Review Article

Influence of Russian pharmaceutical industry on ecology and human health

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ABSTRACT

The pharmaceutical industry is a branch of the economy associated with research activities, the development of new drugs and medical devices, as well as the production of the above. Pharmaceutical industries belong to chemical industries, therefore, they are subject to high requirements for the preservation of good ecology in the adjacent territories. Pollution from the pharmaceutical industry is anthropogenic. In addition to the well-known factors of the influence of environmental pollution on human health, the pharmaceutical industry has an impact on the health of employees. This article analyzes data on the growth of pharmaceutical enterprises and their market share, the volume of production, and the sale of medicines for the period up to July 2021. A brief overview of pharmaceutical enterprises in the south of Russia, an assessment of the ecological state of the respective regions, and also measures taken in these regions to solve environmental problems and high-quality disposal of industrial waste are compiled.

Keywords: Pharmaceutical production, Ecology, Chemical waste disposal, Pharmaceutical enterprise

Introduction

The COVID-19 pandemic has revealed problems for world health: an acute shortage of medical personnel, hospital beds, medicines, and personal respiratory protection equipment [1, 2]. The pharmaceutical manufacturers' market immediately responded to the challenge with an increase in production volumes.

The overproduction of drugs and equipment has become a catalyst for the development of industry, energy, construction, transport, and discoveries in science [3, 4]. These processes are directly related to the release of waste products into the atmosphere. Water and air are the most vulnerable environments. Environmental pollution occurs through them much more actively than through the biosphere. Unfavorable ecology affects human health in a variety of ways, thereby causing chronic diseases of the cardiovascular, respiratory, nervous, immune systems, and gastrointestinal tract [5, 6].

The human right to a healthy environment in Russia is ensured, first of all, by the basic law of the state – the Constitution of the Russian Federation. Since atmospheric air is a vital component of the natural environment, an integral part of the habitat of humans, plants, and animals, it was relevant to adopt 1999 the law "On the Protection of Atmospheric Air", which establishes the legal basis for the protection of atmospheric air and aimed at realizing the constitutional rights of citizens to a favorable environment and reliable information about its condition [7].

The improvement of the environment has long crossed the borders of states. The World Health Organization, whose

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activities are aimed at combating particularly dangerous diseases, and the development of international sanitary rules, draws the attention of the world community to environmental problems and connects the health problem of 20-30% of the world's population with their solution [8]. The World Health Organization has developed a classification system for hazardous industrial waste adopted by the United Nations organization [9]. This classification includes a list of toxic and hazardous components of industrial waste. They include such substances as arsenic and its compounds; pharmaceuticals; carcinogenic polycyclic and aromatic halo-organic compounds, but polymer materials are an exception; mercury and its compounds, and many others. The degree of waste hazard depends not only on the class and concentration of toxic substances contained in the waste but also on the synergistic effect of some components [10, 11].

Pollution enters the atmosphere as a result of natural processes and human economic activity, namely from anthropogenic sources. Pharmaceutical production started with private pharmacy shops, and today they are pharmaceutical corporations with billions of turnover.

Development of the pharmaceutical industry in Russia

According to 2016 data, the volume of the pharmaceutical industry in the Russian Federation amounted to 286 billion rubles, and medical products 52.8 billion rubles [12]. In 2016, the Russian pharmaceutical market ranked 10th in the world **(Figures 1 and 2)**.

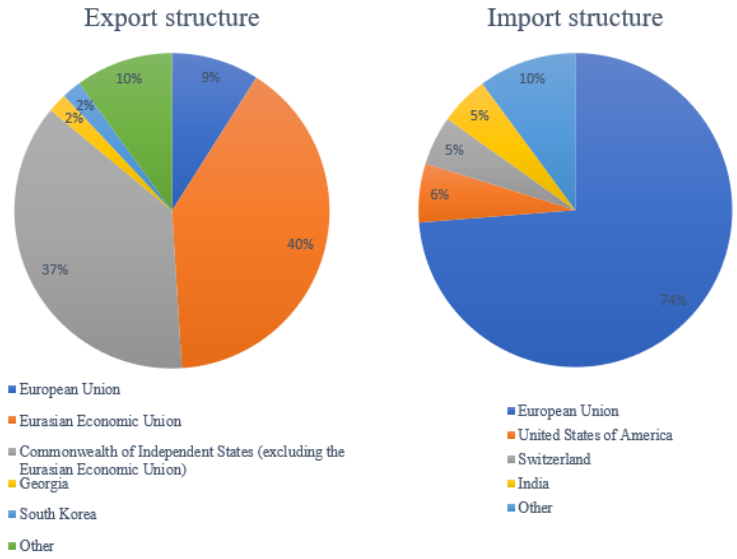

Figure 1. Participation of countries in the import and export of pharmaceutical products [12]

