

Organization of Pharmaceutical Business, Drug Technology, Forensic and Clinical Pharmacy: Multidisciplinary Innovative Nanotechnologies in the Development and Implementation of New Medical Products to Medical and Pharmaceutical Practice

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Abstract. Multidisciplinary research was conducted concerning the use of innovative nanotechnologies in the development of new drugs within the framework of organization of pharmaceutical business, drug technology, forensic and clinical pharmacy. The promising development of nanomedicine and nanopharmacy in the field of drug-design for new drugs was noted. The perspective of further scientific study of the use of nanotechnologies for the pharmacotherapy of covid, post-covid,

long-covid, and comorbid disorders was proven. The possibility of creating of medical and pharmaceutical industrial parks, as well, as medical and pharmaceutical clusters for financial and economic growth on the state and regional levels were substantiated.

Keywords: organization of pharmaceutical business, drug technology, forensic pharmacy, clinical pharmacy, multidisciplinary research, innovation, nanotechnology, development, introduction into medical practice, new drugs.

Introduction. The integration of Ukraine into the European Union contributes to the study of the experience of the USA, India, Japan, and Australia in the practical cooperation of the Quad Leaders' Summit regarding the challenges of the 21st century [1-8]. Among them, the main ones are [9, 10]:

- ✓ ending the COVID-19 pandemic by increasing the production and availability of safe and effective vaccines for all segments of the population;
- ✓ promotion of infrastructure of high standards;
- ✓ partnership on new technologies, nanotechnologies, space, and cyber security;
- ✓ training of talents of the new generation, etc.

Taking into account the experience of the health care systems of the leading countries of the world, determining the direction of financial and economic growth of Ukraine, in particular due to the development of technological parks, can become the basis for the formation of multidisciplinary innovative mechanisms for the development of new drugs in pharmacy. Thus, modern scientific ideas and applied

multidisciplinary innovative nanotechnologies in the pharmaceutical production of medicines stimulate innovation and investment activity and mechanisms of effective use of the scientific, production and personnel potential of Ukraine [11-17].

In Ukraine, before the start of hostilities, about 30 percent of vitally necessary medicines were produced for all categories of patients (disabled persons of I and II groups, participants in hostilities, liquidators of the accident at the Chernobyl nuclear power plant, patients with covid, post-covid, long-covid, cardiovascular, nervous, endocrine, immune, narcological, orphan, comorbid disorders, tuberculosis, etc.) [18-52].

The search and use of economically available, effective, and safe multidisciplinary innovative nanotechnologies in the development of new medicines in the conditions of martial law remains a necessary task.

The purpose of the study was to analyze and systematize data from the literature on conducting multidisciplinary research in the field of pharmaceutical business organization, drug technology, forensic and clinical pharmacy during the use of innovative nanotechnologies in the development and implementation of new drugs in medical and pharmaceutical practice.

Materials and methods. In the period from 2005 to 2021, a review of the scientific literature on the topic of the work was conducted. The information base consisted of foreign and domestic scientific papers [53-70]. Methods of normative-legal, documentary, retrospective, comparative, forensic-pharmaceutical, system and graphic analysis were used to process the results.

The research of the article is a fragment of research works of Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, terms 2016-2020) and "Pharmaceutical and medical law: integrated approaches to the system of drug circulation from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number D/21U000031, terms 2021-2026), also Lviv Medical Institute LLC on the topic "Improvement of the drug circulation system during pharmacotherapy on the basis of evidentiary and judicial pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, terms 2021-2026),

Results and discussion. Innovative nanotechnologies are an interdisciplinary branch of fundamental and applied sciences, technology, and engineering. Nanotechnology represents a set of theoretical techniques and methods used in the study, development, production, and use of nanostructures, which include purposeful control and modification of the shape, size, interaction, and integration of their constituent elements (about 1-100 nm) to obtain objects with new chemical, physical and biological properties [71].

Japan and the USA are world leaders in terms of the total number of capital investments in the field of nanotechnology. Experts believe that in the 21st century, nanotechnology will take a leading place in the development of new medicines. The USA, Switzerland, Great Britain, Japan, and Germany are involved in the innovative development of medical equipment. India and China are taking significant steps in this

area. The American National Institute of Health has included nanotechnology in the top five priority directions in the development of new pharmaceuticals [72,73].

In Ukraine, the leading role in the study and application of nanotechnology belongs to scientists based on their publications. Today, up to 85% of the substances required for the production of finished medicinal products are purchased in India, China, and other countries [74-77].

Nanomedicine and nanopharmacy study the possibility of using nanotechnological developments (nanodevices, nanomedicines) in medical and pharmaceutical practice, on an evidence-based basis, for the prevention, diagnosis, and treatment of various diseases with control of their quality, biological activity, clinical-pharmacological, toxicological action and safety of the obtained products or drugs [78-88].

