2020; Jepsen, 2016). The growth in consumption is explained by global trends, such as: the emergence of new dangerous infections, an aging population, increased requirements for the quality of medical services (more typical for developed countries), a change in the categories of diseases (typical for developed countries), and a constant deterioration of the environmental situation.

If we consider the international market for medical devices in general, then there are more than 20,000 types of medical devices (Global Nomenclature of Medical Devices) (GMDN User Guide, 2010). The leader in production and consumption is the United States, as well as the countries of the European Union; these indicators are shown in Figure 2 (Silva-Vega, 2014; Zdrav.expert, 2020).

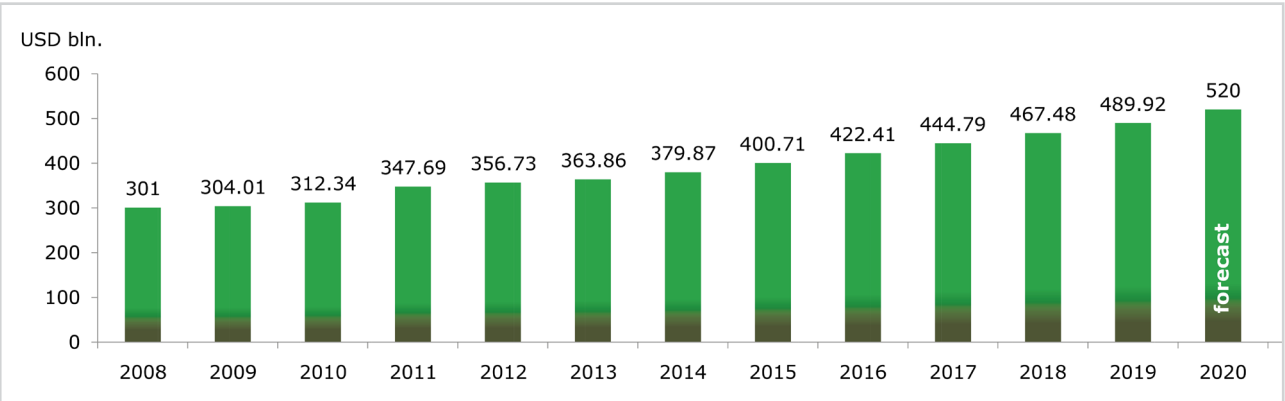

Figure 1:
Dynamics of the global medical devices market from 2008 to 2020
Source: Compiled by the authors based on works by Muir & Kearns (2017), Medical Devices for Professionals (2016), Gromov (2020), and Batirov (2017)

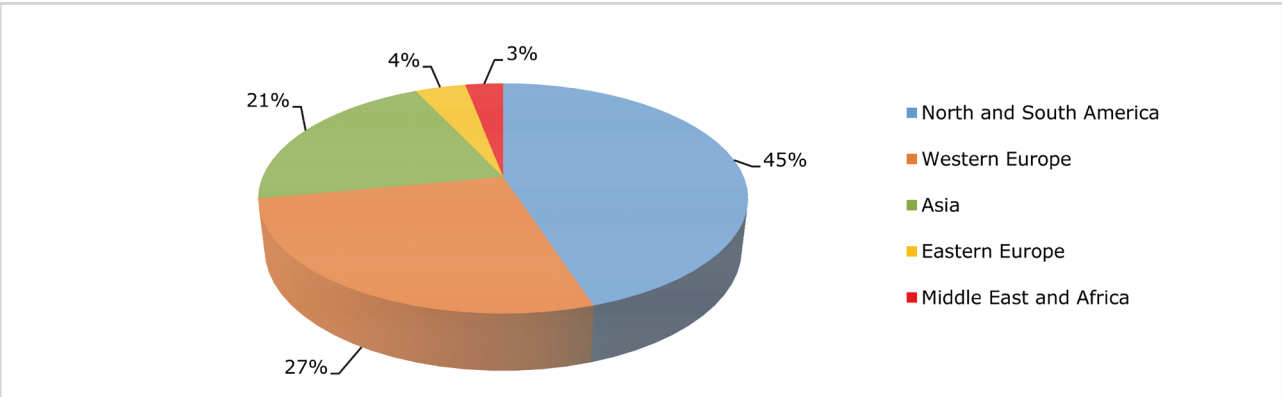

Figure 2:
The structure of the global medical devices market
Source: Compiled by the authors based on work by Silva-Vega (2014)