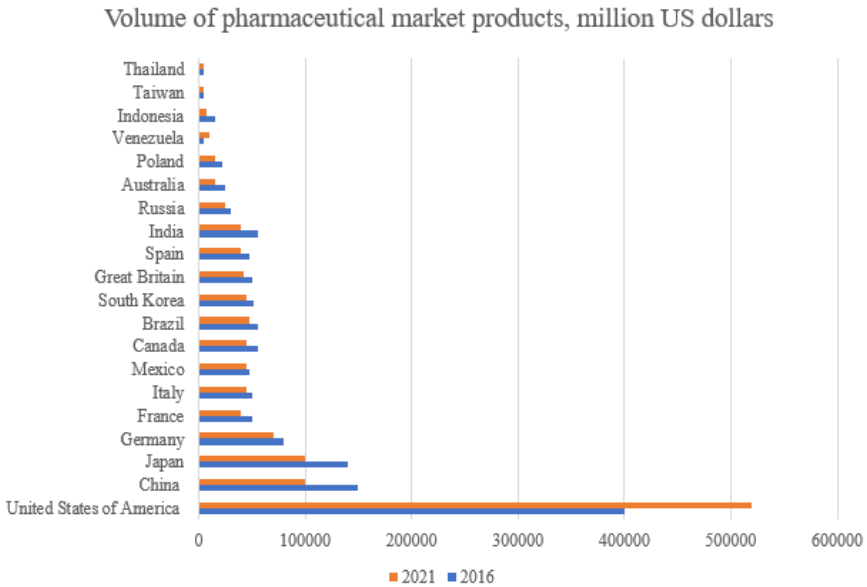

Figure 2. Ranking of countries by pharmaceutical market volume [12]

According to the DSM GROUP, the state of the Russian pharmaceutical market as of July 2021 has already amounted to 89.1 billion rubles **(Figure 3)** [13]. In total, 859 pharmaceutical companies produced medicines sold on the Russian market according to indicators for July 2021. The TOP 10 includes Bayer, Novartis, Otis Pharma, Stada, Sanofi, Servier, Teva, A.Menarini, Abbott, KRKA.

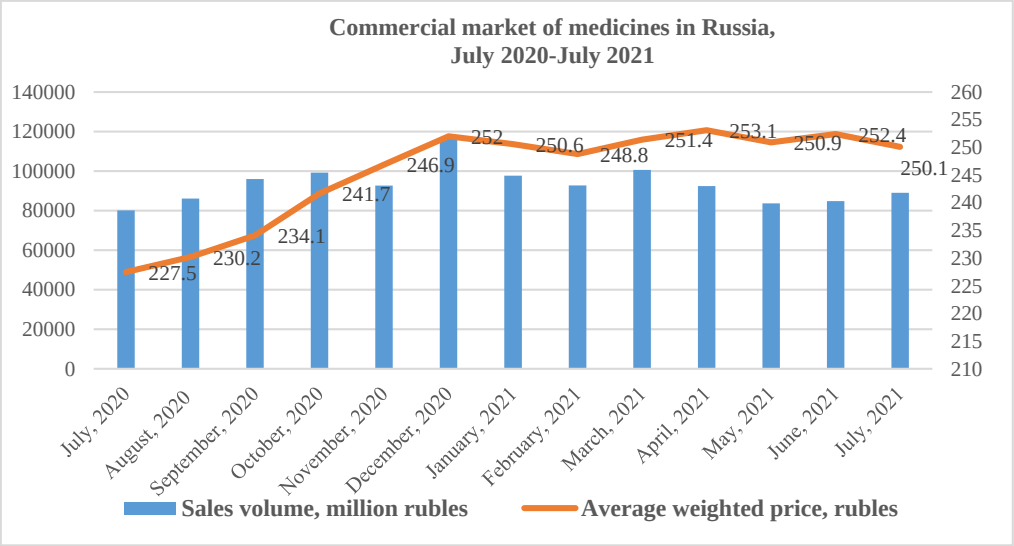

Figure 3. Growth of the Russian pharmaceutical market in ruble equivalent at retail prices [13]

The pharmacy market of biologically active additives in Russia from July 2020 to July 2021 sold 2,103 brands of biologically active additives from 795 manufacturers **(Figure 4)**.

