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RUSSIAN PHARMACEUTICAL MARKET 2018

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Opening speech

DSM Group has been engaged in marketing research and pharmaceutical industry analytics for 20 years. The experience and competencies gained by DSM Group specialists have been recognized by the entire industry community. We present you the results of the Russian Pharmaceutical Market work in 2018.

The main result of 2018 for the Russian pharmaceutical community was minimal market growth. Retail pharmacy market is more than two-thirds of the total Russian Pharmaceutical Market, and the lack of income growth affects it negatively.

The main discussion topic of the year was the "Digital Future" of the pharmaceutical industry. Experts give the most favorable forecast: despite the presence of constraints, of which the main one is the unresolved issue of online medicines sales being regulated by the state, there are opportunities for the e-commerce market's explosive growth. To date, home delivery of drugs, dietary supplements and medical products is impossible, although the consumer's request for this service exists, and it is very active (only in 2018, the market growth towards online orders of medicines amounted to more than 40%).

The pharmaceutical market as a whole depends on the country's economy. Unfortunately, in the context of the economic crisis, we can't expect prerequisites for rapid growth, and this will indirectly affect the entire Russian Pharmaceutical Market. But I am sure that our pharmaceutical community will be able to withstand the existing circumstances and find ways out of the most difficult situations.

Sergey Shulyak,
DSM Group founder and CEO. One of the most frequently media-cited experts of the pharmaceutical market of Russia and CIS countries. A member of the Coordination Council of the Russian Association of Pharmaceutical Marketing.

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Summary

If to describe the current situation in the pharmaceutical market in one sentence, probably, the famous "to be or not to be?" will suit most. This expression applies both to government initiatives and to the processes the participants are involved in. Some issues are resolved with the resolution "to be", while others are put aside with the "not to be" signature. Yet is it going to last long?

In 2018, the issue with the expansion of channels for the medicines' sale in the grocery retail was closed. Another one — permission of online trade in over-the-counter drugs — arose and became acute. Moreover, it is clear that the economy development in all sectors is moving towards e-commerce, while a large pool of legal requirements is imposed on traditional pharmacies — they regulate the work of pharmacies: from obtaining a special license for their activities to the qualification of their employees. How can the simple "to be" avoid breaking the system, which was being built over the years, and thus, on the contrary, avoid reducing drug availability?

Yet the pilot project on RTU drugs labeling has come to the next level. And it is clear that there is no way back. There is a Federal Law that regulates the timing of implementation and distribution of the system to the entire market. There are a number of questions left — crypto coding and its cost for the manufacturer, but the process is started anyway, and the maximum that can be counted on is the next postponement.

Another initiative has remained a pilot project. In this case, we are talking about medical compensation. For several years, possible schemes of its implementation were being discussed. But no new decisions were made in 2018. The regions themselves conduct various "experiments". For example, in Moscow, from March 1 to December 31, 2019, benefit-entitled citizens with a Moscow residence permit may apply for a compensation payment for the purchase of a drug in exchange for receiving a free drug or purchasing drugs with a 50% discount, if the required drug is not available under the Federal Program. Again it means that the experiment involves a limited list of persons.

It is worth noting that all initiatives that are marked as "to be" can lead to significant changes in the market. Since 2019, a new pricing system for vital and essential drugs has been operating. The method is designed to ensure that the prices of medicines included in this list should decrease. Will all manufacturers take this step or will they just choose to leave the market?

Such system-forming laws are adopted in economic conditions which are not very favorable for the pharmaceutical market. Therefore, its participants are looking for new ways of "survival".

In 2018, the volume of the Russian pharmaceutical market reached 1,682 billion rubles, which is 2.6% higher than the previous year. Sales of medicines increased by 1.5% in real terms and amounted to 6.4 billion packages.

The main contribution to market growth was made by the commercial segment of drugs. The dynamics of the retail market continued

the positive trend of 2017 in packaging. Market growth in rubles is lower than in 2017. This was influenced, among other things, by the low incidence of influenza and SARS, which did not lead to an increase in demand for "seasonal" drugs. In 2018, the market was dominated by two trends: a decrease in the share of over-the-counter drugs; market growth due to two price segments — "up to 50 rubles" and "over 500 rubles". Thus, the structure of consumption varies depending on the consumers' income.

In 2018, the state segment, in money, remained at the level of year 2017, but in packages it decreased. The main reason is the redistribution of purchased drugs in 2017 to the needs of the previous year. There is also a continuing growth in the segment of preferential drug provision financed from the regional budget.

The share of imported drugs in the overall market in the end of 2018 was 70.2% in rubles and 39.4% in packages. The first places in the manufacturers' rating were kept by foreign companies: Sanofi, Novartis, Bayer. There are three Russian manufacturers in the TOP-20 rating: "OTCharm", "Pharmstandard" and "Biocad" which appeared in the list for the first time.

Consolidation in the pharmacy market is taking new forms: there are partnerships with "medium" and large (more than 1,000 points) networks, associations for individual pharmacies are organized, and this is in addition to the already established companies. The share of the TOP 20 players accounted for 58%. "ASNA", taking 13.2%, has achieved the best results in the association of pharmacies and pharmacy chains. Among the "traditional" networks, the pharmacy chain "Rigla" has the largest share (5.6%). "Erkafarm" group with a share of 5.3% rose to the third place. TOP 5 marketing associations occupy 12.5% of the market.

In 2018, distributors have changed their relationship with pharmacy chains towards tightening the process of goods' shipment. They began to demand additional guarantees for the return of accounts receivables from pharmacies (insurance or bank guarantees). Changes in the principles of distributors' work affected the results and dynamics of the leaders. TOP 10 companies took about 72%. In 2018, the first place was kept by the "Protek" distributor, taking 16%. "Katren" distributor occupied the second line with a share of 15.5%. These two companies showed a negative turnover trend judging by 2017. In 2018, TOP 3 is closed by "Pulse" distributor with a share of 14.6%.

1. Pharmaceutical Market Volume in Russia

2018 was a difficult year for the pharmaceutical market and all its participants — both from the economic point of view and in matters of state regulation.

The decline in the purchasing power of the population, the decrease in real cash income — all this was one of the factors of low growth in the consumption of medicines. Such dynamics led to the fact that all participants of the distribution chain — manufacturers, distributors, and pharmacy chains — began to revise their relationships in order to maintain profits at least at the level of previous years. The largest distributors of the country announced the transition to the provision of commodity credit. Manufacturers are also trying to change the interaction with pharmacies: they offer preferences for their goods in retail.

When discussing state lawmaking, a number of initiatives immediately arise — in the near future they will significantly change the rules of work in the market.
Year 2018 in the Russian pharmaceutical market was held under the auspices of the project on drug labeling. All market participants were involved in this project. And, probably, one of the negative moments was a certain illogicality and variability in decision-making. First, the regulators laid down completely unthinkable deadlines for the program implementation, later these were slightly shifted but they still remain too optimistic. We shall note that the market entered the year 2018 with already defined rules for labeling. Most of the Russian and foreign manufacturers have purchased and installed the equipment, got engaged in the development of changes in IT-processes. Distributors and networks practiced code reading. However, in April 2018, the Russian Government issued an order that a crypt code is added to the marking. Its application and reading is difficult even in the test mode. Crypto coding increases investments in the system of manufacturers increases the risk of defects when the code is damaged. As a result, a number of manufacturers may simply leave the market.

The operator of the system of marking goods in Russia — Center of Perspective Technology Development — reported that the cost of labeling services will account for 50 kopecks excluding VAT for each unit of product. At the same time, it is assumed that these costs drug manufacturers' bear should not lead to an increase in the prices of drugs included in the list of VED. Accordingly, manufacturers will compensate for the costs by raising the prices of other drugs.

The second most important adopted law is a new method of pricing medicines from the list of VED. In 2019, a large-scale revision of prices for the entire list of such drugs will begin.

Such event is brand new. Globally, prices have not changed since 2009. The result of

these actions can be a noticeable change in the market: the range of pharmacies will change, since, perhaps, some brands will leave the shelves, and the prices for VED drugs will decrease.

Year 2018 made life easier for contract manufacturers. Legislation removed the restriction on the production of two or more drugs under different trade names on the same site. The previous restriction did not allow the manufacturer to start production of a drug identical to the customer's drug, on its site. The adoption of this law, among other things, can increase the market of those own brands, which develop large pharmacy chains.

At the end of November 2019, the Federal Law "On Amendments to Certain Legislative Acts of the Russian Federation on the Introduction of Drugs for Medical Use into Civil Circulation", adopted in 2018, will come into force. In accordance with the new order, before entering into civil circulation of each series or batch of the drug, pharmaceutical manufacturers are required to submit to Roszdravnadzor(Federal Service for Surveillance in Healthcare) the documents confirming the quality of the drug or the documents certifying compliance of the drug with the requirements established during its state registration. For the first three series or batches of the drug, first produced in the Russian Federation (first imported into the Russian Federation), an additional test report by Federal state budgetary institutions accredited in the national accreditation system must be submitted, confirming the compliance of the series or batch of the drug with quality indicators.

> "The second most important adopted law is a new method of pricing medicines from the list of VED. In 2019, a large-scale revision of prices for the entire list of such drugs will begin"

Many changes have taken place in the sphere of public procurement. Thus, since 2018, the rules for the description of the procurement object in respect of medicines have come into force. As a result, there was some ordering and averaging of the approach to the description of the required drug, on the other hand — the customers potentially retained the ability to establish specific requirements in the presence of specific needs.

The Ministry of Health and the FAS (Federal Antimonopoly Service of the Russian Federation) have developed a bill that expands the concept of interchangeability of drugs and sets the following standards: about 70% of drugs on the Russian market should become interchangeable by 2021. Today, in accordance with the current legislation, only 16% of positions can be recognized as interchangeable. On January 1, 2018, an Informational and analytical system for monitoring the procurement of medicines was launched. From 2019, reference prices for interchangeable drugs will be introduced. In the end all this should solve the main task — to prevent overpricing in public procurement.

Certain changes have occurred in the provision of preferences to Russian drugs in procurement. So, since 2019, within the framework of the "three is a crowd" mechanism, it is possible to confirm the

origin not only with CT-1 certificate, but also with the conclusion of the Ministry of Industry and Trade. This allows, for example, using the preferences provided for products manufactured under special investment contracts (the ability to confirm the status of goods produced on the territory of the Russian Federation, until the completion of the actual localization).

We should also mention the specially introduced additional preferences for manufacturers localizing production at the level of not only the finished dosage form, but also of the pharmaceutical substance. In 2018, a decision was made, which was positive for the industry. However, we cannot say that lobbying for this decision was easy. It's all about the initiative to allow selling drugs in non-pharmacy retail. The struggle for this right lasted for 10 years. In 2018, the idea of selling medicines in stores was refused.

Another area of development of non-pharmaceutical segment of the pharmaceutical market is the online sale of medicines. The Draft Law has been under consideration in the State Duma since 2017. There is a high probability that the law will come into force in 2019.

Since January 1, Russia has increased Value Added Tax from 18 to 20%. At the same time, the preferential rate of 10% for medicines remains the same. Yet, despite the fact that the price of drugs does not change, the cost of services throughout the commodity distribution chain will increase at least by the difference in VAT rates. Thus, as a result, we can expect an increase in prices for medicines.

As you can see, all legislative initiatives, on the one hand, should streamline all processes in the pharmaceutical market, but on the other — their impact on its participants is very ambiguous. In particular, they can adversely affect drug availability, which is the main task of "Pharma–2020". The strategy of the program was based on launching the Russian Pharmaceutical Industry and reduces dependence on imported drugs.

In 2018, the Ministry of Industry and Trade already began to develop a "Strategy for the Development of the Pharmaceutical Industry until 2030" ("Pharma-2030"). The tasks outlined in this document are more ambitious. Among them there are the strengthening of state policy to support innovation, the development of local competencies in the chemical and biological synthesis of active substances and pharmaceutical substances. One of the development directions should be export. By 2030, the export of Russian medicines should grow by 5 times. For medical devices, the main goal is still to increase domestic production: by 2030 all critical products must be produced in Russia. Domestic production should grow 3.5 times compared to 2017 — up to 200 billion rubles by 2030.

Talking about figures.

In 2019, the Ministry of Finance of Russia plans to reduce costs in several areas, including health. It will get 459.5 billion rubles, while in 2018 the budget for this sphere was 479.7 billion. Then the costs will increase — in 2020 they will amount to 563.2 billion rubles, in 2021 – up to 572.5. The health budget for 2019 will focus on improving the availability and quality of medical care. For this purpose, old medical institutions will be reconstructed and new ones will be built. As for the ratio of the consolidated budget expenditure in the Russian Federation in the health sector

and GDP growth, in 2019, spending will grow to 3.4 trillion rubles (compared to 3.3 trillion in 2018), and GDP will decrease to 3.2% (in 2018 – 3.3%).

The consumption of medicines is one of the items of expenditure on health care.

At the end of the year, the volume of the pharmaceutical market amounted to 1,682 billion rubles, which is 2.6% higher than in 2017. The dynamics of market growth slowed down since 2016. Prior to this, the annual consumption of medicines was increasing by more than 14%. The main factors affecting the decline in this indicator were low inflation for medicines, the lack of indexation of drugs' prices, which is regulated by the state, as well as general economic factors.

In recent years, there has been a decrease in the capacity of the drug market in dollars and euros. The devaluation of the ruble leads to the fact that the dynamics in foreign currencies is negative. The only exception was in 2017, when there was a strengthening of the Russian currency against dollar and euro.

"At the end of the year, the volume of the pharmaceutical market amounted to 1,682 billion rubles, which is 2.6% higher than in 2017.
The dynamics of market growth slowed down since 2016. Prior to this, the annual consumption of medicines was increasing by more than 14%"

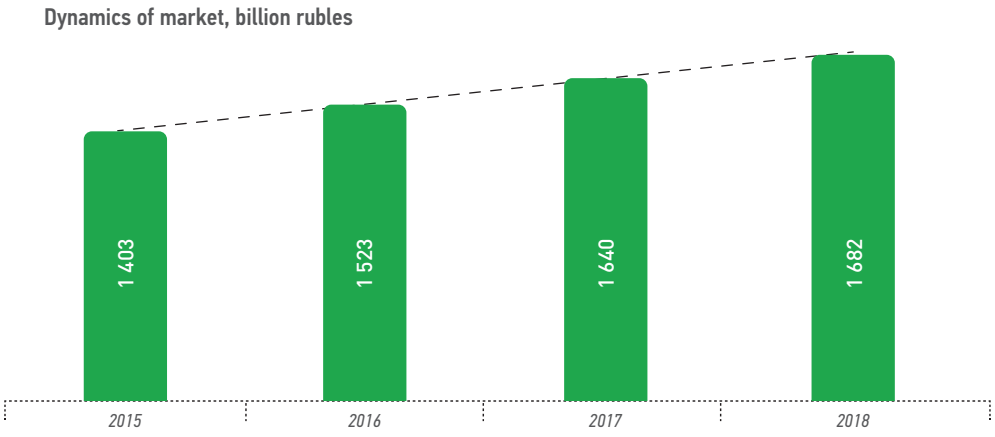
Despite the low dynamics of the market in value terms, in the last two years the consumption of medicines in packages has been growing. And this is one of the drivers of market growth. In 2018, the volume of sales of drugs in real terms increased by 1.5%, and amounted to 6.4 billion packages.

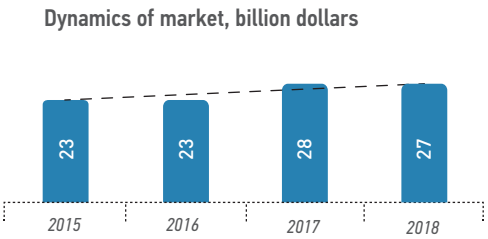
Figure 2 shows the dynamics of the Russian Pharmaceutical Market in 2017-2018 in terms of segments.

The state sector (the volume of the market provided with budget money: hospital purchases, preferential provision of medicines (including 'high-cost ICD', 'Essential Drug Coverage' programs) and regional benefits — occupies about 31% of the drug market volume. In 2017, the share of government spending in the consumption of LP was 32%, thus the indicator fell by 1%. The policy of the government in the sphere of state provision of medicines to the population remains stable, and the items of a social nature are not reduced. As for the executed contracts, in 2018 the volume of purchases in the state segment remained at the level of 2017 in monetary terms and fell by 8% in packages.

The greatest — by 18% — was the increase of purchases of medicines with the regional benefit — up to 89 billion rubles. For the rest of the state segment, there has been a decrease in volumes: the purchase of drugs for preferential categories at the expense of Federal Funds was reduced by 7%, to 108 billion rubles. The volume of financing of drugs for the needs of health institutions amounted to 258 billion rubles, which is 2% lower than in 2017.

The commercial segment of drugs is the main segment of the pharmaceutical





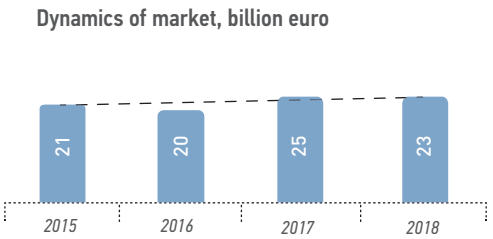
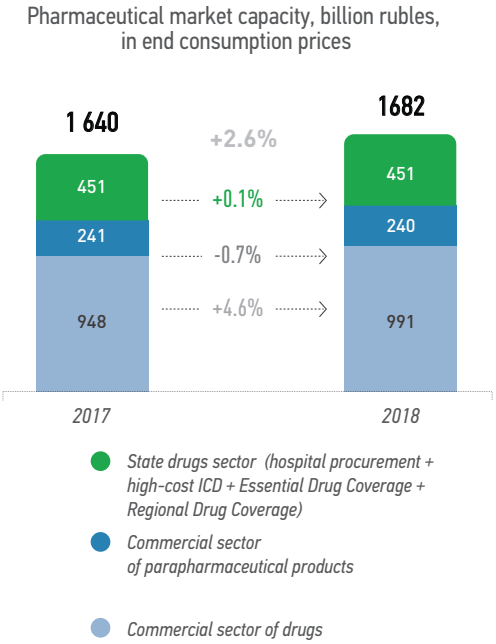


Figure 1

Dynamics of the Pharmaceutical Market



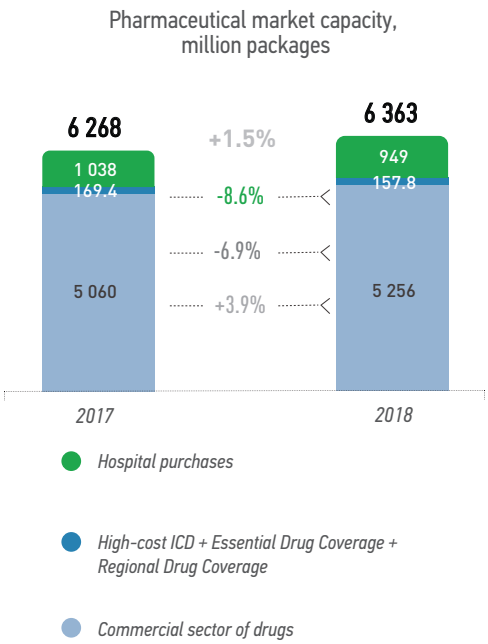


Figure 2

Pharmaceutical Market Capacity

market, which for many years occupies a significant share and shows positive dynamics. Positive dynamics in packages in 2017-2018 indicates a decrease in the financial and economic factors' influence on the pharmaceutical market. At the same time, it is worth noting that there is an increase in the packaging of two segments of cheap (up to 50 rubles) and expensive (over 500 rubles) drugs. Thus, the structure of consumption varies depending on the income of the consumer. Market growth in rubles is lower than in 2017. This was influenced, among other things, by the low incidence of influenza and SARS, which did not lead to an increase in demand for "seasonal" drugs. In 2018, the "flu season" didn't actually come — due to the abnormally warm winter and wide coverage of the population by vaccination.

In 2018, 5,256 million packages of drugs worth 991 billion rubles (in retail prices) were sold through the pharmacy network. This is 4.6% higher than in 2017 in value terms and 3.9% in physical terms.

Market Expressed in Numbers

The share of imported drugs in the overall market in the end of 2018 was 70.2% in rubles and 39.4% in packages. The growth of the market in real terms is provided by a positive increase in sales of domestic drugs in packages (an increase of 2.9%); while sales of imported drugs fell by 0.5% in packages. In ruble terms domestic drugs increased by 6.7%, while imported drugs increased only by 1.7%.
The structure of the drug market by type of issue is quite stable and depends on sales in the commercial segment. About 64.2% in monetary terms account for RX drugs. But due to the lower price OTC drugs prevail in the number packages, and their share is 56.4%.

Note that the main sales volume of OTC drugs is provided through pharmacies (about 94.4% in rubles from the volume of OTC drugs). In the state segment, mainly the RX drugs are sold - they occupy over 93.6% of the volume of consumption in the tender purchases.

Vital and Essential Drugs is a list of the drug products approved by the Government of the Russian Federation in order to regulate the prices for drug products by the state. In the implementation of drugs of the list of VED, the main control is carried out over the formation of prices. Strict rules lead to the fact that inflation on drugs from the list is always lower than the overall inflation in the market. As a whole in 2018, the increase in prices for drugs from the VED list amounted to 3.7%, while drugs not included in the VED list increased by 7.4%

Drugs of the VED list occupy about 50% both in real and in value from the total volume market of drugs.

In 2018, the share of original drugs was 38.7% in value terms and 14.4% in real terms. At the same time, relative to 2017, the share still decreased insignificantly. The hardest switch is noted in the state segment. In pharmacy sales, the same figure is about 0.7%. Yet if the consumer switches to mainly branded generics, the volume of generic drugs sold at the INN is increasing in public procurement.

The ATC rating is headed by the group [A] "Alimentary tract and metabolism", its share is 16.5%, which is significantly higher than the capacity of other ATC groups. The main channel through which the drugs of this group are sold is the pharmacy segment — 79% in rubles account for the purchase of medicines at the expense of the population.

Still the ATC, which occupy the second and third place in terms of volume, are more implemented at the expense of state funding. Group [J] "Antibacterials for systemic use" is purchased for hospital needs (52%) and is also available in pharmacies with preferential prescriptions (7%).

Group [L] "Antineoplastic and immunomodulating agents" includes expensive drugs, the average price of which is 1,600 rubles (this is 7 times more than the average cost of one drug in the market as a whole). Therefore, the main channel through which the issue of medicines of this group is financed is the program of preferential drug provision (Federal and Regional benefits) — 51%. 32% is also spent on hospital purchases.

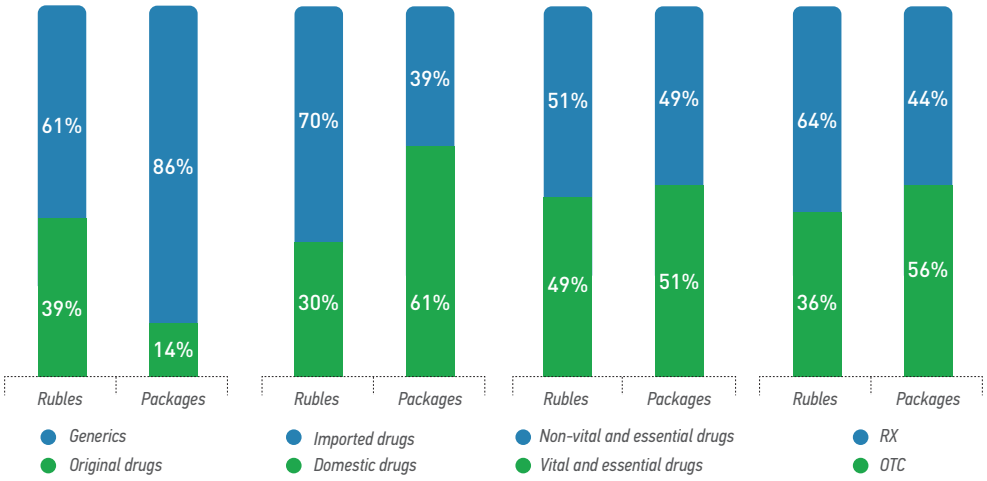


Figure 3

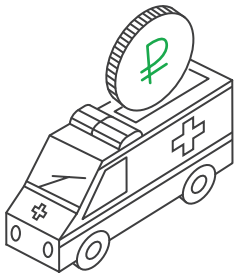
Market Structure in Various Sections, 2018

Table 1

Sales Structure of RTU drugs by ATC groups, 2018

First Level ATC-groups	Group share in sales value, %	Group share in real sale volume. %
A: Alimentary tract and metabolism	16.5%	15.5%
J: Antibacterials for systemic use	12.3%	9.7%
L: Antineoplastic and immunomodulating agents	11.0%	1.3%
C: Cardiovascular system drugs	10.5%	11.8%
N: Nervous system drugs	9.9%	14.9%
R: Respiratory system drugs	9.6%	13.1%
B: Agents affecting blood and blood forming organs	7.6%	7.7%
M: Musculoskeletal system drugs	6.2%	6.5%
G: Genitourinary system drugs and sex hormones	5.8%	1.8%
D: Dermatologicals	4.5%	10.7%
S: Agents affecting sensory organs	2.2%	2.5%
V: Various	1.6%	0.8%
Without ATC	1.4%	2.6%
H: Systemic hormonal preparations (excluding sex hormones)	1.0%	0.8%
P: Antiparasitic products, insecticides and repellents	0.2%	0.4%

2. Commercial segment of RTU drugs



The pharmaceutical segment of medicines has always been and remains to this day the driver of the development of the pharmaceutical market. Therefore, any innovations and possible changes are primarily evaluated by market participants according to the impact on this segment.

On December 17, 2018, the State Duma Committee for Health Protection held a working meeting to discuss the draft Federal Law No. 285949-7 "On Amendments to Certain Legislative Acts of the Russian Federation Regarding the Retail Sale of Medicines by Remote Means".

Market experts agree that the online sale of over-the-counter drugs should be legalized, but there should be a clear definition of control over trading platforms. It's important that it's not the first year when this initiative has been suggested. In 2018, the date of entry into force of the bill on the remote sale of medicines was postponed again; working on it will continue in 2019.

Perhaps, the adoption of the law on online trade will accelerate if the system of electronic prescriptions becomes fully operational in Russia: it will allow regulating the delivery of prescription drugs. The decree of the President of the Russian Federation "On National Goals and Strategic Objectives of the Russian Federation until 2024" provides that by the designated time at least 70 subjects of the country will implement automated management of preferential drug provision and electronic prescriptions issue.

Yet the legislative process in Russia devoted to introducing the digital healthcare system has not yet been completed. For example, the Committee of Moscow Regional Duma on Health, Labor and Social policy is still working on a bill that provides for the possibility of issuing recipes not only on paper, but also in the format of an electronic document. Only in 2019, in St. Petersburg it is planned to provide patients with electronic cards together with the paper version.

In the meantime, the Ministry of Health cannot determine the number of regional medical information systems (MISs), while electronic prescriptions are used only in state pharmacies. In addition, the Ministry of Health of Russia has begun to develop a draft departmental order, according to which doctors will be able to issue prescriptions containing the appointment of narcotic and psychotropic drugs in the form of electronic documents signed with the use of enhanced qualified electronic signature. Now this possibility is not provided – all those in need of such

> Market experts agree that the online sale of over-the-counter drugs should be legalized, but there should be a clear definition of control over trading platforms

drugs can only get a paper prescription. It is planned that the document will come into force in October 2019.

Still the most relevant question on the market remained the one about the pricing methodology for drugs included in the VED list.

The government has adopted a new pricing methodology for vital and essential drugs (VED). Its introduction may lead to lower prices for VED in Russia. The formation of prices for medicines according to the new method will take place in 2019-2020, as it follows from the amendments proposed by the government to the Federal Law "On Drug Circulation". The Ministry of Health and FAS will be engaged in re-registration of prices — they will check all the information submitted by manufacturers.

At the moment drugs from the VED list continue to be traded on the market with the price formed by the previous method. The new and old versions of the methods differ in the list of countries with which manufacturers should compare prices when registering medicines in Russia. According to the new method, all prices for foreign drugs will be set basing on their cost in Hungary, Greece, Belgium, Spain, the Netherlands, Poland, Romania, Slovakia, Turkey, France, the Czech Republic and the country of manufacture. The price in Russia should not be higher than the lowest one in the reference states.

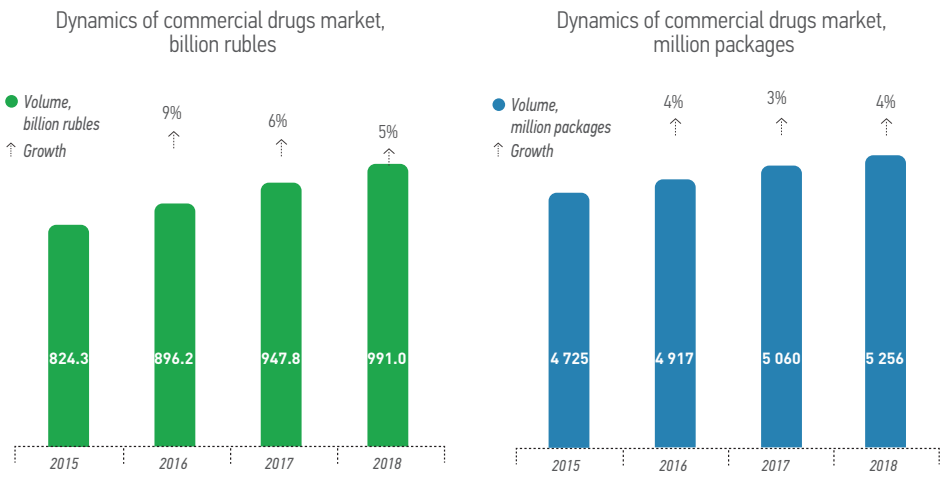
In addition, the new document provides for the reduction of generic drugs' cost (analogs that enter the market after the expiration of the patent for an innovative drug), so that each generic would be necessarily cheaper than an innovative drug.

Despite the fact that the price of VED according to the new method has not yet been fixed, the State Duma is preparing to discuss the bill on the mandatory re-registration of prices for vital drugs. The document proposes to re-register the price each time there is a decrease in any of the reference countries.

It is also proposed to provide for the state registration of selling prices for medicines

Figure 4

Dynamics of Commercial Sales of DP



worth up to 50 rubles, inclusive, in the notification procedure on the basis of the application of the holder or the owner of the registration certificate of the drug, or of an authorized person. At the same time, it is believed that drug manufacturers will be interested in reducing prices in order to get into the cheap segment of the market and to spread the application price registration.

Against the background of the declining dynamics of market growth after the complete re-registration of prices for VED, we may see a negative growth rate of the commercial segment.

In 2018, 5.3 billion packages of drugs for about 991.0 billion rubles (in retail prices) were sold through the pharmacy network. Compared to 2017, drug sales increased by 4.6% in value and by 3.9% in natural equivalent. The main factors influencing the market growth are the weather and the "scale" of seasonal diseases, not macro factors.

Notably, even with the decline in growth rates in value terms, for the last three years, the dynamics of the market in packages is positive, despite the rather high inflation. In 2018, it was 6.1%.

The second and probably a more important reason for the low growth rates in rubles of sales in pharmacies is the unevenness of seasonal diseases from year to year. In 2018, the increased demand for anti-cold and antiviral drugs was observed only in March, while the traditionally high incidence is observed in February-March and September-October. According to this indicator, year 2018 is an exception. Among the factors that influenced this trend, we can name intensive vaccination of the population, as well as an atypically warm autumn.

"Against the background of the declining dynamics of market growth after the complete re-registration of prices for VED, we may see a negative growth rate of the commercial segment"

According to Rospotrebnadzor, 30.3% of Russians were vaccinated against influenza (43.8 million people in Russia). About 11 million of children, 27.8 million of adults, including 161,000 pregnant women, were vaccinated at the expense of the Federal Budget. Other sources funded the immunization of approximately 5 million people, including more than 3.3 million people vaccinated at the expense of employers.

As a result, there have been a number of changes in the trends that have developed on the pharmaceutical market of medicines: a higher share is of prescription drugs, a shift in consumption — in favor of more expensive drugs.

Proportion of Imported and Domestic Drug Sales

The structure of commercial market of RTU drugs by the sales volume of imported and domestic drugs is presented on Figure 5.

Despite the fact that the number of Russian and foreign manufacturers in the market is almost the same (about 600 and 700 companies, respectively), pharmacies have more brands of imported medicines (about 3,926, which is 9,831 SKU). The same figure for Russian drugs is 84% less — 2,135 brands (7,255 SKU). Thus, it is clear

that foreign companies are implementing "unique" positions more — original drugs and branded generics. Russian drugs are produced in large volume in the form of non-branded generics by multiple companies simultaneously.

In 2018, the share of original drugs was 28.2% in value terms and 58.3% in real terms. In addition, the volume of sales of Russian drugs increased more significantly than the sales of imported drugs: +8.3% in rubles and +6.5% in units. As a result, the share of Russian drugs in the structure of pharmacy sales continues to increase, with the growth of the share occurring both in value and in real.

This was due to the increase in sales of such popular Russian brands as "Mexidol" (+13.3% in value terms and +11.5% in real), "Rhinostop" (+28.5% in rubles and +27.2% in packages), "Trimedat" (+47.6% and +34.0% respectively), etc.

In 2018, the weighted average price of one package of a domestic drug in retail prices amounted to 91 rubles (+1.7% compared to 2017), which is approximately 3.6 times lower than the cost of a package of an imported drug (the cost of a foreign-made drug in retail prices of pharmacies was about 325 rubles). At the same time, the price of imported medicines increased more significantly – by 2,7%.

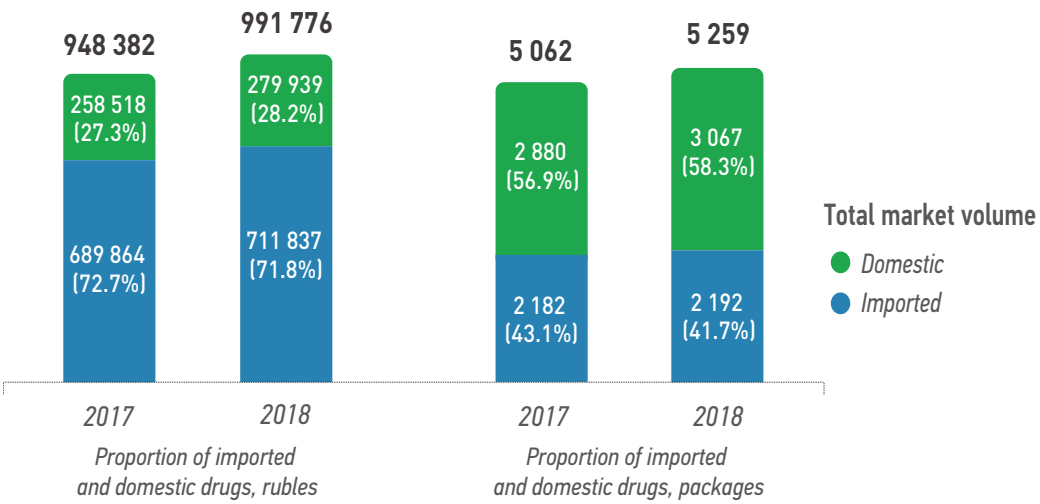
Proportion of Sales of RX and OTC-drugs

Proportion of Rx and OTC-drugs by pharmacy sales is shown in Figure 6.

