Production and use of biologically active substances: economic, social and legal aspects

Ildar Begishev[1,*], *Veronika* Denisovich[2], *Vladimir* Majorov[3], *Nikolay* Kokanov[2], and *Andrey* Sergeev[2]

[1]Kazan Innovative University named after V.G. Timiryasov, Moskovskaya str., 42, 420111, Kazan, Russia
[2]Chelyabinsk State University, Brothers Kashirin str., 129, 454001, Chelyabinsk, Russia
[3]Tyumen Institute of Advanced Training for Employees of the Ministry of Internal Affairs of the Russian Federation, Amurskaya str., 75, 625049, Tyumen, Russia

Abstract. The article analyzes the opinions of researchers on the need to produce and use biologically active substances. The authors of this publication consider not only legal issues, but also socio-economic ones. Due to the integral approach and the use of several basic methods of scientific cognition, a number of progressive conclusions are formulated. It is noted that the quality of biologically active substances and their generics depends not only on the consumer's demand, but also on the substance nature and its legal regulation. Not only advantages of modern approaches to drug production are noted, but also defects, namely high cost and insufficiently effective use of digital technologies.
Keywords: biologically active substances, production of biologically active substances, digital technologies in the production of biologically active substances, synthesis of medications, economics, law

1 Introduction

All over the world, including in the Russian Federation, the issues of production and use of biologically active substances (hereinafter – BAS) remain relevant throughout the entire period of human existence [1]. Moreover, during the period of human development to follow, the need for new technologies of BAS production [2-4], including the use of digital technologies [5-8], will only increase exponentially.

The use of biologically active substances will dramatically expand in relation to people whose status should be labeled as "not in need of medication". A person in such a status does not need constant therapy with medicines in the conventional sense. However, they may need the following types of biologically active substances, the production of which is being increased in the world (this applies both to original drugs and generics): improvement of body parameters, tonic effect and sleep quality, prevention of chronic diseases, correction of children's development from birth and during adolescence, improvement of human reproductive health and increase of fertility in those countries where it is one of the main directions of the state's social policy. In general, all the above-mentioned directions of

* Corresponding author: begishev@mail.ru

pharmaceutical industry development can be united under a single spectrum of action: improving the human life quality, ensuring longevity and performance with maximum efficiency for society [9].

Many researchers both in the field of fundamental medicine, psychology, sociology, genetics, and pharmacology reasonably distinguish two main groups of biologically active substances, which urgently need:

1) BAS that influence and improve the human condition;

2) BAS that influence and accelerate human development.

With the help of digital technologies and active distribution of generic drugs, it is possible to accelerate the process of introduction and distribution of drugs of the first group [10-13].

In this case, the problems of law enforcement can be easily seen. Actually, it is difficult and quite expensive to develop a drug that "improves" the quality of human life, but it is generally possible due to modern achievements of science and technology. However, it is much more difficult to synthesize drugs that would stimulate a child's brain, for example, or provide functional work of internal organs of people suffering from autism, because the quality of their life directly depends on their development, on how their brain works. Such a drug should be maximally effective, non-toxic and available to a consumer, while still meeting the basic market criteria, being "convenient" for a buyer and affordable. To date, not all biologically active substances have such qualities, and this fact is not groundbreaking.

Every year, the requirements for the safety of biologically active substances are globally increasing; hence, the requirements for the mechanism of legal regulation of using these drugs in each country are becoming more complex and robust. Development in this direction will be associated with the use of the safest substances and an individual approach to their use, taking into account genetic and situational changes in the condition of a person. Thus, progress in the use of biologically active substances in the sphere of health care and medicine is closely connected with progress in the creation of generally available methods for observing the human body condition and interpreting the obtained data. The said data can be useful, for example, for conducting large-scale medical examinations of the population. In this area we consider it necessary to use modern digital technologies, which would facilitate the collection and processing of information on the condition of patients, the number of drugs available to doctors not only in a certain district, but also a region or a country. A separate study is required regarding the application of digital technologies to predict the use of biologically active substances by people with a certain set of genetic material, as well as the state of health when beginning to consume certain substances.

The use of biologically active substances of natural origin in medicine and health care is rapidly developing, as well as partial replacement of synthetic compounds with severe side effects. Also, pure substances are replaced by complex substances in which BAS neutralize negative effects on the body.