To develop and maintain high rates of development of the medical device market, developed countries (such as Western Europe, Japan, the USA) use various methods of government incentives, both direct and indirect. Direct methods mean state funding for research aimed at developing and improving technologies and medical mechanisms (a certain list of states, especially the United States, is increasing state funding for the development of medical devices every year). In this case, concessional lending for research works and manufacturers can be called an indirect method. The presented methods are due to the fact that in 5-10 years the developed technologies and innovative products will reduce the expenditure of budgetary funds allocated for health care, since the development of methods and services for early diagnosis, improved methods for detecting and predicting certain types of diseases, which will subsequently allow for early prevention and treatment of diseases at earlier stages.

Demand structure in the period from 2013 to 2019. The following segments are present in the medical device market: diabetes control devices (5%), dentistry (5%), endoscopy (7%), general surgery (7%), ophthalmology (10%), diagnostic imaging (12%), orthopedics and traumatology (12%), cardiology (14%), laboratory diagnostics (17%) and others (11%) (Vibornova & Malahova, 2019; Silva-Vega, 2014) (Figure 3).

The main part of the world medical device market (equipment, devices and medical equipment), namely 40%, is occupied by manufacturers from the United States, and the largest export (from 40% to 54% of the world medical device market) and imports of high-tech medical devices (from 37% up to 46%) (Medtech Europe, 2020).

Another very significant interest of highly developed countries in the development of the medical devices industry is associated with the expansion of the possibility of increasing the share of a highly qualified, socially active and able-bodied population in the general demographic structure, which is one of the key factors in stimulating the growth of the welfare of citizens and the economic power of the state.

The largest markets for the sale of medical devices (primarily high-tech equipment and technology) are Japan, the most developed countries of the European Union (EU) and Canada. The mentioned states and economic unions are both exporters and importers of the latest high-quality medical equipment, modern innovative technologies that form the basis of the global medical industry (Figure 4).

Figure 4 shows the ratio between the volume of imports and exports of medical devices by the largest developed and developing countries (Vilensky, Lozovaya, & Dekhanova, 2015; Medprom.ru, 2013).

The European market for medical devices is formed primarily by the most developed countries of the European Union. Its largest representatives such as Germany, France, Great Britain and Italy are currently in the top ten of the largest medical devices markets in the world. At the same time, attention should be paid to the following circumstance: being highly developed (in terms of volumes and consumption structure), the European market in recent years has shown a rather low growth dynamics by world standards - from 3.6% to 6%, i.e. the potential for further intensive sales growth is not very high (Miklashova, 2015).

At the same time, despite the existence of strong trade and economic ties between the member states of the European Union, the medical device market remains highly competitive. As a

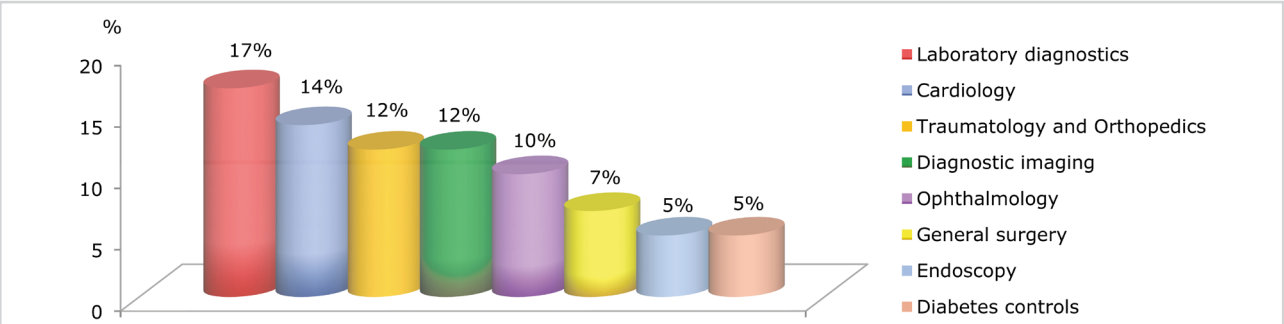

Figure 3:
Sales growth dynamics in the leading segments of the global medical devices market in 2020
Source: Compiled by the authors based on works by Silva-Vega (2014), Miklashova (2015) and available statistical data