According to the results of 2018, sales of both Rx and OTC-drugs increased in retail commercial drug market in monetary terms. In the period of increased incidence of SARS and influenza, on the contrary, the volume of over-the-counter drugs sales increases. In 2018, in the absence of a surge

Figure 5

Proportion of Sales of Imported and Domestic RTU Drugs on Commercial Retail Market



in such diseases, sales of Rx drugs were growing at a higher rate than the volume of OTC-drugs sales: +8.4% in money terms and +9.7% in units. Therefore, the markets share of prescription drugs increased by 1.8% in both equivalents.
The share of Rx-drug products in rubles was 50.8%; in units the most share also is with the OTC-drug product (65.9%).

The average cost of a package of prescribed drug amounted to 281 RUB, OTC drug cost in average 141 RUB for a package in a pharmacy. Prices for both categories of drugs decreased in comparison to the same period of the previous year (by 1.2% and 0.2%, respectively).

Ratio of sales of original and generic medicines

The main trend of the Russian pharmaceutical market in recent years is the switching of consumers to generic drugs. Generics prevail in sales volume, and every year their market share grows. In real terms, the sales of generic drugs increased by 4.6%; the result is that generic drugs could occupy 83.9% of the market in 2018, increasing their share by 0.6%. In monetary terms, the share of generic funds increased from 61.1% to 61.8%.

The consumers' shift to generics is mainly due to the increased demand for

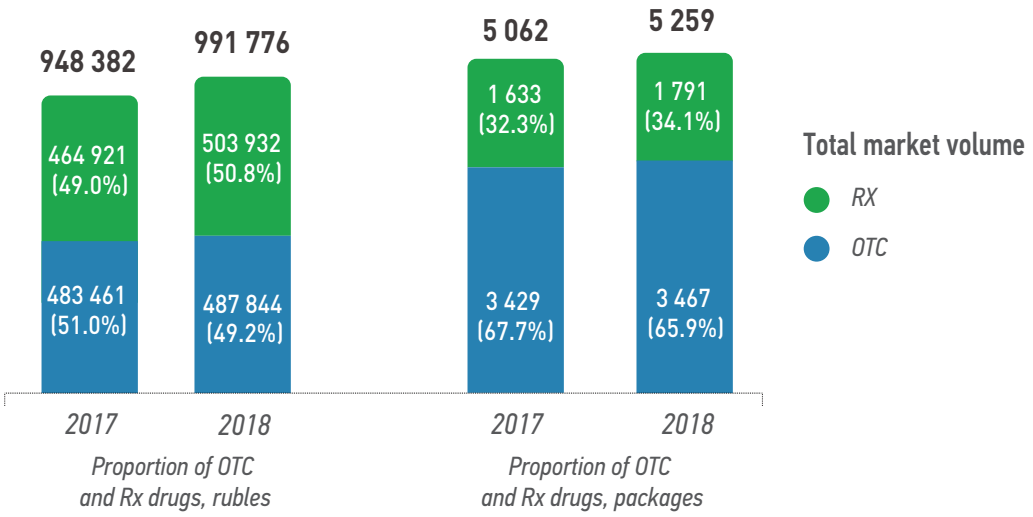


Figure 6

Proportion of Sales of Rx and OTC-drugs on Commercial Retail Market in Russia

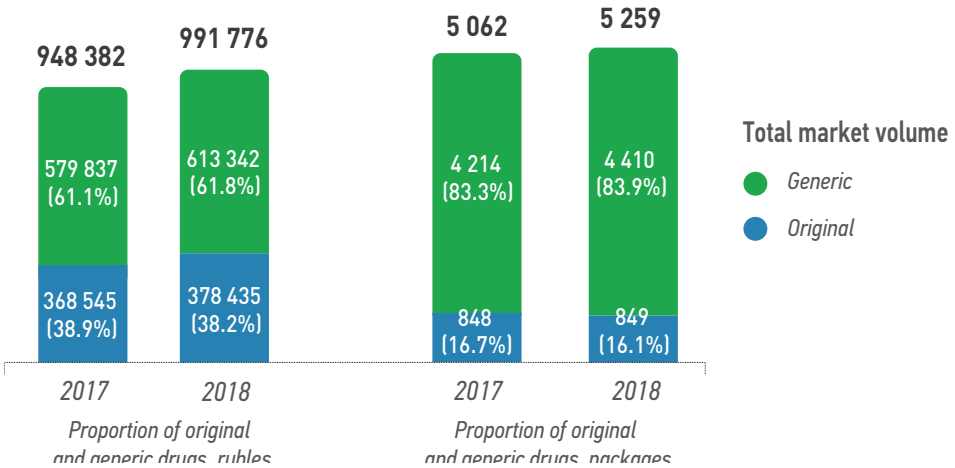


Figure 7

Proportion of Sales of Original and Generic Drugs of the Russian Retail Commercial Market

Table 2

Sales Structure of RTU drugs on Retail Commercial Market by ATC-groups

Note. Without ATS medicines that do not have the ATC-group (homeopathic medicines, medicines of plant and animal origin, substances etc.

First Level ATC-groups	Value, billion rubles	Group share in sales value, %	Natural volume, million pack.	Group growth in volume, %
[A]: Alimentary tract and metabolism	186.7	+2.8%	865.9	+1.5%
[[C]: Cardiovascular system drugs	139.7	+8.9%	664.4	+10.5%
[R]: Respiratory system drugs	124.0	+4.3%	796.1	+3.4%
[N]: Nervous system drugs	112.2	+3.0%	827.3	+1.7%
[M]: Musculoskeletal system drugs	81.6	+5.6%	390.3	+7.4%
[G]: Genitourinary system drugs and sex hormones	80.0	+3.9%	111.5	+1.2%
[J]: Antibacterials for systemic use	73.3	+2.1%	348.8	+2.1%
[D]: Dermatologicals	61.8	+1.3%	618.9	+3.6%
[B]: Agents affecting blood and blood forming organs	47.9	+14.7%	169.4	-2.0%
[S]: Agents affecting sensory organs	28.0	+7.3%	152.6	+18.3%
[L]: Antineoplastic and immunomodulating agents	27.0	+0.1%	60.9	-3.9%
Without ATC	14.3	+1.3%	161.6	+0.7%
[V]: Various	7.3	+0.8%	35.0	+0.8%
[H]: Systemic hormonal preparations (excluding sex hormones)	5.6	+12.5%	32.4	+20.1%
[P]: Antiparasitic products, insecticides and repellents	2.4	+2.6%	23.4	+3.0%

unbranded drugs. Thus, in the packages of drugs sold by INN, increased by 5.5%, and branded generics increased only by 2.8%. Consumers tend to save money and prefer cheaper medicines.

The average cost of a package of the original drug was 446 rubles (+2.6% to the indicator of 2017), while a generic was sold for 139 rubles, on average (+1.1%).

In the future, switching to generics will continue, especially if the relevant law is adopted. The Ministry of Health amended the Federal Law of 12.04.2010 № 61-FZ "On Drug Circulation". The purpose of the amendments is to legally establish the obligation of pharmacies to inform the buyer first of all about the availability of the cheapest drug with the same INN and of other drugs with the same active substance. This duty is also established by the Rules of Good Pharmacy Practice (order of Ministry of Health of 31.08.2016 No. 647н) and the Rules of Medicinal Products' Sale (order of the Ministry of Health of 11.07.2017 No. 403н).

Sales Structure of RTU Drugs on Retail Commercial Market by ATC Groups

The ratio of 1st level ATC groups by pharmacy sales in Russia is shown in Table 2.

The structure of the pharmacy market for ATC-groups of the 1st level has not changed in 2018 compared to 2017:

- The minimum increase in the results of twelve months was shown by ATC-group [L] "Antineoplastic and immunomodulating agents" (+0.1%). Due to this, it moved one line down. This trend is largely due to the low growth of "seasonal drugs" — immunity modulators; at the end of the year, their volume decreased by 0.5% in money.

We shall note that other groups, which include drugs for the treatment of colds and viral diseases, also show gains below the market. This corresponds to the seasonality that was shown in 2018: the epidemics peak was reached only in March, but it was lower than in previous years, and the autumn surge in sales was not observed.

The ATC rating is headed by group [A] "Alimentary tract and metabolism", its share is 18.8%, which is significantly higher than the capacity of other ATC groups. Compared to 2017, this group shows sales growth in money terms by 2.8%. By the number of sold unit, this segment shows sales decrease, which amounts to 1.5%.

Thus, it can be concluded that the observed growth in sales in rubles for this group is due to both an increase in sales in real terms and an increase in average prices for drugs. The leaders in this ATC were the drug for liver diseases and biliary tract treatment "Essentiale", eubiotic "Linex", the third place is taken by a hepatoprotective drug "Heptral". Significant growth in this group is demonstrated by the hepatoprotector "Ursosan" (+25.1%) and by the antiseptic intestinal and astringent "De-Nol" (+24.3%).

About 15.9% of the value of ATC-group [A] sales falls on the subgroup [A07] "Antidiarrheal drugs". The first place by the sales volume in group [A07] is occupied with brand "Linex" with share in rubles, which amounts to 14.7%. Enterosgel and Enterofuryl take the 2nd and the 3rd places with shares 10.3% and 8.1%, respectively. By the number of sold units, the low-cost

mainly domestic drug product "Activated Carbon" is the leader (almost 42.0% of sales [A07]).

In 2018, the subgroup [A11] "Vitamins" fell to the third place in its ATC — the volume of sales decreased by 11.2% in rubles and by 7.3% in packages. One of the reasons is consumers switch to buying drugs registered as nutritional supplements.

The second place in terms of value is taken by ATS group [C] "Cardiovascular system drugs" (14.1%). In this group such brands as "Detralex", "Konkor" and "Lozap" dominate. Such brands as "Valsacor" (+141.0%), "Enalapril" (+27.1%) and "Betalok" (+14.5%) made the maximum contribution to the increase in sales.
ATC-group [S] "Agents affecting sensory organs", which rose to the tenth place in the ranking instead of group [L], showed a sales increase of 7.3% by 2017, which helped it to strengthen its position.

In group [S], the leader is subgroup [S01] "Agents for eyes diseases treatment" — 89.3% of value sales come from this subgroup. The bulk of sales in the subgroup are brands "Taufon" and "Oftan". Pharmacy sales of "Taufon" increased by 19.0% over the year. The "Oftan", on the contrary, showed a drop in sales (-11.5%) compared to 2017.

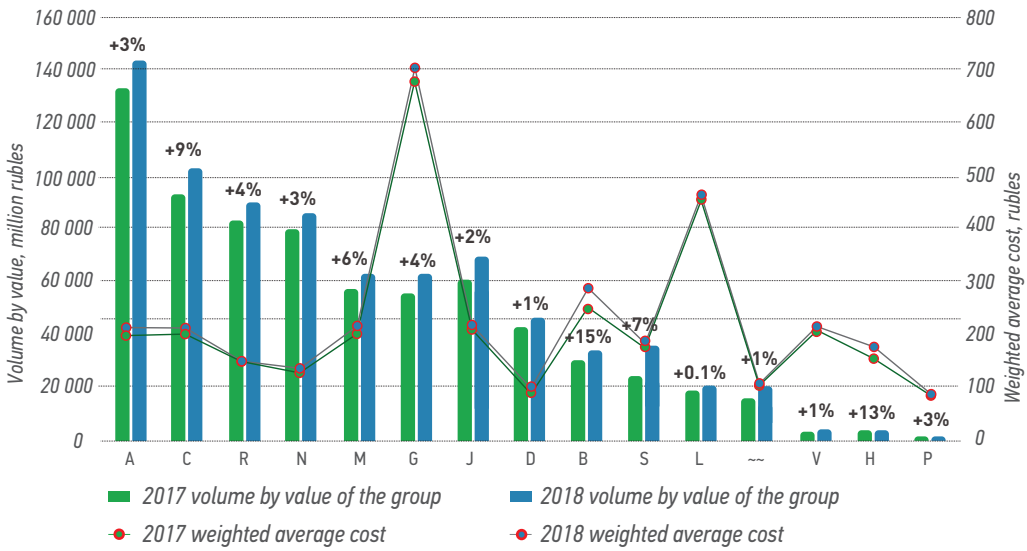
The structure of the commercial market by ATC groups remains rather stable from year to year. The increase in the capacity and the average cost of a unit in ATC-group is shown in Figure 8.

If summarizing the results of year 2018, all ATC-groups showed a positive increase in the value of sales. The highest growth rate was observed in drugs of two groups [B] and [H].

Sales of group [B] "Agents affecting blood and blood forming organs" increased by 14.7%. 16 drugs show an increase in sales in the TOP 20 in this subgroup: "Eliquis" (+116.8%) and "Xarelto" (+50.9 percent) grew the most. In addition to "Xarelto", all leaders have increased in sales — "Cardiomagnyl" (+3,5%), "Actovegin" (+5.7 %).

Figure 8

Structure of Commercial DP market



The largest share of the value of sales in group [B] falls on subgroup [B01] "Anticoagulants" (64.7% of sales in group [B]). "Xarelto" is the leader in the subgroup, which takes about 23.3% of the sales volume for 2018.

Sales of group [H] "Systemic hormonal preparations (excluding sex hormones)" increased by 12.5%. To a greater extent, this dynamics is provided by the growth of the volumes of subgroup [H01] "Hypothalamic-pituitary hormones and their analogues": popular brands showed an increase of more than 40% — "Octreotide" (+151.2%), "Norditropin" (+43.6%), "Jintropin" (+54.3%).

In natural terms, the leaders in increased consumption were groups [H] Systemic hormonal preparations (excluding sex hormones) (+20.1%) and [S] "Agents affecting sensory organs" (+18.3%). The reduction of pharmacy sales in packages was recorded only in 2 groups: [L] "Antineoplastic and immunomodulating agents" (-3.9%) and [B] "Agents affecting blood and blood forming organs" (-2.0%).

The highest weighed average unit cost on the basis of 2017 amounted to 717 rubles for the drugs of group [G] "Genitourinary system drugs and sex hormones". Such a high price is explained by the fact that the unit cost of some of RTU drugs in this group reaches 10 thousand rubles and more. Also high average unit price in noted in group [L] "Antineoplastic and immunity modulating agents" — about 443 rubles, [B] "Agents affecting blood and blood forming organs"— about 283 rubles.

The contribution of various ATC-group to the average growth of the commercial market was determined using weighed increase index: the value taking into account the share of each ATC-group multiplied by its growth rate (Figure 9).

The largest contribution to the increase in the cost capacity of the commercial medical market in 2018 was made by groups [C] "Cardiovascular system drugs", [B] "Agents affecting blood and blood forming organs "

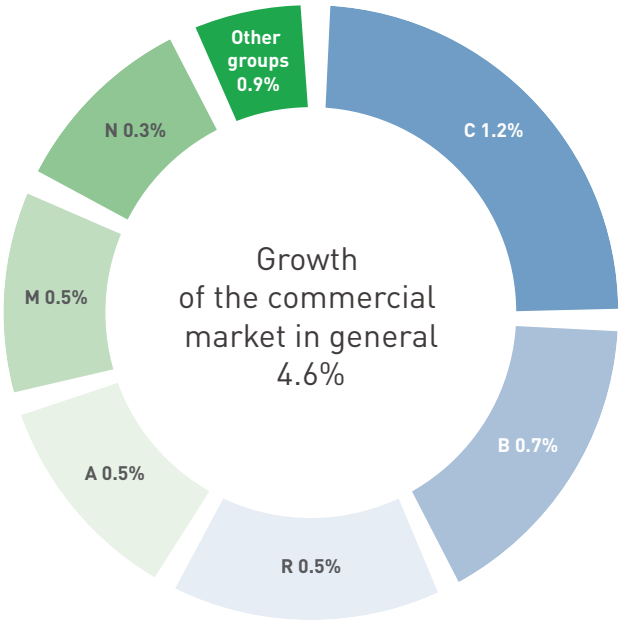


Figure 9

Weighed Increase of DP on Retail Commercial Market by ATC groups

and [R] "Respiratory system drugs", which totaled 2.5% or about 54% of the growth of the market as a whole.

RTU drugs manufacturers on retail commercial market

Table 3 shows TOP-20 manufacturing companies leading by the sales volume on Russian commercial market in 2018.

In 2018, over 1,120 players were presented on the Russian Pharmaceutical Market. Totally, TOP-20 companies cover 54.3% of RTU drug sales volume. Compared to 2017, the total share of the top twenty decreased by 0.4%.

Classically, the first position at the end of the year in the pharmacy segment is held by Bayer (the share of 4.5% in rubles), whose sales in the pharmacy segment decreased by 0.4%. Bayer's portfolio is quite large (73 brands sold in pharmacies). The maximum sales volume of the company is accounted for the drug "Xarelto" — its share in the company's sales at the end of 2018 amounted to 16.0% in monetary terms, while sales for the year increased by 50.9%, which was the largest increase in sales among key drugs. The second place in terms of sales volume growth (from the TOP 10 of Bayer portfolio) is taken by the brand "Qlaira": +27.4% to the level of sales in 2017. In real terms, leaders in the terms of sales are such brands as Relif, Rennie, Bepanten. These three items account for more than 30.1% of the packages sold, which is almost twice the total share of these drugs in the value of the company's sales.

> "In 2018, over 1,120 players were presented on the Russian Pharmaceutical Market"

Sanofi company took the second position in the ranking, losing only 0.3% of the share in rubles to the leader. The company's sales in 2018 increased by 0.2% compared to the previous year. The leading "Essentiale" takes 11.7% of the total sales of Sanofi at the end of 2018, and the share of "Lozap" and "No-Spa", occupying the second and third place, amounted to 11.6% and 6.1%.

In the third place, there is Novartis Corporation with a share of 4.2%. The company's sales growth rate at the end of 2018 was positive (+6.3%). A number of key products of the company were marked by a significant increase in sales — "Linex" (+3.7% to the sales level in 2017), "Amoksiklav" (+8,6%), "ACC" (+14,4%). "Azarga" brand showed the highest growth among the most popular products of the company (+28.4%). Yett it is also worth noting that there was a "falling" group of drugs in the portfolio of Novartis: "Exoderil" (-10.4% compared to the level of sales in 2017), "Ketonal" (-2.6%), etc.

At the end of 2018, 5 companies from the TOP 20 manufacturers of the commercial drug market improved their positions. A Slovenian company KRKA (pharmacy sales of drugs increased by 16.7% due to stable growth in demand for such drugs as "Valsacor", "Roxera", "Septolete", etc.). The rate of growth of Polpharma Corporation was the highest among the TOP-20 — 19.9% to the level of sales in 2017, due to an increase in the sale of a number of brands, in particular, "Omeprazole", "Acyclovir" and "Aquadetrim". GlaxoSmithKline, Berlin-Chemie, Gedeon Richter firms also managed to climb one position up in the ranking.

It should be noted that 12 companies participating in the TOP 20 retained their

positions in 2018. At the same time, most of the producers recorded an increase in sales.

Four companies from the TOP 20 showed a negative trend. Sales of the Teva producer fell most strongly due to the decrease in sales of the antihypertensive agent "Valz". Stada company's sales volume also decreased, this is due to a drop in sales of the main drug of the manufacturer – nasal spray "Snup".

The rating of manufacturers is largely represented by foreign companies: at the end of 2018, only three companies are Russian.

Table 3

TOP 20 DP Manufacturers in Value Terms at the end of 2018

2018 Rating	Changes	Manufacture	Value, billion rubles	Sales volume increase	Share
1	-	Bayer	**45.0**	**-0.4%**	**4.5%**
2	-	Sanofi	**41.5**	**+0.2%**	**4.2%**
3	-	Novartis	**41.5**	**+6.3%**	**4.2%**
4	-	Teva	**36.9**	**-5.3%**	**3.7%**
5	-	Servier	**34.3**	**+5.0%**	**3.5%**
6	-	OTCpharm	**34.1**	**+7.6%**	**3.4%**
7	-	Takeda	**30.0**	**+8.3%**	**3.0%**
8	+1	GlaxoSmithKline	**26.8**	**+0.6%**	**2.7%**
9	+1	Berlin-Chemie	**26.7**	**+3.2%**	**2.7%**
10	+1	Gedeon Richter	**26.7**	**+5.0%**	**2.7%**
11	-3	Stada	**26.1**	**-4.4%**	**2.6%**
12	+1	KRKA	**25.2**	**+16.7%**	**2.5%**
13	-1	Abbott Laboratories	**23.4**	**+7.5%**	**2.4%**
14	-	Johnson & Johnson	**20.2**	**-2.8%**	**2.0%**
15	-	Pharmstandard	**19.4**	**+2.0%**	**2.0%**
16	-	Astellas Pharma	**17.3**	**+10.0%**	**1.7%**
17	-	Dr.Reddy's	**16.7**	**+7.3%**	**1.7%**
18	+1	Polpharma	**16.5**	**+19.9%**	**1.7%**
19	-1	Valenta Pharm	**15.8**	**+3.9%**	**1.5%**
20	-	Pfizer	**14.0**	**+2.6%**	**1.4%**

The maximum share is taken by "OTCpharm" with a share of 3.4%, being situated on the 6-th line.

In packs, leaders of the pharmacy demand are, for the most part, Russian producers. Pharmstandard company holds the maximal share (about 7.5%). OTCpharm covers about 3.5% in pharmacy sold units. The third place is occupied by Ozon (3.3%). The concentration for this indicator is slightly lower than the same indicator in value terms: the TOP 20 manufacturers account for 50.7% of the sale of drugs in real terms.

Table 4

TOP 20 DP Manufacturers on Packaging by the end of 2018

Ranking 2018	Changes	Manufacture	Volume, mln pack. 2018	Natural volume growth	Share
1	-	Pharmstandard	**396.6**	**-2.4%**	**7.5%**
2	+1	OTCpharm	**186.1**	**+8.6%**	**3.5%**
3	+5	Ozon	**175.3**	**+32.6%**	**3.3%**
4	+1	Veropharm	**170.0**	**+5.9%**	**3.2%**
5	-3	Stada	**167.0**	**-6.3%**	**3.2%**
6	+1	Obnovleniye	**158.3**	**+7.0%**	**3.0%**
7	-3	Teva	**147.9**	**-10.1%**	**2.8%**
8	-2	Tula Pharmaceutical Factor	**146.6**	**-1.2%**	**2.8%**
9	+3	Polpharma	**113.7**	**+17.0%**	**2.2%**
10	-1	Novartis	**111.4**	**+0.2%**	**2.1%**
11	-1	Dr.Reddy's	**109.9**	**+4.7%**	**2.1%**
12	-1	Sanofi	**107.0**	**+6.6%**	**2.0%**
13	-	TATCHEMPHARMPREPARATY	**93.1**	**-1.7%**	**1.8%**
14	+2	Takeda	**91.3**	**+7.1%**	**1.7%**
15	-1	Berlin-Chemie	**88.4**	**-1.0%**	**1.7%**
16	+1	Gedeon Richter	**84.4**	**+3.3%**	**1.6%**
17	-2	GlaxoSmithKline	**81.6**	**-4.4%**	**1.6%**
18	+1	Servier	**80.6**	**+2.4%**	**1.5%**
19	+1	KRKA	**79.4**	**+9.9%**	**1.5%**
20	-2	Johnson & Johnson	**78.5**	**-3.5%**	**1.5%**

Drugs of Retail Commercial Market

Table 5 shows TOP-20 brands leading by the sales volume on Russian commercial market in 2018.

A number of significant changes can be noted in the rating of brands leading in terms of value on the commercial market. The first place in the top three is still held by analgesic "Nurofen" with a market share of 0.8%. Anticoagulant drug of direct action "Xarelto" (+11 places) rose onto the second line, showing the maximum increase among the

Table 5

TOP 20 brands in terms of sales in value terms in 2017-2018

2018 Rating	Changes	Brand	Sales value, bln.rub.	Sales volume increase	Share
1	-	NUROPHEN	7.7	+3.1%	0.8%
2	+11	XARELTO	7.2	+50.9%	0.7%
3	-1	DETRALEX	6.8	+8.4%	0.7%
4	-1	KAGOCEL	6.7	+7.6%	0.7%
5	-1	CONCOR	6.3	+3.6%	0.6%
6	-1	CARDIOMAGNYL	6.2	+3.5%	0.6%
7	-	INGAVIRIN	6.1	+7.7%	0.6%
8	-	ACTOVEGIN	6.0	+5.7%	0.6%
9	-	MIRAMISTIN	5.9	+4.8%	0.6%
10	+1	MEXIDOL	5.8	+13.3%	0.6%
11	+1	PENTALGIN	5.4	+6.4%	0.5%
12	-2	TERAFLU	5.2	+0.6%	0.5%
13	-7	ESSENTIALE	4.8	-17.7%	0.5%
14	-	LOZAP	4.8	+3.8%	0.5%
15	+2	CANEPHRON	4.5	+9.8%	0.5%
16	-1	NICE	4.4	+2.8%	0.4%
17	-1	LINEX	4.3	+3.7%	0.4%
18	+2	LORISTA	4.2	+10.6%	0.4%
19	-1	VOLTAREN	4.0	-3.1%	0.4%
20	+2	JAZ	3.8	+4.3%	0.4%

> In 2018, inflation for drugs (6.1%) was higer than the overall State Statistics Committee (SSC) consumer price index (4.26%). Thus, the increase in drug prices outpaced the increase in prices for the main commodity groups

top 20 brands (+50.9%). The veins protecting vein-tonic "Detralex" was removed to the third position.

+11 places of "Xarelto" drug, +2 positions of "Canephron" and "Lorista" can be called significant positive changes. Only a stimulator of tissue repair "Teraflex" (33rd line) left the rating.

In natural terms, "traditional" cheap drugs "Bactericidal patch", "Citramon" and "Acetylsalicylic acid" continue to lead. Only four drugs included in the TOP 20 in packages showed negative dynamics: "Citramon" (-6.6%), "Activated Carbon" (-6.0%), "Valeriana herb" (-5.8%), "Validol" (-3.8%).

The highest growth rates are demonstrated by "Taufon" (+149.7%), "Analapril" (+39.7%) and "Rhinostop" (+27.2%). It's necessary to note that the TOP 20 brands in natural terms takes 21.2% of pharmacy sales, that is, their concentration is higher than in value. The weighted average price in the TOP-20 by units is about 29 rubles.

6 VITAL AND ESSENTIAL DRUGS

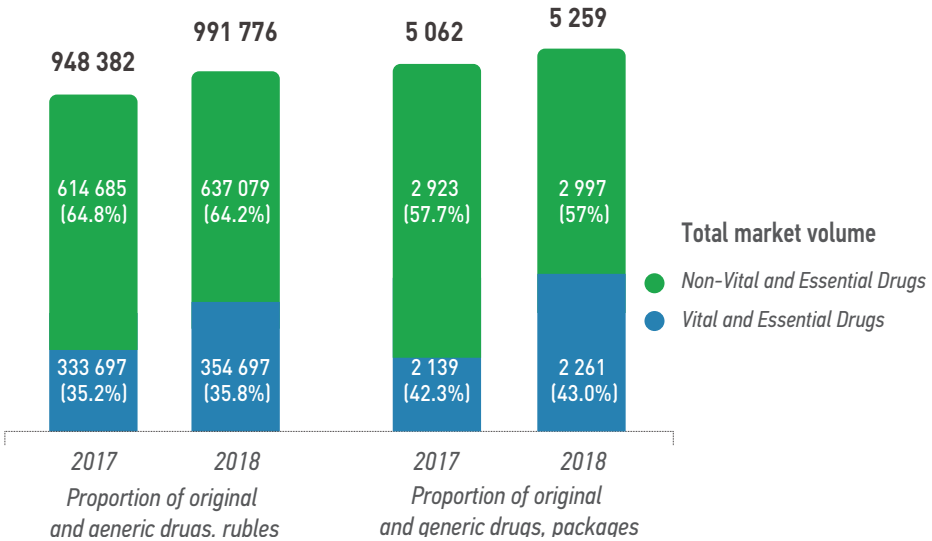
Vital and Essential Drugs is a list of the drug products approved by the Government of the Russian Federation in order to regulate the prices for drug products by the state.

In the reporting year, the list of VED included 699 international non-patented names of medicines. Since 2017, the list of VED has been updated once a year. In December 2018, the Prime Minister signed an order of the Government of the Russian Federation dated 10.12.2018 No. 2738-p, according to which the list of vital and essential medicines will be supplemented in 2019 with 38 drugs and 2 new dosage forms for drugs already included in this list. In total, the list of VED for 2019 will contain 735 INN.

According to the results of 2018, 598 INNs of the list of Vital and Essential Drugs were

Figure 10

Sales Ratio of Vital and Non-Vital Drugs



registered in the pharmacy sales (which accounts for 2,086 brands). The sales volume of the drugs on the list of Vital and Essential Drugs was almost 354.7 billion rubles or 2,261 million of units (Figure 10).

It should be noted that sales volume of Vital and Essential Drugs in value terms increased more significantly than the other drugs (6.3% - Vital and Essential Drugs, 3.6% - non-Vital Drugs). In real terms, there is a similar picture: in the packages, VED drugs increased by 5.7%, while the volume of sales of drugs not included in the list rose by 2.6%.

The share of domestic Vital and Essential Drugs in unit terms was 53.7%, in money terms their share was 28.9%.

At year-end 2018, the weighted average price for Vital and Essential Drugs amounted to 157 rubles; the price of one unit of a domestic drug was about 84 rubles that of an imported drug was 2.9-times higher (241 rubles).

The average cost of Vital and Essential Drugs did not exceed the weighted average price for other drugs (213 rub.). It signifies that in the segment of Vital and Essential Drugs the shift of sales towards expensive drugs is less evident than generally on the market, which can be explained by strict regulation of prices for the drugs on the list of Vital and Essential Drugs.

Figure 11 shows a price index for the various groups of drugs.

In 2018, inflation for medicines was quite high, especially against the background of its absence in 2017 – at the end of December 2018, prices increased only by 6.1% compared to December 2017. The increase in the price of essential drugs was much lower: in 2018 these drugs' price rose by 3.7%. As for the remaining drug items sold in pharmacies, inflation was 7.4%.

RTU drugs sales ranking by INN included in the list of Vital and Essential Drugs is presented in Table 6. INN rating of essential drugs is headed by "Xylometazoline", sales of which grew in 2018 by 3.2% in comparison to the previous year. Notable is that in 2016-2017, "Xylometazoline" also was the leader. As a whole, the balance of power at the top of the rating slightly changed: "Rivaroxaban" INN strengthened

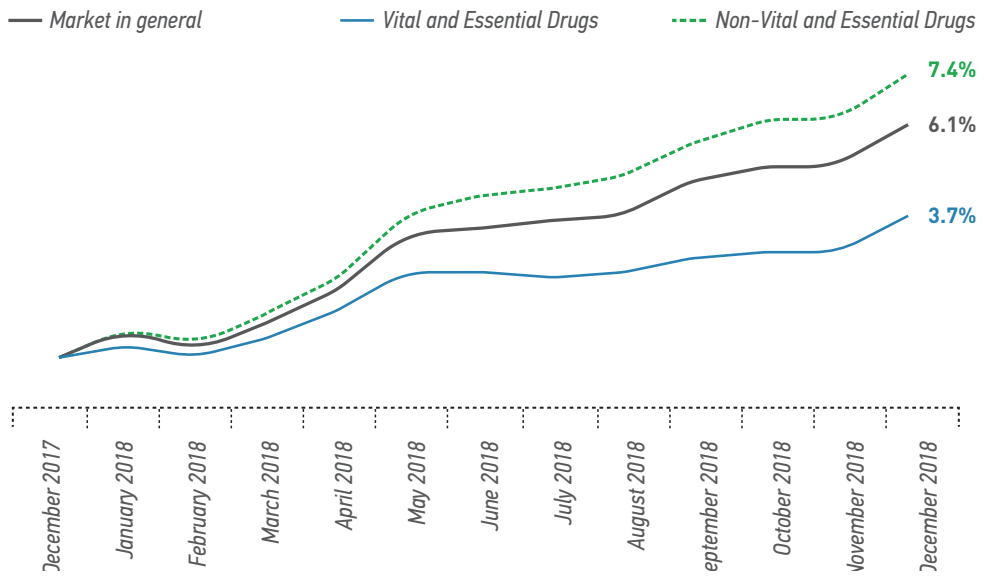


Figure 11

Price Index Dynamics On Commercial Market in 2018

Table 6

Sales Ranking of INN Included in the Vital Drugs List

2018 Rating	Changes	INN	The share in sales of vital and essential medicines, RUB.	Sales volume, billion rubles	Leader among the brands inside the INN
1	-	Xylomethazoline	**4.5%**	**16.1**	Tyzin
2	-	Ibuprofen	**3.3%**	**11.7**	Nurophen
3	-	Pancreatin	**2.7%**	**9.4**	Creon
4	-	Bisoprolol	**2.6%**	**9.4**	Concor
5	+7	Rivaroxaban	**2.0%**	**7.2**	Xarelto
6	-1	Ethylmethylhydroxypyridine succinate	**1.9%**	**6.6**	Mexidol
7	-1	Imidazoliletanamid pentanedioic acid	**1.7%**	**6.1**	Ingavirin
8	-	Atorvastatin	**1.7%**	**5.9**	Atorvastatin
9	-2	Amoxicillin + clavulanic acid	**1.7%**	**5.9**	Amoksiklav
10	+1	Losartan	**1.6%**	**5.7**	Lorista
11	-1	Omeprazole	**1.6%**	**5.7**	Omez
12	+3	Metformin	**1.5%**	**5.2**	Siofor
13	+3	Ursodesoxyholic acid	**1.4%**	**5.0**	Ursosan
14	-5	Ambroxol	**1.3%**	**4.6**	Lazolvan
15	+2	Tamsulosin	**1.3%**	**4.5**	Omnic
16	+2	Cetirizine	**1.2%**	**4.3**	Cetrin
17	+2	Perindopril	**1.2%**	**4.3**	Prestarium A
18	+2	Ademetionine	**1.2%**	**4.2**	Heptral
19	-6	Azithromycin	**1.2%**	**4.2**	Sumamed
20	+1	Amoxicillin	**1.2%**	**4.2**	Flemoxin Solutab

its position rising by 7 lines up due to an increase in sales by 50.9%. This increase in sales volume was ensured by the growing popularity of a direct-acting anticoagulant "Xarelto". Overall sales of all INN in the ratings in 2018 increased in comparison to the previous year. The maximum increase in sales was demonstrated by "Rivaroxaban" INN (+50.9%), "Metformin" (+20.8%) and "Ursodeoxycholic acid" (+17.0%). 2 INN-s demonstrated a decline in sales; the maximum one was shown by "Ambroxol" INN (-15.2%).

