Modern biomedicine in global economy and Ukraine

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Bio-technical revolution has actually started since the XX century last decade and created a powerful wave of innovative products and services in medicine, agriculture, power engineering, i.e., practically in the majority sectors of the global economy. At the beginning of the XXI century EU has developed "Strategy For Europe On Life Sciences And Biotechnology", which has become a basis for EU countries to develop their national policies in the sphere of biotechnologies [1]. That document recognizes that after the information revolution and Information-Communication Technologies (ICT) development biotechnologies and life sciences have become the second innovation wave.

As of today, Organization for economic cooperation and development (OECD) has provided two definitions of biotechnologies: a simple one and a more comprehensive one, which is based on the list notation of the biotechnological equipment. In a simple variant biotechnology is a set of fundamental and applied researches as well as engineering solutions directed to use biological objects, systems or processes in industrial scale. In a broader sense OECD experts have proposed the following list of the modern convergent biotechnologies, which are used in medicine, pharmaceutics and biotechnological industry, bioenergy and agriculture, etc. [2; 3]:

- **DNA/RNA:** genomics, pharmacogenomics; gene sensors or gene detectors; DNA/RNA-sequencing/synthesis and amplification (determining macro-molecules' primary structure; strengthening the process of DNA/RNA copying; genetically based profiling, etc.);
- **Proteins and other molecules:** sequencing/synthesis and construction of proteins and peptides, including big hormone molecules; improved system of medical drug delivery to specific human body points on the bases of big molecules; proteomics; proteins isolation and purification, alarming and identifying cell receptors;
- **Cell and tissue cultures and their engineering:** fermentation that uses bioreactors; bioprocesses; bio-treatment; wood softening with the help of wood destroying fungi; bio-desulfation; biological treatment of the soil contaminated with organic waste with the help of fungi; bio-filtration, etc.;
- **Genes and RNA-vectors:** gene therapy, virus vectors;
- **Bioinformatics:** genomes databases' engineering; protein sequencing; modelling complex biological processes, including systems biology;
- **Nano-biotechnologies:** tools and processes that use nano- and micro-technologies to engineer equipment for studying bio-systems and to be also applied in the systems of medical drugs delivery in human body, diagnostics, etc.

On the basis of the "comprehensive" definition of biotechnologies, OESD has developed a conceptual model for biotechnological and statistical indicators, which incorporates a wide spectrum of scientific-technological and innovative performances, and could be used for determining "contents of the bio-society", formulating the national and global innovative bio-policy and developing bio-strategy. At the same time, the difference between pharmaceutical industry and modern industrial biotechnology is noted in the practical domain: pharmaceutics develops comparatively low-molecular drugs, while biotechnologies – big bio-molecules, as, for example, functional proteins and anti-bodies. As of today, erythropoietin protein (it stimulates creation of erythrocytes) may serve as an example, as well as recombinant human insulin, human interferon, human and animal growth hormone, therapeutic antibodies, etc.

Outlook on innovations in biotechnology and living systems was discussed in OECD in 2007-2008 within the framework of International Futures Program (IFP) [4]. At the same time OEDD implemented the project "The Bio-economy to 2030" as the most important element of NBIC-revolution [5].

Therefore, in medicine and health care bio-technologies are used in the field of therapy, diagnostics, pharmacogenetics (branch of the genetics, the subject of which is genetically determined organism's reactions to medicines), functional food products and nutraceuticals (food products with pharmacological properties), as well in the medical equipment. Some bio-technologies, like, for example, bio-pharmaceutics and «in vitro» diagnostics, have already been commercialized and have access to the world market.

For example, experimental bio-therapy with using bio-technologies, includes cell engineering, therapeutic vaccination, research in the field of stem cells, lytic viruses, genes, etc. OECD determines the indicated directions as "experimental", because they have not been widely market-wise approved by government authorities of OECD countries, which are responsible for designing and approving the corresponding legal decisions in the field of medicine. At the same time exactly those spheres determine the most advanced trends in medical bio-technologies area, which are increasingly used

by bio-technologic companies during development, testing and production of pharmaceutic products. For example, research and clinical testing of new molecular drugs bio-NME (New Molecular Entities) demonstrate the bio-pharmaceutics development level in OECD countries. For example, as of today, globally developed bio-NME averagely has undergone 56% of testing. Denmark has the lowest level of bio-therapy per capita, the second place belongs to Switzerland, the USA ranks the third [4; 5].

By 2030, and especially by 2050, health care costs in OECD countries and other world countries would increase. If in 2005 OECD countries budget outlays for health care were on overage 5.7% GDP, by 2050 they could reach 12.8% GDP. But if we also consider private sector, the outlays would be even higher. This could be attributed mostly to the application of new technologies in health care sphere, including also bio-technologies and converged NBIC-technologies. Main application of nano-technologies in health care sphere, for example, would be connected with the production of nano-size equipment and appliances that would be able to interact with bio-molecules both on cell surface and inside it [3, P.40].

Therefore, biomedicine as one of the directions to use NBIC-technologies convergence, would, by different estimates, cause the most radical break-through in this innovations sphere. As expected, in the XXI century nano-technologies achievements will lead to creating new methods in therapy as well as potential preconditions for increasing human physical capacities.

To develop nano-biotechnical research and commercialize its results in Ukraine the Ukrainian National Academy of Science has started a special purpose comprehensive interdisciplinary program for scientific research: "Fundamental grounds for molecular and cell biotechnologies" for the period 2010 – 2014, as specified in the resolution of the Ukrainian Academy of Science Presidium dated 07.07.2010, №222 [6]. Within the framework of the adopted Program concept it was decided to carry out purposeful research in the following areas of modern biology:

- Study the properties and functioning mechanisms of bio-macro-molecules, permolecular systems, sub-cell and membrane structures in norm and pathology;
- Develop fundamental grounds of molecular and cell technologies for diagnostics, prevention and treatment of diseases and for genetic improvement of living organisms;
- Structural, functional and comparative genomics of humans, animals, plants and micro-organisms;
- Modern aspects of creating biologically active drugs, new forms of plants and micro-organisms.