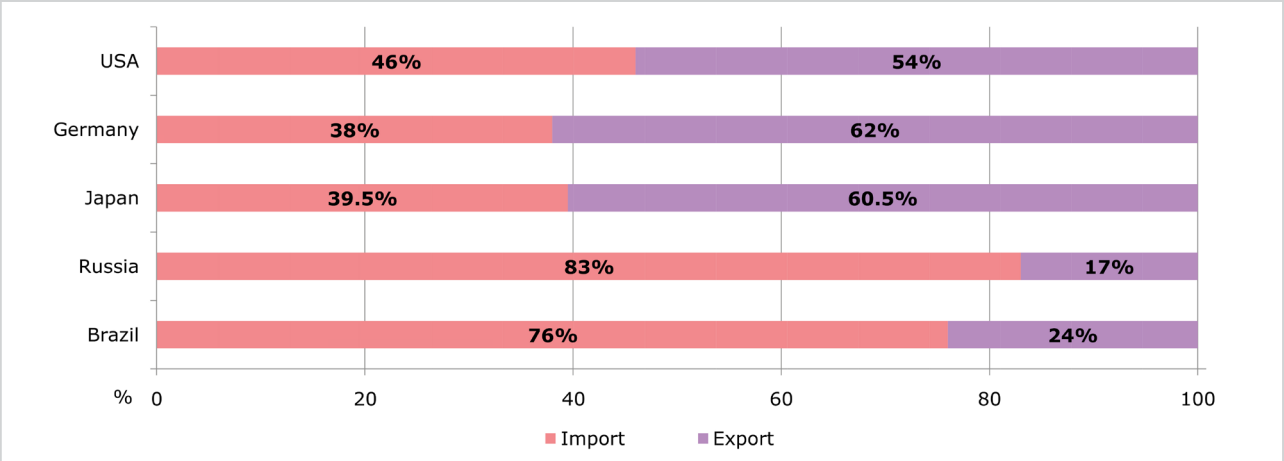

Figure 4:
The ratio of exports and imports of medical devices in the largest developed and developing countries
Source: Compiled by the authors based on work by Center for Certification of Medical Products (2013) and available statistical data

result, some Eastern European countries: Poland, Czech Republic, Hungary, Bulgaria, Slovenia, Serbia, Croatia have now lost their positions in the European medical market.

Considering the Asia-Pacific region, one should especially highlight the markets of countries such as Japan, China, Australia, and also India. The largest markets for medical devices consumers and exporters are Japan and China, while India is the fastest growing in terms of growth. The key trend seen in the Asia-Pacific market is a gradual increase in the share of Chinese manufacturers of medical devices, which, although not yet creating problems for traditional leaders - European and Japanese companies, is gradually intensifying competition. In 2013, the total volume of the Asia-Pacific market for medical devices approached the figure of 70 billion dollars, and in 2020 the total growth in sales ranged from 6.8% (Japan) to 11.7% (China) (Vilensky, Lozovaya, & Dekhanova, 2015; GMDN User Guide, 2010).

At the same time, attention should be paid to the trend of a fairly intensive growth in the consumption of medical devices, which is demonstrated by such developing countries as Greece (growth of 14.8%), Macedonia (growth of 12.4%), Sri Lanka (growth of 12.3%), Kazakhstan (11.7% growth) and Bolivia (11.1% growth) and note the potential prospects of these markets (Silva-Vega, 2014; Sayapina, 2018).

After analyzing the data of the global market for medical devices, let's move on to finding future trends. If we consider the general situation in the global market, then, of course, the most obvious trend in the market for medical devices has become the provision of the population and medical institutions with all medical devices related to PPE (personal protective equipment), ventilators and test kits, along with the subsequent shortage of these devices, indicating that companies are doing their best to keep pace with the ever-growing needs of healthcare providers.

Also, to determine current trends, surveys were conducted based on the opinions of a significant number of respondents (1,374 people) who are professionals in the medical industry; ratings of trends that can be expected in the near future on the international medical market were compiled. The growth prospects of most markets in developing and developed countries in 2020 have been established (the markets of the USA and Europe will retain the highest growth rates) (Malukhina, 2019; Vilensky, 2013). The main reason for this distribution is the relative economic stability in the US and European countries, which may withstand the regulation of medical devices sales. Also, it is worth noting that the respondents' answers were received before the onset of the crisis associated with the coronavirus infection pandemics, the consequences of which can strongly affect the resulting indicators. Changes in growth expectations compared between 2019 and 2020 can be seen in Table 1.