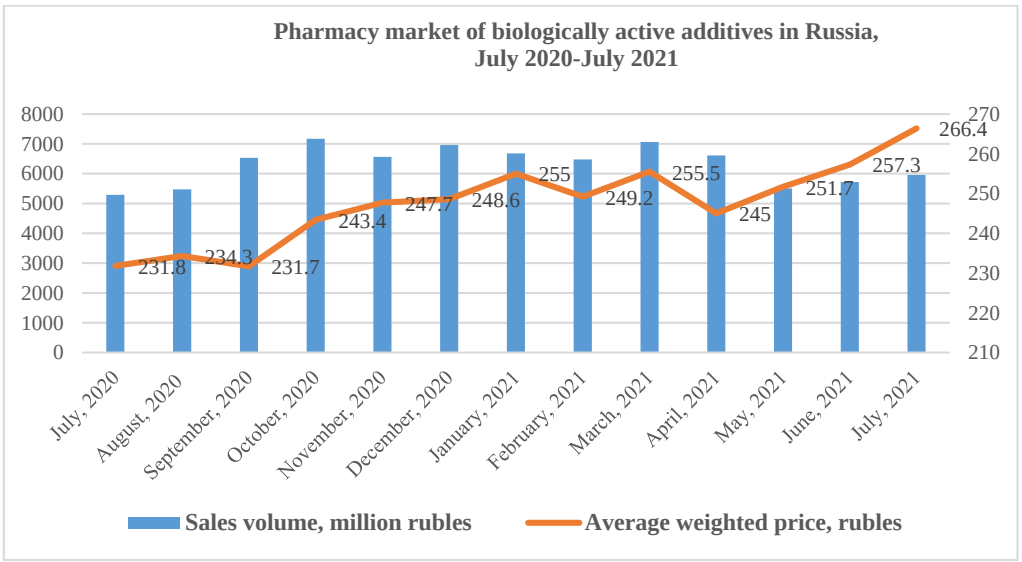

Figure 4. Pharmacy market of biologically active additives in Russia [13]

The leader in the production of biologically active additives in Russia has named the company "Evalar", whose growth was 13.6% [13].

The main pharmaceutical manufacturers in the South of Russia

On the territory of the Southern Federal District and the North Caucasus Federal District pharmaceutical companies are located in Armavir (Armavir biofactory), in Stavropol (Stavropol biofactory, ESCOM (the largest manufacturer of intravenous solutions)), in Slaviansk-on-Kuban (Yuzhpharm), in Rostov-on-Don (Rostov Pharmaceutical Factory). Armavir Biofactory produces 19 names of medicines, 51 names of veterinary medicines, and more than 80 immunobiological preparations, including vaccines participating in the state order system. The company has implemented a risk analysis system for product quality. Stavropol Biofactory is one of the leading domestic manufacturers of immunobiological preparations for veterinary medicine and offers a full range of medicines (viral, bacterial, antifungal, antiparasitic vaccines, hyperimmune therapeutic serums) designed to improve the health, well-being, and

productivity of various species of animals and birds [14]. To date, the assortment of biological preparations of the Stavropol Biofactory has more than 45 names. There is a wide range of vaccines against leptospirosis, colibacteriosis, salmonellosis, pasteurellosis, antimycotic, and antiviral biologics. ESCOM (Stavropol) is one of the leading companies in the pharmaceutical market of Russia and the only one in the south of Russia for the production of infusion solutions: the production of effective and affordable medicines; the production of import-substituting products; the introduction of new scientific developments in medicine. More than 80% of the ESCOM Group's drugs are included in the "List of Vital drugs" [15]. Yuzhpharm (Krasnodar Krai, Krymsky district) – founded in 2007 and is a modern pharmaceutical enterprise of Krasnodar Krai, which has a history of formation and development from a small production site producing antiseptic and disinfecting drugs to modern industrial production with a production volume of more than 60 million packages per year. Rostov Pharmaceutical Factory specializes in the research, development, and production of medicines (oncological, antiviral, autoimmune, orphan, pulmonological, etc.), laboratory equipment, and medical equipment. Production facilities are located in the cities of Yaroslavl, Rostov, Moscow, and the Kostroma region. Severnoye, Baku (Azerbaijan), Illertissen (Germany), Moscow Region, Dubna.

No information about environmental safety for the region was found on the above-mentioned companies' websites.

Environmental pollution by pharmaceutical industry enterprises

Pharmaceutical companies place high demands on the chemical purity of their products, and the complete sterility of drugs, there is a significant consumption of raw materials and materials. The production of medicines consists of a large number of stages. The main unfavorable operating factor of the production environment in pharmaceutical industries is the pollution of the air in the working area, clothing, and skin with harmful organic and inorganic substances [16, 17].

