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ANALYSIS OF THE ANTIMICROBIAL DRUGS MARKET IN RUSSIA

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ABSTRACT

Most inflammatory diseases in the human body are provoked by microorganisms. Bronchitis, pneumonia, otitis media, conjunctivitis, cystitis, endometritis, inflammation of the fallopian tubes and ovaries, and many other diseases in modern treatment protocols of all countries contain antimicrobial substances. Treatment of various bacterial infections (for example, chlamydia, scarlet fever, streptodermia, meningitis, and tuberculosis) is impossible without antimicrobial therapy. Viral diseases (herpes infections, chickenpox, hepatitis B and C, HIV) at the present stage are susceptible to the effects of antiviral drugs. Fungal diseases of the skin, nails, mucous membranes, and systemic mycoses are treated with antibiotics. Protozoa cause such protozoal infections as giardiasis, amoebic dysentery, trichomoniasis, malaria, and toxoplasmosis. In such infections, antiprotozoal antimicrobial medications are prescribed. Thus, the spectrum of effects of these agents is directed at bacteria, fungi, viruses, and protozoa. This article provides a brief description of the types of antimicrobials, as well as an analysis of the antimicrobial drugs market in Russia.

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Introduction

All antimicrobial substances can be divided into three groups: antiseptics, disinfectants, and chemotherapeutic medications. Details on each group are given below.

Antiseptics

These are antimicrobial substances that are applied to the skin, mucous membranes, burn, and wound surfaces, in the body cavity of patients [1]. They lead to the death of microorganisms. To prevent infection during operations and prevention of nosocomial infections, the medical staff treats hands with antiseptics. At the same time, substances affect almost all pathogens of infections and inflammation due to a wide range of actions [2, 3].

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The most common antiseptics in medicine and everyday life are alcohols (ethyl, propyl, isopropyl, and their mixtures), hydrogen peroxide, iodine, brilliant green, boric acid, miramistin, chlorhexidine, benzalkonium chloride, octenidine dihydrochloride [4, 5].

Antiseptics are used for preventive and therapeutic purposes: for external therapy of wounds, abrasions, cuts, burns, trophic ulcers and bedsores, and some dermatological diseases [6].

Disinfectants

Disinfectants. These are broad-spectrum antimicrobial substances that are used to disinfect environmental objects (surgical instruments, medical devices, furniture in medical institutions, etc.) [7].

Both antiseptics and disinfectants have a wide range of antimicrobial activity. Most of them have a detrimental effect on all bacteria (including tuberculosis pathogens), viruses, mycoses (candidiasis and dermatophytosis), and protozoa [8]. They are available for use in pure form, as concentrates for dilution with water and disinfecting wipes [9]. There are the following classes of disinfectants:

1. Halide-containing: chemical compounds of chlorine, iodine, and bromine. The most widely used chlorine-containing disinfectants are: chloramine, bleach, calcium/sodium hypochlorite, chlorsept, and chlorhexidine. Chlorine compounds cause metal corrosion, irritate the mucous membranes of the respiratory tract and eyes, and pollute the environment, so their careful use is important [10, 11].
2. Oxygen-containing (oxidizing agents): based on hydrogen peroxide ("Alaminol"), peracids, perborates, and percarbonates [12].
3. Surfactants: used as detergents and disinfectants, for sterilization and cleaning of medical products. They are low-toxic, so they are suitable for general cleaning, and do not damage tools and equipment [13].
4. Aldehyde-containing substances: formalin, formaldehyde. Most of them are toxic, have a pungent odor, and often cause contact allergies [14].
5. Phenol-containing ("Triacid" and others). They have high antimicrobial activity, especially against tuberculosis, but their use is limited by alleging and irritating effects, a pungent odor [15].
6. Guanidines. These compounds are low-toxic, but in the presence of biological contaminants have weak antimicrobial activity. When processing surfaces, a protective bactericidal film is created [16]. They have proven themselves well for hand disinfection. Processing copper products is not recommended.
7. Alcohol-containing solutions based on ethanol, propanol, and isopropanol. They are mainly used as skin antiseptics and for the disinfection of metal tools and products [17, 18]. Many combined substances contain several groups of disinfectants.

Chemotherapeutic Medications

Chemotherapeutic medications. They are used in the treatment of bacterial, viral, fungal, and protozoal infections [19].