A modern review of the literature shows that nanotechnologies of drug design of new drugs have recently become widespread, among which microencapsulation, as well as nanotechnologies for obtaining matrix, multilayer, shell tablets and capsules, should be indicated. For example, platform technologies for the creation of nanoscale complexes of medicinal substances with biocompatible synthetic and natural polymers have been developed and patented, which leads to an increase in the pharmacological activity of the drug by 2-4 times. Platform technologies of controlled drug release are relevant for the targeted delivery of anticancer drugs specifically to diseased tissues, while the drugs are not released instantly, but as the polymer degrades [89-96].

The directions of application of nanotechnology are shown on the Fig. 1.

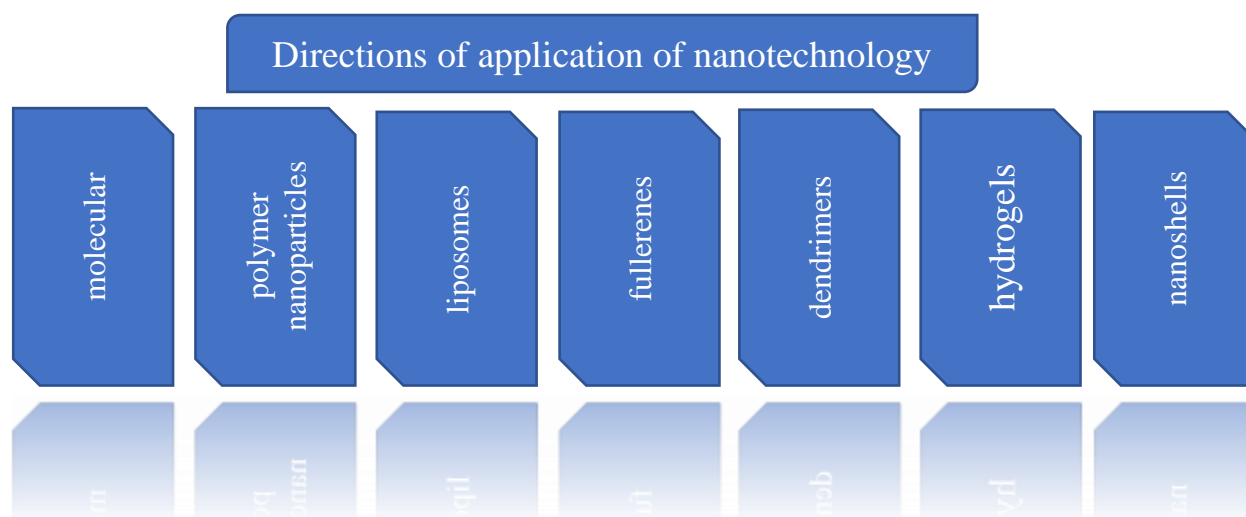


Fig. 1. Applications of nanotechnology.

In addition, molecular nanotechnology, polymer nanoparticles, liposomes, fullerenes, dendrimers, hydrogels and nanoshells should be highlighted among the areas of nanotechnology application. The size of the molecule ranges from 0.1 nm (simple molecules) to 50 nm (complex molecules – enzymes). For example, 1 nm is one billionth of a meter (10^{-9} m), and a nanoparticle is a structure with a diameter of 1 to 100 nm. The industry of directed development and construction of new drugs, or drug design (drug – medicine, design – projecting, construction) is directly related to nanotechnologies in nanopharmacy and nanomedicine, since interacting objects - drugs

and targets are molecular objects. Among the means of drug delivery, nanoparticles are used: liposomes, bacteria; polymer nanostructures (nanospheres, nanocapsules); dendrimers; carbon nanoparticles (nanotubes, fullerenes); compounds of silicon oxide, as well as various metals (gold, silver, platinum) [97-101].

It was noted that nanoparticles can be in the form of compositions of drug molecules of various clinical-pharmacological and classification-legal groups. For example, compositions: paracetamol molecules + diazepam molecules + caffeine molecules; Ketanov molecules + metamizole molecules + diazepam molecules; acetylsalicylic acid molecules + caffeine molecules + phenobarbital molecules, etc. [102-108].

At the same time, one of the varieties of the targeted drug delivery system is the use of polymer nanoparticles, which consist of colloidal structures that carry drugs inside the polymer matrix. Polymer nanoparticles are synthesized in the form of nanospheres or nanocapsules. Nanospheres are vesicular systems of carriers in which the active substances of the drugs are located in the central cavity surrounded by a polymer matrix. The effectiveness of polymer nanoparticles is superior to traditional methods of drug administration (intravenous, oral). Such advantages arise from their main properties: their small size allows penetration through the walls of capillaries, which leads to an increased concentration of the drug directly in the target; this applies to the central nervous system, where drug delivery is limited due to their inability to cross the blood-brain barrier; the use of polymers allows drug to be slowly released at the target site for a long time [109].

