

## **Prospects for the development of the field of pharmaceuticals and biotechnology**

Biotechnology is rightly considered an innovative branch that is rapidly developing and takes a leading place in the development of technologies for obtaining new multifunctional products of microbial synthesis, the lion's share of which is used in industrial pharmacy as active pharmaceutical ingredients for the production of medicines. Thus, biotechnology and pharmacy are inextricably linked in the issues of obtaining original medicinal substances based on biologically active compounds. The creation of new, high-quality and affordable medicines, food products, environmental protection is one of the most urgent issues on a global scale, the solution of which is impossible without the use of biotechnology methods. That is why biotechnology is one of the most promising specialties of the 21st century, not only in Ukraine, but also in the whole world.

Biotechnology ensures the production of medicines, food products, the creation of transgenic microorganisms, plants and animals, etc. The achievements of biotechnology are used in almost all fields of science and technology, because it helps to create high-quality and inexpensive products. Currently, a significant contribution of biotechnology is observed in the field of health care. The possibility of unlimited obtaining of natural protein bioregulators and biologically active substances, including rare and expensive, opens new perspectives in the treatment of various diseases. Biotechnology is engaged in the development of vaccines, in particular to combat such diseases as AIDS, hepatitis, malaria, and some cancers. Today, pharmaceutical companies spend about 20% of their budget on biotechnological research, and biotech specialists are among the TOP 10 specialties that are most in demand and promising [1].

Pharmaceuticals and biotechnology are modern high-tech industries of various countries of the world and are one of the key factors in the creation of a modern innovative economic system of many countries, including EU countries, providing the basis for significant competitive advantages, stimulating economic growth and creating new jobs. Developments in the field of biotechnology are used in medicine, food production, agriculture, forestry, etc. According to the calculations of the experts of the European Commission regarding the state of research and development (R&D) expenditures in the industrial sector, it was established that among the sample of Top-2000 companies of the EU, the USA, Japan and some other countries, the fields of pharmaceuticals and biotechnologies are in first place by the volume of investments, in particular in 2012 in 2018, the share of expenditure on the development of the R&D was 18.1%. Regionally, the share of R&D expenditures in the fields of pharmaceuticals

and biotechnology is as follows: in the EU — 17.5%, in the USA — 22.1%, in Japan — 10.8%. This shows that in terms of the level of economic development, the biological industry of the EU ranks second in the world after the USA, special attention in the European approach to the development of biotechnology is paid to its ecological direction [3].

Most of the classic biotechnologies belonging to the medical and pharmaceutical industry are somehow related to the microbial synthesis of biologically active substances, mainly antibiotics. The discovery of the main groups of antibiotics and the entire complex of genetic and biochemical research of their producers (bioagents) in the 40s and 50s of the last century, which allowed for the large-scale production of fundamentally new medicinal products, can be attributed to the most important achievements of biotechnology. The demographic explosion in some countries and the sharp increase in the competitiveness of life in others at that time were largely due to antibiotics. Among the products of the pharmaceutical industry of developed countries, antibiotics rank first in all indicators. Despite the knowledge of the structure of almost all known substances with antibiotic action, their chemical synthesis is cumbersome and ineffective. In industry, antibiotics for medical or veterinary purposes are obtained using the ability of the corresponding producer strains to generate this antibiotic in a certain phase of growth and a given mode of cultivation.

An example of modern medical biotechnologies in our country are the latest biotechnologies in the diagnosis, treatment and prevention of human diseases, developed by scientists of the Institute of Emergency and Restorative Surgery named after V.K. Husak of the National Academy of Medical Sciences of Ukraine, who became laureates of the State Prize in the field of science and technology in 2013. They studied the peculiarities of the course of the wound process in various burns in children and adults, changes in immunophenotypic characteristics and the effectiveness of surgical treatment of burn disease with the use of allogeneic and autologous fibroblasts and keratinocytes, including the use of a conditioned medium for the cultivation of fibroblasts [2]. The future of medicine will be determined precisely by biotechnologies and the creation of new medicines with their help — more effective and safer ones that selectively act on pathological processes in the body for a number of serious diseases that were previously incurable. However, with the advent of new biotechnological drugs, a number of problems have arisen. Key among them is the high cost of such medicines, which is due to the complexity of their development and production. Considering this, as well as the considerable duration of treatment, its total cost becomes “unaffordable” not only for the patient, but also for the state.

The standard way to solve the problem of increasing the availability of modern drugs for the general population is to replace the original drugs with their cheaper reproduced copies. For chemically synthesized drugs, provided bioequivalence is proven, a cheaper generic drug is identi-

cal to the original drug, has the same effectiveness and safety, which allows generics to be widely used and replaced by original drugs. But the characteristic features of biotechnological drugs, their differences from conventional synthetic drugs, modern approaches to ensuring their quality, efficiency and safety require the formation and application of new thinking, leaving behind “generic” habits, as well as the training of new highly qualified personnel in the field of biotechnology to study biosimilarity (biosimilarity) [3]. It is believed that the original and reproduced drugs are identical to each other, have the same effectiveness and safety, so they are confidently prescribed by many medical specialists. The most attractive biosimilars, as well as other generic drugs, from the point of view of price, which increases the availability of their use not only for the population, but also for use in government programs for the provision of medicines. However, despite the economic advantages, biosimilars can rarely be compared to the original in terms of efficacy and safety, since it is impossible to create two absolutely identical banks of cells that are used to obtain the active substance and accurately repeat the long and complex production process [4].

Today, the biotechnology industry is far from organizational completeness, because its possibilities from the point of view of practical application and business processes are not yet fully utilized. However, it succeeded on an international scale in mobilizing private and state investments in the creation of scientific knowledge and technologies, their dissemination and application, creating a significant potential of human resources, research, education and technological infrastructure. So, summarizing the above facts, we can say that although the situation in the pharmaceutical field Ukraine is rather shameful compared to its foreign competitors, but by applying at least some of the proposed measures, it is possible to increase the competitiveness of the domestic drug market, set a course for the development of the pharmaceutical market of Ukraine and reach the level of development of its global competitors.

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