Chemotherapeutic antimicrobial medications include:

- Antibacterial substances. Antibacterial substances can have a bactericidal and bacteriostatic effect on bacteria [20]. In the first case, the bacteria die due to the destruction of the cell wall and protein denaturation.
- Antimycotics. Antimycotics are intended for the treatment of various fungal diseases: candidiasis of the skin and mucous membranes, dermatophytes of the skin, hair, and nails, and systemic mycoses with damage to internal organs. They can cause fungicidal and fungistatic effects [21].
- Antiviral medications. Antiviral medicines are represented by a large group of medicines. They are widely used in the treatment of herpesvirus infections, HIV infection, hepatitis B and C in the active stage, and influenza [22].
- Antiprotozoal medications. Antiprotozoal medications suppress the development of infections caused by protozoa: giardia, trichomonas, amoebas, malaria pathogen, toxoplasmas, and others. In Russia, they are mainly represented by nitroimidazoles – synthetic antimicrobial drugs [23].

The Russian Market of Antiseptics

The production of antiseptics is one of the few branches of the economy that have received a powerful impetus for development in the new economic conditions. The World Health Organization (WHO) has officially identified alcohol-based hand sanitizers as the only known product for the rapid and effective destruction of a variety of potentially dangerous microorganisms, so the demand for them began to grow rapidly [24, 25]. In Russia, in the spring of 2020, the volume of sanitizer production increased 6 times. Large perfumery, cosmetics, and pharmaceutical companies, as well as some manufacturers of alcoholic beverages, have entered this market. Analysts predict an increase in the consumption of alcohol disinfectants by 2024-2025 by 4-6 times due to the changed sanitary and hygienic standards both at home and at industrial enterprises and in public places [26].

It should be noted that the production of antiseptic disinfectants in Russia was actively growing even before the pandemic of 2020. So, in 2018, the volume of this market in physical terms added a little more than 30%, and in 2019 – more than 90%. By the time the coronavirus appeared in Russia, five leading enterprises were producing 17 million liters of this product. Almost 23 million liters more were imported from abroad (the share of imports was 56.8%) [27]. Thus, the total market volume by the end of 2019 amounted to almost 40 million liters.

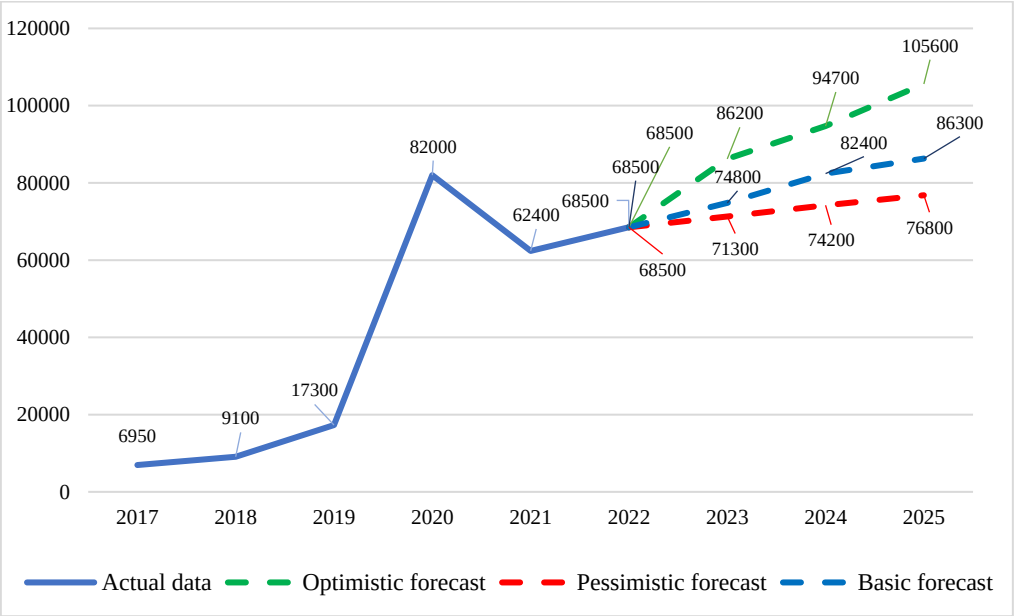


Figure 1. Dynamics of the Russian antiseptic market, thousands of liters

But despite significant volumes, with the beginning of the spread of coronavirus infection, antiseptics were very quickly sold out and became an acute shortage of goods [28]. This happened, on the one hand, because of the high demand from the population, on the other hand, because of the mandatory order of distribution of these products (priority for hospitals and polyclinics). In addition, by order of the state authorities, from 2020, each organization must have a certain supply of disinfectants, otherwise, it does not have the right to continue its activities.