Price Segmentation of Drugs on Retail Commercial Market

In 2018, the average unit price of RTU drugs on the commercial market increased by 0.7% and amounted to 189 rubles. We now consider the components of this value.

The commercial market structure and the average price per unit in different price categories in 2017-2018 are presented in Figure 12.

According to Figure 12 the share of drugs with the cost of less than 50 rubles has not changed over the past year. It is worth noting that the share of these drugs in the VED list increased by 0.1%. There is a tendency to shift demand in favor of the "cheapest" and "most expensive" drugs. This is due to the change in consumers' preferences, which largely depend on the solvency: when the situation worsens, the consumer switches and begins to save money; in a stable situation, he/she can afford medicines with a higher price.

If we "fix" the consumer basket at the level of 2017 (regardless of drug price in 2018, it falls into the same segment, which it is in

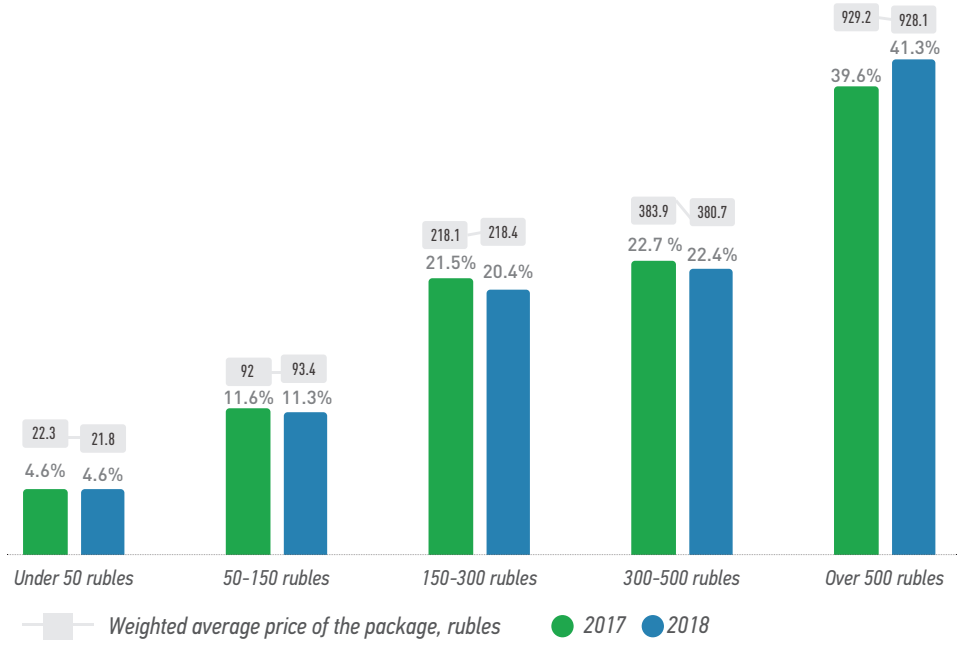


Figure 12

Value Sales Structure of Commercial Market RTU drugs by Price Categories

according to the results of 2017), in 2018, the share of the drugs priced less than 50 rubles was 5.4%, i.e. by 0.8% higher than in 2017. This indicates that there is a shift in demand towards cheaper drugs due to increased consumption, and not due to lower prices. This factor is confirmed by the fact that the share of middle segments decreased in comparison to 2017. And only the segment with a price of over 500 rubles increased by 1.6% in rubles. Thus, there is a consumer's focus on cheaper and more expensive medicines.

The segment of the drug products with price up to 50 rubles has still the greatest capacity in the unit terms and amounts to 40.1%. In comparison with 2017, there was an increase in the share of this price category by 1.2%.

The fastest growing price group both in value (+8.9%) and in unit (+9.0%) terms is a group of drugs priced over 500 rubles, its share increased by 1.6% and amounted to 41.3% in rubles. In packages, the share of this group is not so high — 8.4%.

Sales volume of the remaining price segments were growing at a slower pace and increased by 4.5%.

Price Index of Drugs on Retail Commercial Market

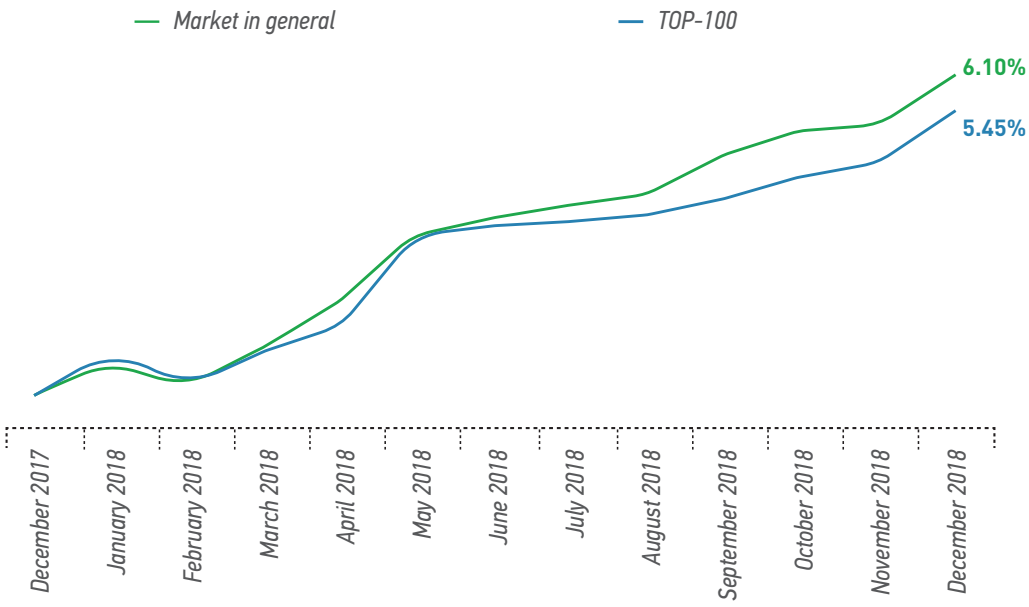
To make an objective estimatation of drug price change on the retail commercial market, price index based upon a fixed list of ready-to-use drugs was considered.

Despite the growth of the market in packages, the price factor also contributed to the growth of the pharmacy market. This was largely due to a change in the structure of sales. But it is worth noting that the inflation for drugs was quite high. At the end of December 2018, prices increased by 6.1% compared to December 2017.

In 2018, inflation for drugs (6.1%) was higer than the overall State Statistics Committee (SSC) consumer price index (4.26%). Thus,

Figure 13

Change in Prices of RTU drugs on the Russian Commercial Market in 2018



the increase in drug prices outpaced the increase in prices for the main commodity groups.

The most popular drugs were growing in price slightly slower than the overall inflation for drugs: the price index for the TOP 100 trade names in turnover in 2018 amounted to 5.45% (Fig. 13). Note that until May 2018, the increase in the cost was almost the same, but since the summer, pharmacies began to work with the range in different ways, trying to attract consumers with lower prices for running positions, but increasing the prices for the rest of the range more significantly.

The price index for imported and domestic drugs for 2018 is shown on Figure 14.

High growth of prices for drugs is noted in all subgroups: imported drugs have increased in price by 5.9%, Russian drugs have become more expensive by 6.5%. Rx drugs on average cost by 4,9% more, over-the-counter ones — by 7,3%.

According to the State Statistics Committee, in 2018, medicines took a share of about 2.16% in the basic structure of consumer spending in Russia, this figure increased by 0.03%. Thus, the State Statistics Committee annually slightly increases the

High growth of prices for drugs is noted in all subgroups: imported drugs have increased in price by 5.9%, Russian drugs have become more expensive by 6.5%. Rx drugs on average cost by 4,9% more, over-the-counter ones — by 7,3%

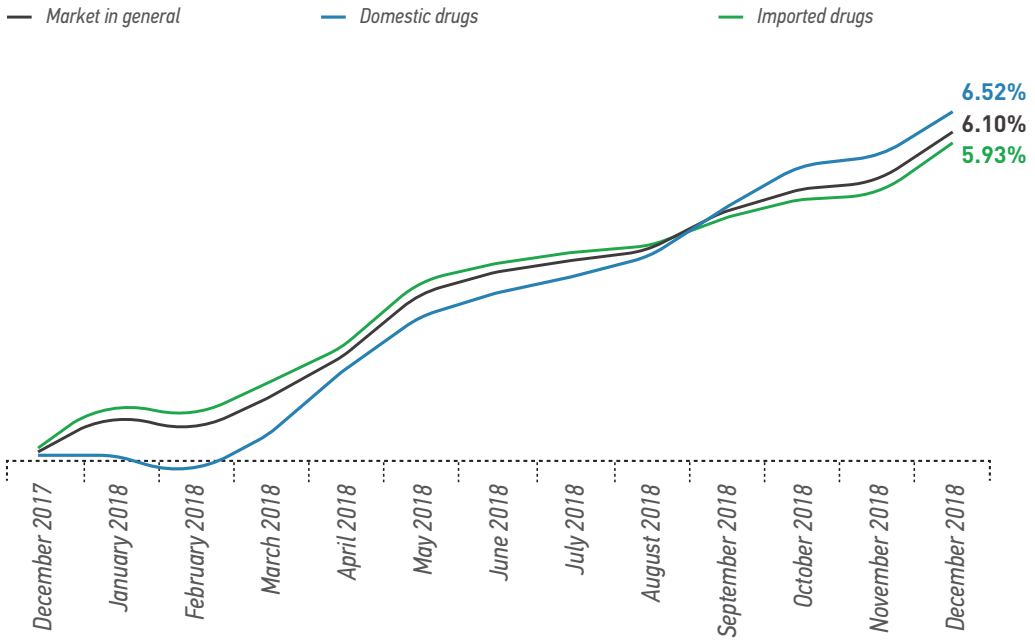


Figure 14

Price Index for Drugs of Domestic and Foreign Manufacturers on the Russian Commercial Market in 2018

Table 7

TOP-20-new Brands on the Commercial Market of the Russian Federation in 2018

Position No.	Brand	Manufacturer	Volume, millions of rubles	Date of appearances in pharmacies
1	Angidak	Grotex	**173.0**	**April 2018**
2	Detragel	SERVIER	**136.7**	**March 2018**
3	Artogistan	Grotex	**117.1**	**January 2018**
4	Trialgin	PharmVILAR	**114.1**	**January 2018**
5	Costarox	Novartis	**94.9**	**April 2018**
6	Desgrippin	PharmVILAR	**86.7**	**February 2018**
7	Corvalol forte	Pharmac	**81.3**	**February 2018**
8	Fri-Al	Alsi Pharma	**65.9**	**January 2018**
9	Midzo	Lasa Labaratorios	**61.9**	**April 2018**
10	Angiorus	Marathon Pharma	**44.1**	**January 2018**
11	Ranavexim	Avexima	**38.1**	**January 2018**
12	Picodinar	Grotex	**36.3**	**March 2018**
13	Prestilol	Servier	**30.2**	**April 2018**
14	Mexilec	Lekpharm	**27.0**	**February 2018**
15	Telzap	Sanofi	**25.6**	**April 2018**
16	Imnovid	Celgene	**25.4**	**March 2018**
17	Revmart	Alsi Pharma	**23.7**	**April 2018**
18	Encetron-Solopharm	Grotex	**23.2**	**July 2018**
19	Forliver-Help	PharmVILAR	**21.7**	**August 2018**
20	Tadalaphil	Severnaya Zvezda	**20.6**	**July 2018**

importance of drugs in consumer spending: for ten years the weight has increased by 0.6% (in 2009 — 1.56%).

Figure 15 shows the overall consumer price index and price indices for various categories of goods and services.

In 2018, the overall consumer price index amounted to 4.26% with the highest price rise observed in gasoline (9.2%). The lowest growth was observed in different services (3.9%).

New Drugs of Retail Commercial Market

In 2018, for about than 300 new brands of drug products appeared in pharmacies. In 2018, the overall sales volume of the new drug products exceeded 1.8 billion rubles and 6.0 million of units, which was equivalent to 0.2% of value and 0.1% of unit volume of pharmacy sales of all drug products on the retail commercial market. The weighted average price of one unit of a new drug product was 302 rubles.

Let's take a look at the brands, which constituted the TOP-20 ranking of the new trade names on the commercial market of the Russian Federation by the end of 2018. The highest sales in terms of value among the drugs that entered the market in 2018 were shown by the Russian brand "Angidac" ("Grotex"). This brand belongs to the group of non-steroidal anti-inflammatory drugs and is used in dentistry as a dosed spray for topical use. Sales volume of this drug product was 173.0 million rubles.

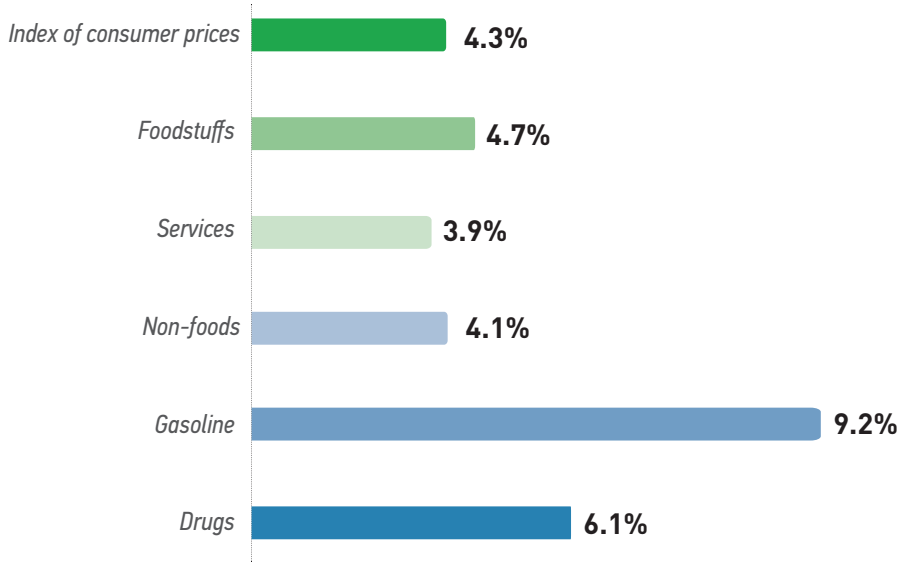


Figure 15

Index of Consumer Prices in Russia (December 2018 compared to December 2017)

The second place of the rating is a tonic for veins "Detragel" by a French pharmaceutical company Servier in the form of a gel for external use with a volume of 136.7 mln RUB. "Detragel" is a drug intended for the treatment of the syndrome of varicose veins. The active ingredient of this brand is "sodium Heparin+phospholipids+escin".

Another new product from "Grotex" company — a stimulator of tissue repair "Artogistan" in the form of a solution for intramuscular injection—is the third of the leaders with the amount of 117.1 mln RUB. Sales of this brand in pharmacies have been recorded since January 2018; it is the Russian analogue of the German drug "Teraflex". "Artogistan" is considered to be a very effective medicine used in degenerative diseases of the joints and spine, as well as to accelerate the formation of callus in fractures.

"Trialgin" drug ("PharmVILAR") with the active substance "Caffeine+Metamizole sodium+phenobarbital" is available in the tablet form. This Russian drug is used for pain syndrome of different genesis (toothache, headache, muscle and joint pain, painful menstruation), as well as to reduce the symptoms of acute respiratory diseases and colds.

A new anti-inflammatory and anti-rheumatic drug "Costarox" (Novartis), sales of which amounted 94,9 mln in the period under review, entered the market in April 2018. It contains an active substance "Etoricoxibum" in its composition. This product, which is available in the form of film-coated tablets, belongs to the segment of expensive drugs (over 300 rubles/pack.).

As a conclusion, it should be mentioned that most of the new drug products were manufactured by foreign companies. Nevertheless, in 2018, Russian companies released on the market 143 new brands and 12 of them were included in TOP-20 of new trade names in the value terms for the indicated period of time.

3. Drug Reimbursement Program (DRP)

A program involving the issuance of free or preferential medicines for a certain category of citizens has existed in Russia for several years. According to statistics, about 15.5 million people in the country are entitled to such drugs. 77% of people from this list prefer to receive monetary compensation instead of preferential drugs, and only 3.5 million people actually use this opportunity. The legislation of the Russian Federation guarantees preferential provision of certain categories of citizens with medicines at the expense of budgetary funds of various levels.

One of the fundamental programs of Drug Reimbursement Program is **Essential Drug Coverage**, which provides beneficiaries with the necessary drugs in accordance with the standards of medical care. The exact list of preferential medicines is annually regulated by the government of the Russian Federation — the Ministry of Health and Social Development. We are talking about the approved document, which is regularly updated — some drugs are excluded, while others, on the contrary, fall into the list. For example, in 2019, the list of medicines to provide certain categories of citizens is supplemented by 27 medicines, and by 3 new dosage forms for medicines already included into this list.

The set of social services for privileged categories of citizens is regulated by the Federal Law of 17.07.1999 № 178-FZ "On State Social Assistance". In addition, the law establishes the standard of financial expenses per month for one citizen receiving state social assistance in the form of social services to provide medicines, medical products, as well as specialized medical food for children with disabilities. In 2018, the standard increased by 2.0%: expenses increased from 807.2 to 823.4 rubles. In April 2018, the standard was once again changed to 826.3 rubles per month for 1 citizen. In 2019, the standard will be 861.8 rubles.

Initially, the Government of the Russian Federation distributed a total of 31.651 billion rubles of subventions from the Federal Budget to the regions in 2018 (order of the Government of the Russian Federation of 27.12.2017 № 2965-p) to provide certain categories of citizens with preferential medicines. But during the year, this amount was adjusted several times. Thus, in the second quarter, the amount of funding amounted to 34.262 billion rubles (also due to the increase in the number of citizens eligible for state social assistance, 129.4 thousand people more).

In 2019, the government allocated 31.367 billion rubles (order of the Government of the Russian Federation No. 2973-p of 28.12.2018) from the Federal Budget to the regions to finance the program of preferential drug provision.

Separate regulation is presumed for the provision of drugs to persons with special categories of diseases — the

"7 nosologies" program or high-cost ICD: hemophilia, cystic fibrosis, pituitary dwarfism, Gaucher disease, malignant tumors, multiple sclerosis, the state after transplantation of organs or tissues. In 2018, there were 181,054 people in the register of persons under this program. Most of the registered persons have nosology "malignant neoplasms" (47%) and "multiple sclerosis" (35%). Every year there is an increase in the number of patients in the register (8-15%).

Initially, the budget of the high-cost ICD program for 2018 was approved in the amount of 43.6 billion rubles. The increase in financing of drug provision for certain categories of citizens in the current year amounted to more than 5.6 billion rubles, of which 4.35 billion rubles was directed to the provision of palliative care, including the provision patients with painkillers. During the tender procedures, the Ministry of Health managed to save more than 543 million rubles, for which an additional volume of medicines was purchased.

The high-cost ICD program, as mentioned above, includes 7 nosologies. And this fact has not changed throughout the existence of this program since 2008. The inclusion of new drugs occurred only within the fixed groups. Thus, since January 2018, the list of drugs purchased under the high-cost ICD program has been supplemented with three more names: "Teriflunomide", "Nonacog Alfa" and "Eliglustatum". As a result, the high-cost ICD list included 27 INN.

Yet since 2019, the list of high-cost ICD was replenished with 5 more nosologies (hemolytic uremic syndrome, juvenile arthritis with systemic onset and mucopolysaccharidosis of I, II and VI types). For the treatment of patients with these diseases one will need to purchase 8 drugs additionally. Thus, now the high-cost ICD program also has a new name — "12 nosologies". The draft budget for 2019-2021 provides for an increase in funding under the high-cost ICD program, taking into account the expansion of this program by 12 billion rubles.

The law "On the Basis of Public Health Protection" establishes that persons suffering from diseases included in the list of life-threatening and chronic progressive rare (**orphan**) diseases are also provided with appropriate medicines. As of the beginning of 2018, the Ministry of Health of the Russian Federation included 24 orphan diseases. Providing citizens with medicines for the treatment of rare (orphan) diseases is carried out at the expense of regional budgets.

Provision of orphan drugs is necessary for a narrow circle of persons included in the relevant Federal Register — 17,651 thousand people (including 8,940 children). In 2017, drugs for a total of 16.2 billion rubles were given to persons suffering from orphan diseases, while the deficit amounted to about 6.1 billion rubles. In 2018, a deficit of 7 billion rubles was projected.

> Yet since 2019, the list of high-cost ICD was replenished with 5 more nosologies (hemolytic uremic syndrome, juvenile arthritis with systemic onset and mucopolysaccharidosis of I, II and VI types)

Over the past few years, the topic of transferring funding for the purchase

of medicines for patients with orphan diseases from the regional to the Federal level has been actively discussed. However, the Minister of Health, Veronika Skvortsova, suggests another way to support the regions instead of centralization of procurement. Assistance to the subjects of the Federation will be carried out through the allocation of subsidies. Thus, the Ministry of Finance provided 7.9 billion rubles in the Federal budget for 2019-2021 to co-finance the purchase of medicines for orphan diseases.

In addition to the Federal Program, there is a territorial one implemented at the expense of **regional** budget funds (the purchase of orphan drugs is part of this program). This program provides for the receipt of medicines free of charge or with a 50% discount and is regulated by the decree of the Government of the Russian Federation of 30.07.1994 "On State Support for the Development of the Medical Industry and Improving the Provision of Population and Health Care Facilities with Medicines and Medical Products". To some extent, the program can be a replacement for the Federal Provision of Essential Drug Coverage, because the beneficiary can be both federal and regional.

Therefore, the Ministry of Health of the Russian Federation plans to create a unified register of recipients of preferential drugs for the whole country in 2019, so that there is no duplication.

The volume of regional subsidized drug list is comparable to the Federal Program. In 2018, drugs were purchased for 89 billion rubles, which is 76.8 million packs. This is 18% more in money terms than in 2017. But at the same time in real terms there was a drop of 14%.

In total, in 2018, the financing of drugs for preferential categories of citizens amounted to 196.3 billion rubles, which is 2.9% higher than in 2017. In packages, there is a tendency to reduce volumes — in 2018, 157.8 million packages were bought (-6,9% in comparison to 2017).

If to consider preferential programs in parts, separately, it can be noted that there is a tendency of growth of regional subsidized drug list. But the share of high-cost ICD, on the contrary, decreases. The share of drugs for common diseases, remains at the level of 30–33%.

For the first time since the introduction of 'High-cost ICD' subprogram, there has been a

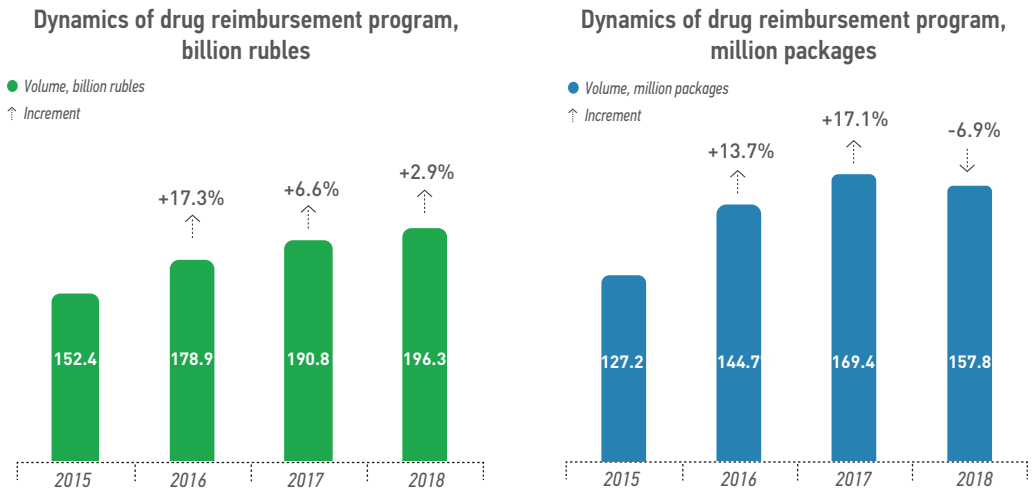


Figure 16

Dynamics of the Drug Reimbursement Program

> If to consider preferential programs in parts, separately, it can be noted that there is a tendency of growth of regional subsidized drug list. But the share of high-cost ICD, on the contrary, decreases

decrease in the money spent on the purchase of drugs. The main reason is the decrease in the number of packages that have entered the 'High-cost ICD' system. This was due to the fact that the purchase of drugs at the Federal Level allows redistributing the remains of medicines between the subjects, which reduces the risk of defective drugs or their write-off in the country subjects. Thus, drugs that were purchased in a larger volume in 2017, were transferred to the provision of beneficiaries in 2018. On the other hand, the Federal Level allows us to buy medicines on more favorable terms due to the volume, as well as there were domestic analogues of original drugs, but with a lower price. Due to this, the reduction in the cost volume is 2 times higher than the reduction in purchases in packages.

In 2018, 45.4 billion rubles were spent on the 'High-cost ICD' program, which is 23% less than in 2017, and about 4.3 million packages were sold, which is 11% lower than in 2017.

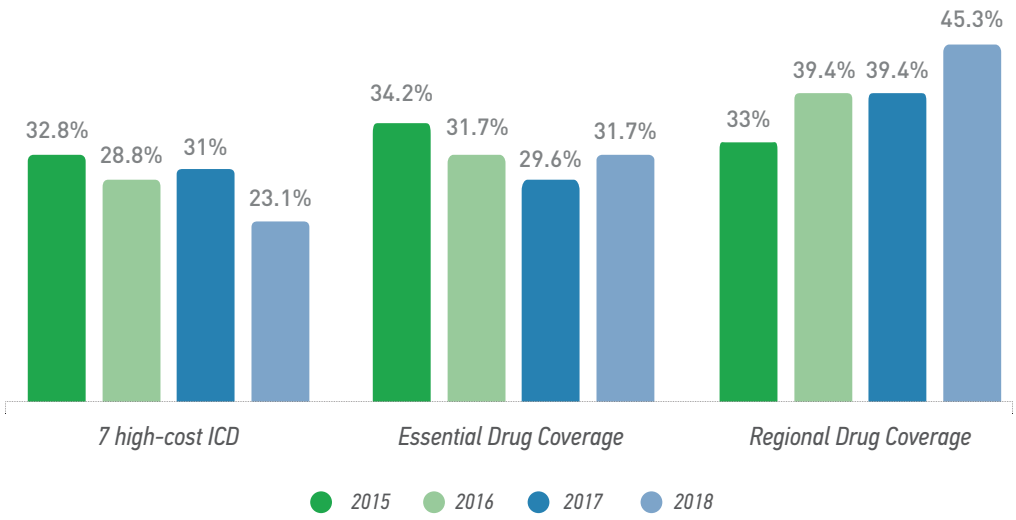
The volume of Essential Drug Coverage program funding in 2018 amounted to 62.2 billion rubles, which is 10% more than in 2017. In real terms, there was a slight increase in purchased packages: about 76.7 million packages, which is 1.8% higher than in 2017.

Proportion of Imported and Domestic Drugs within DRP

According to year 2018 results, the share of domestic drugs in real terms increased by

Figure 17

Proportion of Expenses under the Programs of the High-cost ICD and Essential Drug Coverage in the Total Volume of Funds spent under the Drug Reimbursement Program, in rubles



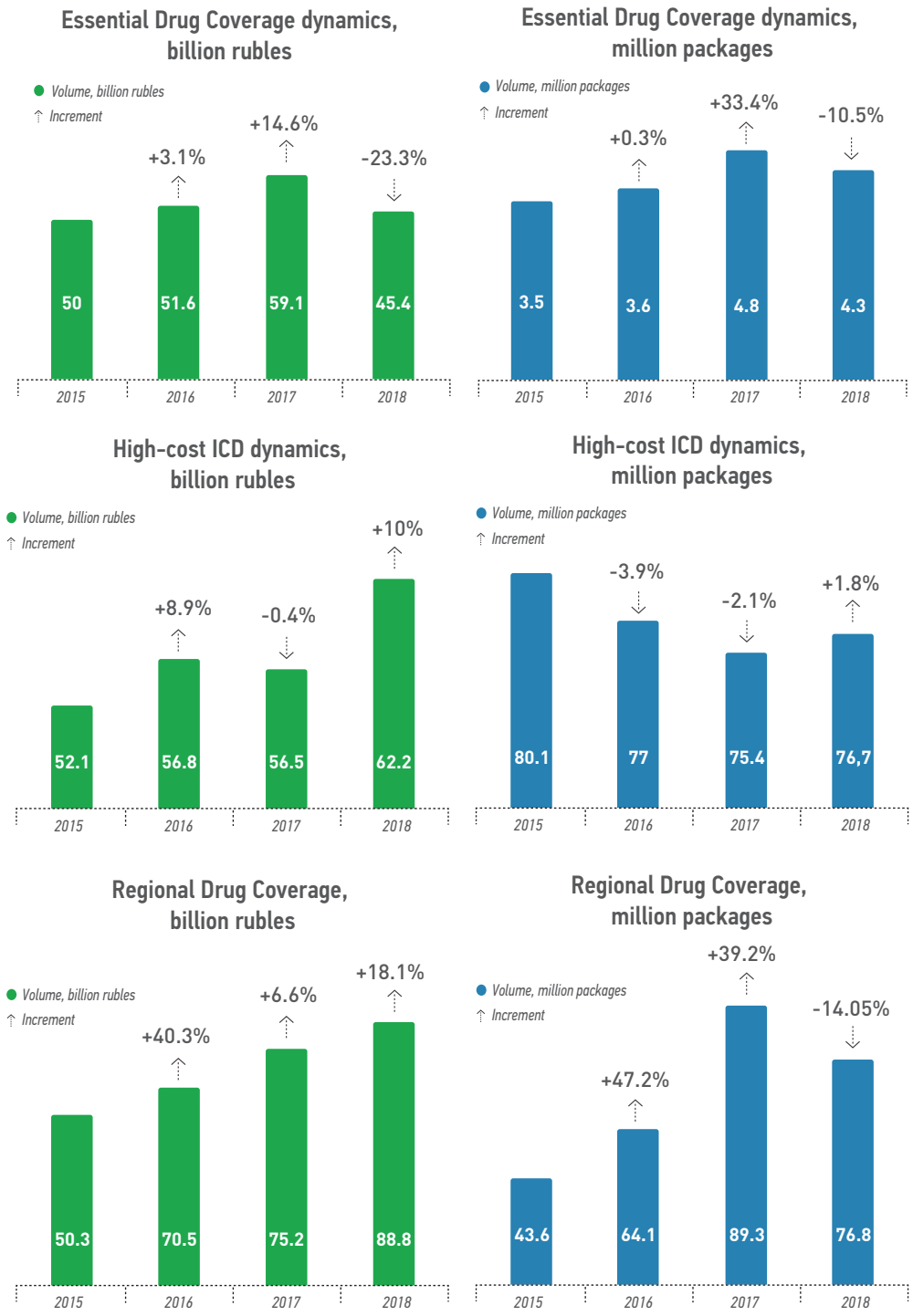


Figure 18

Dynamics of expenses under Reimbursement Program

2.4% (Fig. 19). The volume of consumption of domestic drugs showed a negative trend (-2.5%), while the volume of imported funds decreased even more — by 11.6%. The increase in costs in money for the purchase of domestic drugs remained at the level of 2017 (-0.4%), while imported drugs were spent 4.2% more. Due to this, the share of drugs from foreign manufacturers increased by 0.9% for the first time in many years; before that there was always a reverse process due to "import substitution".

The ratio of domestic and imported drugs in monetary terms remained in favor of imported drugs. In 2018, 72% of the sales value credited to the imported drugs, 28% credited to the domestic drug products.

The ratio of sales of imported and domestic drugs according to program "7 nosologies", Essential Drug Coverage, Regional Drug Coverage is shown in figure 20.

In the part of the Drug Reimbursement Program corresponding to high-cost nosologies, the share of domestic drugs in the value volume decreased by 7% for the first time (due to a drop in purchases by 37%). Such dynamics is due to several factors, the emergence of a large number of generics, including imported ones with a lower price. In packages, the volume did not decrease, but also increased by 3%.

Figure 19

Proportion of Imported and Domestic Drug Sales

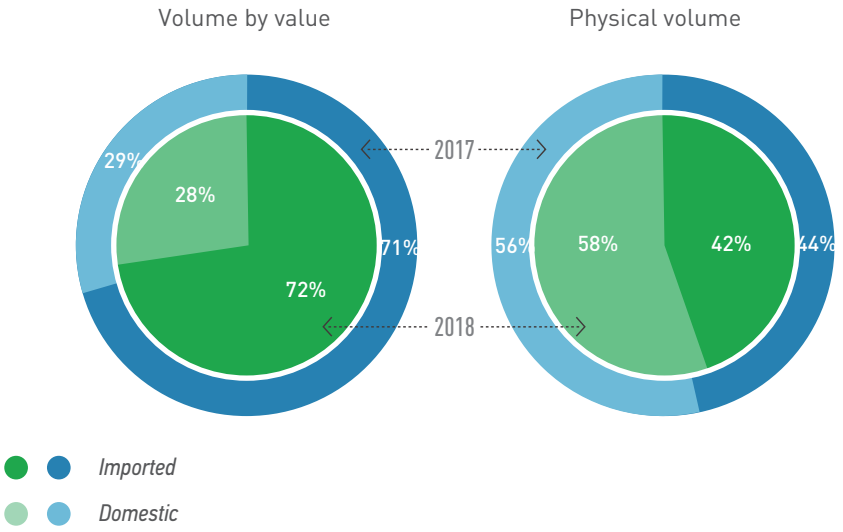


Figure 20

Proportion of Imported and Domestic Drug Sales by subprogram's

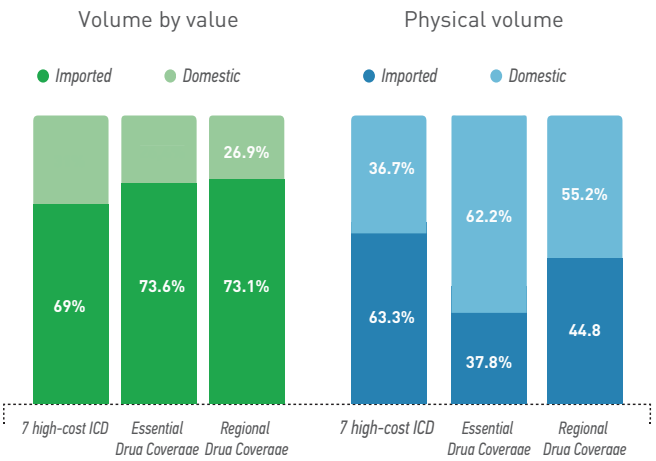


Table 8

Top-10 INN by Import Substitution

INN	Share of domestic drugs, rubles		Growth of the share	Leader, 2017	"Switch" drug, 2018
	2017	2018			
Dasatinib	0.00%	84.45%	84.45%	Sprycel (Bristol-Myers Squibb)	Dasatinib (Nativa)
Sunitinib	2.02%	64.61%	62.58%	Sutent (Pfizer)	Sunitinib (Nativa)
Capecitabine	35.28%	93.67%	58.39%	Xeloda (F.Hoffmann-La Roch)	Capecitabine (Ozon)
Sorafenib	0.00%	53.08%	53.08%	Nexavar (Bayer)	Sorafenib (Nativa)
Temozolomide	34.73%	78.58%	43.85%	Temomid (Jodas Expoim)	Temozolomide (Biocad)
Valganciclovir	47.61%	86.96%	39.35%	Valcid (F.Hoffmann-La Roch)	Civalgan (Izvarino Pharma)
Bosentan	1.62%	40.57%	38.95%	«Tracleer (Actelion Pharmaceuticals)	Bosenex (GK Protech)
Infliximab	0.00%	31.70%	31.70%	Remicade (Merck & Co)	Infliximab (Biocad)
Interferon Beta-1a	20.65%	48.20%	27.55%	Genfaxon (Genfa Medica)	Teberif (Biocad)
Trastuzumab	64.25%	91.33%	27.08%		Herticad (Biocad)

According to the Essential Drug Coverage program, the share of Russian drugs increased and amounted to about 26.4% in money terms (against 24% in 2017) and about 62.2% in packages (in 2017, they accounted for 57%).
In the regional subsidized drug list, imported drugs prevail in the money (73%, but there is also a reduction in the share), medicines of Russian factories occupy 55% in the packaging.