Different single-component and multi-component liposomes formed in lipid solutions have been known for a long time. For practical purposes, liposomes with a size of no more than 20–50 nm can be of interest, which are used as a means of delivering a drug to a biological target. Bacteria, as nanobiomachines, can be used as means of point delivery of drugs to diseased tissues [110].

Nanospheres and nanocapsules belong to the family of polymer nanostructures that can be obtained from natural or synthetic polymers (polysaccharides, polylactic and polyglycolic acids, polylactide, polyacrylates, acrylic polymers, polyethylene glycol). Nanospheres are entire matrices on the polymer surface of which drugs are distributed. In nanocapsules, the polymer shell forms a cavity filled with liquid. Medicinal products of nanostructures are released into the patient's body by various mechanisms: from nanospheres (the release is exponential); from nanocapsules (release occurs at a constant rate for a long time) [111].

Of special interest are dendrimers – a new type of polymers that have a non-linear, but "branched" structure. The first sample of dendrimers was obtained in the 50s of the 20th century, and the main methods of their synthesis were developed in the 80s of the 20^t century. The term "dendrimers" appeared earlier than the term "nanotechnology", and at first, they were not associated with each other. However, recently, dendrimers are increasingly mentioned in the context of their nanotechnological applications in nanopharmacy and nanomedicine. Dendrimers are obtained from monomers by conducting successive convergent and divergent polymerizations, thus setting the nature of branching. On the surface of dendrimers, it is possible to stereospecifically place the necessary functional groups that will interact

with viruses and cells with maximum effect. An example of the creation of a drug based on a dendrimer is vivigel – a gel capable of protecting against HIV infection.

The facts indicate that in 1991, long, cylindrical carbon formations, which were called nanotubes, were discovered. They are characterized by a variety of shapes: large and small, single-layer and multi-layer, straight and spiral. Nanotubes can be used as microscopic containers for the transport of many chemical or medicinal substances. For nanopharmacy and nanomedicine, what is valuable about nanotubes is their increased affinity with lipid structures, the ability to form stable complexes with peptides and DNA oligonucleotides, and even the ability to encapsulate these molecules [112].

It should be noted that among carbon nanoparticles formed only by carbon atoms, in addition to nanotubes, fullerenes are widespread, which can be obtained using various chemical or physicochemical methods. The main feature is their frame shape: the molecules look like they are closed, empty inside the "shell". The most famous of the carbon frame structures is fullerene C₆₀, based on which drug delivery devices are being developed for the treatment of patients with the circulatory system, HIV/AIDS, drug addicts, and other categories [113].

So, inorganic nanoparticles, one of the most important classes of nanoparticles, include compounds of silicon oxide, as well as various metals (gold, silver, platinum). Often such a nanoparticle has a silicon core and an outer shell formed by metal atoms. The use of metals makes it possible to create carriers with a number of unique properties. One of the simplest and most effective ways of delivering drugs to the patient's body is transdermal (through the skin). Precisely because of its simplicity, there are still no theoretical prohibitions on the delivery of most known drugs in this way, regardless of their molecular weight (size) or physicochemical properties. However, for the nanocarriers described above, the transdermal method is considered as one of the possible ways of transporting nanoobjects.

Research into the toxic mechanism of cardiovascular damage caused by nanomaterials worldwide is still in its infancy. There is very little relevant research evidence on biological endpoints to determine the relationship between physicochemical parameters (shape, size, size distribution, surface structure, electrochemical properties, etc.) of nanoparticles and cardiovascular toxic effects. Therefore, scientists need to conduct more research on the toxic effects on the cardiovascular system and the mechanisms of typical effects of nanomaterials in order to better use the positive effects of nanomaterials to prevent, reduce or eliminate possible negative health effects. In addition, it will provide a theoretical and technical basis for the creation of technology and standards for safety assessment of nanomaterials [111].

In the future, it is promising to create conditions for further interregional development of Kharkiv National Medical University (KhNMU – <https://knmu.edu.ua/>), Kharkiv Medical Academy of Postgraduate Education (KhMAPE), Lviv Medical Institute and Estonian Scientific Publishing House SSP OÜ (<https://ssp.ee/index.php/mpm/article/view/40>) regarding promotion at the regional and national levels of infrastructural changes and competencies in the medical field

and the pharmaceutical industry based on high international and European standards, namely:

- collection, summarization and forwarding to relevant authorities of changes and additions to legislative, regulatory, instructional and methodical documents of the state and regional levels regarding pharmaceutical and medical activities in accordance with the world level;
- motivating for the scientific and pedagogical workers by inviting them to cooperate, cultivating and supporting of talented young people of the new generation, creating conditions for planning and training precisely on the basis of the KhNMU, KhMAPE and LMI of doctors of philosophy and doctors of medical and pharmaceutical sciences;
- raising the level and effectiveness of research activities of higher education institutions on R&D topics. For example, the R&D "Improving the drug circulation system during pharmacotherapy on the basis of evidentiary and forensic pharmacy, organization, technology, biopharmaceutics and pharmaceutical law" open research and development at LMI, state registration number 0120U105348 [115]. It is possible to plan candidate and doctoral theses in medical and pharmaceutical sciences at the dental, medical and pharmaceutical departments (for example, scientific specialty: 15.00.01 – drug technology, organization of pharmaceutical business and forensic pharmacy) with the participation of scientists from KhNMU, LMI and KhMAPE on clinical, pharmaceutical and pharmacy bases of the health care system of the Kharkiv and Lviv regional military administrations;
- organization and holding on the November 17-19, 2022 of the XIX international multidisciplinary scientific and practical conference "Medical and pharmaceutical law of Ukraine: organization of pharmaceutical business, general, forensic and clinical pharmacy, pharmacotherapy of health disorders" (register of congresses, congresses, symposia and scientific and practical conferences to be held in 2022 year, agreed upon by the National Academy of Sciences of Ukraine and approved by the Ministry of Health of Ukraine and Government Agency "Testing Center" under items No. 656 and No. 665) [115];
- determining the direction of financial and economic growth, in particular due to the creation of medical and pharmaceutical industrial parks and medical and pharmaceutical clusters [5, 6, 116].
- establishment of cooperation with foreign and domestic pharmaceutical enterprises ("Zdorovya Pharmaceutical Company" LLC, "Zdorovya Narodu" LLC, DNCLZ LLC, Lekhim-Kharkiv JSC, Chempharmzavod Chervona Zirka JSC, "Stoma" CJSC, LLC "Micropharm", PJSC "Kharkiv Enterprise for the Production of Immunobiological and Medicinal Products "Biolik", LLC "Scientific-Production Pharmaceutical Company "Aim", LLC "Veterinary Medicine", LLC "Vetsintez", Kharkiv State Biological Factory);
- optimization of cooperation with JSC "Halychpharm" [117];

- the formation of an innovative mechanism at the KhNMU and KhMAPE for the identification of modern scientific ideas and applied development of new drugs with further implementation of the results;
- introduction into medical practice of new drugs Halopril, Valcofen, Cardacet, Parsicol, Calevit C, Difenal, Dynalgin, Theophedrine-Plus, etc.;
- creation of an Advocacy Clinic and a "hotline" to provide the population and patients with affordable medical, pharmaceutical, and legal assistance;
- optimization of cooperation in the chain "doctor-patient-pharmacist" or "hotline-inquiry-appeal" regarding the provision of patients with medical services or discounted vital drugs in accordance with the current regulatory and legal acts of Ukraine [118-121].

The National Health Service of Ukraine guarantees availability of state-guaranteed medical and pharmaceutical services to citizens, regardless of health status and financial capacity [118]. The procurement conditions are designed for health care facilities that have already provided medical services under the Medical Guarantee Program, as well as for health care facilities that wish to enter into a contract for the first time. Patients should not suffer financial costs in case of illness or refuse to receive necessary medical care due to inability to pay for it. In the conditions of martial law, the spread of covid, post-covid and long-covid disorders, modern challenges in the form of new infections, the importance of multidisciplinary innovative nanotechnologies for the development of new drugs and optimization of pharmacotherapy is increasing [122-124]. The implementation of the system of integration competences of Ukraine to the EU will contribute to the increase of competences of political and legal, financial and economic, medical and pharmaceutical, and socially guaranteed security at the state and regional state levels.

Conclusions. Multidisciplinary research was conducted on the use of innovative nanotechnologies in the development of new drugs within the framework of pharmaceutical business organization, drug technology, forensic and clinical pharmacy. Scientific sources were analyzed and systematized according to the topic of the work. Areas of application of nanomedicine and nanopharmacy are given. The promising nanotechnologies of drug design of new drugs are noted. Types of innovative nanotechnologies aimed at developing and designing new drugs are systematized. Systems of targeted drug delivery using nanotechnology are given. The perspective of further scientific study of the use of nanotechnology for the pharmacotherapy of covid, postcovid, long-covid, comorbid disorders is noted. The possibility of creating medico-pharmaceutical industrial parks and medico-pharmaceutical clusters for financial and economic growth is substantiated. Implementation of the system of integration competences of Ukraine to the EU will contribute to the increase of competences of political and legal, financial and economic, medical and pharmaceutical, and socially guaranteed security at the state and regional levels.

Conflict of interests. The authors declare that they have no conflict of interests or/and competing interests.

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