By the beginning of March 2020, the volume of production of alcohol disinfectants was 50 thousand liters per day, and 10 companies were already supplying these products to the market, most of which specialized in this type of activity [29]. In mid - April, the following indicators were recorded:

1. The volume of production has grown to 300 thousand liters per day.
2. The number of manufacturing companies has increased to 60.
3. 25% of all antiseptics produced were manufactured by enterprises in the perfume and cosmetics industry.
4. It became known about plans to establish the production of alcohol-containing disinfectants at factories that manufacture alcoholic beverages. The new direction will allow liquor companies to compensate for the drop in revenue due to a decrease in demand for spirits [30].

Large manufacturers reacted to the increase in demand quite quickly:

- Bentus Laboratories, the largest manufacturer of disinfection products, recorded a threefold increase in demand in the domestic market. At the time of peak demand, all production facilities are maximally loaded and exports are significantly limited;
- pharmaceutical concern "Evalar" introduced a line for bottling alcohol-containing cosmetics even before the outbreak of the epidemic. Within a week, it was converted to the production of antiseptics, and the company was able to obtain a license in an accelerated manner;
- perfume and cosmetics giant Faberlic has repurposed its production to produce about 6 million packages of sanitizers per month. According to the company's executive director, it will produce as many antiseptics as the market needs.;
- The Laboratory of Modern Cosmetics also introduced alcohol disinfectants to its range even before the spread of the coronavirus — in August 2019. Shortly after the outbreak of the pandemic, the company completely stopped the production of cosmetics and refocused all its capacities on the production of antiseptics. Now it is ready to supply up to 600 thousand units of products per month.

The peak of coronavirus infection has passed, it has been replaced by other varieties of viruses, which, nevertheless, did not cause such a stir among the population. Thus, the demand for sanitizers is on the decline. The market is waiting for less active growth, but it will occur at much higher levels than before the crisis, since sanitary standards at enterprises and in public places will become much tougher, including in terms of new legislation [31].
In all scenarios (optimistic, pessimistic, and basic), a slight correction of the market is expected, which, nevertheless, has positive dynamics. The most restrained forecast assumes an increase in the market volume in 2025 by 4.4 times compared to 2019. In the future, the number of enterprises engaged in the manufacture of antiseptic solutions will grow.

The Russian Market of Antibiotics

Broad-spectrum antibiotics are suitable for the treatment of various infectious diseases affecting the digestive tract, respiratory and genitourinary systems. This group is one of the most numerous among medicines. Currently, there are more than 100 different active substances on the market, classified as antibiotics. Taking into account the form of release and dosages, the number of drugs exceeds 1,700 names [32].

According to statistics, the volume of consumption of PBX-group "Antibacterial drugs for systemic use" in 2020 amounted to 82 billion rubles, which corresponds to 548 million packages of drugs. In dynamics, the group of antibiotics shows a negative trend in packages up to 2020, and then there is a sharp jump. In value terms, a slight positive increase was noted, but to a greater extent, it is due to a shift in demand towards more expensive medicines, as well as a significant increase in the cost of a unit of goods. 2020 was the peak of sales of antibacterial drugs. This is because some antibiotics have been included in the treatment regimens for COVID-19. As a result, the sales volume of the group of broad-spectrum antibiotics increased in value terms by 19% [33].

Antibiotic treatment regimens involve both inpatient and outpatient use [34]. In this regard, the structure of sales of antibacterial drugs is distributed between two channels: the bulk is purchased at the expense of the population's funds in pharmacies (62% of the total capacity of the group), medical and preventive institutions annually purchase drugs of this group for 21.8 billion rubles at the expense of the state (this corresponds to 38% of the group's consumption) **(Table 1)**.