Below there is a table of the TOP 10 INN (from the TOP 100 in volume terms), for which there was a noticeable "switch" from imported to domestic drugs.

Proportion of Rx and OTC-drugs Within the DRP

The Drug Reimbursement Program is mainly represented by Rx-drugs, which are prescribed by a doctor strictly in accordance with the indications for use.

In 2018, the share of prescription drugs amounted to 93% in value (-2% compared to 2017), in kind – 90% (-0.5%).

Drug Sales Structure by ATC groups within the DRP

The ATC ranking by sales volume in accordance with DRP is quite stable. The market is quite concentrated in terms of value — the first three ATC groups occupy 75% of the market.

Group [L] drugs "Antineoplastic and immunomodulating agents " remain the most funded item of the Drug Reimbursement Program. In 2018, about 42.6% of the total state funding was spent on their purchase. This is the most expensive group of drugs in DRP — weighted average price per unit is about 9,940 rubles (over the past two years, there has been a downward trend in this indicator due to the emergence of domestic generics). The purchase costs of these funds compared to 2017 increased 1.4% in RUR. The increase in packages was 2.8%. In 2018, the brand "Revlimid" (INN "Lenalidomid") produced by Celgene remained the leader of the group, despite a decrease in the volume of drugs procurement by 18%. The second and third places are occupied by domestic brands "Soliris" (INN "Eculizumab") by Alexion Pharma and "Acellbia" (INN "Rituximab") by "Biocad" company. Drugs occupy about 7% and 4%, respectively, of the value of the [L]"Antineoplastic and immunomodulating agents group sales".

ATC, located in the second place, has a volume of more than 2 times less than the leader. In 2018, this place belongs to [A] "Alimentory tract and metabolism". In comparison with 2017, there were released by 14.4% more of the group's drugs in rubles and by 6.2% more in packages. About 76% of this group concern the drug products for treatment of diabetes mellitus ([A10]). In 2018, the leader of this group in terms of value sales was the drug "Toujeo Solostar" (INN "Insulin Glargine") manufactured by Sanofi. "Levemir" takes the second place. "NovoRapid" closes the top three.

Group [B] "Agents affecting blood and blood forming organs" (14%) occupies the third place in the ranking. In 2018, this group lost 2.2% in value terms. In packages, purchases decreased by 17%.

In 2018, the structure of the DRP of the fifth leaders by ATC-groups did not change in comparison with the previous year: the share in value volumes increased by 1%, and amounted to about 87.2%. The main growth was provided by the group

Table 9

Drug Sales Structure by ATC Drugs on the DRP Market

First Level ATC-groups	Sales value, mln rub.	Group share in sales value, %	Real sales volume, millions of units	Group share in real sale volume, %
Antineoplastic and immunomodulating agents (L)	83 632.9	42.6%	8.4	5.3%
Alimentary tract and metabolism (A)	36 650.3	18.7%	46.2	29.2%
Agents affecting blood and blood forming organs (B)	27 562.0	14.0%	8.9	5.6%
Antibacterials for systemic use (J)	13 803.3	7.0%	9.3	5.9%
Nervous system drugs (N)	9 526.8	4.9%	26.9	17.0%
Respiratory system drugs (R)	8 311.2	4.2%	10.5	6.6%
Systemic hormonal preparations (excluding sex hormones) (H)	5 244.6	2.7%	2.0	1.3%
Cardiovascular system drugs (C)	4 444.9	2.3%	36.2	22.9%
Other drugs (V)	3 490.2	1.8%	2.5	1.6%
Musculoskeletal system drugs (M)	2 540.5	1.3%	3.8	2.4%
Genitourinary system drugs and sex hormones (G)	553.1	0.3%	1.4	0.9%
Agents affecting sensory organs (S)	400.0	0.2%	1.0	0.7%
Dermatologicals (D)	121.6	0.1%	0.6	0.4%
Drugs that do not have ATC-group	102.2	0.1%	0.3	0.2%
Antiparasitic products, insecticides and repellents (P)	15.8	0.0%	0.1	0.0%

[A], which is implemented mainly in the Regional Drug Coverage and Essential Drug Coverage.

It is interesting to look at how much money is spent under the DRP for treatment of main disease groups. With this purpose, we correlated the drugs with the corresponding indications for use. As a result, we received the following cost ranking in DRP by diseases (Table 10).

According to year 2018 results, drugs for the treatment of immune system diseases have maintained a leading position in the ranking of sales. The greatest increase in posts in this group is noted for drugs that have immunomodulatory and immunosuppressive action. The bulk of the costs is for regional subsidized drug list.

The second line in the ranking is occupied by the drugs for the oncology treatment, which account for 20.3% of the whole DRP segment value. 50% of medicines are released under the high-cost ICD program.

The third line in 2018 was taken by drugs for the treatment of diabetes mellitus, which are equally distributed both under the Essential Drug Coverage program and at the regional level.

Manufacturers in the DRP Segments

Table 11 shows TOP-20 manufacturers leading by the consumption volume in the DRP in 2018.

In 2018, under the Drug Reimbursement Program, drugs produced by 742 companies were purchased. Moreover, high-cost ICD program involves only 39 manufacturers, 353 participate in Essential Drug Coverage, and for the regional subsidized drug list are purchased from 722 enterprises. This picture is due to the fact that the lists of drugs in the high-cost ICD program and Essential Drug

Figure 21

Sales Proportion by ATC groups in the Drug Reimbursement Program

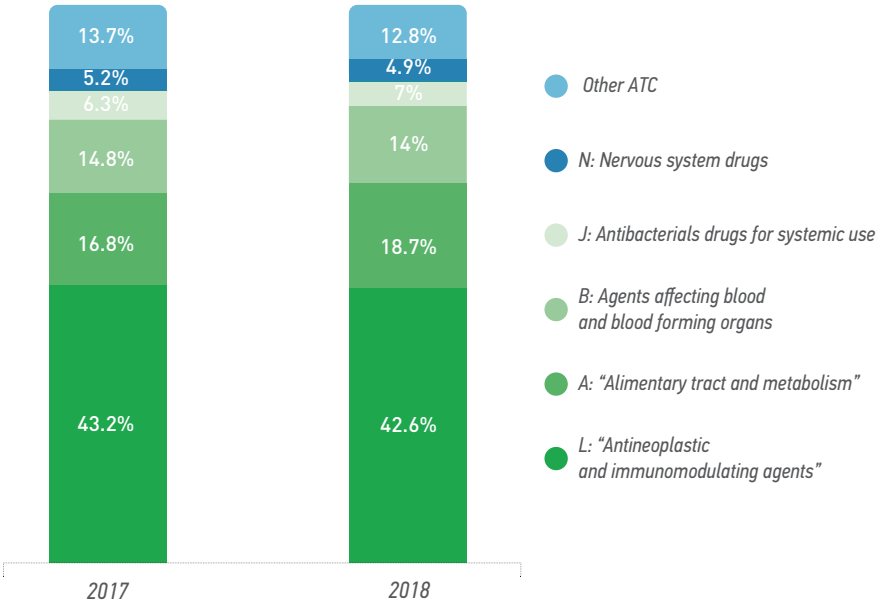


Table 10

Cost ranking in DRP by diseases, 2018

Disease	Volume, millions of rubles	Increase	Share, in RUB.		
			High-cost ICD	Provision of necessary medicines	Regional Drugs Supply
Immune system diseases	40 605.1	-1.9%	14.8%	36.6%	48.6%
Oncologic diseases	39 858.0	2.0%	48.8%	19.4%	31.9%
Diabetes mellitus	28 603.7	21.5%	0.0%	44.3%	55.7%
Disorders of blood and blood forming organs	26 895.1	-2.7%	64.3%	17.1%	18.6%
Nervous system disorders	9 725.7	-4.4%	0.0%	24.6%	75.4%
Infectious agents diseases	9 553.1	-2.5%	0.0%	46.0%	54.0%
Respiratory disorders	8 604.8	35.6%	13.1%	36.0%	50.9%
Alimentary disorders	8 457.6	-4.2%	0.0%	34.5%	65.5%
Hormonal disorders	5 236.7	13.7%	12.9%	29.3%	57.8%
Cardiovascular disorders	4 160.5	-13.6%	5.2%	55.4%	39.4%
Musculoskeletal disorders	2 545.2	-5.0%	0.0%	40.2%	59.8%
Ocular disorders	316.3	-12.7%	0.0%	53.4%	46.6%
Male and female reproductive disorders	219.5	-11.2%	0.0%	47.3%	52.7%
Dermatological diseases	98.0	-17.4%	0.0%	28.1%	71.9%
Others	11 520.0	3.2%	0.0%	11.5%	88.5%

Table 11

TOP-20 Drugs Manufacturers by the Consumption Volume in the DRP in 2018

2018 Rating	Changes	Manufacture	Sales value, mln.rub. 2018	Sales volume increase	Share
1	1	Sanofi	13 920.6	25.7%	7.1%
2	1	Biocad	11 899.0	10.2%	6.1%
3	2	Johnson & Johnson	9 503.8	0.6%	4.8%
4	7	Novo Nordisk	9 287.2	32.8%	4.7%
5	5	Novartis	9 237.0	25.6%	4.7%
6	0	Baxter	8 240.5	3.3%	4.2%
7	-3	Celgene	8 071.3	-16.2%	4.1%
8	-7	Nativa	7 763.1	-31.8%	4.0%
9	0	AstraZeneca	7 703.6	0.3%	3.9%
10	-2	Generium	6 561.3	-15.0%	3.3%
11	-4	F.Hoffmann-La Roche	6 539.6	-15.4%	3.3%
12	3	Alexion Pharma	5 650.4	52.7%	2.9%
13	3	Pfizer	4 574.3	28.8%	2.3%
14	-2	Merck & Co	4 171.6	-22.7%	2.1%
15	-1	Octapharma	3 894.4	-4.4%	2.0%
16	1	AbbVie	3 820.6	9.7%	1.9%
17	1	Takeda	3 502.8	18.5%	1.8%
18	1	GlaxoSmithKline	3 423.7	22.2%	1.7%
19	2	Pharmstandard	2 784.2	15.5%	1.4%
20	5	Bayer	2 501.9	20.8%	1.3%

Coverage are legally regulated, while in the regional subsidized drug list they correspond to the needs of a particular beneficiary.

The rating quite markedly reversed itself. Only one company was able to maintain its position. The rest moved to new lines. Sanofi company became the leader of the rating with a share of 7.1%. Its drugs were purchased by 26% more than in 2017. The main growth was due to "Toujeo Solostar" insulin and the "Abadjio" immunosuppressant.

The second place went to the domestic company "Biocad", the volume of sales of which is 6.1% of preferential drugs. The dynamics of procurement of the company's drugs is positive. In 2018 it was due to antineoplastic drugs "Herticad" and "Avegra", as well as through the implementation of the "new" immunomodulators "Teberif" and "Timexon".

The third line went to Johnson & Johnson last year. The increase in the purchase of anticancer drugs "Imbruvica" and "Tizabri" allowed the company to climb two places up despite the low volume increase of the manufacturer in general.

Yet the leader of 2017 "Nativa" moved 7 positions down. Its sales were 32% down. In particular, this has occurred because of the appearance of cheaper analogues on the market; they belong to the same INN brands "Philachromin", "Axoglatiran".

Table 12 shows the rating of producers participating in Program "7 nosologies", Essential Drug Coverage and Regional Drug Coverage.

Celgene company retained the leading position in Program "7 nosologies", Sanofi company is the leader in Essential Drug Coverage and Regional Drugs Supply programs. In each of the subprograms there are five domestic manufactures.

Drugs in the DRP Segments

The sales share of the TOP 20 brands in 2018 amounted to 30% of the value volume, which is slightly less than in 2017.

The first line of the rating of sales value is still occupied by the foreign brand "Revlimid" produced by Celgene, the second line is also for an immunosuppressant "Soliris". The third line has been taken by insulin "Toujeo Solostar" which has developed sales volumes by 52%.

In 2018, the rating had only 7 "newcomers": a hemostatic "Vilate" by Octapharm Company rated up to 32 positions. The maximum growth was shown by an anticancer drug "Afinitor" by Novartis Company (91%).

The weighted average price for top-20 brands was about 8,000 RUB/pack. "Soliris" was the most expensive of the TOP 20 drugs in 2018, its weighted average cost is slightly higher than 367 thousand rubles, while a hypoglycemic drug "Humalog" appeared to be the "cheapest" (about 1.6 thousand rubles).

Most of the top 20 drugs belong to group [L] Antineoplastic and immunomodulating agents (9 brands). The second place, according to this indicator, is divided between group [B] Agents affecting blood and blood forming organs and [A] Alimentary tract and metabolism (5 brands).

Most of the drugs in the rating are drugs sold under the high-cost ICD program (9 brands). But if belonging to high-cost ICD program virtually eliminates the release of drugs for other programs (less than 5% gets into the regional subsidized drug list, the Essential Drug Coverage list drugs, very often in the same amount, are also released for the regional subsidized drug list. For example, "Toujeo Solostar", "Humira" have equal proportions between OLS and Regional

Table 12

TOP-20 drugs Manufacturers by the Sales Volume in Drugs Reimbursement Program according to programs High-cost ICD, Essential Drug Coverage, Regional Drug Coverage

	High-cost ICD		Essential Drug Coverage		Regional Drug Coverage	
2018 Rating	Manufacture	Sales value, mln rub.	Manufacture	Sales value, mln rub.	Manufacture	Sales value, mln rub.
1	Celgene	**7 682.9**	Sanofi	**5 141.5**	Sanofi	**7 015.4**
2	Baxter	**6 977.2**	Novo Nordisk	**3 988.4**	Novo Nordisk	**5 145.7**
3	Generium	**5 850.1**	AstraZeneca	**3 665.5**	Novartis	**4 973.4**
4	Biocad	**5 423.8**	Novartis	**3 531.4**	Alexion Pharma	**4 866.7**
5	Octapharma	**3 706.2**	Nativa	**3 499.3**	Johnson & Johnson	**4 319.5**
6	Johnson & Johnson	**1 904.9**	Johnson & John-son	**3 279.4**	Biocad	**4 195.2**
7	Sanofi	**1 763.7**	Biocad	**2 280.0**	AstraZeneca	**4 038.1**
8	F.Hoffmann-La Roche	**1 533.8**	F.Hoffmann-La Roche	**2 232.1**	Nativa	**3 345.4**
9	CSL Behring	**1 490.4**	Pfizer	**1 854.5**	F.Hoffmann-La Roche	**2 773.6**
10	Dr.Reddy's Laboratories	**1 175.6**	AbbVie	**1 538.4**	Pfizer	**2 719.6**
11	Merck & Co	**1 079.0**	GlaxoSmithKline	**1 293.4**	AbbVie	**2 282.2**
12	Genfa Medica	**1 072.3**	Protek	**1 248.9**	GlaxoSmithKline	**2 130.4**
13	Cinnagen	**1 013.8**	Merck & Co	**1 177.9**	Takeda	**2 072.7**
14	Nativa	**918.5**	Takeda	**1 170.7**	Merck & Co	**1 914.7**
15	Astellas Pharma	**749.0**	Pharmasyntez	**1 145.5**	Bayer	**1 699.1**
16	Novartis	**732.2**	Pharmstandard	**1 125.4**	Pharmstandard	**1 421.6**
17	Pharmasyntez	**677.3**	Boehringer Ingelheim	**1 072.6**	Boehringer Ingelheim	**1 291.0**
18	Takeda	**259.3**	Eli Lilly	**1 025.7**	Pharmasyntez	**1 212.5**
19	Pharmstandard	**237.2**	Bristol-Myers Squibb	**980.0**	Protek	**1 176.3**
20	Talecris BioTherapeutics	**215.3**	Thermo Fisher Scientific	**961.1**	Abbott	**1 076.3**

Table 13

TOP-20 Brands by Sales Value in the DRP in 2018

2018 Rating	Changes	Brand	Manufacture	Sales value, mln.rub. 2018	Sales volume increase	Share
1	0	Revlimid	Celgene	**7 693.3**	**-17.6%**	**3.9%**
2	1	Soliris	Alexion Pharma	**5 527.1**	**49.4%**	**2.8%**
3	1	Toujeo Solostar	Sanofi	**4 777.0**	**51.9%**	**2.4%**
4	8	Levemir	Novo Nordisk	**3 573.1**	**56.0%**	**1.8%**
5	-3	Acellbia	Biocad	**3 266.3**	**-36.5%**	**1.7%**
6	0	Advate	Baxter	**3 030.7**	**6.0%**	**1.5%**
7	13	Imbruvica	Johnson & Johnson	**2 964.4**	**72.5%**	**1.5%**
8	3	Humira	AbbVie	**2 853.5**	**23.8%**	**1.5%**
9	4	NovoRapid	Novo Nordisk	**2 648.6**	**16.5%**	**1.3%**
10	-3	Lantus	Sanofi	**2 624.7**	**-7.2%**	**1.3%**
11	18	Afinitor	Novartis	**2 601.4**	**90.8%**	**1.3%**
12	12	Herticad	Biocad	**2 532.4**	**64.7%**	**1.3%**
13	-3	Octofactor	Generium	**2 439.0**	**0.8%**	**1.2%**
14	1	Feiba	Baxter	**2 269,2**	**10.8%**	**1.2%**
15	-7	Coagil	Generium	**2 027.7**	**-27.5%**	**1.0%**
16	18	Tizabri	Johnson & Johnson	**1 889.4**	**51.0%**	**1.0%**
17	32	Vilate	Octapharma	**1 716.9**	**83.9%**	**0.9%**
18	7	Humalog	Eli Lilly	**1 609.0**	**11.1%**	**0.8%**
19	14	Enbrel	Pfizer	**1 565.8**	**23.2%**	**0.8%**
20	24	Octreotide	Different	**1 538.5**	**46.1%**	**0.8%**

> The action of the program «import substitution» worked correctly — the main task of increasing the availability of drugs is performed

Drug Coverage Program. There are positions, the volume of which in the Regional Drug Coverage Program, despite their presence in the Essential Drug Coverage, is significantly greater. "Soliris" (with the ratio 14% to 86% with Regional Drug Coverage Program prevailing) or "Levemir" (38% to 62%) illustrate this.

That is why the ratings of Essential Drug Coverage and Regional Drug Coverage Program are very similar. At the same time in the TOP 20 brands on Regional Drug Coverage Program there are positions not represented in other preferential programs ("Diaskintest").

Segments by Price in the DRP

In 2018, the average price per unit in the DRP increased by 10% and amounted to about 1,240 rubles. If we talk about subprograms, the most expensive drugs are in the Regional Drug Coverage Program: on average, one package is purchased by the state for 10,667 rubles. The regional subsidized drug list price is 1,150 rubles. Essential Drug Coverage program drugs are the "cheapest"— 810 rubles.

The drug consumption structure within the DRP is presented in Figure 22.

The purchase volume in the High-priced program following the expensive segment (over 50,000 rubles) decreased by 11%, while by 5% more packages were purchased. Thus, the action of the program "import substitution" worked correctly — the main task of increasing the availability of drugs is performed.

At the same time, the reverse picture is observed in the regional subsidized drug list. The share of expensive drugs is growing: 43% more drugs with a price above 50 thousand rubles were purchased in 2018 than in 2017.

Figure 22

Structure Drug Reimbursement Program

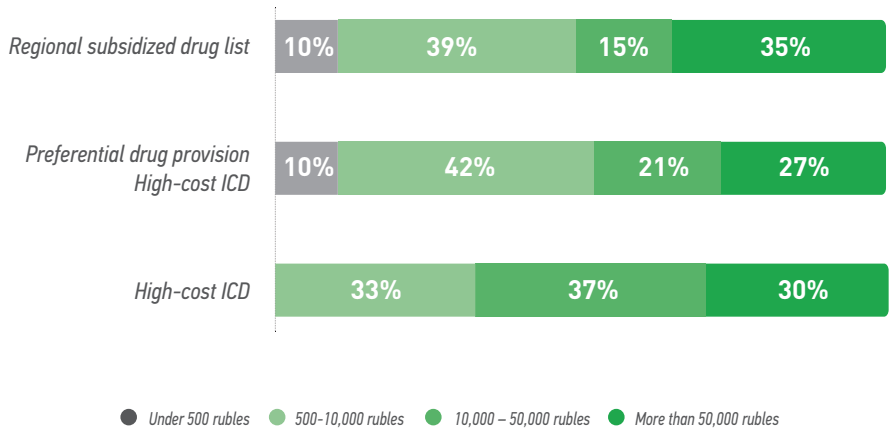
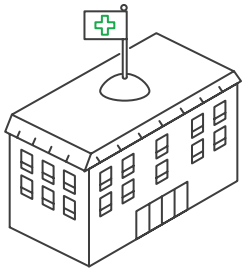


Table 14

TOP-20 Brands by Sales Value in the Drug Reimbursement Program according to Regional Drug Coverage Program, Essential Drug Coverage, High-cost ICD

	High-cost ICD		Essential Drug Coverage		Regional Drug Coverage	
2018 Rating	Brand	Sales value, mln rub.	Brand	Sales value, mln rub.	Brand	Sales value, mln rub.
1	Revlimid	**7 682.9**	Toujeo Solostar	**2 360.5**	Soliris	**4 771.1**
2	Acellbia	**3 058.1**	Humira	**1 454.8**	Toujeo Solostar	**2 416.5**
3	Adveit	**3 030.7**	Afinitor	**1 444.7**	Levemir	**2 206.4**
4	Octofactor	**2 438.4**	Levemir	**1 366.7**	Imbruvica	**1 787.8**
5	Feiba	**2 264.0**	NovoRapid	**1 343.9**	Humira	**1 398.7**
6	Coagil	**1 965.7**	Lantus	**1 231.1**	Lantus	**1 393.6**
7	Tizabri	**1 858.4**	Herticad	**1 195.3**	Herticad	**1 337.1**
8	Vilate	**1 716.9**	Imbruvica	**1 176.5**	Novorapid	**1 304.8**
9	Octanat	**1 452.7**	Enbrel	**879.3**	Afinitor	**1 156.7**
10	Infibeta	**1 354.9**	Eralfon	**875.0**	Avegra	**975.7**
11	Pulmozyme	**1 254.1**	Humalog	**865.2**	Metformin	**866.8**
12	Reddytux	**1 175.6**	Octreotide	**864.1**	Elapraza	**815.1**
13	Rebif	**1 078.0**	Octreotide – Long FS	**809.0**	Sovriad	**776.7**
14	Genfaxon	**1 047.0**	Iressa	**806.0**	Humalog	**743.7**
15	Sinnovex	**1 013.8**	Zoladex	**766.6**	Enbrel	**686.5**
16	Teberif	**964.2**	Soliris	**756.0**	Octreotide	**674.4**
17	Abadjio	**934.0**	Ketosteril	**742.9**	Novomix	**672.5**
18	Ceresim	**829.6**	Faslodex	**719.5**	Enplate	**661.3**
19	Timexon	**811.5**	Spiriva	**606.4**	Diaskintest	**648.4**
20	Gemate P	**729.4**	Formisonid	**592.4**	Iressa	**643.0**



4. Sales Value in the Segment of Healthcare Institutions (HCI)

Modernization of the health care system is constantly taking place in the country, among the key programs there is additional provision of drugs to preferential categories of citizens (since 2005), "Health" national project (2006 — 2013), the law on compulsory health insurance (since 2010), the presidential decree on improving health policy (since 2012) and, finally, the "road map" of the Russian Federation government aimed at achieving certain indicators in this area by 2018.

All the changes are to some extent aimed at standardization of medical technologies, the formation of integrated programs and health care.

One of the means of improvement is optimization, and most often it is associated with reduction. At the beginning of 2018, the Russian health care system, according to RosStat, was represented by 5.3 thousand hospital organizations and 20.2 thousand medical outpatient organizations. The optimization resulted in a shortage of beds: the number of hospital beds decreased by 29.2% compared to year 2000 (from 1,671. 6 thousand to 1,182. 7 thousand). All this has led to a decrease in the availability of medical and drug care. As a result, the reverse process began. Since 2013, there has been an increase in outpatient clinics, medical and obstetric points, offices of general practitioners in rural areas: in just 5 years they have increased by 3.7 thousand institutions.

The number of medical personnel is also decreasing as the number of hospital organizations is outnumbered. In 2018, the number of health-care staff in hospitals decreased by 35%. Less significantly, the number of nurses (2.7%) and doctors (1.2%) decreased too.

Against the background of reductions, the number of appeals to medical institutions even increased. For example, the number of visits to polyclinics increased from 3.5 million to 3.9 million per year over 16 years, and from 243 to 266 per 10,000 people. The incidence also increased from 106 thousand in 2000 to 115 thousand in 2016 (registered patients with a diagnosis established for the first time in life).

The state health care system in Russia requires reforms in all areas of work: capital construction, repair, new equipment, increasing the doctors' salaries. The government has developed and introduced a reform of the medical sphere, which is designed for a long period — until 2035.
As part of the national "Health Care" project, eight Federal Projects are planned: the development of the primary health care system, fight against cardiovascular diseases, fight against oncology, the development of children's health care, staffing, the development of a network of national medical research centers, the digitalization of health care, and the development of medical services export.

We note some areas of the project that will affect the work of medical organizations in the near future:

1. The list of targets of the "Health" national project states that no later than by 2022 all public health institutions must be connected to the Uniform State Health Information System. At the same time, at least 80% of medical organizations should not only connect to this system, but also participate in electronic document circulation, and by 2023 at least 70% of medical institutions should implement a system of issuing electronic prescriptions and directions for drug provision.

2. Since January 1, 2019, clinical recommendations have gained legal force and become mandatory for use in practical medicine due to amendments to the Federal law №323 "On the Basics of Public Health Protection in the Russian Federation". The Ministry of Health has established a scientific — practical council, the main function of which is to review the developed clinical recommendations, the final list of which is planned to be created before December 31, 2021.

3. The Obligatory Medical Insurance System also underwent a reform. The prospect of using the Obligatory Medical Insurance policy to receive assistance in both public and private medical institutions is considered, the main task is to cover a part of the costs of commercial medical services.

In 2019, the program was started to promote public health, prevention and formation of responsible attitude to one's own health, including the safety of working conditions, the fight against non-communicable diseases, reduction in the consumption of alcohol and tobacco, and promotion of active aging and healthy lifestyle. The project envisages that each year up to 2024 the information campaigns will get up to 403.5 million rubles. Thus, it is planned to spend 2.825 billion rubles on the campaigns motivating Russians to conduct healthy lifestyle.

> "Since January 1, 2018, uniform rules for the description of medicines for medical use have been established in order to unify the procedure for their purchase for state and municipal needs"

On November 29, 2018, Federal Law No. 459-FZ "On the Federal Budget for 2019 and for the planned period of 2020 and 2021" was adopted, according to which the volume of expenditures for the state program "Development of Health Care" in 2019 will amount to 506.1 billion rubles, which exceeds the expenses of 2018 by 31%. In 2020, expenses in the amount of 761.2 billion rubles are envisaged; in 2021 they will make 694.6 billion rubles. In total, in the next three years, 1 trillion 961.9 billion rubles are planned to be allocated to the state program.

One of the items in the total health care costs is the medicine procurements for medical institutions (hospitals). Since January 1, 2018, uniform rules for the description of medicines for medical use have been established in order to unify the procedure for their purchase for state and municipal needs. In particular, it was determined that, customers giving a description in the

procurement documentation, in addition to the information provided by the provisions of the Procurement Law, indicate the dosage form of the drug, its dosage with the possibility of supplying the drug in a multiple dosage and double quantity, the remaining shelf life of the drug.

According to the results of 2018, the volume of hospital procurements decreased by 2% (in comparison with 2017) and amounted to 254.2 billion rubles. In real terms, the volume of purchased drugs decreased more significantly — by 9% — to 949 million packages. Notably, the dynamics of hospital procurements is uneven: one year there is an increase, another year — there is a decrease. This is due to the adjustment and volume of expenditure of some groups of drugs, primarily it relates to infusion solutions. On average, the level of consumption, especially in real terms, remains at about the same level — about 1 billion packages.

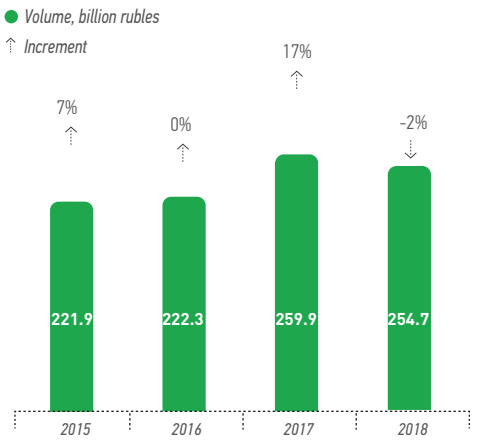
The average price of one unit of an RTU drug purchased by HCI was 269 rubles. Compared to 2017, the cost of a package for the segment of HCI increased by 7.3%.

Hospital procurement as part of the general system of public medicine procurements fall under the control of one of the targets set out in the Presidential Decree of 2012, which provides a point that by 2018 it is necessary to achieve "Bringing the Volume of Production of Domestic Medicines according to the Nomenclature of the List of Strategically Important Medicines and the List of Vital and Essential Medicines to 90 percent." This parameter is also known as "import substitution". The rule "three is a crowd" in recent years allows to systematically increase the share of domestic producers in the supply of drugs to hospitals. Herewith, as in the previous year, the largest share in the sales value in HCI segment is covered by imported drugs, whereas by the real sales volume domestic drugs take the leading positions. The domestic drugs cover about 40% of the volume in money terms and about 76% in unit terms. If to compare the figure with 2015, the share increased by 9% in value terms. At the same time, the changes in the

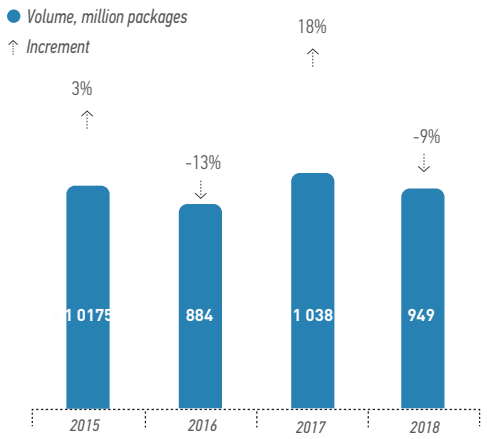
Figure 23

Dynamics of Hospital Procurement

Dynamics of hospital procurement of drugs, billion rubles



Dynamics of hospital procurement of drugs, million packages



packages amounted to about 5%. Thus, it is clear that there is a switch to domestic drugs for high-cost ICD.

In 2018, the purchase volume of the imported drugs decreased both in rubles and in units: -9% and -16%, respectively. "Sodium Chloride" INN is now bought by 3.7 million packages less. The second place of decrease is taken by "Cefotaxime" INN: -2.1 million pack. High positive growth was noted with "Cefazolin" INN: +1.8 million packs and this trend has been maintained in recent years.

The volume of purchases of domestic drugs showed multidirectional trends: in rubles, the increase was 10.9%, in packages there is also a drop of 6%. The first place on the absolute increase is taken by "Vaccine for the prevention of influenza inactivated" INN (+2.6 million pack.), purchased under the program "National Vaccination Calendar". A significant increase of domestic producers in real terms is associated with an increase in the volume of "Sodium Chloride" INN — in the reporting year, 2.2 million more packages were purchased: thus, the switch from imported drugs to domestic ones is obvious. Hospitals purchased 6.1 million fewer packages of domestic spiritus ("Ethanol" INN), this fact is well demonstrated by the procurement irregularity of some items (in 2017, on the contrary, an increase of 9 million units was observed).

Below we present the TOP 10 INN with the maximum share of "switching" to domestic drugs from the TOP 100 in terms of procurement (the INN data make 59% of all hospital procurements in money).

We shall note that in 2017 the list consisted of other INN, so the process of "import substitution" covers every year an additional amount of nomenclature.