In general, it should be noted that the production and use of biologically active substances should be considered in the broadest sense, namely: in production, agriculture, industry, forestry, and in water management industry. Of particular relevance are the issues of using new technologies, for example, for the production of fertilizers, biological additives for water purification, production of biologically active components that improve the environment through the products of their life activities.

2 Materials and Methods

The study uses various methods of scientific cognition, among which the basic one is the dialectical method of cognition of social processes and phenomena. In accordance with it, the production and use of biologically active substances are considered through the prism of socio-economic and legal aspects.

In addition, a system of general and specific research methods was used. The authors used such general scientific methods as deduction and induction, analysis and synthesis, system-structural and formal-logical methods of cognition. The specific methods used include formal-legal method, expert evaluation, analysis of documents, etc.

3 Results

Modern scientific research from various fields, including law and economic content analysis, show that, despite the measures taken to make the use of biologically active substances maximally effective, fast and safe, there are a lot of disputable issues regarding how eliminate patients' sufferings.

Still problematic are the issues related to the use of BAS containing poorly studied molecules of the original substance; this is aggravated by the use of unofficial names of components that raise questions among specialists from different countries. As a result, the drug cannot be used on the territory of the state, its effectiveness was not proved, there are no analogs, nor grounds for conducting experimental studies. In the Russian Federation, for example, questions may arise regarding simultaneous application of several regulatory legal acts: Federal Law "On consumer rights protection", Civil Code of the Russian Federation, standards requiring testing of food additives, and rules of drug production. We consider it reasonable to use the unified international classification and terminology of drugs and their components, in order to eliminate misleading a consumer, fraudulent actions of a manufacturer, and unfair advertising [14].

A separate issue is the effectiveness of certain biologically active substances. Undoubtedly, each drug deserves individual attention, comments on the composition, rules of intake, peculiarities of dosage and use. However, modern manufacturers often use the standard phrase "consult your doctor before use". This has turned into a catchphrase, and the drugs intake has become largely uncontrolled. There is also a reasonable explanation for this. Patients have ceased going to polyclinics and hospitals if they do not find significant health problems, but they are concerned about one-time symptoms of illness. Medical institutions do not always provide a favorable atmosphere for medical care, which prevents full and comprehensive consultation, especially when it comes to children. These are just two reasons that lie on the surface. A patient, even considering oneself healthy but feeling unwell, goes to a pharmacy and buys a drug after a consultation with a pharmacist, not with a physician, and sometimes does not coordinate their choice with anyone, focusing on the drug price and description in the Internet.

In this situation, the use of digital technologies becomes particularly relevant, because they accelerate collecting information (on supply and demand for certain biologically active substances, for example) and creating programs to study vaccines, antibiotics, etc.

It is already obvious that the developed approaches to the creation and production of immunobiological preparations, in particular, vaccines, do not allow timely response to newly emerging epidemic threats, as was clearly demonstrated by the pandemic caused by the SARS-CoV-2 virus.

In this regard, the most promising direction is the development of universal platform technologies and corresponding state-of-the-art production facilities. It is necessary to recognize that modern production capacities, technologies and economic opportunities of the states must radically restructure and rapidly adapt to the growing demand for new BAS and generics, as well as to their timely delivery all over the world. It is still difficult to implement the economic component – to make production cheap or to find active and progressive investors. A number of revolutionary decisions have already been made within the framework of world-class science centers (WCRC). Digital platforms are being created for the development and production of vaccines based on the original technology of self-

replicating RNA (srRNA). The organization of new facilities for the manufacture of biologically active substances of various groups requires new technological solutions using bioinformatics, mathematical modeling and other digital technologies.

Researchers recognize that scientific and experimental works should provide answers to the main questions of theoretical bioinformatics:

"1. what factor and mechanism contributes to the greatest therapeutic effect of a particular substance?

2. what is the mechanism of the therapeutic effect of drugs?

3. why dilutions makes the spectrum of drug action wider, efficiency higher and 'depth' greater?" [15].

Every year chemists synthesize, isolate and characterize from 500 to 600 thousand new substances. By the beginning of the new millennium, scientists had produced more than 20 million individual substances. Many of these substances are undergoing initial testing to detect a particular biological activity (basic screening of a substance) [15].