Table 1. Structure of antibiotic sales from 2020 to 2022

	Share, rubles				**Share, packaging**			
By the place of production								
Localized	47%				67%			
Imported	53%				33%			
By origin								
Original	81%				9%			
Generik	19%				6%			
By entering the rating of vital medicines								
Is included	77%				89%			
Is not included	23%				11%			
By the method of purchase								
Hospital purchases	38%				33%			
Pharmacy purchases	62%				67%			
By price segmentation, rubles								
	<50	50-150	150-500	>500	<50	50-150	150-500	>500
Hospital purchases	7%	13%	26%	54%	51%	25%	18%	7%
Pharmacy purchases	6%	14%	51%	29%	36%	28%	29%	7%

On average, one package of a drug-related to broad-spectrum antibiotics costs about 238 rubles. Until 2020, this increase was about 6% on average per year, but during the pandemic, the price jumped by 19%. The demand for some groups of antibiotics in 2020 led both to an increase in prices for popular items and to the "washing out" of cheaper drugs from the system. As a result, there was a forced transition to the consumption of more expensive medicines [33]. For example, in the INN group, azithromycin is in demand for 9 months. It grew by 71% in money and by 58% in packages. The most common dosage in this INN is "Azithromycin tab. 500 mg No. 3". Its average cost has increased from 73 rubles in 2019 to 101 rubles in 2020. According to data at the beginning of 2023, the cost of azithromycin in this dosage starts from 151 rubles [33]. However, there is a sharp shortage of this drug in pharmacies in the country.

Buyers prefer cheap antibacterial medicinal products with a price of fewer than 150 rubles. This price range accounts for 64% of sales in kind. At the same time, antibiotics from the price segment "from 150 to 500 rubles" bring the greatest profit to pharmacies (51.0% of sales in rubles) **(Table 1)**. The state spends the most money on drugs with a price of over 500 rubles (54%). But in packages, on the contrary, the segment belonging to the minimum price range of up to 50 rubles (51%) occupies the maximum share [35].

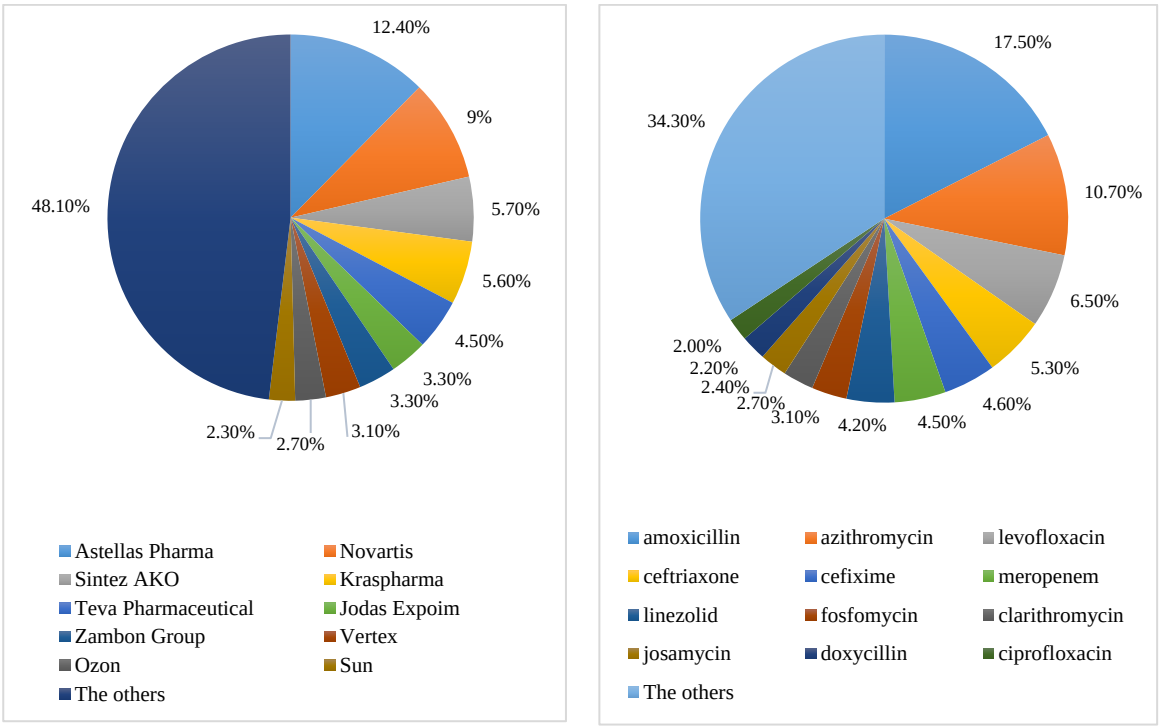
The peak of sales of systemic antibacterial drugs falls in the autumn-winter period [36]. Such a picture is more inherent in pharmacy sales of this group. Seasonality is caused by the incidence of colds and viral infections. Patients often resort to self-medication and, uncontrolled taking of antibiotics for a common cold largely contributes to the development of resistance of microorganisms to antimicrobial drugs. In the summer months, the consumption of antibacterial drugs decreases by 1.5 times relative to the winter season.