According to data for 2017, out of 2,061 INN, which were purchased by hospitals, the share of domestic drugs exceeds 90% in 640 INN. At the same time, there are still 1,014 INN, in which imported drugs predominate (their share in purchases is more than 90%), and 43 of them fall into the TOP 100 in volume terms. The most

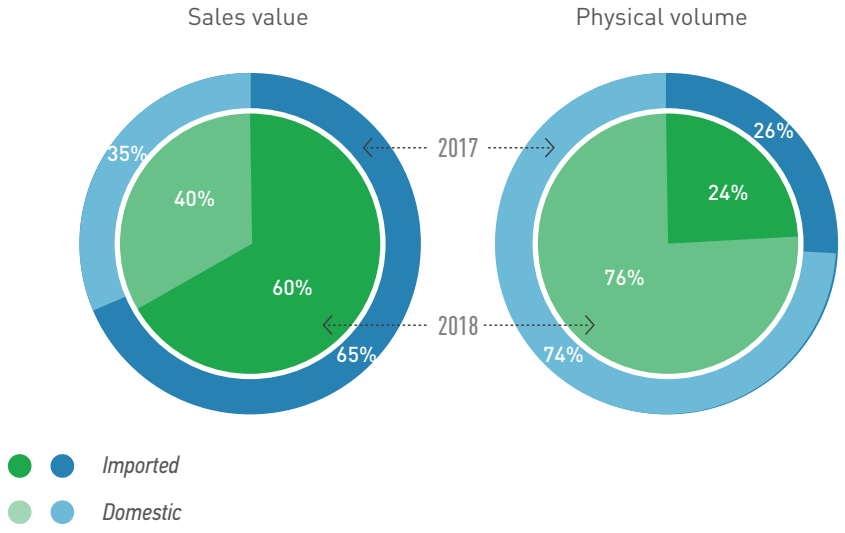


Figure 24

Proportion of Imported and Domestic Drug Sales

Table 15

Top 10 INN on "import substitution"

INN	The share of domestic drugs, RUB.		The share growth	Leader, 2017	"Switched" drug, 2018
	2017	2018			
Atazanavir	**28.06%**	**99.19%**	**71.13%**	Reyataz (Bristol-Myers Squibb)	Simanod (Pharmasyntez)
Darunavir	**44.84%**	**93.13%**	**48.29%**	Prezista (Johnson & Johnson)	Kemeruvir (Pharmasyntez)
Pemetrexed	**2.17%**	**48.17%**	**46.00%**	Alimta (Eli Lilly)	Pemetrexed (Nativa)
Sorafenib	**0.00%**	**35.63%**	**35.63%**	Nexavar (Bayer Ag)	Sorafenib (Nativa)
Rituximab	**52.39%**	**83.46%**	**31.06%**	Different	Acellbia (Biocad)
Ademetionine	**37.21%**	**61.16%**	**23.95%**	Heptral (Abbott Laboratories)	Heptor (Veropharm)
Abacavir	**73.78%**	**95.22%**	**21.44%**	Different	Olitid (Pharmasyntez)
Sunitinib	**0.97%**	**21.70%**	**20.72%**	Sutent (Pfizer Inc)	Sunitinib (Nativa)
Sodium enoxaparin	**40.45%**	**60.51%**	**20.05%**	Clexane (Sanofi)	Enixum (GK Protek), Anfibra (Veropharm)
Trastuzumab	**64.63%**	**82.26%**	**17.63%**	Herceptin (F.Hoffmann-La Roche)	Herticad (Biocad)

capacious INNs, presented by imported drugs only, are still: "Vaccine for the prevention of pneumococcal infections", "Raltegravir", "Etravirine" — these three INNS make 5% of hospital purchases.

The cost of one unit of an imported drug product is 4.8 times higher than the cost of one unit of a domestic drug product purchase by a HCI, although the difference in the weighted average price of a unit continues to decrease, mainly due to the increase of purchases of the domestic drugs of more expensive segment. In 2018, one imported unit of a RTU drug cost 675 rubles on average; one domestic unit was 141 rubles. In comparison with 2017, the cost of one purchased imported unit increased by 8.3%, the cost of one domestic unit in 2018 cost by 18% more. The structure of hospitals procurement by price categories is shown in Figure 25.

> The cost of one unit of an imported drug product is 4.8 times higher than the cost of one unit of a domestic drug product purchase by a HCI

In 2018, there were minor changes in the procurement price structure. All price categories except the segment of funds with a value of "min 500 rubles" marked a reduction in the share in the volume of HCI medicine procurements.

In real terms, the segment of drugs priced up to 50 rubles is the one with the most capacity; its share covers 62%. However, over the past few years, this segment has been reducing the volume of purchases:

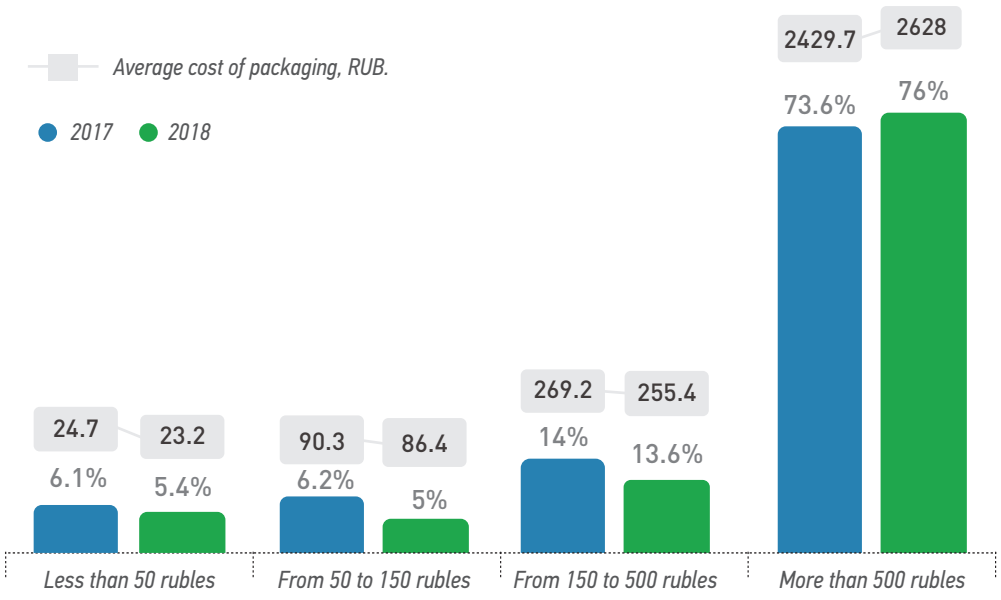


Figure 25

Structure of HCI Segment By Price Categories in 2017 and 2018

in 2018 by 8% compared to 2017. Such decrease happens due to the transition of the part of drugs into more expensive segment. As before, here, the most purchased drug is "Sodium Chloride" INN (36.5% of the natural volume of the segment "less than 50 rubles").

Among imported drugs, the largest share is occupied by the segment of drugs with a price category of more than 500 rubles (85%) (Figure 26). Domestic products occupy a low share in the price categories "less than 50 rubles" (11.6%), "150 to 500 rubles" (8.1%) and "50 to 150 rubles" (18.8%), and the largest sales volume, which amounted to 62%, — in the segment "more than 500 rubles". Note that this figure increased by 7% compared to 2017.

If in the segments with unit price up to 500 rubles, the difference between the weighted average price of imported and domestic drugs is not significant, in the segment with the most capacity "more than 500 rubles", the difference between domestic and imported drugs is still significant: it makes approximately 1.5 times.

The ratio of hospital procurements of the drugs by first level ATC-groups in Russia according to the results of 2018 is presented in Table 16.

The ranking of the drugs in HCI segment by ATC-groups differs significantly from that of commercial market. The rating of ATC groups has not changed in comparison with 2017.

In hospital procurements group [J] "Antibacterials for systemic use" remains the leader. Since 2012, there has been a positive trend in the growth of this group (in 2018, the growth was minimal: +0.6%). It was mainly due to the increase in vaccine sales [J07] (+15.8%). The increase in purchases in subgroup [J07] "Vaccines" was true for such drugs as "Sovigripp" (+51%), "Pentaxim" (+35%) and others. A new flu vaccine "Flu-M" entered the TOP 6 of purchased medicines.

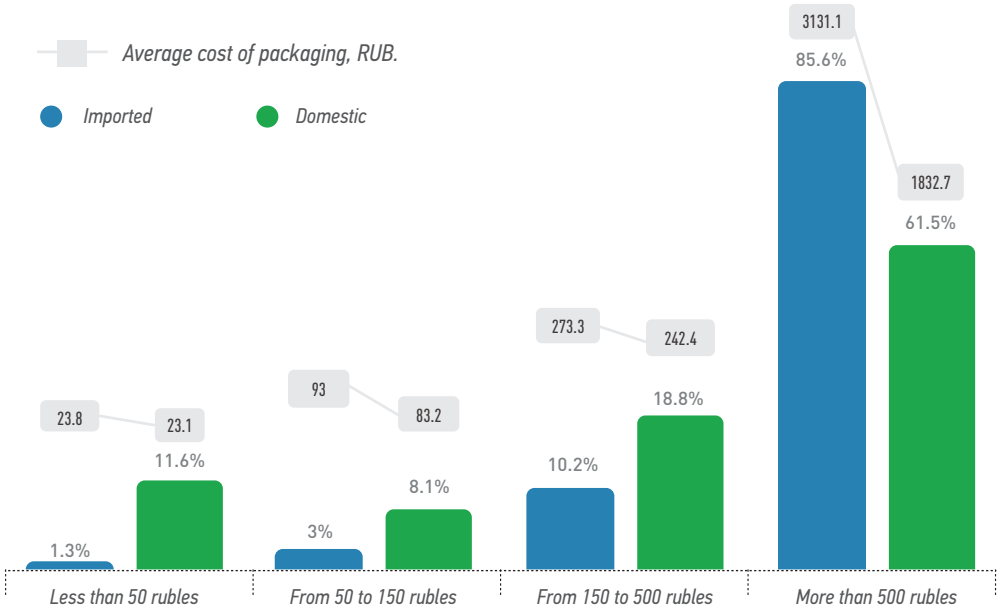


Figure 26

Structure of HCI Segment by Price Categories for Imported and Domestic Drugs in 2018

Table 16

Hospital Procurements Structure of RTU Drugs by ATC-Groups in 2018

First Level ATC-groups	Sales value, mln.rub.	Group share in sales value, %	Real sales volume, millions of units	Group share in real sale volume. %
[J] Antibacterials for systemic use	91 197.9	35.8%	257.5	27.1%
[L] Antineoplastic and immunomodulating agents	50 658.6	19.9%	11.9	1.3%
[B] Agents affecting blood and blood forming organs	33 658.1	13.2%	313.6	33.1%
[N] Nervous system drugs	20 471.0	8.0%	92.0	9.7%
[A] Alimentary tract and metabolism	14 596.0	5.7%	75.7	8.0%
[V]: Various	12 523.7	4.9%	13.7	1.4%
[C] Cardiovascular system drugs	6 869.7	2.7%	48.7	5.1%
[R] Respiratory system drugs	5 577.9	2.2%	25.4	2.7%
[M] Musculoskeletal system drugs	4 722.8	1.9%	22.5	2.4%
[G] Genitourinary system drugs and sex hormones	3 251.4	1.3%	4.4	0.5%
[H] Systemic hormonal preparations (excluding sex hormones)	3 105.7	1.2%	16.1	1.7%
[S] Agents affecting sensory organs	3 081.0	1.2%	5.3	0.6%
[~] drugs that do not have an ATC-group	2 503.6	1.0%	2.4	0.3%
[D] Dermatologicals	2 476.5	1.0%	59.1	6.2%
[P] Antiparasitic products, insecticides and repellents	30.7	0.0%	0.3	0.0%

Table 17

TOP-20 Manufacturers in HCI Segment According to the Results of 2018

2018 Rating	Changes	Manufacturer	Sales value, mln.rub.	Sales volume increase	Share
1	0	Pfizer	**11 460.5**	**-13.1%**	**4.5%**
2	6	Pharmasyntez	**11 237.5**	**36.7%**	**4.4%**
3	3	Biocad	**10 932.9**	**32.3%**	**4.3%**
4	3	«Микроген»	**10 389.9**	**26.3%**	**4.1%**
5	-3	Merck	**10 057.2**	**4.2%**	**3.9%**
6	-3	Abbvie	**9 902.3**	**10.3%**	**3.9%**
7	-3	Johnson & Johnson	**8 289.1**	**-4.1%**	**3.3%**
8	-3	Sanofi	**7 576.6**	**-11.8%**	**3.0%**
9	3	Veropharm	**6 994.8**	**27.9%**	**2.7%**
10	-2	Novartis	**6 897.9**	**-12.7%**	**2.7%**
11	5	GlaxoSmithKline	**5 720.7**	**43.3%**	**2.2%**
12	-1	Bayer	**5 609.7**	**-0.1%**	**2.2%**
13	-3	AstraZeneca	**5 074.1**	**-14.5%**	**2.0%**
14	0	Takeda	**4 721.5**	**2.5%**	**1.9%**
15	0	F.Hoffmann-La Roche	**4 517.1**	**4.4%**	**1.8%**
16	-3	Marathon Pharma	**4 415.3**	**-17.5%**	**1.7%**
17	0	Pharmstandard	**3 567.9**	**-1.3%**	**1.4%**
18	1	Boehringer Ingelheim	**3 290.7**	**-3.4%**	**1.3%**
19	16	Grotex	**3 238.4**	**81.3%**	**1.3%**
20	2	Protek	**3 227.8**	**2.7%**	**1.3%**

The unchanged leader of group [J] — subgroup [J05] "Antiviral drugs for systemic use" — reduced the volume in rubles by 2%. In this subgroup [J05] among the most capacious brands there are drugs "Kaletra" (+2% in rubles), "Isentress" (-17%), "Intelence" (-9% in rubles). The group gets its high dynamics of growth due to relatively new drugs "Eviplera", "Simanod", "Tivicay".

The second place in the ranking of ATC groups in the hospital segment at the end of 2018 was taken by group [L] "Antineoplastic and immunomodulating agents". Since 2013, there have been positive trends in the subgroup: the value of purchases of drugs in this group has increased by 19.8%. In real terms, there is also one of the maximum growth indexes: +22.3%.

The increase in sales in group [L] was mainly due to the increase in purchases in the largest subgroup [L01] "Antineoplastic agents" (+25% in rubles). The most "purchased" drug in this subgroup was "Herticad", which in the framework of "import substitution" displaces the leader of last years — "Herceptin". Brand "Averga" ("Biocad"), which almost completely replaced "Avastin" (F. Hoffmann-La Roche) took the second place. The third place in the group is taken by the original drug "Erbitux" (Merck), which has no analogues on the market.

Group [B] "Agents affecting blood and blood forming organs" retained the third position in terms of hospital procurement, despite a decrease of 7%. The most capacious subgroup is [B05] "Plasma-substituting and perfusion solutions", which account for 45% of the group. Both in monetary terms and in-kind procurement, leaders are drugs based on "Sodium Chloride" INN.

Group [L] showed the highest growth in rubles among ATCs: +19.8%. 11 ATCs of the 1st level show a drop in the procurement volume. The biggest drop (-49.3%) is with drugs of group [P] "Antiparasitic products, insecticides and repellents".

It should be noted that, despite the fact that cardiovascular diseases (CVD) are the most acute problem of modern medicine, as mortality from heart and vascular diseases is in the first place along with tumors, in 2018 the procurement volume of this group of drugs decreased by 24.6%.
Table 17 presents the rating of the TOP 20 manufacturers in the HCI segment at the end of 2018, which has changed significantly compared to 2017.

Foreign manufacturer Pfizer remained the leader of 2018. In 2018, this company showed a drop in the procurement volume in the hospital segment: -13%. The reason for this was the reduction of purchases of the brand leader "Prevenar", by 17%. This drug accounts for 61% of Pfizer's hospital portfolio.

A Russian company "Pharmasyntez" took the second place for the year due to one of the highest growths in the TOP 20. The company supplies more than 80 brands to the hospital segment. "Simanod" and "Kemeruvir" show high volumes too. More than 10 new drugs were purchased by hospitals in 2018: "Retwiset", a generic of "Ritonavir" INN, the drug for HIV infection treatment, immediately entered TOP 10 brands of "Pharmasyntez".

The third place was also taken by the domestic manufacturer "Biocad". The hospital portfolio already consists of 29 brands, which replace imported analogues under the import substitution program.

Domestic producers, which are in TOP 20, are already represented by 8 companies

Table 18

TOP-20 Brands in HCI Segment According to the Results of 2018

2018 Rating	Changes	Brand	Sales value, mln rub. 2018	Sales volume increase	Share
1	3	Sovigripp	**7 152.2**	**50.9%**	**2.8%**
2	-1	Prevenar	**6 962.1**	**-16.6%**	**2.7%**
3	-1	Sodium Chloride	**6 284.3**	**-6.7%**	**2.5%**
4	-1	Kaletra	**5 933.8**	**2.0%**	**2.3%**
5	1	Vaccine	**3 218.1**	**23.9%**	**1.3%**
6	-1	Isentress	**3 118.6**	**-16.6%**	**1.2%**
7	5	Herticad	**2 933.2**	**77.1%**	**1.2%**
8	-1	Intelence	**2 341.7**	**-8.8%**	**0.9%**
9	27	Eviplera	**2 317.5**	**146.0%**	**0.9%**
10	67	Avegra	**2 261.0**	**275.2%**	**0.9%**
11	33	Simanod	**2 259.9**	**163.3%**	**0.9%**
12	10	«Diaskintest	**2 192.2**	**68.9%**	**0.9%**
13	0	Pentaxim	**2 156.2**	**34.6%**	**0.8%**
14	748	Tivicay	**1 994.0**	**3309.2%**	**0.8%**
15	6	Viekira Pak	**1 783.7**	**32.0%**	**0.7%**
16	-7	Curosurf	**1 750.7**	**-5.6%**	**0.7%**
17	-6	Sevorane	**1 725.2**	**3.0%**	**0.7%**
18	-3	Actilyse	**1 724.3**	**9.2%**	**0.7%**
19	-9	Ultravist	**1 697.4**	**1.1%**	**0.7%**
20	-1	Ceftriaxone	**1 535.3**	**10.3%**	**0.6%**

(+3 compared to 2017). Almost all of them show high positive dynamics. The best result was shown by the company "Grotex" (+81% in rubles and +16 places in the ranking). The company actively sells "Sodium Chloride" in the hospital segment (it makes 60% of the company's sales).

The largest movement up (+5 places) among foreign companies was shown by the manufacturer Glaxosmithkline: its volume of purchases increased by 43%. The growth of the company was provided by an antiviral drug of direct action "Tivicay".

The maximum drop in the procurement volume compared to 2017 was noted in the domestic company Marathon Pharma, which combines three plants: "Biocom", "Synthesis (Kurgan)" and "Fort". Such dynamics could also be due to the change of the company's owners.

Table 18 presents the TOP 20 brands in HCI Segment According to the Results of 2018. The share of the TOP 20 brands in the hospital procurement is 24.2%, which is higher by 3% than in the previous year.
In 2018, none of the drugs maintained its position since 2017. The changes in the ranking are quite significant. "Sovigripp" vaccine moved to the first line, its volume of purchases increased by 50.9 %. Such dynamics is associated with the vaccination program, which was actively carried out in the autumn of 2018. And the drug "Sovigripp" is included in the list of Recommended Domestic Sera.

"Prevenar" drug moved to the second place, while the procurement volume fell by 16.6%. Also, the volume of "Sodium Chloride" decreased by 6,7%, this contributed to a decrease in the occupied position by one line.

The ranking includes both expensive imported drug products and cheap domestic drug products (SODIUM CHLORIDE, CEFTRIAXONE).

The largest increase was shown by the drug "Tivicay", which we have already mentioned. A significant increase in volumes in value terms allowed the brand to immediately take the 14th position.

In 2018, such drugs as "Taxacad", "Ultrix", "Lucentis", "Fraxiparine" left the rating. The first two were pushed out of hospital procurements by the domestic counterparts.

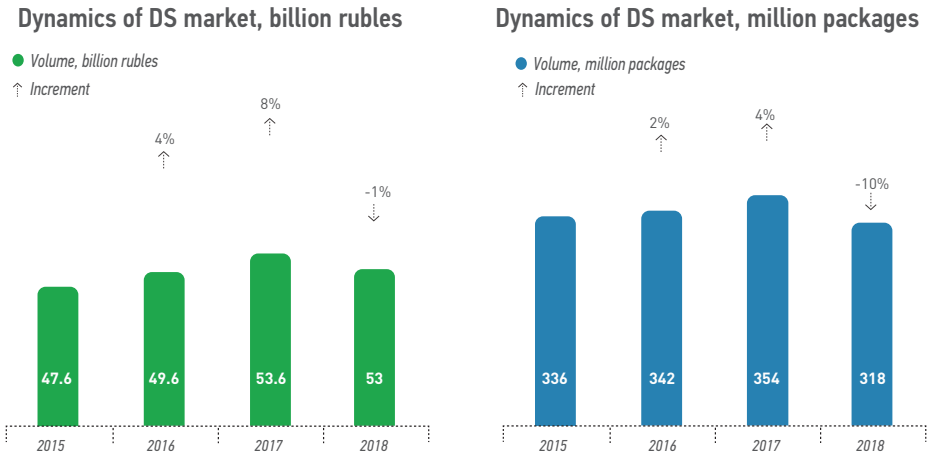
5. Dietary Supplements

Pharmacy market of dietary supplements (DS) has changed noticeably in the last several years. The main trend is to tighten the Rules Governing the Turnover of DS, which are the main tools in promoting this category of range. Rospotrebnadzor proposed to oblige manufacturers of dietary supplements to indicate on the package that these products are not drugs, by marking "Not a drug". The document also prohibits the use of DS names similar to the names of medicines. The criterion of similarity is semantic, phonetic or transliteration (associated with the use of another alphabet) sign that determines the similarity of invented names. The draft of the relevant document was published on February 15, 2019 on the Portal of Draft Regulations.

The DS pharmacy market, which has recently been developing so successfully, for the first time in the last few years showed a drop in sales volume. In 2018, retail sales volume amounted to 318 million packages of dietary supplements in the amount of about 53 billion rubles (in retail prices). During the year, the DS market decreased by 1% in rubles and by 10% in packages. Main reasons for the decline are seasonal fluctuations and decline in real incomes of Russians. Though being a near-medical category, in general, DS aren't essential commodities. Therefore, with the deterioration of the financial and economic situation in the country, the growth of the category slows down. Among the reasons we can also mention the close attention the

Figure 27

Volumes of Pharmacy DS sales in Russia



inspection bodies pay to some groups of DS, which led to a change in the structure of consumption.

It is also necessary to note that in order to maintain competitive prices pharmacies have to reduce the margin on this group of assortment (by the results of 2018, the margin on DS was 36.7%, while a year earlier the same figure was at the level of 38.3%).

When analyzing the monthly dynamics of food additives' sales in value terms, it can be noted that the main decline in sales was in October — the market fell by 11.4% compared to the same month of previous year. The most successful months were July and August: the volume of DS sales increased by 6.9% and 8.4%, respectively. In real terms, there is a steady decline in demand. The maximum drop in sales was noted in October (-21.6%) and November (-21.3%). DS are losing their relevance against the background of low growth of pharmacy sales in general. The middle price segment has lost its market share to cheap and expensive additives.

> The DS pharmacy market, which has recently been developing so successfully, for the first time in the last few years showed a drop in sales volume

On average, one DS package cost 167 rubles (retail price). The average price increased by 15.4 rubles in 2018. In the purchase prices of pharmacies, the average DS cost is about 122 rubles.

The most popular among consumers were supplements with a price of less than 50 rubles. This segment accounts for about 46.5% of DS sold in kind (the price structure is given with retail prices). At the same time, we note that due to the low price, the share of the cheap segment in value terms does not exceed 6%. Delicious "Hematogen" and "Ascorbic acid" make up half of the sales volume in the packages of the segment with the price "less than 50 rubles".

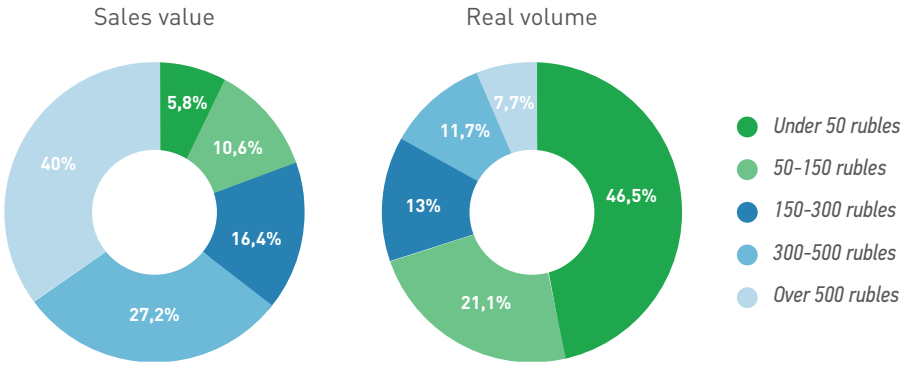


Figure 28

Proportion of DS Sales by Price Segments

> The most expensive DS bring the highest revenue to pharmacies; the share of this segment is 40.0%.

The most expensive DS bring the highest revenue to pharmacies; the share of this segment is 40.0%. A significant share (27.2%) is also occupied by additives from the category "from 300 to 500 rubles". During the year, the structure of the DS market has changed in favor of a high price segment "over 500 rubles", the only one which showed an increase in sales: +11.9% in rubles and +10.0% in units. The first 5 places in terms of sales of this segment are occupied by various vitamin complexes.

As well as in sales of medicines, there is a tendency to reduce the share of "cheap" DS both in value and in real. In comparison to 2017, the share of DS with a price of less than 50 rubles decreased from 6.4% to 5.8% in value terms and from 46.8% to 46.5% in kind.

DS price dynamics was analysed using the Laspeyres price index. One of the reasons for the growth of average prices was inflation on DS, which index again increased noticeably. In 2018, prices in rubles for DS increased by 6.1%.

Pharmaceutical manufacturers position dietary supplements as means to prevent various diseases. The existing Official Classifier is not very convenient for assessing the DS market, since many DS used for the prevention of the same pathologies, are in different sections of the classifier (for example, drugs that improve vision). Therefore, DSM Group specialists developed their own DS classifier, which reflects the realities of today's DS market more accurately. DS Classifier action consists of 17 chapters, most of which have the 2nd sublevel, and some sections have the 3rd.

Traditionally, the most popular on the market are universal supplements of group [V] "DS affecting whole body" (30.1% share). During the year, this DS group slightly reduced its sales by 0.5%.

Figure 29

Change in DS Prices on Russian Pharmacy Market

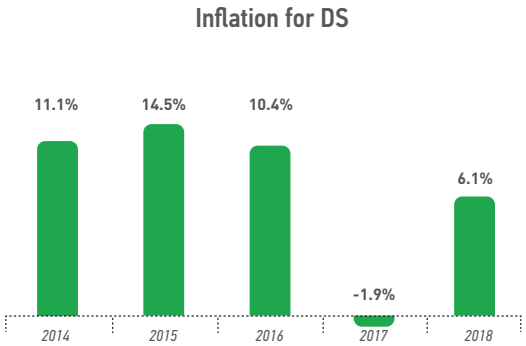


Table 19

Sales Rating by sections of the DS Classifier

2018 Rating	Changes	Group	Sales value, millions of rubles	Sales volume increase	Share
1	-	V DS affecting whole body	**15 950.7**	**-0.5%**	**30.1%**
2	-	A DS affecting digestive system	**11 376.5**	**-0.9%**	**21.4%**
3	-	G DS affecting reproductive system	**6 066.5**	**-3.1%**	**11.4%**
4	-	N DS affecting function of central nervous system	**5 138.7**	**2.2%**	**9.7%**
5	1	C DS supporting cardiovascular system function	**2 415.2**	**-4.2%**	**4.6%**
6	-1	W Slimming and cleansing DS	**2 275.5**	**-11.7%**	**4.3%**
7	-	M DS affecting respiratory system	**1 739.7**	**9.6%**	**3.3%**
8	1	D DS for skin and hair problems	**1 557.7**	**6.0%**	**2.9%**
9	-1	S DS affecting sensory organs	**1 546.4**	**-0.7%**	**2.9%**
10	-	R DS affecting respiratory system	**1 428.8**	**-2.2%**	**2.7%**
11	-	B DS affecting hematopoietic system	**1 175.9**	**-18.0%**	**2.2%**
12	-	U DS affecting urinary system	**784.2**	**12.6%**	**1.5%**
13	-	T DS used in poisoning and intoxication	**546.0**	**5.4%**	**1.0%**
14	-	H DS function of endocrine glands	**523.9**	**6.0%**	**1.0%**
15	-	I DS supporting immune system function	**359.4**	**4.7%**	**0.7%**
16	-	O DS used for treatment and prevention of oncology diseases (other than reproductive system tumours)	**88.1**	**-4.5%**	**0.2%**
17	-	J DS used in virus, bacterial, fungous disease	**70.4**	**-17.7%**	**0.1%**

The most popular in the group [V] was the brands Solgar (share in group sales is 10.4%) by Solgar Vitamin And Herb and "Femibion" (8,9%) by manufacturer Merk Selbstmedikation.

The second place was taken by group [A] "DS affecting digestive system", showing a drop in sales by 0.9%. In this group, the most popular positions are taken by "Phytolax" (14.6%) of a domestic producer "Evalar" and "Maxilac" (10.5%) by Genexo. On the third line there is group [G] "DS affecting reproductive system", which showed a decrease in sales (-3.1%). The group was headed by the drug affecting the female reproductive system — "Indinol" (8.7 percent) by the manufacturer "Miraxbiopharma". The second place in this group is taken by DS eliminating erectile dysfunction in men — "Vuka Vuka" (5.1%), replacing "Viardo" (4.3%) to the third position. The main role in this arrangement of brands was played by a ban on the sale of brands "Sealex Forte Plus" and "Ali Caps Plus" by St. Petersburg holding "RIA Panda".

Ten subgroups showed a negative trend. The largest decrease in sales was noted in the following groups: [B] "DS affecting hematopoietic system" (-18,0%) — Hematogen in various versions is not so popular with the buyer; [J] "DS used in viral, bacterial and fungal diseases" (-17,7%) — sales of the group leader, "Chamomile" brand fell by 22,9%; [W] "Slimming and cleansing DS": -11,7% due to the main line "Turboslim" sales fall by 7.5%.

Still the sales of group [U] "DS affecting urinary system", on the contrary, increased by 12.6%. The volume of sales of the additive in the form of capsules "Phytolysin", contributing to the maintenance of normal functioning of the kidneys and urinary tract, increased by 335.3% during the year.

TOP 20 DS Brands, leading in Terms of Sales in the Russian Market

For pharmacies, dietary supplements remain the most important category of non-drug range. In 2018, 2,718 different DS brands produced by 968 companies were presented on the pharmacy shelves, and 311 new positions appeared on the market. Yet if earlier new positions were constantly brought to the DS market, and provided successful promotion they could immediately take high places in the rating, at the moment this process has slowed down, and introducing "interesting" products has become difficult. The most successful was the "novelty" "Livesil Premium" in the form of capsules maintaining the liver, which at the end of the year entered the TOP 100 (sales volume is 108.9 million rubles).

A number of significant changes can be noted in the ranking of the TOP 20 brands leading in terms of value sales. The market leader, as last year, was the line of vitamin complexes Solgar, affecting the body as a whole and some individual systems (share 4.8%). The second place in the ranking for 2018 was "Doppelhertz" brand (the proportion is 3.3%). The third place was taken by DS with laxative effect "Phytolax" by manufacturer "Evalar" with a share of 3.1%. It should be noted that "Evalar" company is the most represented in the rating: 5 brands from the TOP 20 occupy a total share of 9.5%

Among the significant positive changes there is an increase in sales of such brands as "Vitrum" (+212,0%), "Indinol" (+91,6%) and "Bac-Set" (+58,3%), among the

Table 20

TOP-20 DS Brands by Sales in Russia in 2018

2018 Rating	Changes	Brand	Value, millions of rubles	Sales volume increase	Share
1	-	Solgar	2 531.7	**30.1%**	**4.8%**
2	-	Doppelhertz	1 728.9	**-2.3%**	**3.3%**
3	-	Fitolax	1 662.1	**-3.6%**	**3.1%**
4	-	Phemibion	1 425.0	**4.6%**	**2.7%**
5	2	Maxilac	1 189.7	**-4.4%**	**2.2%**
6	-	Turboslim	1 176.4	**-7.6%**	**2.2%**
7	3	Evalar Glycine	967.2	**5.9%**	**1.8%**
8	-3	Vitamishki	947.4	**-27.6%**	**1.8%**
9	-	Normobact	908.5	**-8.2%**	**1.7%**
10	7	Bac-Set	841.3	**58.3%**	**1.6%**
11	-3	Hematogen	817.4	**-29.7%**	**1.5%**
12	4	Supradin	688.3	**26.7%**	**1.3%**
13	2	Complivit	683.2	**9.5%**	**1.3%**
14	-	Ovesol	667.5	**-0.1%**	**1.3%**
15	-2	Alphavit	620.5	**-21.6%**	**1.2%**
16	43	Vitrum	597.7	**212.0%**	**1.1%**
17	-6	Evalar Pustyrnik (Motherwort)	579.9	**-32.8%**	**1.1%**
18	20	Indinol	525.1	**91.6%**	**1.0%**
19	-7	Univit	485.4	**-39.0%**	**0.9%**
20	-	LINEX for children	468.9	**-7.3%**	**0.9%**

negative ones: -39,0% from brand "Univit" by a domestic company "OTCpharm".

Among the brands located below the TOP 20, Natures Bounty brand – the same name with a line of DS products with a wide range of action (+168,0%) and "Vuka Vuka" – an additive that supports men's health, produced by Stada (+57,9%) are worth noting.

TOP 20 DS Manufacturing Firms, Leading in Terms of Sales in the Russian Market

In contrast to the market of medicines, the market of dietary supplements is dominated by means of domestic production. Russian DS account for 56.2% of value and 81.4% of total sales. As a result of the multidirectional dynamics of domestic (-2.7%) and foreign additives (+1.1%), the share of Russian companies decreased in monetary terms during the year. In real terms, the market structure has changed in favor of domestic DS, but there is a decrease in the activity of both domestic nutritional supplements producers (-7.6%) and imported ones (-11.7%).

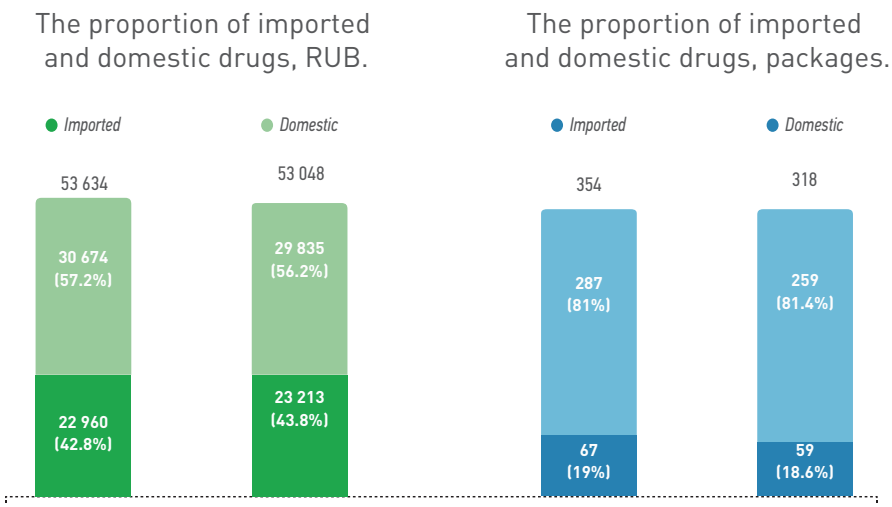
The average cost of a domestic drug pack in 2018 amounted to 115 rubles (+7.9% by 2017), which is approximately 3.2 times lower than the cost of an imported drug pack. In the same period, the cost of a DS pack of foreign production averaged 392 rubles — the average price increased by 14.6%.