It is generally accepted that only those drugs can be synthesized on an industrial scale that are highly active, comprehensively studied, and have data on side effects.

The problem of biologically active substances classification is still relevant. Currently, it is generally accepted to distinguish three main types of drugs classification:

1. by therapeutic effect: classification by therapeutic groups depending on their effect on the body;

2. by source: classification by biological or chemical origin, i.e. from what natural source the drug is obtained;

3. by chemical structure: classification based on the chemical structure, or drug molecules structure.

As we can see, the classification is standard, but an average person does not know it and, in fact, is not interested in it. What an average person wants is to be healthy and comfortable; that the drug is cheap and available, can be found in almost any pharmacy, ordered and delivered; if a person doubts its purpose, the information about it should be available [16].

Notably, after the world faced the 2020 pandemic and its consequences, it became obvious that a detailed revision of the existing WHO classification is required.

The Russian citizens are as willing to invest in their health as they were in 2020 and 2021. The situation has stabilized, but the demand is still not decreasing. BAS are in steady demand. Statistics indicates an increase in demand by 15-18% in each reporting period, depending on the diseases seasonality. Marketing agencies (DSM Group, for example) confirm the increase in pharmaceutical companies' revenues from selling original drugs and their generics, the effectiveness of which is not sufficiently high. In 2022, the Russian Federation income increased by almost 9.2 billion rubles due to selling biologically active substances of various groups. The population has not been stopped by the fact that the Russian legislation on healthcare strengthened the requirements for prescription drugs and control over their sale. This confirms the main idea of this article: in the age of digital technologies, electronic payments and deliveries, it is possible to use digital space to obtain medical consultations with leading specialists in medicine, as well as to obtain test results and make an appointment with a doctor. The process of obtaining medical services, prescriptions, and buying drugs in the Internet accelerated.

In Russia, there is also one peculiarity – purchasing medications "as a reserve", when a patient realizes that there are medicines that are needed always and everywhere, are used in many difficult situations and have a wide range of action. Such purchases in advance, to prepare for cold and vacation seasons, ensure a constant demand for medications, which supports the economy of pharmaceutical companies.

4 Discussion

Any new research, especially the study of the human genome, involves the use of digital technologies. Prevention and therapy of some common non-infectious diseases are currently based on the understanding of external and internal risk factors that can lead to their development. Such theoretical advancements allowed creating effective preventive and therapeutic measures. However, a careful analysis of the aspects reveals the rationality and feasibility of moving from the medical level, characterized by the risk factors concept, to the general biological level, which can provide more general and fundamental results.

This is the situation in which risk groups arise among practically healthy individuals, which requires the intake of new biologically active substances of the latest generation [17].

We do not deny that it is necessary to be responsible for one's behavior and lead a healthy lifestyle. Many researchers shift the focus of attention from the use of BAS to methods of disease prevention, namely: patient-friendly physiotherapy and sanatorium-resort methods that increase the adaptive potential of a human body.

5 Conclusions

Today, the industry of biologically active substances is one of the leading in the world in terms of sales. At the same time, doctors and patients often do not think about the composition of modern medicines produced as pills, powders or suspensions. Apparently, a person does not really care whether the drug main component is natural or synthetic. The most important thing is how effective it will be, whether it will relieve pain, help to cope with allergies, improve the body performance and the brain capabilities, etc. The second conclusion is also reasonable: biologically active substances of plant or synthetic origin can differ significantly in their effectiveness, therefore, in treating certain diseases. Side effects may greatly reduce confidence in certain drugs. It may be necessary to convince a patient to tolerate the negative consequences of the drug intake for the sake of obtaining the desired effect [18].

We must not abandon what has already been achieved, nor yield the existing research. We should develop further, but taking into account the progressive achievements in various branches and sciences. It is necessary to clearly understand what biologically active substances can be used by humans.

Synthetic drugs differ from natural ones both in their effectiveness and the direction of action, as well as in the presence of side effects. One should not think that at a certain stage of pharmaceutics development it will be expedient to completely abandon the use of natural medications in favor of the artificially synthesized ones. We should not forget about the experience accumulated by mankind for thousands of years.

Thanks to modern digital technologies and technological advances in the synthesis of biologically active substances, most of the results remain reliable and confirm the study effectiveness.

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