In the hospital segment, the consumption of antibiotics is more systemic. To a greater extent, the volume of purchased drugs is associated with financing and the schedule of tenders given, the number of which is higher in the second half of the year. Accordingly, in the first half of the year, hospitals receive 44% of the annual need, and 56% of the volume is concentrated in the second half of the year.

The Russian pharmaceutical market is dominated by imported antibacterial drugs in value terms, but their share is gradually decreasing (37% in 2022, 53% in 2020, 64% in 2015), which indicates the effective work of the "import substitution" program [37]. In packages, the preponderance is 67% towards antibiotics produced in Russia. The cost of Russian drugs in 2020 was about 128 rubles/pack (167 rubles/pack in 2022), and foreign drugs - were 289 rubles/pack (412 rubles/pack in 2022).

The Russian market of antibacterial drugs is a generics market [38]. In rubles, they account for about 81%, and in packages - almost 94%. Original drugs occupy only 6% of packages. Due to the higher price in value terms, their share is 19%. Original drugs are sold mainly in pharmacies [39]. In the hospital segment, the share of generic drugs prevails - they account for 98.4% of all purchases in packages. The weighted average cost of a generic drug in 2022 was 184 rubles/pack, of the original - 760 rubles/pack.

According to data for 9 months of 2020, out of 106 INNs related to antibiotics, only 10 INNs are represented on the market exclusively by original drugs and so far have no analogues. The most capacious positions are: josamycin - 2.4% of the volume in rubles, thiamphenicol glycinate acetylcysteinate - 0.87%, and ceftaroline fosamil - 0.78%. All antibacterial drugs for systemic use are dispensed in pharmacies by prescription, that is, they are prescription drugs. Most antibiotics are included in the list of vital and essential drugs, therefore, their cost is regulated by the state [40].



a) b)

Figure 2. Segmentation of Russian antimicrobial drugs market: a) Rating of manufacturers of antibacterial agents for systemic use in 2020-2021; b) Rating of antibacterial agents for systemic use in 2020-2021.

More than 220 companies are manufacturers of antibiotics sold in Russia. The top 10 players account for 52% of the value of sales **(Figure 2a)**. The rating includes both foreign companies and domestic factories. The leader in sales of antibacterial drugs is Astellas Pharma with the main brands Suprax, Flemoxin Solutab, Unidox Solutab, and Vilprafen. The largest number of different antibiotics are sold by domestic companies. The top 20 INNs account for over 76% of the value of antibacterial drugs **(Figure 2b)**. Most often, companies produce such INNs as metronidazole (54 manufacturers), ciprofloxacin (46 manufacturers), ceftriaxone (44 companies), azithromycin (38 companies), levofloxacin (37 companies).

In total, sales of these INNs grew in 2020 by 31% in rubles. and 16% in packages. INNs such as azithromycin and levofloxacin grew the most.

Conclusion

Treatment of various bacterial and viral infections, and fungal diseases is impossible without antimicrobial therapy [41]. All antimicrobial substances can be divided into three groups: antiseptics, disinfectants, and chemotherapeutic drugs [42, 43]. The market for antiseptics and disinfectants in Russia has been actively developing since 2017, and in 2020 the demand for these

drugs was abnormally high (82,000 thousand liters of antiseptics). In 2021, demand dropped significantly to 62,400 thousand liters per year, but since then, the production of antiseptics has been steadily growing.
Concerning the market for broad-spectrum antibiotics, the following trends should be noted:

- an increase in the number of Russian manufacturers, and an increase in their volume, of packages;
- a decrease in the number of goods from foreign manufacturers, especially from 2022;
- systematic increase in prices, including for medicines from the list of essential medicines;
- more than 90% of the antibiotics market is represented by generics, with hospitals being the main consumers of generics.

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