Among foreign manufacturers DS manufactured in Germany (31.6%), USA (20.2%) and Canada (12.0%) take the leading positions. The list of German manufacturers is headed by Queisser Pharma (Doppelhertz DS series) and Stada Arzneimittel (Bactistatin and Vuka Vuka brands). Among American DS, products by company Solgar Vitamin and Herb (DS SOLGAR) is the most popular one. Among Canadian producers, Bausch Health company (Naturino DS) and Pharma-Med (Phitomucil) are leading.

The concentration of Food Additives Producers on the pharmaceutical market is quite high — the TOP 20 companies occupy 66.1% of the market. Significant changes can also be noted in the rating of manufacturers. Not all companies

Figure 30

Proportion of Imported and Domestic DS Sales



from the TOP-3 managed to retain their positions in 2017. For example, the Canadian manufacturer Bausch Health lost the third place to the American company Solgar Vitamin and Herb, which increased its sales by 30.1% during the year.

"Evalar" company has been the market leader for many years (at the same time, in 2018, a negative increase in sales was recorded: -2.1%). The negative dynamics is due, among other things, to the decline in the popularity of DS for weight loss in general by 11.7%, which includes the line of "Turboslim" manufacturer. The high dynamics of the new generation line of products with the effect of body rejuvenation from the inside Anti-Age (+1,364.3%) and collections of herbal tea "Evalar Bio" (+22.5 %) are worth noting. At the moment, "Evalar" portfolio contains 276 different names of DS, combined into 126 lines with one trade name. Every year new products of the company are launched on the market: in 2018, about 26 new DS appeared on the shelves of pharmacies, taking into account the dosage, purpose and form of production. The most successful novelty is "Evalar Potassium+Magnesium Forte tablets 316 mg+280 mg 1,2 g №60" - an additive for maintaining the cardiovascular system health — sales amounted to about 13,9 million rubles.

To implement its products, the manufacturer uses other distribution channels (not pharmacies): opens the "Phitomarkets", develops its own pharmacy chain (at the end of year 2018 — 41 pharmacies), expanding sales through the Internet channel. However, "Evalar" postponed the launch of a new production of pharmaceuticals in Biysk till the first quarter of 2019.

In addition, "Evalar" has signed a contract with the Australian pharmaceutical distributor API and has already shipped the first batch of products for sale onto the Australian market. "Evalar" will supply a line of 15 products – 9 DS and 6 types of tea. Despite the strict regulation of the DS market in Australia, where DS are considered as a medical supplements, and their turnover is controlled by the Ministry of Health, this market is estimated by the company as very promising. According to the analytical data of the company, more than 60% of the Australian population regularly uses DS, while in Russia this figure does not reach 20%. The annual turnover of the DS market in Australia reaches $ 5 billion.

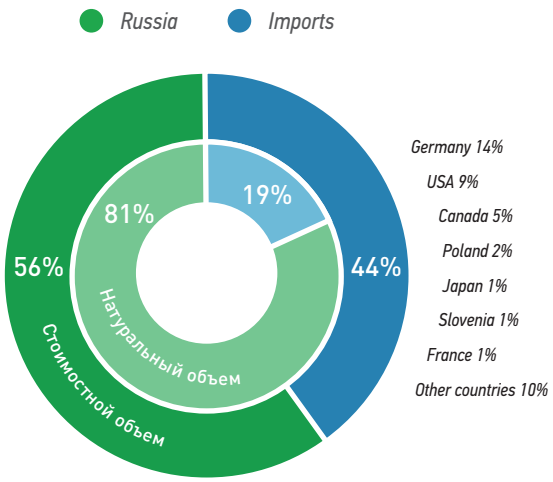


Figure 31

Proportion of Imported and Domestic DS Sales by Countries

Table 21

TOP-20 DS Manufacturers in Russia in 2018

Ranking 2018	Changes	Company	Value, millions of rubles 2018	Sales volume increase	Share
1	-	Evalar	9 896.8	-2.1%	18.7%
2	-	Pharma-Med	2 867.6	-5.5%	5.4%
3	2	Solgar Vitamin And Herb	2 531.7	30.1%	4.8%
4	-	OTCPHARM	2 089.0	-1.8%	3.9%
5	-2	Bausch Health	1 911.3	-18.2%	3.6%
6	3	Acvion	1 741.3	19.3%	3.3%
7	-1	Queisser Pharma	1 728.9	-2.3%	3.3%
8	-	Stada Arzneimittel	1 612.3	7.2%	3.0%
9	1	Merk Selbstmedikation	1 425.0	4.6%	2.7%
10	1	Obolenskoye	1 189.7	-4.4%	2.2%
11	2	Genefar	1 074.1	-3.6%	2.0%
12	6	Takeda	1 052.1	85.4%	2.0%
13	-1	Recordati	1 014.6	-17.2%	1.9%
14	5	Bayer	822.1	46.6%	1.5%
15	1	Diod	774.8	3.0%	1.5%
16	-2	Pharm-pro	752.2	-22.5%	1.4%
17	-10	RIA “Panda”	738.2	-51.5%	1.4%
18	-3	B-Min	656.3	-18.3%	1.2%
19	4	Quadrat-C	601.9	54.2%	1.1%
20	6	Miraxbiopharma	583.7	90.0%	1.1%

The second place is taken by Pharma-Med, almost all positions of which have reduced their sales volumes. The main brand of the company — chewing marmalade for children "Vitamishki" — lost 27.6% of sales. However, due to the increase in sales of "Bac-set" supplement for the digestive system by 58.3%, the company managed to retain the second line and lose only 5.4% of sales.

Since July 2018, Valeant Corporation was renamed as Bausch Health. However, the decision of the company's management to rebrand did not save the situation. Due to a significant reduction in sales of Bausch Health (-18.2%), the American manufacturer Solgar Vitamin and Herb (+30.1%) rose to the third position, promoting a line with a wide range of action of the same name — Solgar.

A pharmaceutical holding "RIA Panda", specializing in production and sale of nutritional supplements, lost 10 lines in the ranking as a result of a significant drop in sales by 51.5% in monetary terms. In May 2016, Rospotrebnadzor revoked the certificate of state registration from two of the most popular DS of the company – "Sealex Forte" and "Alikaps" since "Tadalafil" — the active ingredient of the prescription drug to increase potency — was found in both additives. Further negative development of the situation was caused by a criminal case of tax evasion in the amount of more than 144 million rubles. A direct violation of the law led "RIA Panda" holding to bankruptcy.

The high growth rates are demonstrated by the manufacturer "Miraxbiopharma" (+90.0%), the most popular brand of the company is "Indinol", which affects women's health — its sales increased more than 2 times.

The second place in terms of growth rates is taken by Takeda manufacturer (+85.4%). There are only 3 brands in the company's portfolio. In 2018, the Japanese pharmaceutical company closed a deal on buying "Vitrum" brand from Unipharm, which at the end of the year showed the best results compared to last year (+212.0%), and got to the 16th place of the rating.

Another TOP-20 "rookie", in addition to "Miraxbiopharma", was the Russian company "Quadrat-C" (+54,2%). The manufacturer has a small range of products — only 21 brands, the main growth of the company was provided by additives "Lizoprim LOR" (+773,5%), recommended for infectious diseases of the throat, and "Magnesium B6 Vitamir" (+505,1%), used as an additional source of magnesium and B2 and B6 vitamins.

6. Cosmetics

In recent years, cosmetics have thoroughly entrenched in the non-drug range of pharmacies, becoming an integral part of it. The main distinctive feature of pharmacy cosmetics is that it passes mandatory certification procedure, which confirms its reliability, effectiveness, medicinal properties, etc. Consumers are becoming more demanding on the composition and quality of products. At the same time, pharmacies act as guarantors of quality, confidence in the recommendations.

Competent marketing policy is considered to be the basis for the promotion of cosmetic products on the market. At the moment, pharmacies sell cosmetics that not only have a therapeutic effect, but also are responsible for the care and beauty. Cosmetics can be for the face, hair, hands, etc., depending on age. Networks and single points need to systematically study the cosmetic brands that appear on the market to meet consumer demand and keep track of new products.

In 2018, large networks, such as "Mega Pharm" and "Erkapharm" began to develop a new net format — Drogerie. Drogerie is a classic pharmacy store: in addition to medicines, the range of the outlet includes household chemicals and parapharmaceutical (nutritional supplements, cosmetics, products for children, household chemicals, products for animals and goods of daily demand, etc.). "Magnit" retailer plans to merge its pharmacy with the store "Magnit cosmetics". The new format differs from conventional pharmacies by a more pronounced desire to work with marginal and popular positions among consumers.

In 2018, Russian pharmacies sold 1,711 different brands of cosmetics, more than 15 thousand full names. The range of pharmacy chains is constantly changing and supplemented with new products — manufacturers have offered the consumer more than 70 new brands. The leaders of sales were CeraVe (line of skin care products designed to moisturize, restore and strengthen the natural protective barrier) and "Licener" (anti-pediculosis shampoo). These brands were able to enter the TOP 300 in terms of sales value, as their sales for the first year exceeded 95.6 million rubles.

Cosmetics are not essential goods, so the dynamics of their sales often reflect the "health status" of the economy and consumer opportunities. Of course, the cosmetic range has a multi-channel implementation, and it is possible to transfer the buyer from the pharmacy to specialty stores, from hypermarkets to the online channel. Yet, in general,

> "Networks and single points need to systematically study the cosmetic brands that appear on the market to meet consumer demand and keep track of new products"

the dynamics of 2018 shows negative trends (-4% in value terms, according to the GFK "Rus'", the first half of 2018). "The general trend for all cosmetics stores is a drop in the average check with a stable frequency of purchases. The buyer is now looking for the best deals and gradually leaves for online." Perhaps this factor is associated with the stagnation of sales of cosmetics in pharmacies. In one way or another, consumers whose real incomes are falling are beginning to save on the parapharmaceutical group of goods.

In 2018, Russian pharmacies sold 184.9 million packages of cosmetics for the amount of 44.8 billion rubles (in retail prices). In the ruble equivalent, the market of pharmaceutical cosmetics increased by 0.6% compared to the same period last year, in real terms, sales remained at the level of 2017. We shall note that the same picture was in 2016.

When analyzing the monthly data, you can see the unstable dynamics both in rubles and in packages in comparison to 2017. The most significant drop was observed in April (-5.2% in rubles and -6.9% in packages) and June (-5.3% and -6.3% respectively). The most successful month was September — the sales volume of cosmetics increased by 10.2% in value terms and by 5.4% in kind. In September, when the activity of ultraviolet radiation falls, and the winter cold is still ahead, there comes a favorable and safe season for cosmetic procedures, which may explain the increase in sales. In half of the year, the dynamics of cosmetics sales is negative. Even the holidays of March 8 and the New Year do not contribute to the active growth of this segment, although earlier these periods accounted for both the peak in absolute terms and the maximum growth.

Cosmetics differ by price, by designation, product form. DSM Group analyzed the items and offers their classification of beauty goods. Cosmetics, which are sold in pharmacy networks, are divided into 3 groups:

Mass Market Cosmetics are the affordable cosmetics intended for skin, hair and nail care and sold both in pharmacy institutions, and other points of sale (Garnier, Nivea, etc.).

Active (Medicinal) Cosmetics are applied for treatment and prevention of certain diseases, contain various biologically active substances ("Sofya"

Pharmacy cosmetics dynamics

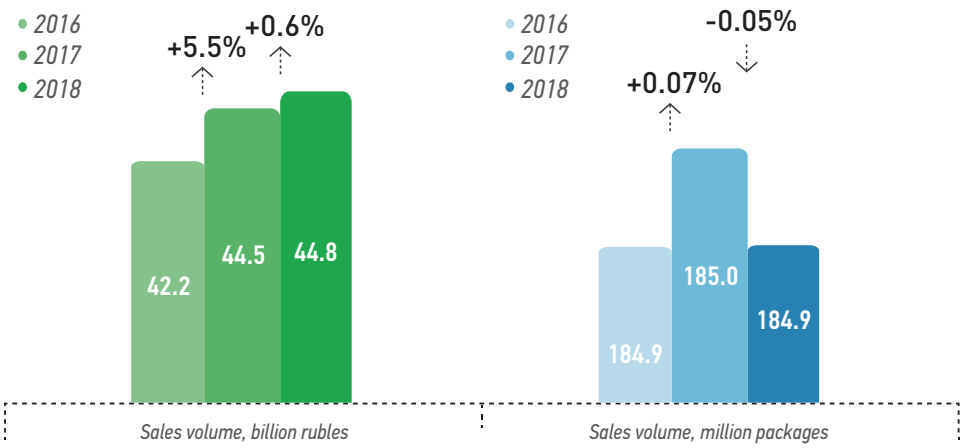


Figure 32

Sales Volumes of Cosmetics in Russia

(creams and balms), "Boro Plus" creams, etc.).

Selective (Premium and Luxury) Cosmetics are characterized by availability of specialized lines, clearly distinguished between each other and intended for certain skin or hair state. As a rule, cosmetics of such a type are sold mainly via pharmacy institutions (Vichy, Avene, Uriage, etc.).

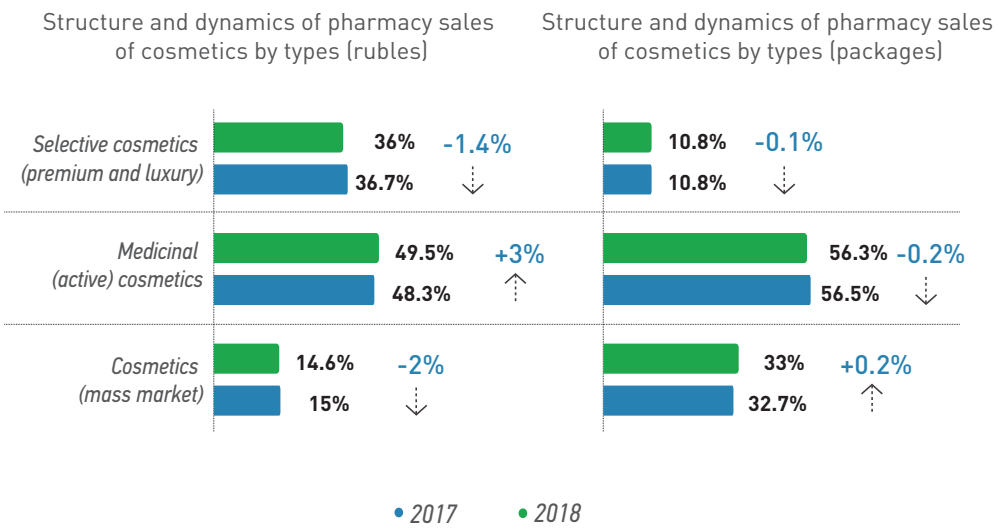
A stable segment of Active (Medicinal) Cosmetics ensured the growth of sales of cosmetics in monetary terms in the pharmaceutical market. This group occupies 49.5% of the market in rubles (+3.0% to the sales volume in 2017) and 56.3% in packages (-0.2%). This is the most widely represented segment in pharmacies: in 2018 it was possible to buy 830 different brands of medical cosmetics from 445 manufacturers (4,172 full names).

Sales of Selective Cosmetics in 2018 decreased both in rubles and in packages. Just for the segment of "expensive" cosmetics, the most real threat is losing the consumer "to the Internet". Moreover, the manufacturers themselves contribute to this, starting work with large online stores. Thus, the positioning of selective cosmetics as pharmacy cosmetics ceases to be relevant. Compared to 2017, the volume of premium and luxury cosmetics decreased by 1.4% in rubles and 0.1% in packages. As a result, the share of this segment decreased from 36.7% to 36.0%. In real terms, the weight of premium cosmetics is much lower — 10.8%.

For mass-market cosmetics, a pharmacy is not the main promotion channel. However, this sub-segment occupies 33.0% of the market in real terms and is popular among Russians, as it is represented by sufficient budgetary funds. Therefore, the share of mass market cosmetics in rubles is 14.6%.

Figure 33

Proportion of Pharmacy Sales of Cosmetics by Type



The average cost of cosmetics in retail prices for 2018 amounted to 242 rubles per package. Compared to the same period in 2017, the price increased by 0.7%. When looking at the market segments, you can see that all categories, except medical cosmetics, fell in price. The cost of one package of active cosmetics has become more expensive by 3.4%, while the price of mass market products and premium segments decreased by 2.6% and 0.9%, respectively.

Pharmacy offers customers a huge selection of cosmetics in different forms of production and with different purposes. The most popular cosmetics was multifunctional (it accounted for 34.8% in packages). This is not surprising, as more than half of the market in the structure of universal cosmetics is occupied by brands of medical cosmetics. Yet most of the money brought to the pharmacy comes from cosmetics for the face (25.4% of the total sale of cosmetics). Such volume is provided by selective brands: 75% in rubles and 44% in packages are accounted for by brands belonging to this category. These means for the face show a negative trend too. The rest cosmetics groups are rising.

Foot products (+8.3% in rubles and +10.0% in packages) showed the largest increase among all the groups of cosmetics. The maximum decrease in the sales volume was noted in hand and nail products (-32.5% in rubles and —19% in packages).

The largest share in the structure of cosmetics by age criterion is cosmetics, designed for all age categories (78.0% of the value of sales and 78.7% of natural volume). The second line is taken by cosmetics for children (from 0 to 14 years): 9.0% of the cost and 15.7% of natural volume. The third place was taken by cosmetics for middle-aged people (after 25 years) with a market share of 5.6% in value terms. In this category, there is preponderance towards premium and luxury cosmetics — 77.5% of the volume in rubles of this category falls on selective

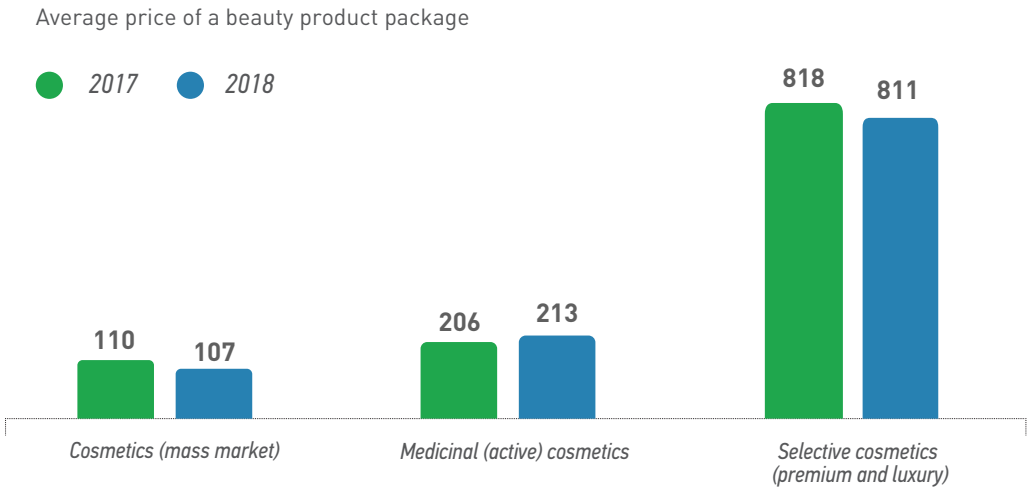


Figure 34

Weighted Average Price for Cosmetics

cosmetics. A large advantage of expensive cosmetics is also observed in the segment for the elderly (after 60 years), in this category, selective cosmetics occupy 77.9% of the value of sales. At the same time, the segment of cosmetics for the elderly shows the maximum rate of decline in money (-68.7%).

Russian cosmetics are most in demand in the pharmaceutical market than foreign. Domestic cosmetics occupy more than 73.7% of the natural volume of sales. When analyzing sales in monetary terms, it can be noted that the market is almost divided in half, but there is preponderance towards imported cosmetics (about 52.1% of sales).

Within the segments there is a different ratio of domestic and foreign cosmetics.

In 2018, premium and luxury cosmetics were represented mainly by imported

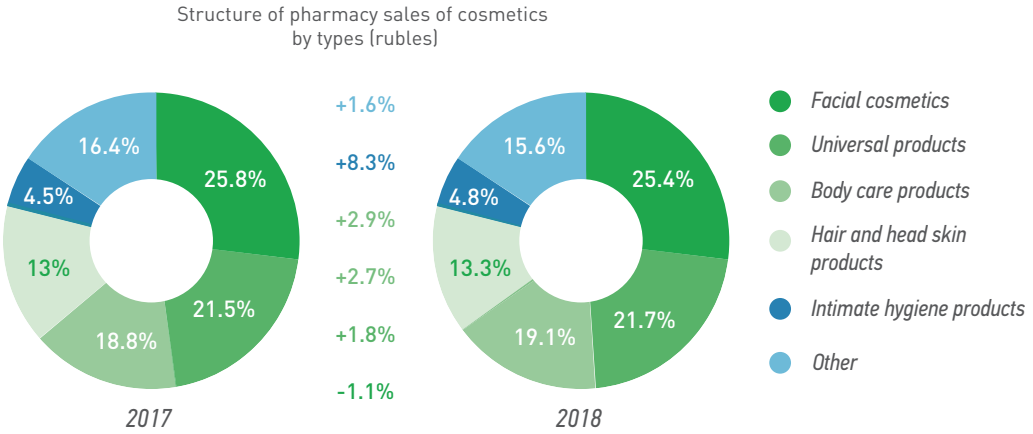
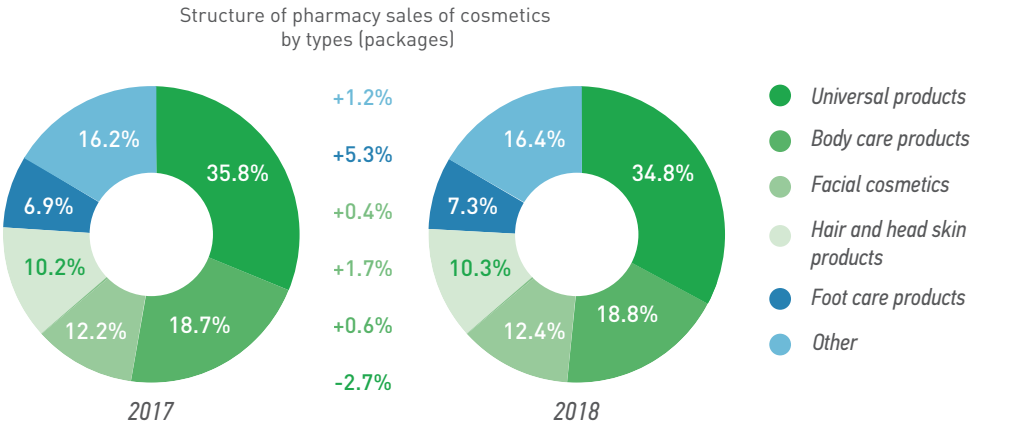


Figure 35

Structure of Cosmetics by the Place of Application



cosmetics, which occupy 77.0% of the market in rubles and 53.9% in packages. A domestic brand Librederm, which is partially produced in our country, takes 100% of domestic selective cosmetics sales in rubles.

The segment of medical cosmetics, on the contrary, is mainly represented by Russian brands, which are leading both in terms of cost (64.3%) and with natural (78.5%) indicators.

In the mass-market segment, the share of domestic cosmetics increased compared to last year in value terms and amounted to 53.8%. The main domestic brands are "Kora" and "Detskiy krem", which together occupy about 20% of the market in rubles.

Selective Cosmetics

BIn 2018, pharmacies sold 19.9 million packages of selective funds for the amount of about 16.1 billion rubles (in retail prices). This is 1.4% less than in the same period of 2017 in value terms and 0.1% less in kind. The rating of selective brands is quite stable. The leaders from the 1st to the 8th place kept their positions. One company left the TOP 10 (Lierac), giving way to Ducray cosmetics in the ranking. Only 4 brands managed to increase their sales relative to last year.

Librederm was able to keep the leading position in the category of selective cosmetics, despite the negative dynamics: the brand's market share decreased from 25.2% to 23.9% in the value of the segment. At the same time, sales of the brand decreased by 6.3% compared to 2017. Such dynamics can be connected with the outflow of consumers to their own stores with the same name, which are opened in large cities. Librederm line accounts for 47.1% of the natural volume in packs. Therefore, at the moment, Librederm can be called the most popular brand of selective cosmetics. The line includes more than 240 different trade names, but a large share is occupied by products for the face (31.0% in rubles).

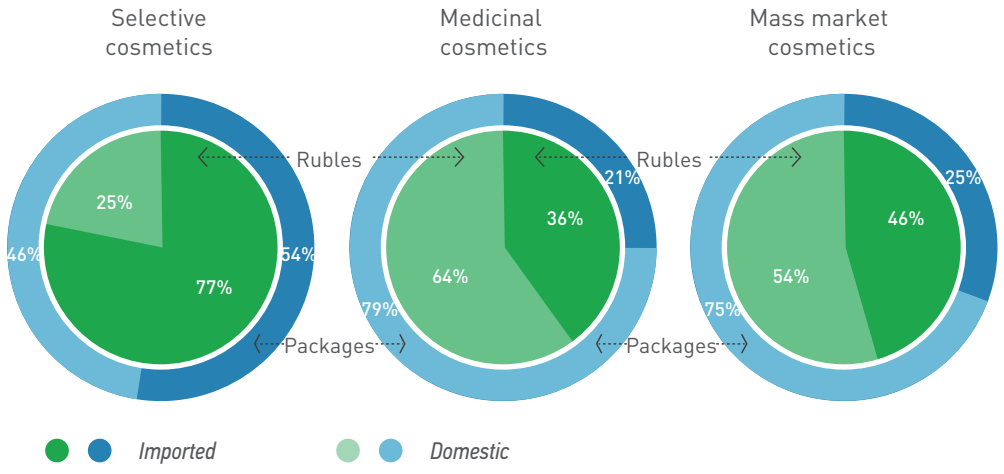


Figure 36

Proportion of Pharmacy Sales of Cosmetics by Type, 2018

La Roche-Posay showed a 15.2% increase in sales and came close to the leader; there were months when sales of La Roche-Posay exceeded Librederm. La Roche-Posay cosmetics, developed on the basis of thermal water, are specifically designed for problem skin, so about 65% of the brand's sales are products for the face. The main product lines of the brand are Effaclar (special series for pimples, blackheads and acne) and Lipikar (products for the face against irritation and itching).

The third place is taken by the French brand Vichy. In 2018, sales of products under this brand increased by 2.5% for the first time in several years after negative trends. About 400 full names of Vichy were presented in pharmacies, about 44% in value terms accounted for products for the face, also in Vichy line there is a large assortment of products for the body (18%) and hair (17%).

Six leading brands of selective cosmetics were marked in 2018 by a decrease in sales in rubles. The highest rate of decline was demonstrated by Filorga; sales of products under this brand decreased by 23%.

"Medicinal" Cosmetics

Active cosmetics, which have a therapeutic effect, occupy the leading position in the pharmacy market. If selective cosmetics solves the problems of the skin to a greater extent, the active cosmetics has a wide range of indications for use. The

Table 22

TOP-10 brands of selective cosmetics

Number in the rating	Change in the rating	Brand	2018 share in rubles	2018 / 2017 growth in rubles
1	-	Librederm	23.9%	-6.3%
2	-	La Roche-Posay	23.4%	15.2%
3	-	Vichy	19.9%	2.5%
4	-	Avene	8.2%	1.6%
5	-	Bioderma	5.9%	-16.5%
6	-	Uriage	4.4%	-8.7%
7	-	Mustela	2.6%	-15.8%
8	-	Filorga	2.0%	-23.4%
9	+1	Klorane	1.6%	-3.4%
10	+ 1	Ducray	1.6%	10.1%

main share in this range group sales is occupied by the positions used for sprains, bruises, diseases of joints of inflammatory character (12,4%), various damages and diseases of skin – cracks, abrasions, cuts and burns (8,5%), for the skin inclined to allergic reactions (7,9%).

The TOP 10 brands account for 27.7% of sales of active cosmetics, which is significantly lower than in the segment of selective brands (93.6%). At the same time, pharmacies sell about 830 different brands of "medicinal" cosmetics.

The first place among the brands of this type is held by Horse Force (Loshadinaya sila), despite the decline in sales by 5.4%. About 42% of the brand's sales in rubles account for body products used for sprains, bruises and joint diseases.

The second line is now taken by Lactacyd, which is a line of products for intimate hygiene, due to sales growth of 13.2%. The range of products includes about 20 items. 26% of the volume accounted for "Lactacyd means for intimate hygiene, delicate 200 ml №1".

Alerana is a cosmetic product created for hair and scalp care. Therefore, 66.4% of products manufactured under this brand are shampoos. As a result of the multidirectional dynamics with Lactacyd, Alerana lost the second place and fell to the third place (-5.6%).

Table 23

TOP-10 Medicinal (Active) Cosmetic Brands

Number in the rating	Change in the rating	Brand	2018 share in rubles	2018 / 2017 growth in rubles
1	-	Horse Force	**5.5%**	**-5.4%**
2	+1	Lactacyd	**3.4%**	**13.2%**
3	-1	Alerana	**3.2%**	**-5.6%**
4	-	911	**2.8%**	**1.8%**
5	-	Emolium	**2.6%**	**3.1%**
6	+2	Boro plus	**2.3%**	**5.0%**
7	-	Dry Dry	**2.1%**	**-5.4%**
8	- 2	Sofya	**2.0%**	**-12.8%**
9	-	Micostop	**2.0%**	**9.0%**
10	+6	Pediculen	**1.7%**	**43.0%**

The maximum growth rate was noted with "Pediculen" (+43%), which in 2018 managed to climb 6 positions up and take the 10th place of the rating. The main growth of a line of products designed for lice treatment provided a shampoo "Pediculen Ultra shampoo 200 ml №1". A decrease in sales of "Sofya" by 12.8% can be called one of the negative changes. The product for lice and nits elimination "Paranit" left the rating (-7 positions down) due to a decrease in sales by 29%.

"Lipobase" (+56%), Cetaphil (+25%), "Spasatel' (Lifeguard)" (+22%) have demonstrated high growth rates in recent years. If such dynamics is maintained, we will be able to see them in the TOP 10 ranking of active cosmetics in 2019.

Mass Market Cosmetics

Mass-market cosmetics by 42.7% consist of universal products and are more intended for purification (13.5%).

Changes in mass-market cosmetics rating are many more than in the other two groups. Not all the leaders have been able to maintain their positions. Sales of the American line of nail care products "Smart enamel" decreased by 10.7%. As a result, "Detskiy krem (Children's cream)" rose to the third line: its sales increased by 30%.

The first place is traditionally occupied with Johnsons Baby baby care cosmetics (share of 9.0%). The second is "Kora" (4,8%). It should be noted that leaders of 2018 showed a negative trend.

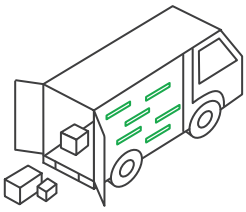
Yet the brands that occupy the rating positions from the third place down showed mainly positive dynamics. Thus, Evo demonstrated the maximum growth in rubles (+54.2%) in the reporting period, as a result of which it was in tenth place in TOP 10. +2 lines for "Floresan" whose sales increased by 18% is among the positive changes.

One of the features of mass market sold in pharmacies cosmetics rating is a large number of brands related to children's brands. 32% of sales are in the category intended for children and young people. Four brands fall into the Top 10 and are the main in this category (they account for 66% of all children's cosmetics purchased in pharmacies).

Table 24

TOP-10 Brands of Mass Market Cosmetics

Number in the rating	Change in the rating	Brand	2018 share	2018 / 2017 growth in rubles
1	-	Johnsons Baby	**9.0%**	**-13.0%**
2	-	Kora	**4.8%**	**-1.5%**
3	+3	Detskiy krem	**4.7%**	**29.6%**
4	- 1	Smart Enamel	**4.2%**	**-10.7%**
5	2	Floresan	**4.2%**	**17.9%**
6	-2	Nivea	**4.1%**	**2.5%**
7	-2	Bubchen	**4.1%**	**11.4%**
8	-	Moye solnyshko	**3.6%**	**4.2%**
9	-	Neutrogena Norwegian Formula	**3.1%**	**5.1%**
10	+6	EVO	**2.1%**	**54.2%**



7. Drug Import

Import substitution in Russian pharmaceutical industry is not just a classic way of developing domestic products, but a wider "route": the transfer of technologies and competencies, localization and provision of preferences to domestic producers. Moreover, the new state program of development "Pharma-2030", which is being discussed now, sets even more ambitious tasks, such as export orientation of the pharmaceutical industry, production of pharmaceutical substances, development of innovative drugs and technologies.

Over the past ten years, more than 20 plants of foreign medicines manufacturers have been opened in different regions of Russia. But so far it has not particularly affected the dynamics of import of either drugs or substances. Thus, the dependence of the Russian Pharmaceutical Market on import policy is still very high and any possible restriction, first of all, will affect the consumer.

Thus, in the spring of 2018, the possibility of banning the import of drugs into Russia if their analogues are produced either by domestic pharmaceutical companies or manufacturers from states that have not joined the anti-Russian sanctions was considered as one of the measures of counter-sanctions. One of the measures proposed to completely limit the supply of drugs from the United States. In adopting such a decision, 90 drugs that have no analogues would not be able to enter the market. The total volume of sales of these drugs is 37 billion rubles. In general, more than 1,000 drugs produced in the United States are sold on the market.

In addition to drug availability for the population, the ban on the import of drugs could have a negative impact on the development of new drugs by domestic companies. In modern studies, three categories of drugs are used: studied drugs, comparison drugs, and basic therapy drugs. If the "prohibited" drug is in any of these three categories, a clinical trial of the domestic drug will not take place.

Finally, everything ended well: the drugs were derived from possible measures of counter-sanctions. However, this does not prevent the producers themselves to make decisions on the termination of supplies to the territory of the Russian Federation. Most often, the reason for such decisions is the decrease in sales volumes due to the appearance of domestic analogues or more modern drugs. For example, BMS stops the supply of three drugs for HIV-1 infection treatment ("Reyataz" capsules; "Zerit" in the form of powder for solution preparation for intake; "Videx", capsules and powder for oral administration). Bayer stops delivering X-ray contrast product "Urografin" to Russia.

Quite often there is an initiative to allow parallel import of medicines in our country. In the European Union, these rules are applied, but only within its borders. That is parallel import of medicinal products exclusively from the market of one of

the members of the European Union onto the market of another. Parallel imports from the external borders of the European Union are prohibited.

At the moment, the permission of parallel import of medicines in Russia should be agreed with the countries that are members of the Customs Union. Today, all countries except Belarus have confirmed their consent to parallel imports.