The Ukrainian Academy of Science Presidium decree №573, dated 01.09.2010, "On approving the list of projects integral to comprehensive interdisciplinary program for scientific research: "Fundamental grounds for molecular and cell biotechnologies" established a range of projects for the named program [7]. Within the framework of that program it is planned to perform the following actions by ways of employing novice methods of molecular physiology, biochemistry and genetic engineering:

- Develop new approaches to counteract the most common and dangerous human and animals diseases;
- Create scientific grounds for developing new medicinal drugs, their therapeutic application and efficient systems for their delivery in organism;
- Develop up-to-date methods for diagnosis and treatment of socially important human diseases;
- Study modern aspects of creating new forms of plants and micro-organisms – producers of medicinal drugs with the help of genetic engineering;
- Develop new environmentally friendly biotechnologies enhancing productivity and sustainability of agricultural plants at unfavorable biotic and abiotic factors;
- Research molecular mechanisms of biologically active substances action to create new high-efficient fertilizers' growth-regulators and means of plants protection.

Since 2013 The State Special-Purpose Scientific-Technical Program To Develop New Technologies For Creating National Medicinal Drugs To Ensure Human Health Care And Satisfy The Needs Of Veterinary Medicine In The Period 2011 - 2015 has been under way.

The Program purpose is to develop molecular and cell technologies for creating the national medicinal drugs to ensure human health care and satisfy the needs of veterinary medicine. The ways to reach the indicated goal are as follows [8]:

- Develop technologies of targeted generation of synthetic chemical compounds and luminescent bio-medical diagnostic materials with the determined biological activity;
- Create new diagnostic means on the bases of DNA- and RNA-technologies;
- Develop diagnostic means on the basis of recombinant proteins and immune-chemical approaches;
- Create therapeutic drugs and agents on the basis of recombinant proteins and anti-bodies, blood- and plasma-derived products and drugs for cell therapy;
- Create medical drugs' exploratory prototypes and develop master batch records for their production.

The program tasks are as follows [9]:

1. Create and support functioning of the research scientific-production basis of molecular and cell bio-technologies;
2. Create new diagnostic means on the basis of DNA- RNA-technologies;

3. Develop diagnostic means on the basis of recombinant proteins-bodies and immune-chemical approaches;

4. Create therapeutic drugs on the basis of recombinant proteins, anti-bodies and DNA- , RNA-technologies;

5. Create and implement innovation systems for developing medicinal substances.

On the basis of the above mentioned facts [10-14] we may conclude:

1. Biotechnologies similarly to nano-technologies, information-communication and cognitive technologies, in the global scientific community are regarded as "global technologies" because they include a wide spectrum of scientific disciplines, economy sectors and are spread over huge territories of the planet. According to the leading world experts, the list of the modern convergent biotechnologies that are used in medicine, pharmaceutical and biotechnological industries, in bioenergetics and agriculture, should include: DNA/RNA; proteins and other molecules; cell and tissue cultures and their design; genes and RNA-vectors; bioinformatics; nano-biotechnologies.

2. Biomedicine, as one of the directions that use convergence of NBIC-technologies, by different evaluations would cause the most radical break-through in this branch of innovations. As expected, in the XXI century nano-technologies achievements would provide for creating new methods in therapy as well as potential preconditions to increase human physical capacity. Practical implementation of the fundamental developments in the mentioned branches would manifest itself in the development of personified medicine, to include also gene-diagnostics; proteomics; pharmacogenomics; bio-analytical technologies; implementation of nano-technologies for medicinal drugs; bio-informatics.

3. In Ukraine, within the frameworks of the special purpose comprehensive interdisciplinary program for scientific research: "Fundamental grounds for molecular and cell biotechnologies" launched by the Ukrainian Academy of Science, and using modern methods of molecular physiology, biochemistry and gene engineering in the period 2011–2013 the following was achieved: new approaches to counteract the most widely spread and dangerous human and animal diseases were developed; scientific grounds for developing new medicinal drugs, their therapeutic application and efficient systems for their targeted delivery in the body were set; modern diagnostics and treatment methods were developed to counteract socially important human diseases; modern aspects of creating new forms of plants and micro-organisms – producers of medicinal drugs, were studied with the help of gene engineering methods; new, environmentally friendly biotechnologies to enhance productivity and sustainability of agricultural plants in unfavorable biotic and abiotic conditinos were developed; molecular mechanisms of biologically active substances action were researched to create new high-efficient fertilizers-growth-regulators, and plants protection means.

4. Within the framework of the Ukrainian State Special-Purpose Scientific-Technical Program To Develop New Technologies For Creating National Medicinal Drugs To Ensure Human Health Care And Satisfy The Needs Of Veterinary Medicine In The Period 2011–2015, as of the end of 2013 the following was accomplished: technologies for targeted obtaining of synthetic chemical compounds and luminescent biochemical diagnostic materials with the determined biological activeness were developed; new diagnostic means on DNA- and RNA-technologies basis were created; diagnostic means on the basis of recombinant proteins and immune-chemical approaches were developed; therapeutic drugs and means were created on the basis of recombinant proteins and anti-bodies, blood and plasma products as well as products for cell therapy; research prototypes of medicinal drugs were created and master batch record for their production was developed. With this regard the Ukrainian scientists' developments could be widely used in medical practice both in the world developed countries and in Ukraine.

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