Air pollution with toxic substances can be absolutely at all stages of the technological process: during preparatory, main, and final operations. The main reasons for the content of harmful substances in the air of industrial premises are imperfection of equipment, violation of technological regimes, absence or insufficient mechanization of many operations related to transportation, loading, and unloading of materials from devices, the use of leaky equipment, overflow of chemical products when filling devices, damage to devices used in processes [18].

The composition of substances polluting the air of the working area at most enterprises for the production of medicinal products is complex, due to the simultaneous presence of many chemical ingredients in the form of aerosols, vapors, or gases. Depending on the stage of the technological process, and the type of drug obtained, the air of industrial premises may be contaminated with initial, intermediate, and finished products of chemical synthesis [19]. At the same time, the intake of harmful substances into the body is carried out primarily through the respiratory tract and to a lesser extent through the skin and gastrointestinal tract [20].

The effect of a harmful substance on the body is possible at various stages of the technological process: in the preparation of raw materials, the implementation of the actual processes of drug detection, and final operations. At the same time, the degree of severity and nature of the impact of the chemical factor on the body of the working personnel are determined by the perfection of technology and equipment, the formulation of the medicinal substance, as well as the construction and planning solutions of the premises and the organization of air exchange in them [21].

An important characteristic of the environmental safety is the impact of pharmaceutical waste

Pharmaceutical waste includes expired, unused, spilled, or contaminated pharmaceuticals and preparations in the solid or liquid state [22]. Also, such waste includes narcotic drugs to be destroyed and unused vaccines. Pharmaceutical waste is generated in pharmaceutical industries, hospitals, pharmacies, and veterinary hospitals, that is, in all institutions where medicines and vaccines are used [23].

All products of pharmaceutical plants are chemicals of varying degrees of toxicity. For this reason, the disposal and neutralization of pharmaceutical waste should be carried out by specialized companies that have a license to carry out this type of activity. Disposal of pharmacological products by incineration leads to serious pollution of the atmosphere, hydrosphere, and soil with toxic substances, and, consequently, to serious problems and diseases in the population. At the moment, the method of crushing medicines in such a device as a shredder is actively used. After crushing, the crumbs from the medicines are mixed with other waste and used in the production of cement and concrete. This method of disposal makes it possible to make the disposal of pharmaceutical waste environmentally safe [22].

Pharmaceutical products with expired shelf life are one of the most specific types of waste. The removal of such waste to a regular landfill or landfill is strictly prohibited. The removal of pharmaceutical waste must be carried out by specialized organizations with the appropriate technical base and a package of necessary permits. Export pharmaceutical products that have expired and are not suitable for use in sealed containers. For liquid pharmaceutical products, a glass container is used, which is tightly closed and ensures tightness. If a large volume of pharmaceutical waste is exported, it is necessary to draw up a passport for them and issue a nomenclature list, as well as make a list of exported waste [22].

The chemical and petrochemical industry is one of the main sources of pollution, as emissions that affect the quality of air, water, and soil are carried out in the production process.

The main source of pollution is chemical industry enterprises that emit poisons, and inorganic impurities together with waste. If the effluents are not sufficiently cleaned of these emissions, they can get into large reservoirs and spread their pollution. Wastewater

contains aldehydes, ammonia, resin, and other petroleum products. As a result of chemical processing, these wastes enter the water, reducing the oxygen level.

The development of the chemical industry affects not only the environment but also human health [24]. A person's reaction to pollutants depends on his gender, age, and health. Small amounts of pollutants can have a stronger impact on children and the elderly, as they belong to a vulnerable group. If toxic substances enter the human body regularly, they can cause chronic poisoning. Chemical industry waste is materials containing harmful substances that pose a threat to human health [25]. These include residual products during production. These can be harmful fuel compounds, dust, slag, or ash. Now this industry is engaged in processing a large volume of raw materials, after which there is waste that is potentially harmful to health and the environment.

What is the danger of waste from pharmaceutical enterprises?

Hazardous waste is generated at all stages of drug development. For example, during the development of ten biologically active substances, up to ten thousand potentially toxic materials are used in laboratories [26]. But the biggest danger is direct production.

Pharmaceutical waste contains bioactive chemicals that can harm soil, water, air, and living organisms. With a random interaction, they can enter into an uncontrolled reaction and give an unexpected result. Water is especially sensitive to bioactive chemical pollutants [27].