From the potential for growth in sales / turnover of medical devices by region, the main favorites in the next 5 years are the countries of Asia (India, China, and Japan) (according to 1,528 respondents, who are professionals in the medical industry). This is confirmed by the annual growth of markets over several years, as well as the expectations of the companies themselves in the region.

56% Asian companies predict high growth potential over the next 5 years in their own market; North American firms have this figure at 43% and European firms 45%. It should be noted that developed markets remain stable, but have low growth potential (Table 2).

Based on the tables, we can draw some conclusions about the prospects for the developed and emerging medical devices markets. As it was determined earlier, at present, experts are looking at developed markets with a positive side. This is due to the fact that, first of all, these countries have a stable economy, a developed healthcare system and a large percentage of the population aged 65 and over. At the same time, companies should gradually develop a strategy for working with developing countries, since, according to experts, in the next 5 years, the greatest growth will be observed in the Asian region, such as in China or India.

Table 1:
Respondents expectations of sales / turnover growth in global markets between 2019 and 2020

Market	March 2019	March 2020
Australia	8%	8%
Brazil	10%	11%
China	20%	22%
Europe	36%	37%
India	10%	12%
Japan	9%	11%
Mexico	6%	7%
USA	42%	40%

Source: Compiled by the authors based on data by Emergo (2020)

Table 2:
Opinion of respondents about the potential for sales / turnover of medical devices in the regions over the next five years

Regions	High growth potential	Average growth potential	Low growth potential
Africa	31%	33%	36%
Asia	65%	30%	5%
Europe	19%	52%	29%
Middle East	31%	50%	19%
North America	30%	56%	14%
South America	27%	52%	21%

Source: Compiled by the authors based on work by Emergo (2020)

3.2. The Market of Medical Devices in Emerging Markets (on the Example of the Russian Market)

The medical device market is one of the fastest growing industries in Russia. In 2019, the Russian market was estimated at 304.9 billion rubles (over USD 4.049 billion). The demand for medical devices is expected to grow as the quality of healthcare in Russia improves (Emergo, 2020). Leading domestic enterprises are such companies as Electron, Geppik, Amiko, MTL, Ural Optical and Mechanical Plant, Izhevsk Mechanical Plant.

If we consider in more detail the main indicators of the Russian medical device market and the level of competitiveness of Russian goods. In the period from 2014 to 2019 the Russian medical device market showed a fairly high and stable dynamics, demonstrated high growth rates (the average indicator for this period was 9.3% per year) (Alekhin, 2019).

The main reasons for this growth are government support and the implementation of many projects to modernize healthcare and a high level of demand from solvent private and corporate clients. Figure 5 demonstrates the positive dynamics of the Russian medical device market.

After the fall of the medical device market in 2014, associated with the devaluation of the ruble, in 2015 the production of medical devices in Russia increased by 12%, and in 2018 compared to 2015 by 55% (Alekhin, 2019; Emergo, 2020). There are not so many domestic manufactures on the territory of Russia, but when holding tenders and making purchasing decisions, preference falls on domestic production than on imported products. Access to the tender system and public procurement is the secret of success in the Russian market. If we consider in more detail, the limitation of the purchase of foreign products in the process of state orders played a significant role. For example, domestic companies signed about 5.3 thousand contracts worth about 5 billion rubles in 2015. Not so long ago, the Government of the Russian Federation expanded the list