FAS has already prepared amendments to the Civil Code on the legalization of imports without the permission of trademark owners. Since 2021 and for up to five years, they allow the government to open the border for parallel imports of certain goods. Now the Civil Code prohibits it — only the right holder or the official dealer can import the goods to Russia. Although in February 2018, the Constitutional Court allowed the import of goods without the permission of the overpricing brand owner.

The decision on parallel import may come into conflict with the development of the labeling project in Russia, as the goods may be imported from the market of foreign countries that do not have such labeling.

In general, the transition to "labeled" drugs may have a negative impact on the volume of imported drugs. The Association of European Business (AEB) believes that the forced transition to a new system of drugs' labeling in Russia will lead to a disruption in supplies. By 2020, all suppliers should start labeling drugs using the new technology, which requires certain investments from manufacturers, which are estimated at "several million dollars for one plant" by the AEB. Foreign manufacturers, which are engaged in small deliveries to Russia, will not be able to afford it. As a result, it will become a prohibitive barrier to trade in Russia.

> Medicines from the European Union, the USA and Japan that have not passed clinical trials in Russia can be admitted to the domestic pharmaceutical market to speed up patients' access to new drugs

One of the positive proposals for increasing the availability of new drugs was the issue of admission of imported drugs onto the domestic market without clinical trials. Medicines from the European Union, the USA and Japan that have not passed clinical trials in Russia can be admitted to the domestic pharmaceutical market to speed up patients' access to new drugs. Such a proposal is voiced in the "road map" "Development of Competition in Health Care". The medicines are planned to be marked with a warning sign that the drug has not passed clinical trials in the territory of the Russian Federation. On each package, it will be noted that the drug has been studied only in the European Union, USA or Japan. Drugs for cancer patients, for epileptics and orphan drugs for treatment of rare diseases may be in demand among the imported drugs not tested in Russia.

More than 1,000 different organizations are engaged in import of foreign medicines today: these are foreign manufacturers, distributors, and domestic companies. To streamline and control this process, in October 2018, the government proposed to create a single importer of drugs that

have no analogues that are produced in the country for the needs of state medical institutions. It is expected that the volume of purchases will be about 200 billion rubles per year. In addition, the same company needs to obtain the authority to export Russian medicines which have no analogues abroad in the amount of $500 million annually. Discussions about a single state distributor have already been raised before, now they are talking about the importer. The desire to monopolize the whole process in one organization is connected with the need for tighter control over prices. On the other hand, "monopoly" does not promote competition, and can be fatal for the suppliers of original drugs.

Drug Import

The dynamics of imports over the past few years shows negative trends in real terms. For 5 years, the volume of drugs' import decreased by a third: from 3.34 billion packs in 2013, up to 2.28 billion packs in 2018. The main decline happened in 2015: due to currency fluctuations, importers were afraid to import large quantities of drugs and used the formed reserves. In 2018, the volume of imported drugs also decreased by 14%. Here, the main reason can be the emergence of domestic analogues in the market and their preferences in public procurements.

In dollars, the volume of imported medicines in 2018 amounted to 10.5 billion

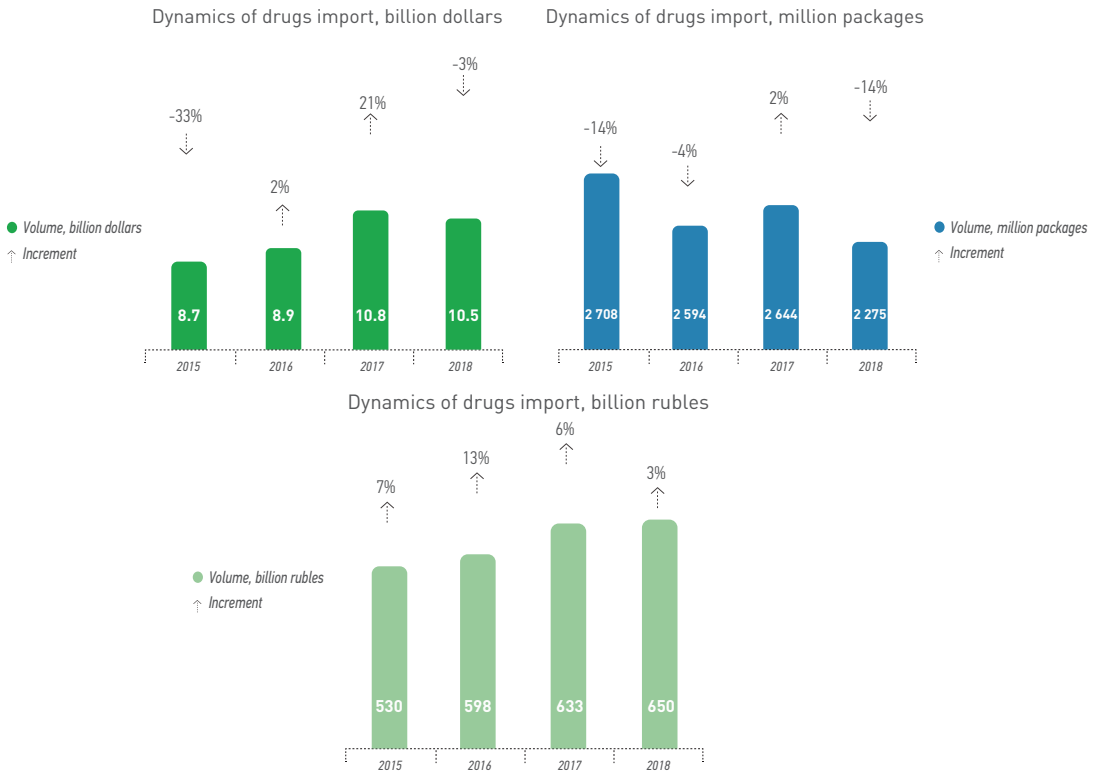


Figure 37

Drugs Import Volume

dollars. This is 3% lower than in 2017. The imported medicines value in ruble terms shows a positive trend from year to year — in 2018, the increase is 3%. Such dynamics practically corresponds to the growth of the market as a whole.

Table 25 shows the shares of different groups of drugs importers to Russia.

As it can be seen from Table 25, in 2018, about 76% of the volume of drug imports falls on the group of importers — representatives of foreign manufacturers. Compared to 2017, the supply of this category of importers decreased by 4.3%.

"Distributor Companies" has taken the second place in capacity, but over the past 4 years its share has decreased by 6.5% — as well as the volume of imports by this group of importers. They also have the maximum negative dynamics among all the categories.

In 2018, "Domestic Drug Manufacturers" showed high dynamics, and the share was already 7% (in the structure of import). The increase is due to the volume increase by the group leader by 6.4%. The main importer among domestic drug manufacturers is Pharmstandard; its share according to the results of 2018 was 39%. The second is Nizhpharm with a share of 18%. The third is "Veropharm" with a share of 10%. Re-qualification of domestic manufacturers-importers is associated with the processes of import substitution: localization of drugs at the plants of foreign companies or, as for "Nizhpharm" and "Veropharm", the transfer of production to domestic sites after entering the international corporation. "Direct Import Companies" also demonstrates positive dynamics. A major player in this

Table 25

Shares of different groups of Drug Importers in Russia in the Volume of Drug Import

Importers	Share of the import volume, %				Increment, dollars 2018 / 2017
	2015	2016	2017	2018	2018/2017
Distributor Companies	**15.7%**	**13.9%**	**9.7%**	**9.2%**	**-8.5%**
Representatives of Foreign Companies	**72.7%**	**74.1%**	**76.9%**	**76.3%**	**-4.3%**
Direct Import Companies	**5.4%**	**5,1%**	**7.0%**	**7.5%**	**3.4%**
Domestic Drug Manufacturers	**6.1%**	**6.9%**	**6.3%**	**7.0%**	**6.4%**

segment is the company "Pharmaceutical Import, Export"; its share is 53%. It is followed by "Orfe" with its share of 11%.

Table 26 shows TOP-10 among the representatives of foreign manufacturers by import volume in 2018.

In 2018, "Representatives of Foreign Companies" decreased by 4.3% in dollars. At the same time, the concentration of importers in "Representatives of Foreign Companies" group slightly increased compared to 2017. Although almost all the companies (7 out of 10) show a negative trend.

"Novartis" remains the leader of the group "Representatives of Foreign Companies", as in previous years, with the share of 9.1%. This is one of the few companies that have not fallen in terms of imported medicines. The second place is traditionally taken by "Sanofi" representative office. In 2018, the volume of imported drugs from this manufacturer increased by 20% (the leader in the Top-10). Due to this, there was an increase in the share by 1.7%. The third place in the reporting year was taken by the representative office of "Bayer", the delivery of their drugs decreased by 1.4%.

Of the companies that showed high growth, the representation of "Beringer" is worth noting (+13%). A drop of around 20% was demonstrated by "Teva" and "Berlin-Chemie".

Of the companies not included in the TOP 10, we have to note the representative offices of "Merck" and "Rosh" manufacturers; their turnover of imported drugs increased significantly (by 94% and 35%, respectively). Thus, companies have more actively begun to deliver drugs through their offices.

Table 26

TOP-10 Representatives of Foreign Manufacturers in the Drugs Import Volume

	Representatives of foreign manufacturers	Share by import volume of the "Representatives...", %		Increase to 2017, dollars
		2017	2018	
1	Novartis	8.6%	9.1%	0.4%
2	Sanofi	6.3%	8.0%	19.6%
3	Bayer	5.0%	5.2%	-1.4%
4	Pfizer	4.7%	4.8%	-3.0%
5	Johnson & Johnson	4.7%	4.8%	-4.0%
6	Teva	4.8%	4.1%	-19.5%
7	Abbott	4.2%	3.7%	-15.4%
8	Berlin Chemie	4.3%	3.7%	-19.2%
9	Beringer	3.1%	3.7%	12.7%
10	GlaxoSmithKline	3.5%	3.5%	-6.0%
	Total:	49.1%	50.5%	

Table 27 shows the TOP 10 distributors by volume of drugs imports to Russia.

In 2018, the share of 10 largest distributor-importers in the total import volume of the "Distributor Companies" equaled to 87%.

As it can be seen from Table 27, the largest distributor of 2018 in terms of imports volume in "Distributor Companies" is "Protek" with a share of 23%. Then you can select three players: "R-Pharm", "Puls", "Katren", which are approximately at the same level — 15-18%. Of these companies, only "R-Pharm" shows an increase in the volume of imported drugs, and the figure is one of the maximum ones: +33%.

The high dynamics is also demonstrated by "Grand-Capital", due to this, the supplier has improved its position in the rating by 4 positions (from the 10th to the 6th places).

Periodically, distributors with H.Q. outside of Moscow which carry out the delivery of drugs to pharmacies within this and the surrounding regions are also beginning to work as importers. Thus, in 2016, "Godovalov" whose head office is located in Perm independently began to supply drugs to Russia. In 2017, the company even got into the TOP 10 rating. But in 2018, the volume of drug imports fell by 70%. The same dynamics is demonstrated by a Voronezh company "Norman", which was first noted in imports in 2017: during the reporting year, deliveries decreased by 55%.

Yet, "Pharmperspektiva" distributor from Samara continues to increase volumes in this direction, demonstrating an almost 2 times increase in supplies, due to which the share reached 2%, and the company entered the TOP 10. Of the distributors that are located below, we can also note Moscow "Medintorg" and Omsk "Zdravservice", which have significantly increased the volume of deliveries since 2017.

Table 27

TOP 10 Distributors by Drugs Import Volume

	Distributor	Share in the import volume in the group "Distributor Companies", %		Increase to 2017, dollars
		2017	2018	
1	Protek	**25.2%**	**22.7%**	**-18.5%**
2	R-Pharm	**12.4%**	**18.3%**	**33.4%**
3	Puls	**15.8%**	**15.6%**	**-10.6%**
4	Katren	**15.2%**	**14.8%**	**-12.5%**
5	Pharmcomplect	**3.1%**	**3.2%**	**-4.0%**
6	Grand Capital	**2.1%**	**3.1%**	**34.0%**
7	Euroservice	**3.1%**	**3.0%**	**-14.0%**
8	SIA	**3.1%**	**2.7%**	**-22.1%**
9	Biotec	**3.9%**	**1.9%**	**-56.1%**
10	Pharmperspektiva	**0.9%**	**1.9%**	**90.3%**
	Total:	**84.7%**	**87.1%**	

Table 28

TOP-20 Manufacturing Companies by Volume of Drugs Import to Russia by all groups of Importers

Ranking		Manufacturer	Share of import volume by value, %		Increase to 2017, dollars
2017 г.	2018 г.		2017	2018	
1	1	Novartis	6.1%	6.0%	-6.4%
2	2	Sanofi	4.7%	5.9%	17.7%
4	3	Bayer	3.6%	3.9%	0.8%
10	4	Takeda	3.0%	3.8%	17.6%
5	5	GlaxoSmithKline	3.5%	3.6%	-2.4%
6	6	Johnson & Johnson	3.5%	3.4%	-8.9%
8	7	Celgene	3.4%	3.3%	-8.1%
3	8	Teva	3.8%	3.2%	-19.1%
9	9	Abbott	3.2%	3.2%	-7.8%
13	10	Merck	2.6%	3.0%	8.0%
7	11	Berlin-Chemie	3.4%	2.8%	-23.5%
11	12	Gedeon Richter	2.8%	2.7%	-9.7%
15	13	Boehringer Ingelheim	2.2%	2.6%	10.8%
12	14	Pfizer	2.6%	2.4%	-15.9%
20	15	F.Hoffmann-La Roche	1.7%	2.3%	28.1%
14	16	AstraZeneca	2.5%	2.0%	-23.3%
18	17	Baxter	1.8%	1.9%	3.5%
16	18	KRKA	1.9%	1.9%	-8.3%
19	19	Dr.Reddy's Laboratories	1.8%	1.8%	-4.8%
23	20	Bristol-Myers Squibb	1.3%	1.7%	28.7%
		Total:	59.4%	61.3%	

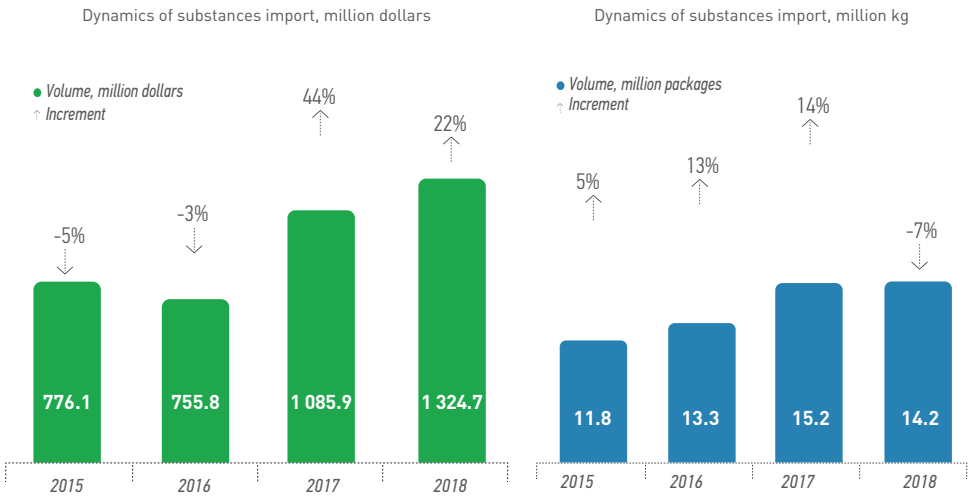
Table 28 shows the TOP 20 manufacturers by volume of drugs import to Russia by all groups of importers.

The share of TOP-20 drug manufacturers by volume of import in Russia in 2018 was 61%. Novartis, Sanofi are the largest manufacturers by volume of drugs import in Russia. Bayer rose to the third place from the fourth place. Of the TOP 20 manufacturers in terms of sales on the pharmaceutical market (see Section number 10 "Production"), three companies do not fall into the rating of importers — these are Stada, which is localized in Russia (the corporation includes "Nizhpharm" plant); Servier, whose plant was launched in 2007 on the territory of New Moscow; Astellas Pharma, localizing its drugs at the "ZiO-Zdorovie".

Import of Substances

The main issue of drug safety is the problem of small production of substances in Russia. Currently, a number of measures are being developed to support domestic producers of substances. The Ministry of Industry and Trade has started to develop amendments aimed at simplifying Russian APS producers' access to foreign markets.

In general, domestic companies are beginning to move towards the development and production of their own substances. "Pharmasyntez" will invest $ 200 million in the production of pharmaceutical substances with the planned launch of the plant in 2021.



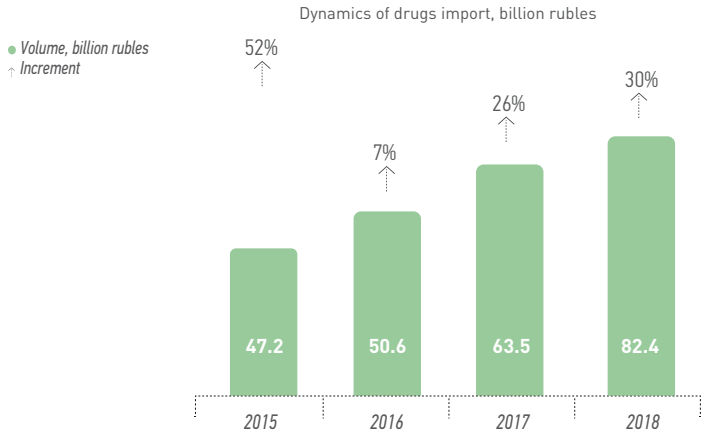


Figure 38

Volume of Substances Import

Table 29

TOP-10 Countries of Substances' Origin

Ranking	Country	Share, dollars 2018	Growth 2018/2017
1	China	**19.8%**	**11.3%**
2	France	**15.8%**	**3.6%**
3	Germany	**12.7%**	**105.6%**
4	India	**10.4%**	**11.7%**
5	Slovenia	**8.4%**	**5.5%**
6	Switzerland	**6.4%**	**47.2%**
7	Italy	**6.0%**	**-5.6%**
8	Hungary	**4.2%**	**38.2%**
9	Ireland	**3.6%**	**13.9%**
10	Spain	**2.0%**	**41.6%**
		89.2%	

Ranking	Country	Share, kg 2018	Growth, 2018/2017
1	China	**56.4%**	**-13.0%**
2	India	**16.7%**	**3.8%**
3	France	**12.2%**	**13.7%**
4	Germany	**4.4%**	**-2.9%**
5	Hungary	**2.2%**	**0.2%**
6	USA	**1.1%**	**-59.6%**
7	Slovenia	**1.0%**	**51.2%**
8	Italy	**1.0%**	**-3.7%**
9	Spain	**0.8%**	**25.3%**
10	Czech Republic	**0.6%**	**288.9%**
		96.3%	

Table 30

TOP-10 Names of Substances, Imported to Russia

Ranking	Name	Share, dollars 2018	Growth, 2018/2017
1	Insulin	**12.0%**	**164.2%**
2	Perindopril	**8.0%**	**-2.1%**
3	Tamsulosin	**4.4%**	**107.9%**
4	Raltegravir	**4.2%**	**-5.9%**
5	Hesperidine+Diosmin	**4.1%**	**10.3%**
6	Losartan	**3.6%**	**-20.2%**
7	Indapamide	**3.4%**	**7.9%**
8	Rivaroxaban	**3.1%**	**-**
9	Obinutuzumab	**3.1%**	**5667.3%**
10	Lizinopril	**3.0%**	**111.8%**
		48.9%	

Ranking	Name	Share, kg 2018	Growth, 2018/2017
1	Paracetamol	**15.4%**	**-13.1%**
2	Acetylsalicylic Acid	**15.2%**	**7.2%**
3	Metformin	**14.6%**	**30.6%**
4	Sorbitol	**6.7%**	**21.0%**
5	Ascorbic Acid	**5.8%**	**45.5%**
6	Metamizole Sodium	**3.6%**	**-25.9%**
7	Omeprazole	**3.3%**	**-15.4%**
8	Panangin	**2.5%**	**-7.1%**
9	Silicon Dioxide	**2.1%**	**2.5%**
10	Calcium Carbonate	**2.0%**	**-28.7%**
		71.1%	

"Geropharm", "Biocad", "Nativa" are not a complete list of companies that will produce medicines on a full cycle.

In the meantime, medicines produced in the country are mostly made from imported substances. Domestic companies produce only about 15% of the necessary substances, which barely covers their own needs.

The volume of substances' imports in 2018 amounted to about 14.2 million kg. In value terms, this figure is about $ 1,324 million or 82 billion rubles. Positive dynamics of supply in tonnage, which was observed in recent years, broke up last year. The country was imported by 7% less in real terms than in 2017.

In 2018, deliveries were made from 42 countries.

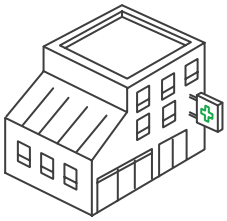
In terms of value and in real, the substances of Chinese production predominate (20% and 56%, respectively). Notably, the dynamics of substances' import from China slowed down, and has even negative values in tonnage (-13%). Collectively, the largest volume is imported from European countries — about 64% in monetary terms. France ranks first among European importing countries and second in the ranking as a whole.

Substances from the USA show a negative trend in tonnage (-60%).

In 2018, there were no deliveries from Finland and Argentina. On the contrary, Singapore, New Zealand, Hong Kong were added to the list of importing countries. In 2018, substances import from Ireland and the Czech Republic increased significantly. Substances with "Tamsulosin" INN were supplied from Ireland in 2018, which was carried out by Astellas manufacturer for the localization of "Omnik" at the plant "ZiO-Zdorovie".

In the reporting year, more than 770 different types of substances were imported. The top three substances in terms of value are: "Insulin" (12%), "Perindopril" (8%), "Tamsulosinum" (4,4%). The Top three substances in terms of value by tonnage are: "Paracetamol" (15%), "Acetylsalicylic Acid" (15%), "Metformin" (15%).

8. Pharmacy Chains



In the current market environment, obtaining reliable information about sales in pharmacies is one of the pressing issues. Pharmacy chains are associated with manufacturers via marketing contracts, but the latter are increasingly talking about distrust due to overflows, reporting, which is printed in Excel. Prompt provision of accurate data should be a prerequisite for partnership between retail and production. It is on the path of transparency that the market is now moving — first 54-FZ and online cash register, in the future — RTU drugs labeling system. 3 major pharmacy chains ("Erkapharm", "Rigla" and "Neopharm") adopted a decision on joining the Union of Professional Pharmaceutical Organizations (UPPO). Now UPPO Association will represent the entire commodity distribution chain and express the opinion of the industry.

Thus, the sources of market data may change in the next 5 years. Yet first of all, such transparency will entail a change in the conditions of the "pharmacy chain-manufacturer" interaction, which has developed today. And, probably, the big question will be, "will the large number of marketing associations that have developed on the market and continue to appear there *remain alive*"?

One of the "young" unions was organized in November 2018. The following nets decided to enter the contracts with producers representing the new pharmacy association: "Planeta zdorovya (Health planet)" (social pharmacies "Opeka (Care)"), "Maxivit" and "Social pharmacies" (Rostov). In December, the pharmacies chain "Monastyrev.rf" joined the partnership. Thus, there are more than 2,300 outlets of sales, collectively, in the Union.

A chain from Khabarovsk, consisting of two brands: "Novaya apteka (New pharmacy)" and "Minitsen Pharmacy" (161 outlets in 32 cities and towns) joined the pharmacy partnership "IRIS". The entry of a new partner allowed the Association to enter a new region — the Far Eastern Federal District. As a result, the total number of outlets increased to 1,563 pharmacies at the end of 2018.

Thus, a new trend can be fixed in the market — the creation of partnerships by medium and large (more than 1,000 outlets) chains. Such kind of partnership allows chains to improve financial performance, and manufacturers — to improve their management.

In addition, small chains and single outlets are also combined. Marketing Alliance of pharmacies "ProApteka", by the end of 2018, brought together more than 5,700 participants in all regions of the Russian Federation. Within the framework of the Alliance, partnerships have been established than 100 manufacturing companies for the joint promotion of medicines, as well as of beauty and health products with more. Pharmacies-members of the Alliance enjoy benefits for the purchase of

drugs, participating in marketing programs of manufacturers, receiving financial guarantees from "PROTEK" Implementation Center. They also have access to their own trademarks (CTM). By early October more than 1,000 members of "ProApteka" marketing Alliance moved to cheque reporting to pharmaceutical manufacturers. Since the 2Q2019, "ProApteka" plans to scale the franchise under brands "ProApteka" and "ZdravCity".

Creating a pharmacy association on the basis of a large distributor is also becoming a trend. In 2017, the marketing Union "SOZVEZDIYE (CONSTELLATION)" appeared. It is developed by "Puls". According to the year results, it has already acquired around 1,600 pharmacies.

Against the background of consolidation processes, there is a reverse trend. For example, since 2019, Kursk chain "Pharmacy Traditions" leaves the pharmacy Association "ASNA". According to experts, this is due to the owner's desire to independently form a commodity matrix and to build relationships with manufacturers.

Reformatting the Russian Pharmaceutical Market in favor of Federal Pharmacy Chains has become an irreversible reality. Today, major players are actively entering regional markets — global consolidation and unification.

> "Reformatting the Russian Pharmaceutical Market in favor of Federal Pharmacy Chains has become an irreversible reality"

In the framework of its development strategy, in 2018, "Melodiya Zdorovya (Melody of health)" pharmacy chain (owned by "Katren") absorbed several pharmacy chains: "Medicina Dlya Vas (Medicine for you)" (87 outlets in Moscow and Moscow region), "Stoletnik" (57 outlets), "Russkiy Gospital (Russian hospital)" (13 pharmacies in Reutov), "Gorniye Vershiny (Mountain peaks)" (13 outlets in St. Petersburg).

"April" group of companies swallowed "Kazanskiye Apteki (Kazan drugstores)" chain (112 outlets in Tatarstan). Most of the pharmacies started working under "Aptechniy Sklad (Pharmacy warehouse)" brand. Market experts estimated the deal as 400-600 million rubles.

"Sotsial'nyie Apteki (Social pharmacies)" acquired several chains in Rostov region: pharmacy chain "Yug-Pharma (South-Pharma)" (about 50 outlets) and several pharmacies "Panacea-Pharm".

The Federal Chain "Pharmland" adheres to tactics of strengthening its positions in regions by purchase of local players. So, in the spring of 2018, they announced the purchase of two regional players in the Urals — "Mediki (Medical workers)" (Chelyabinsk region) and "Farmaty" (Ekaterinburg). As a result, "Pharmland" added 18 pharmacies to its outlets in the Chelyabinsk region, including 12 with its own premises, and 22 in Yekaterinburg.

In 2018, the pharmacy chain "Rigla" (part of the "PROTEK") was actively developing not only in Moscow and Moscow region, but also in the Russian regions. It acquired several pharmacy chains: "Apteki 003 (Pharmacies)" (29 outlets in Pskov), "Panacea" (31 outlets in Kostroma and Yaroslavl), "Apteka-city" (14 outlets in Yekaterinburg), "Atec" (28 outlets in Crimea). In the reporting year, "Rigla" also

closed the deal on the assignment of premises lease of Irkutsk pharmaceutical retailer "Rusichi", so now the chain will open 8 outlets of "Bud' Zdorov (Be healthy!)" neighbourhood shop pharmacies, in Irkutsk. Already in 2019, a deal is announced to acquire a stake in "Apteka №313", which will allow the Federal Player to strengthen its position in Nizhny Novgorod market.

In addition, "Rigla" has launched a franchise program in those regions where the chain is less represented. The franchise package includes not only a sign and corporate identity, but also price and assortment matrices, procurement automation, control of balances and loyalty programs. 26 pharmacies were opened by August 2018; another 20 outlets have opened recently.

But if "Rigla" prefers to buy a small regional chain, "Erkapharm" takes on larger players. So, in 2018, "Erkapharm" bought a large Moscow chain of pharmacies-discounters "Samson Pharma" (59 outlets) with a record average check for Moscow— 1,290 rubles. "Samson Pharma" is a significant part of the market in Moscow that allowed "Erkapharm" to bypass one of its main competitors in the rating — a "Pharmacy Chain 36,6".

Transactions in 2018 led to the fact that in total the TOP 20 chains grew by 17% in 2018 compared to the same period in 2017. Share of TOP-20 was 58%, which is 7% higher than in 2017. The figure shows that the processes of mergers and acquisitions in the last 3 years have more affected the TOP 10, which led to an increase in the concentration of 20% in this segment. The share of the TOP 3 increased by only 1% in comparison with 2017.

Figure 40 shows growth of TOP-20 pharmacy chains by sales turnover and number of outlets in 2015-2018. In the last three years there has been a significant increase in the number of outlets, as the chain began to grow actively due to the merger and acquisition transactions. The growth in the number of TOP-20 chains is 134% to the level of 2014. In the ranking of 2018, 10 chains already have over 1,000 outlets. Together, the TOP 20 players are managed by more than 58% of all pharmacy outlets in Russia, of which there

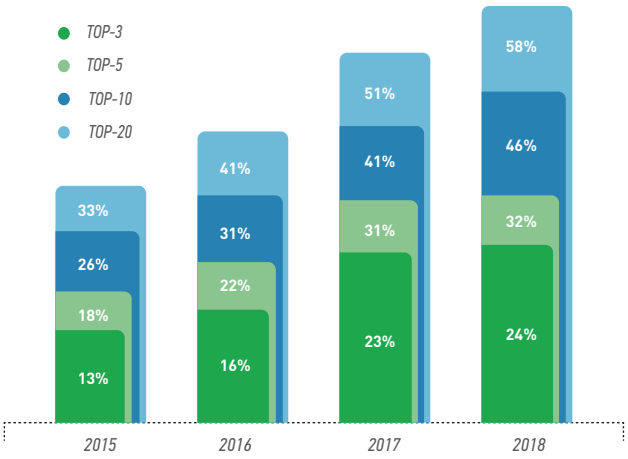


Figure 39

Concentration of TOP-20 Pharmacy Chains

are more than 63 thousand at the end of 2018 (the number of pharmacy outlets increased from 61.0 thousand in 2017).

Table 31 shows the ranking of pharmacy chains in commercial sector with quantitative and value growth parameters in 2018.

In recent years, the rating has changed quite a lot: a few big names have disappeared from it, there are new alliances, and there is a constant rotation of players within the TOP 20.

One of the relatively new players is consistently in the rankings. By the end of 2018, the Mega Pharm chain already has about a thousand pharmacies in 30 regions of Russia. Now it combines pharmacies with signs "A-Mega", "Da, Zdorov!", as well as premium pharmacies "Azbuka LIFE".

"Evalar" continues to expand its own pharmacy chain. The company made a bet on the opening of flagship pharmacies in major cities: over the past six months, 8 new outlets have opened in Moscow, St. Petersburg, Volgograd, Nizhny Novgorod and Samara.

Still the position of one of the oldest pharmacy chains in the ranking continues to go down. This is due to the development strategy of the chain, and another change of the owners. In March 2018, it became known that "36,6" shareholders divided the pharmacies. The exit condition for Vladimir Kintsurashvili and Ivan Saganelidze was the transfer of pharmacies to these businessmen. They became the owners of 12 premium retail outlets operating under the brand A. v. e. Luxury, as well as of St. Petersburg chain "Pharmakor", which was attached to the " Pharmacy chain 36,6" at the end of 2017. Therefore, in 2018, after the change of the team, "36.6" again got engaged in the reduction: more than 20% of pharmacies that were unprofitable were closed. At the end of the year, the chain kept a little more than 1,300 outlets. "36.6" is also going to develop themselves in regions and enter the public procurement market, as the pharmacy direction of the group remains unprofitable.

Figure 40

Dynamics of TOP-20 Pharmacy Chains Growth of Sales Turnover and Number of Outlets

Dynamics of TOP-20 pharmacy chains (commerce)

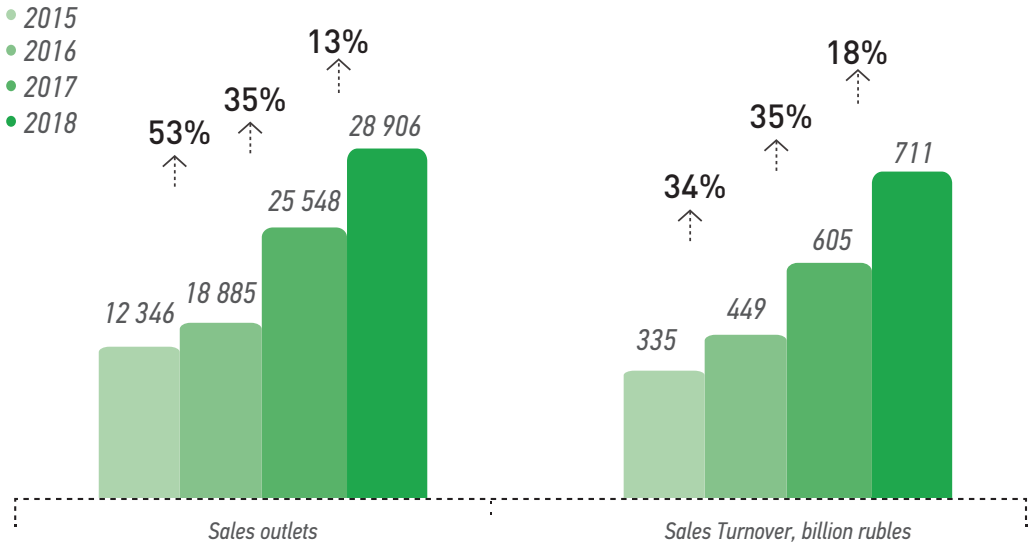


Table 31

Chain Ranking by Sales Turnover in 2018 on the Commercial Pharmacy Market

Ranking	Pharmacy Chains	Value. billion rub.	Share in commercial market	Turnover increase compared to	Outlets number
1	«АСНА»	162.2	13.2%	2%	8 585
2	Rigla	69.4	5.6%	24%	2 417
3	Erkapharm group	64.9	5.3%	48%	1 266
4	Pharmacy chain 36.6	50.6	4.1%	-12%	1 319
5	Implosia	49.1	4.0%	5%	2 710
6	IRIS [1]	40.7	3.3%	14%	1 563
7	Planeta zdorovya	35.7	2.9%	14%	1 650
8	Neo-pharm	34.9	2.8%	37%	606
9	Vita	32.5	2.6%	63%	1 700
10	April	31.0	2.5%	43%	1 135
11	Pharmland	25.0	2.0%	25%	1 114
12	Pharmaimpex	18.5	1.5%	9%	720
13	Apteka-Timer	17.2	1.4%	29%	869
14	36.7C&Maxavit	15.4	1.3%	11%	488
15	Melodiya Zdorovya	14.0	1.1%	42%	830
16	Pharmaceut+	12.8	1.0%	27%	405
17	Mega Pharm	10.4	0.8%	136%	835
18	IDEA[2]	9.7	0.8%	4%	204
19	Nevis	8.9	0.7%	7%	427
20	Zdorov.ru	8.7	0.7%	24%	63
21	Gubernskiye apteki	7.8	0.6%	7%	277
22	Aloe	6.9	0.6%	33%	268
23	Monastyrev.rf	5.9	0.5%	7%	47
24	Zdorovye (Ust'-Labinsk)	5.8	0.5%	34%	144
25	Pharmeconom	5.4	0.4%	8%	110
26	Antey	5.2	0.4%	14%	224
27	Deshyovaya apteka	5.0	0.4%	3%	80
28	Volgopharm	5.0	0.4%	-4%	157
29	Peterburgskiye apteki	4.8	0.4%	9%	90
30	Aliya-pharm	4.1	0.3%	2%	145
	Rating of Marketing Associations				
	ProApteka	66.1	5.4%	48%	5 740
	MFO	44.8	3.6%	3%	2 550
	Sozvezdiye	16.2	1.3%	NEW	1 577
	Vesna	15.5	1.3%	26%	1 242
	PharmHub	11.2	0.9%	89%	680

[1] "IRIS" includes the following regional pharmacy chains: «Pharmakopeyka», «Apteki Farmani», «Zdes' Apteka», «Tvoy doctor», «HELMI», «Aptechestvo», «Gorodskaya apteka», «Novaya apteka», «Apteka Minitsen»,
[2] «IDEA» brings together chains «Rodnik Zdorovya», «LekOptTorg» and «Apteka Dlya Berezhlivykh».