Every day pharmaceutical companies face the problem of substandard residues. For example, for every 100 kg of suppositories, an average of 1.17 kg of active substance remains, which is not subject to further use. It also generates approximately 1.3 kg of packaging waste and 1.4 kg of auxiliary materials for sanitary and hygienic preparation of production [28].

Waste is collected in hermetically sealed containers and bags of black color with an indication of the hazard class ("G") and a description of the contents. Containers are stored in a special building or an isolated room with a separate entrance. They must meet strict requirements for sanitary and fire regulations. The storage room must be equipped with a thermometer, hygrometer, fire and ventilation system, and inventory for the safe movement of containers. It is forbidden to place packages on the floor or a pallet together with the waste of other categories. Cytostatics and genotoxic drugs are pre-disinfected [29].

Specialized companies with the appropriate technical base and a package of permits should export waste from pharmaceutical enterprises. When exporting large volumes, a passport is drawn up and a nomenclature list is drawn up, and after disposal, appropriate action is provided [30].

There are 4 methods of waste disposal in this category [31]:

1. Incineration in special furnaces at a minimum temperature of 1200 °C (the method is used less and less concerning these wastes).
2. Draining into an industrial sewer (permissible only for completely soluble preparations, but there is always a danger of incorrectly calculating the concentration).
3. Placement in landfills (only for waste with a low degree of danger, after disinfection by physical or chemical methods, pressing, sintering or grinding).
4. Crushing in a shredder (the resulting mass is mixed with other crushed waste and used in cement production).

Recyclables from the disposal of medicines and other pharmaceutical waste are prohibited from being used for the manufacture of medical products, children's products, and products that interact with food or water. Complex in chemical composition pharmaceuticals is inferior in terms of toxicity only to radioactive waste and pesticides [32]. The uncontrolled release of garbage from pharmaceutical industries will soon disrupt the ecological balance on the planet.

Ways to solve environmental problems in the South of Russia

After assessing the state of the region and assessing the main problems for environmental protection and restoration of natural resources of the region, the following measures should be taken:

1. Create a network of protected areas. It should provide ecological corridors in the main directions of animal migration.
2. To withdraw from economic use especially valuable zones of various natural zones, taking into account the location, richness of flora, and fauna.
3. Landscape restoration. This requires changing the technology of plowing and abandoning "wild" pastures.
4. Increase the funds allocated for the purification of natural sources and the protection of forests.
5. Improve environmental control of enterprises.
6. It is necessary to install waste recycling plants, waste paper, and wood recycling.

Taking into account the unique natural features, the zone is assigned the status of a specially protected resort region. The Stavropol Environmental protection program has been approved at the federal level. The main directions for restoring the ecosystem and preventing its further destruction are the control of enterprises, the creation of authorized landfills, and the development of waste processing plants [33]. The ecological situation in the Krasnodar Territory is so alarming that it is among the 10 most polluted regions. The greatest danger is caused by industrial enterprises, the least is caused by agriculture. Natural sources are polluted – rivers, lakes, and the Sea of Azov, where liquid waste and untreated sewage are dumped, and in the Black Sea, near the coast, spots of fuel oil are constantly noticed.

The human factor hurts the state of the region. Untreated wastewater pollutes natural reservoirs and groundwater, and carbon monoxide, vanadium pentoxide, and sulfur are released into the atmosphere [34-37]. Moreover, soils are depleted, and

besides harmful substances accumulating in them, animals and plants die [38-42].

The Ministry of Ecology of the Krasnodar Territory is constantly engaged in improving environmental protection measures. Adopt new laws, hold seminars and conferences, establish posts, and create commissions that monitor the state of natural resources. But, so far, the ecological situation of the Krasnodar Territory remains in an unsatisfactory state. It will not be possible to improve its situation without the joint work of the regional authorities and the population.

Conclusion

The pharmaceutical industry is developing intensively. The growth of pharmaceutical enterprises from year to year is recorded by organizations that collect statistical data. The pharmaceutical industry belongs to the chemical industry, which means it harms the ecology of the regions and the country. Pharmaceutical companies must comply with all environmental requirements for the production and disposal of waste, modernize production, and compensate for the damage caused to the ecology of the region. The working conditions of employees of enterprises are the main problem of the influence of pharmaceutical products on human health.

At all stages of pharmaceutical production, substances are formed that have a bad effect on the health of employees. The main task of pharmaceutical production is to create the safest workplaces, a healthy microclimate in workshops and laboratories, and also restore the health of employees with sanatorium treatment.

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