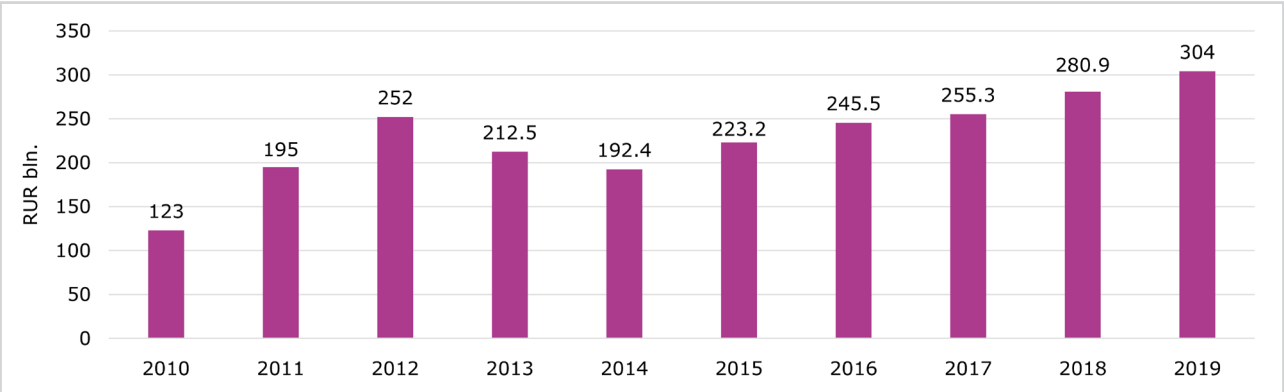

Figure 5:
Volume and dynamics of the market of medical products in Russia, 2010-2019
Source: Compiled by the authors based on works by Emergo (2020) and Alekhin (2019)

to 128 items which caused strong criticism from many experts about this approach (Ministry of Industry and Trade of Russia, 2020). At present the main buyer of medical devices in Russia is the government, represented by large medical institutions.

One of the problems of the Russian medical device market is the predominance of imports over exports. Despite the government's emphasis on the Russian industry, the healthcare system continues to purchase expensive imported innovative and high-tech products. The most popular areas of procurement are diagnostic systems, orthopedic items, ophthalmic, cardiovascular drugs, medical devices for cardiovascular surgery and neurosurgery, orthopedics, general surgery, resuscitation and anesthesiology.

Germany, Japan, Italy, China and the United States are the main countries that import medical devices to the Russian Federation. At the same time, the export of Russian-made medical devices from Russia does not exceed 2%. So, for example, in 2012 the share of exports was 1.63%, in 2014 - 1.4%, 2017 - 6.8% (Starikova & Heifets, 2020). Such a low indicator indicates that Russian products have sufficient competitive properties in comparison with foreign manufacturers. Geography is represented mainly by the countries of the post-Soviet space. First of all, these are the countries that are members of the EAEU and the countries of the Central Asian region.

However, in 2020, in connection with the pandemic of coronavirus infection in Russia, there is a significant increase in the consumption and procurement of personal protective equipment and equipment associated with accompanying patients with severe forms of the disease. The latter contributes to the massive return of production from abroad and the creation of incentive programs for domestic companies. As a result, 10.1 percent more funds were allocated from the budget for health care compared to 2019, which amounted to 1.01 trillion rubles. (Rissoshru.ru, 2020). At the same time, the state spent at least 210 billion rubles on the procurement of goods and services to combat coronavirus. Of these, 61% were expenses for medical equipment, 10% - means of protection, 5% - means for asepsis, 1% - laboratory diagnostics (Project Media, 2020; Timerbulatov & Timerbulatov, 2020).

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Typical trends for the Russian market of medical devices are also typical for most developed countries, such as: aging of the population, an increase in the number of diseases by specific categories of diseases associated with a deterioration of the environmental situation; growth in the well-being of the population; an increase in the number of social programs; development

of a new direction in the provision of medical services - telemedicine (Vanin & Estrin, 2015; Vybornova & Malakhova, 2019).

In Russia, under current conditions, it is extremely difficult to compete with leading manufacturers of medical devices in the American, European markets, as well as the markets of industrially developed countries (with the exception of narrow segments). The markets of the EAEU countries are extremely interesting and promising, where Russian medical devices can have some competitive advantages.

4. Conclusions and Recommendations

Analysis of the main indicators of the international medical device market made it possible to draw the following conclusions:

1. The international market of medical devices is characterized by high dynamics of development, based on the use of high technologies, innovations, dependent on state policy, and requires significant financial investments.
2. The US and European markets are highly developed and will maintain the highest growth rates.
3. In connection with the coronavirus pandemic, there has been a significant demand for low-margin medical products (as personal protective equipment and consumables for laboratory tests and patient support), as well as for devices focused on lung ventilation and the determination of oxygen in the blood.
4. The most promising in terms of development rates is the Asian medical devices market. The MD market in South Africa and the Middle East has high potential.
5. The Russian market of medical devices has a dynamic development, but it has a certain number of problems, such as technical backwardness, a high level of government regulation, and problems with the registration of new medical devices.
6. Russian manufacturers will be able to find their bearings and determine the main trends in the medical device market and create healthy competition for foreign manufacturers.

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