Despite the large number of working pharmacies and the difficulties that have recently been on the market, pharmacy retail remains attractive for the opening of new sales outlets and the emergence of new players. This is confirmed by the plans of the largest retailer "Magnit" for the development of its own direction "Magnit Apteki". Now around 100 pharmacies are working under this name. These shops are present in many regional towns and townships. Most of the pharmacies are also opened in villages with the population of 3-5 thousand people where there is no competition with Federal and regional chains, but where there is already a "Magnit Cosmetics". In general, "Magnit" pharmacy chain has a way to grow, as the bridgehead in the face of "Magnit Cosmetics" today has almost 4 thousand outlets across the country. In November, "Magnit" has completed the acquisition of a pharmaceutical distributor "SIA International". The retailer justified the interest in the transaction by "SIA"'s logistics and warehouse infrastructure for its range of cosmetics and pharmaceutical products.

Of course, the review of the pharmacy segment will be incomplete if we do not pay attention to legislative initiatives that are being actively discussed and continue to be discussed in the market.

"Despite the large number of working pharmacies and the difficulties that have recently been on the market, pharmacy retail remains attractive for the opening of new sales outlets and the emergence of new players"

Discussions on the access to the over-the-counter drugs in the stores have been hold since 2012. And finally, in 2018, this issue was put to an end. The Cabinet of Ministers stopped working on a resonant bill of the Ministry of Industry and Trade, allowing retailers to sell OTC drugs in the presence of an appropriate license. The project was discussed at different levels and received sharply negative feedback from the expert community. Pharmacies remain the only legal channel for the sale of medicines; so many representatives of the grocery retail are developing their own pharmacy projects.

Probably, this topic has lost its relevance also because pharmacy chains actively cooperate with grocery retail and develop a joint format — "shops – pharmacies within". Many large pharmacy chains have similar projects. In 2018, "Melodiya Zdorovya " also began to work at it. The chain actively cooperates with "Dixi" retailer, opening pharmacies in the checkout areas of the store. The parties have already launched 32 points, in early 2019 it is planned to open 28 pharmacies more.

At the same time, another question which can significantly change the market situation remains open. We are talking about the Internet trade in medicines. To date, it is prohibited by law. Let's recall that in December 2017, the State Duma adopted a bill on Internet Drug Trade developed by the Ministry of Health of the Russian Federation in the first reading. After that, the work on the document was put on ice. In 2019, it is planned to resume discussion of the draft law On Electronic Trade in Medicines that can be Purchased without a Prescription. The Ministry of Health is cautious about the Internet trade in prescription drugs. "It is necessary to see how the sale of over-the-counter drugs will take place after the adoption of the relevant law by the State Duma." Russian President Vladimir Putin also says that "this is where we need to move." Therefore, there is no doubt that the resolution

of the Internet trade in medicines will happen in the near future.

The trend of moving the para-pharmaceutical range from pharmacies to "big retail", including online, is already gaining momentum, especially for cosmetics.

Of course, pharmacy chains and distributors have long been preparing for online trading. Many of them already have their own websites with a system of booking medicines in a specific pharmacy chosen by the consumer.

Similar services on ordering medications are provided by major distributors — "Katren" (Apteka.ru) and "Protek" ("Zdravcity"). Now Apteka.ru is the largest service in Russia for searching and ordering pharmaceutical products, in 2018, it was the second year in a row among the five largest pharmacy sites in the world (SimilarWeb rating). And in the rating by Data Insight Analytical Agency, which forms the rating of E-Commerce in Russia, Apteka.ru took the 21st place in the overall ranking; it is 2 positions higher than a year earlier. According to the rating, the volume of sales and the number of orders made with the help of the service in 2017 increased by 30%. In its total number of orders Apteka.ru takes the 6th place.

Recently, in addition to the official pharmacies' websites, there are many marketplaces of pharmacy products in the market. Here you can order the delivery of medicines to the pharmacy, and then pick up the order. In September 2018, Ozon.ru refused joint projects with companies "36,6" and "Zdravcity", as it was not profitable to be just an "online showcase" of medicines. As a result, the online store Ozon.ru received licenses for pharmaceutical activities (in Moscow and Tver), and opened two offline pharmacy points. The company has caused a stir in the market by testing the drug delivery system.

In April 2018 "Vse apteki" (vseapteki.ru) service was launched by Mail Group which is now working only for ordering. More than 28 thousand pharmacies are connected to the system.

In mid-May, "Yandex.Market" company and "Sberbank" launched a marketplace "Beru (I Take it!)" (beru.ru) which will be developed by the pharmaceutical company "Protek". In this category it will be possible to buy more than 70 thousand commodity items: medicines, medical devices and cosmetics.

"Yuteka" company has launched an app that allows you to find and book medicines using a mobile application. The principal difference of the new service is cooperation with several large pharmacy chains and pharmaceutical distributors, so that consumers can find the best offer on the market.

By the way, foreign experience shows that with the legalization of online drug trade, about 10% of sales are carried out online, the remaining sales are realized within the framework of traditional pharmaceutical retail. Therefore, perhaps, this channel will not greatly affect the development of traditional pharmacies. The main thing is to precisely define all the rules and laws under which the Internet trade in medicines will have to get: how it will be possible to trade in medicines and who can deliver them.

It should be noted that the activity of Internet resources even for booking and ordering medicines also falls under state regulation. Federal Law No. 250-FZ "On Amendments to the Law of the Russian Federation "On Protection of Consumer Rights", which entered into force on January 1, 2019, expands the scope of legal regulation of relations with consumers and includes Internet platforms that aggregate information about goods and services that were not previously responsible to consumers. The new law also applies to pharmacy aggregators.

According to the information published on the website of Rospotrebnadzor, the law introduced the concept of "The Owner of Information Aggregator about Goods (Services)", as well as the obligation of the owners of such services to provide consumers with information about themselves and the seller (contractor), as well as all changes in such information. Aggregators are also responsible for consumer losses due to inaccurate information about the product or the seller.

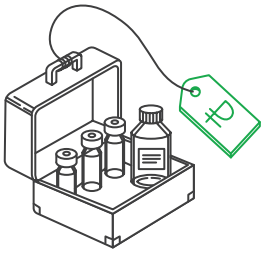
Public organization for consumers' rights protection "Public Consumer Initiative" presented the data of the study of leading online stores and aggregators. Perpetrators, who belong to the pharmacy aggregators, were among them. So, 5 Internet addresses from "Pharmacies" category immediately got in the category of "Shops with no names of the Seller": farm-m.ru, likitoriya.com, smed.ru, apteka-klassika.ru, amt.allergist.ru and one optic: optix.su. 4 of the 5 online pharmacies listed above also demonstrated the absence of a legal address of the seller on the website. The stores, which do not have the actual address on the website, are Apteka.ru, zhivika.ru, likitoriya.com, smed.ru.

Private pharmacy chains are mostly in the ranking, and on hearsay. Despite this, in Russia there are about 180 state pharmacy chains, which combine about 5.4 thousand points of sale. Of these, about 100 exist in the form of State and Municipal Unitary Enterprises (and their variations). State and Municipal Unitary Enterprises bring together a total of 3.0 thousand pharmacies which is slightly above 3% of the market. State and Municipal Unitary Enterprises meet the needs for narcotic drugs; only they have production departments, most often it is in them that beneficiaries can receive drugs within the Drug Reimbursement Program.

The Government has submitted a Draft Law № 554026-7 to the State Duma: "On Amendments to Certain Legislative acts of the Russian Federation (in terms of Banning the Establishment and Operation of Unitary Enterprises)." The document assumes that only the State Unitary Enterprises and Municipal Unitary Enterprises in the sphere of defense, state security or natural monopolies will remain on the market. The Government intends to liquidate all other enterprises before January 1, 2021. Thus, about 3 thousand points can be closed after the signing of the relevant law.

2018 was a difficult and ambiguous year for pharmacy retail. The changes will continue in 2019. Consolidation is a trend that will prevail in the market for some time. But what will this process be: a "rockfall" that will sweep away single pharmacies or a "soap bubble" that will burst because of its own size?

9. Rating of Russian Pharmaceutical Distributors



In the complex relationship between the pharmacy chains and the manufacturer, the distributor has recently been the aggrieved party. The market has not seen such a number large wholesale companies leaving the market in recent years.

Over the past few years, three players have disappeared from the rating and from the market: "Imperia-Pharma", "Oriola", Alliance Healthcare. However, this did not prevent Alliance Healthcare ("Apteka-holding") to expose financial claims to Yekaterinburg network "Valeta", which were found unfounded by the court. Now "Valeta" intends to collect its expenses associated with litigation from the distributor.

In 2018, the bankruptcy procedure of "ROSTA" was held. In January, the company introduced surveillance. Despite the sale of the pharmacy chain "Raduga ", a part of "ROSTA" group to "Erkapharm" the company failed to pay off all the debts. "ROSTA" group's plant in St. Petersburg is for sale. The property is pledged to "Sberbank", which the company has owed over 4 billion rubles. Pharmaceutical distributors also can claim it. Here one can consider fast-growing companies that are either not yet represented in St. Petersburg, for example, "Pharmcomplect", or that may be interested in developing their presence in the region: "Grand Capital", "Puls" or "Profit-med". The equipment of the plant, the production capacity of which reaches 1 billion tablets or capsules per year, is pledged to the manufacturer of medicines "Nizhpharm" (Russian structure of the German Stada).

That is why distributors speak positively about the prospects of switching only to logistics services. The most common problem is not with the major networks, and small and medium-sized ones. As a result, being a logistics operator becomes more reliable for them. In 2017-2018, many pharmacy chains began to switch to direct contracts with manufacturers which also weaken the pharmaceutical distribution market. Manufacturers are just getting used to the new possibility. But there are already representatives of the industry who are actively implementing the practice of using the distribution link as a logistics mono-channel for a certain category of pharmacy chains.

Despite this trend, the distributor is an important link in the distribution chain on the pharmaceutical market. In 2018, in order to protect themselves financially, "wholesalers" had to change the relationship with pharmacy chains towards tightening the process of goods shipment. Distributors began to demand additional guarantees for the return of receivables from pharmacies (insurance or bank guarantees). Conditions for manufacturers have also been tightened: suspension of payment in case of reaching the threshold volume of effluents for specific products.

> Moving to more stringent conditions of relations with pharmacies, distributors do not lose anything

Thus, since 2018 "Protek" has been issuing tied credits under bank guarantees, as well as demanding guarantee contracts. For some of the networks that refused to provide the collateral, the tied credit limit was reduced. Thus, the company insures the business, preventing the growth of accounts receivable.

The distributor of "Puls" also tightened its work with pharmacy chains, transferring about 70% of the company's customers to providing financial guarantees. The wholesaler mainly requires guarantees from small pharmacies, respectively, this leads to a decrease in the share in the supply of small turnover customers. This policy is implemented despite the negative impact on the company's revenues.

In order to reduce bad receivables "Katren" published a register of unscrupulous counterparties with an indication of the amount of debt and penalties collected by the court. The table shows the name of the legal entity, the region, the availability of collateral, the last names of directors and owners at the time of filing lawsuits, as well as the sale price. The list included 417 debtors.

Moving to more stringent conditions of relations with pharmacies, distributors do not lose anything. Almost all of the top 10 companies within the holding have a retail network, which will be able to generate a stable turnover. At the same time, suppliers continue to diversify.

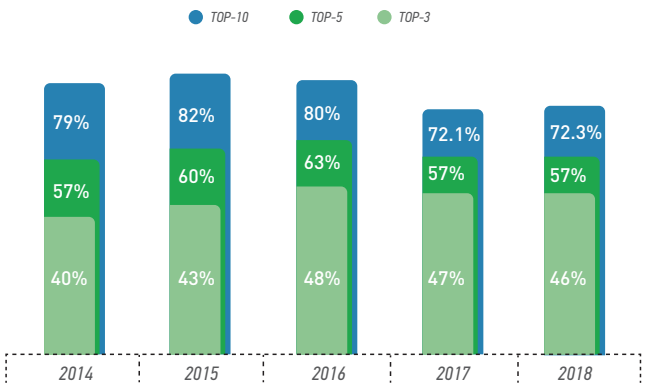
The trend of recent years is marketing alliances. "Protek" (ProApteka) and "Puls" (Sozvezdiye) already have such ones.

In addition, companies develop the virtual direction: "Katren" owns service for online booking and ordering pharmacy range "Apteka.ru", "Protek" develops the Internet portal of the order of medicines and goods for beauty and health, "Zdravcity". Within the framework of these projects, distributors are preparing, among other things, for permitting the Internet trade in medicines.

So, in October 2018, "Utkonos" launched a new direction "Apteka". There is an opportunity to order medicines on the online hypermarket website. The partnership was signed with the online drugs booking service "Zdravcity". Beside "Utkonos", "Zdravcity" also works with Internet sites beru.ru, uteka.ru, vseapteki.ru.

Figure 41

Concentration in the Distribution Segment



Both "Katren" and "Protek" actively advertise their services in the mass media. In the first stage of the campaign, which took place in November-December of 2018, "Zdravcity" online medicines ordering service revenue increased almost three times – to 180% in comparison with the previous period. In the second half of 2019, the advertising campaign will be resumed in cities with a population of 100 thousand people. Thus, the population is getting used to "buy" medicines on the Internet.

Changes in the principles of distributors' work affected the results and dynamics of the leaders. The volume of the pharmaceutical market in Russia, in terms of distributor price, was 1,401 billion rubles, which is 5% higher than in 2017. At the end of 2018, the total share of the 10 largest distributors in the pharmaceutical market was 72.3%. Compared to 2017, this figure has not changed: the increase in concentration was +0.2%. Yet there has been a positive trend after a three-year negative trend. The top 10 occupied 82% of the market in 2015.

The leaders of the rating at the end of 2018 show a reduction in revenue, and then of the market share. The composition of the first three players has not changed compared to 2017, but the difference between the companies has already approached the limits of statistical error, so, in 2019, the struggle for leadership will unfold with renewed vigor.

Judging by the results of 2018, there was a drop in sales of "Protek" Implementation Center within 7%. This is an expected result for the company, which was the result of a new credit policy aimed at minimizing risks and clearing the market from unscrupulous players. However, "Protek" still tops the rating of distributors.

The second line of the rating is taken by "Katren". Wholesale turnover in the pharmaceutical market in 2018 also decreased by almost 8%, which led to a decrease in the share by 2.1%. At the same time, "Katren" is the only national pharmaceutical distributor which was noted by Roszdravnadzor in 2018. The list of companies that distinguished themselves in the implementation of state programs to improve the quality and availability of drug and medical care, as well as in the field of circulation of medical devices and medicines was published on the Agency's website. The practices implemented by "Katren" in its warehouses are recommended by Roszdravnadzor for use in all regions. "Katren" was awarded for the implementation of the quality management system in accordance with the requirements of GDP good practices.

"Puls" continues to increase the turnover and has almost approached the leaders. The gap between the first and the third place is only 1.4%. Individual approach to customers and suppliers allowed developing mutually beneficial solutions, which led to a qualitative improvement in the company's performance. Effective work on optimization of logistics processes has increased operational efficiency and ensured sustainable growth in an unstable economic situation. "Puls" has already reached the second line, coming ahead of "Katren" with its turnover for the second half of 2018.

The companies located below the 6th place demonstrate high positive dynamics (with the exception of "SIA"), and it is due to them that the concentration in the distribution segment grows. We shall note that "Grand Capital" rose from the 8th place in 2017 to the 6th place in the ranking for 2018; at the same time, the player shows the maximum growth rate in the TOP 10. "Avesta Pharmaceuticals"

moved to the 10th place (+4 positions), demonstrating an increase in sales by 48%.

"Scandals" surrounding "R-Pharm" did not abate for the whole year. The distributor has repeatedly been seen in violations of state contracts. As a result, the Ministry of Health sent several lawsuits to the court against the unscrupulous supplier. Previously, FAS suspected the Ministry of Health and "R-Pharm" of collusion. This conflict did not prevent the company from showing positive dynamics in the market and maintaining its market share.

In 2018, the fate of "SIA" distributor was determined. The purchase, which many have already begun to doubt, still took place. The new owner of "SIA" was the retail company "Magnit", the transaction was completed in the autumn. The pharmaceutical company was estimated as 5.7 billion rubles taking into account the debt. The deal will be paid in shares of "Magnit" for this amount, purchased under the extended buy-back program.

Having bought "SIA" "Magnit" will be able to build an effective logistics for the network of pharmacies and provide synergy with the stores of drogerie format. In 2019, "Magnit" plans to open about 2 thousand pharmacies integrated into drogerie stores, as well as into the food formats of the retailer — "near the house" stores and supermarkets. Thus, both in the rating of distributors and in the rating of pharmacy chains, a new player may appear.

Table 32

TOP-10 Distributors in the Pharmaceutical Market

Rank 2018	Distributor	Sales volume, billions of rubles	Increase	Share
1	Protek	224.7	-7.1%	16.0%
2	Katren	216.6	-7.9%	15.5%
3	Puls	205.0	24.0%	14.6%
4	Pharmcomplect	80.0	22.0%	5.7%
5	R-Pharm	65.9	1.5%	4.7%
6	Grand Capital	58.9	59.0%	4.2%
7	BSS	52.4	13.2%	3.7%
8	Profit-med	43.4	34.0%	3.1%
9	SIA	40.0	-32.9%	2.9%
10	Avesta Pharmaceuticals	26.0	48.0%	1.9%

10. Manufacturing

In the development of the manufacturing segment of the pharmaceutical market, there are a number of issues that have been on the hearing for the last few years: GMP, import substitution, SPIC. But in 2018, one of the high-profile topics discussed in the industry was the development of the labeling project.

Despite the technical unavailability of the labeling system and the participants for the launch, a draft law on medicines' labeling was signed in December 2018. The history of the issue began with Federal Law No. 425 of December 28, 2017 "On Amendments to the Federal Law "On Drug Circulation", which provided for the creation and implementation of the state information system for monitoring the movement of medicines from the manufacturer to the end user using control identification signs, starting from January 1, 2019. The main objective of the system is to ensure transparency and the ability to track trade in the pharmaceutical market, to prevent the spread of counterfeit and fake products.

According to Russian Federation Government Decree №1557 of December 15, 2018, labeling will be made in the DataMatrix format in accordance with the GS1 International Standard. The uniqueness of the Russian labeling system is that it will be uniform for all trading groups, and by 2024 it will cover the entire market. All participants of the turnover will work in a single space — without adapting their business processes to different systems or maintaining multiple accounts.

The stumbling block in the issue of labeling for most participants has become the length of the crypto code "tail". In February-March 2018, the participants of the pilot project learned that a protective "crypto-tail" had been introduced, increasing the size of the marking data by 92 characters (88 characters — the cipher and 4 characters — the key). In total, the 2D code has grown to 119 characters. As a result, the quality of printing and data recognition in the system has significantly decreased. This means that there are risks that the packaging which is already in the process of turnover will cease to be read by scanners. Despite the adoption of the final law on labeling, the decision on the length of the crypto code remains open.

Since November 1, 2018, there has been a transition of the information system of the experiment on drugs labeling from FTS to the "Center for the Development of Advanced Technologies". According to that, more than 11,800 participants

> The uniqueness of the Russian labeling system is that it will be uniform for all trading groups, and by 2024 it will cover the entire market

(65% of all manufacturers, as well as the largest wholesale enterprises, medical organizations, pharmacy chains) have been registered in the experiment on drugs labeling. In total, since February 2017, 1,800 drugs have been registered in the information system for monitoring drugs movement, 17,965,737 packages of drugs have been marked.

2019 is the last year of voluntary inclusion in the national drug labeling program. Russian Federation Government Decree №1557 of December 15, 2018 also defined the terms of labeling implementation: it will become mandatory from January 2020; for manufacturers of orphan drugs included into the state program "12 high-cost ICDs", as well as those from the list of vital and essential drugs. Entering information about all operations into the system will become mandatory from October 2019.

The introduction of the rules of Good Manufacturing Practice (GMP) in Russia should fully work from 2021: the certificate of GMP conformity will be a mandatory document for all pharmaceutical companies in the EAEU member states.

For three years (from 2016 to 2018), the State Institute of Medicines and Good Practices conducted 1,376 inspections checking the compliance with GMP standards in the production of medicines in 68 countries, of which 667 inspections in 57 countries in 2018. At the moment, about a third of pharmaceutical companies have not been tested. In addition, there are examples of entire series of drugs being withdrawn from the market if they are produced by manufacturers who have not received a certificate on compliance with GMP rules.

The Ministry of Industry and Trade of the Russian Federation assigned the State Institute of Medicines and Good Practices with the main function of checking, inspecting sites for the medicines production abroad. The first country in which the Russian Inspectorate worked is Slovenia. A schedule of inspections for 2019 has been formed; inspections in Spain, Palestine, Chile are expected. It should be noted that the Russian Inspectorate was one of the first in the world to introduce the practice of inviting colleagues from other inspectorates as observers.

The issue of import substitution in the drug market in 2018 has existed for 5 years and still it remains one of the priority tasks, as it is not possible to achieve the planned indicators, despite all the measures of state support of domestic production.

The most important innovation of the second half of 2018 was the publication of a new act on preferences of domestic products — the order of the Ministry of Finance of the Russian Federation №126н, according to which the preference for mixed applications was canceled — now an application will be considered foreign, if at least one package of a foreign-made drug is offered in it. There was almost a complete ban on the replacement of drugs during the execution of the contract on foreign drugs — it won't be possible to change any foreign drug to another foreign one, even if domestic drugs are not available on the market. In addition, the order introduced additional preferences for manufacturers of Russian medicines, which, since November 2018, will be able to sell medicines to the state 25% more expensive than the minimum price of the contract. We are talking about public procurement of drugs produced from domestic active pharmaceutical substances.

Another measure to increase the share of drugs produced in Russia, is a Special Investment Contract (SPIC). A special investment contract is an agreement between the investor and the Russian Federation (or its subject), which sets out the obligations of the investor (to master the production of industrial products within the prescribed period) and the Russian Federation or its subject (to guarantee the stability of tax and regulatory conditions and to provide incentives and support measures).

"NovaMedica" and "Octapharma-Pharmimex" have become SPIC holders in the pharmaceutical industry in 2018:

- The fifth SPIC was signed on 7 March 2018 between "NovaMedica" ("ROSNANO" portfolio company), the Ministry of Industry and Trade of Russia and the administration of Kaluga region. Under the contract, "NovaMedica" will invest about 3 billion rubles into the construction of "Vorsino" industrial park in Kaluga region. The plant will localize 24 sterile injectable drugs Pfizer related to vital and essential drugs. Among them there are antineoplastic agent, including child treatment, for general anesthesia, hemostatic and anti-inflammatory drugs, for the treatment of severe bacterial and fungal infections. In addition to localized, the company plans to produce drugs developed within its own R&D program.

- On September 25, 2018, SPIC was signed between the Ministry of Industry and Trade of Russia, the Government of Ryazan region, "Octapharma-Pharmimex" LLC, as well as "Pharmacevticheskiy Import, Export" JSC and "Skopinskiy pharmacevticheskiy zavod" LLC. As a part of the project, the company will invest more than 5 billion rubles. The contract provides for the implementation of an investment project for the creation and development of industrial production of a full cycle of biopharmaceuticals, substances and human blood plasma products, including those that have no analogues, produced in Russia, with a production capacity of 600 thousand liters per year.

In 2018, many production sites were announced and launched: they will allow not only to implement the import substitution program, but also to produce innovative medicines in Russia.

Localization and import substitution stimulated foreign manufacturers to conclude agreements with Russian companies on the production of their drugs at their capacity. As a result, 7 plants owned by foreign manufacturers appeared in Russia, more than 80 companies localized production at the sites of domestic enterprises.

The process was continued in 2018:

- Gilead Sciences Companies and "Pharmstandard" signed the agreement in which framework, the production capacities of "Pharmstandard" company served the base for the production of drugs "Sovaldi" ("Sofosbuvir" INN) for chronic hepatitis C treatment and of "Truvada" ("Emtricitabine/tenofovir fumarate disoproxil" INN) for HIV treatment. The first batches of localized medicines will enter the market in 2019.

- Takeda International Pharmaceutical Company localized a full cycle manufacture of an innovative drug for patients with multiple myeloma "Ninlaro" at its plant in Yaroslavl. The latest high-tech line, equipped with equipment for labeling, will make it possible to produce 200 thousand capsules of the drug per year.

Table 33 *Key Projects on Organization of New Manufactures in Pharmaceutical Market in 2018*

Initiator company	Region	Description of manufacture	Capacity	Volume of investments
JSC "Veropharm" (Abbott group)	Belgorod	The production line of the hormone drug "Duphaston" for the maintenance of women's reproductive health.	200 mln of pills per year	11,4 bln rubles
"Biokhimik" JSC	Saransk	More than 20 types of both import-substituting and original antibacterial drugs (by 2020).		500 mln rubles
"Advanced Trading" LLC (Advanced)	Belgorod region	The first stage of the plant for the production of anti-tuberculosis drugs. In the future, the plant will produce drugs for the treatment of tuberculosis, gastroenterological and other socially dangerous diseases.	The production capacity of the first stage for the production of solid dosage forms is 100 tons per year	1,5 bln rubles
"Pharmstandard-Leksredstva" JSC	Kursk region	A new site for the production of import-substituting anti-asthmatic drugs (powders), 14 items.	More than 5,4 mln packages per year	1,9 bln rubles
"Novo Nordisk" LLC	Kaluga "Grabtsevo" site	Production of insulin from the original substance on a full cycle in cartridges, injectors and disposable multi-dose syringe pens "FlexPen".		8 bln rubles
"PharmFirma "Sotex" JSC ("Protek" group)	Belikovo village Sergiev-Posad region	Department for the production of pre-filled syringes.	13 mln of pre-filled syringes per year	245 mln rubles.
"Geropharm" LLC	Pushkin	Production of active pharmaceutical substances for original products of the company, as well as APS of genetically engineered insulin and insulin analogues.	1,000 kg of substance per year	Total investment in the project - 3,3 bln rubles.

“Medtekhservis” LLC	Irkutsk region	Production of glucometers and test strips for them to measure blood sugar levels based on technology using GDH-FAD enzyme and electrodes carbon sputtering.	3 mln units of medical products per year	470 mln rubles
“NTFF Polisan” LLC	St. Petersburg	The third stage of the plant for the production of a full cycle of cardiological drug “Xarelto” by Bayer, as well as the expansion of the production of its own antiviral drug “Cytoflavin”.	From 300 mln of pills per year (2 shifts) to 550 mln of pills (3 shifts, without days-off) https://medi.ru/news/15341/	More than 4,5 bln rubles
“Vector-Bialgam” JSC	Novosibirsk	A line for bottling injectable dosage forms of drugs (vaccines, serums) into syringes, including vaccines against hepatitis A.	It is going to increase from 1 to 10 mln syringe doses per year	650 mln rub
“ZiO- Zdorovye” CJSC	Podolsk	The second production line for the production of drugs included in the list of VED used in the treatment of the respiratory system diseases, gastrointestinal tract, genitourinary system.	More than 1,2 bln of pills and capsules per year	1,214 bln rubles
“Petrovax Pharm” Research and Production Association	Moscow region	Production of tetravalent vaccine for the prevention of influenza“Grippol® Quadrivalent” on a full cycle technology. The third line for the production of substances, tablets and suppositories.	The volume of production of pharmaceutical substances increased by 2.5 times, that of pills increased by 7 times, that of suppositories increased by 4 times	1 bln rubles

- Takeda actively involved in development and production of innovative cancer drugs. In 2018, the pharmaceutical corporation localized "Brentuximab Vedotin", an innovative oncohematological drug for the treatment of patients with Hodgkin's lymphoma, at the facilities of the domestic manufacturer "Pharmstandard-UfaVITA".

- In October 2018, the first production of a medicinal product of a full cycle by Novartis was launched. The manufacturer invested 150 mln dollars into the localization of "Galvus", intended for the treatment of type 2 diabetes.

- In 2018, MSD and "Akrikhin" announced the start of local production of finished dosage forms of oral antidiabetic drug for the treatment of type 2 diabetes — "Sitagliptin" in dosage of 100mg.

- AbbVie and "R-Pharm" completed the transfer of production technologies of the antiretroviral drug "Kaletra" ("Lopinavir+Ritonavir" INN). The full cycle of production of the dosage form of "Kaletra" will be carried out in the pharmaceutical complex "R-Pharm" in Yaroslavl from the substance produced by AbbVie.

- Woerwag Pharma localized the production of "Magnesium Oroat" in Belgorod, at the plant of "Pik-Pharma Lek" company. Production capacities of Belgorod enterprise allow making more than 1 mln packs of the drug per year. The cost of the project exceeds 1 bln rubles.

- In November 2018, Pfizer and NTFF "Polisan" companies announced the completion of the process of technological transfer and the launch of production of the drug "Equinus" by Pfizer ("Tofacitinib" INN) for the treatment of rheumatoid arthritis, ulcerative colitis, psoriatic arthritis and plaque psoriasis.

- "Merck" company launched a full cycle of production of the drug from diabetes "Glucophage" ("Metformin" INN) at "Nanolek" plant (Lyovintsy village, Orichevskiy district). The production capacity will be 400 mln tablets per year. In terms of output, Russian production will become one of the largest in the world after France and Greece. Access to full production capacity and refusal of imports is planned for the next 2 years.

- In early December, the pharmaceutical manufacturer "Akrikhin" entered a full-scale production of 4 modern drugs localized by MSD innovative international company: antidiabetic agents "Renitek", "Januvia and Janumet", as well as a medication for cardiac diseases treatment "Zocor".

In 2019, the results of the implementation of the Presidential Decree 2012 orders are being summed up, which provides for the point that by 2018 it is necessary to achieve the following indicator: "Bringing the volume of production of domestic medicines according to the nomenclature of the list of strategically important medicines and the list of vital and essential medicines to 90 percent". Despite the fact that, in general, it is still far till the planned values are met, the share of domestic drugs is growing steadily from the year to year.

> "The share of imported medicines continues to decline. At the end of the year it is 70.2% in money and 39.8% in packages"

The share of imported medicines continues to decline. At the end of the year it is 70.2% in money and 39.8% in packages. At the same time, domestic drugs occupied a 1% higher share in value terms than in 2017. The growth of consumption of domestic drugs is observed in almost all the segments, with the exception of the Federal Privilege. In general, imported drugs fell by 0.5% in real terms, while domestic ones grew by 2.9%. In ruble terms, drugs from foreign manufacturers increased by 1.7%, while domestic ones increased by 6.7%.

Foreign manufacturers represent 85% of the ranking of drug manufacturers in Russia. In the TOP-20 rating, there are three domestic manufacturers: "OTCpharm", "Pharmstandard" and "Biocad", for the first time.

Despite the fact that manufactures that got into the rating are more or less unchanged, in 2018 there were many movements within it. This is one of the factors indicating that the market is not stable. Only 9 companies were able to maintain their position. **Total share of**

Table 34

TOP-20 Manufactures by Sales Volume in the Russian Pharmaceutical Market in 2018

Rating 2018	Changes	Manufacture	Sales value, mln rub. 2018	Sales volume increase	Share
1	-	Sanofi	63 029	3.1%	4.4%
2	-	Novartis	57 612	6.2%	4.0%
3	-	Bayer	53 116	0.5%	3.7%
4	+2	Abbott	41 948	9.4%	2.9%
5	-1	Teva	39 826	-7.5%	2.8%
6	+2	Takeda	38 263	8.4%	2.7%
7	-2	Johnson & Johnson	38 017	-2.3%	2.6%
8	-1	Servier	36 033	1.5%	2.5%
9	-	GlaxoSmithKline	35 899	7.5%	2.5%
10	-	OTCpharm	34 686	6.9%	2.4%
11	-	Pfizer	30 081	-1.2%	2.1%
12	-	Stada	28 524	-5.2%	2.0%
13	+1	Gedeon Richter	28 019	3.0%	1.9%
14	+3	KRKA	27 923	11.1%	1.9%
15	-2	Berlin-Chemie	27 563	0.2%	1.9%
16	-1	Merck	26 264	-2.3%	1.8%
17	+1	Pharmstandard	25 800	2.8%	1.8%
18	-2	AstraZeneca	24 490	-3.4%	1.7%
19	-	Biocad	24 039	17.2%	1.7%
20	-	Astellas Pharma	22 299	9.2%	1.5%

TOP-20 manufacturers in 2018 was 49%.

In 2018 TOP-3 didn't change as compared to 2017. The top position is held by Sanofi with a margin of 0.4% by share. Retail segment continues to prevail for the company (about 66% of turnover is represented by pharmacy sales). In second place, there is Novartis. At the same time, the company's sales growth is twice higher than that of the leader. Novartis also has a high share due to sales in pharmacies (72%). The third place remained with Bayer, although its sales compared to 2017 year have not changed. Only 15% of his sales are represented by state procurement. Main sales volume is represented by commercial segment.

Johnson&Johnson, Pfizer, Merck and AstraZeneca (over 40%) hold a high share in public procurement from the companies represented in the TOP 20. "Biocad" is almost completely working in the state segment — its share reaches 95%.

Among the manufactures not included in the rating, noticeable moves from domestic producers are worth noting: "Microgen" (+5, 27th line), "Pharmasyntez" (+8, 32nd line), "Grotex" (+16, 48th line). These companies have improved their position in the market by increasing sales in the public segment of the pharmaceutical market.

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