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**ORGANIZATIONAL AND METHODOLOGICAL  
FRAMEWORK FOR PHARMACEUTICAL CLUSTERS  
FORMATION AND DEVELOPMENT**

*Organizational and methodological framework for pharmaceutical clusters formation and development is substantiated, principal problems in their creation in Ukraine are investigated, the structure of pharmaceutical cluster is proposed, organizational and economic mechanism of interaction between pharmaceutical cluster, region and state is developed, the priority areas for pharmaceutical clusters development are identified.*

*Keywords: pharmaceutical industry; organizational economic mechanism; clustering; pharmaceutical cluster.*

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**ОРГАНІЗАЦІЙНО-МЕТОДИЧНІ ЗАСАДИ ФОРМУВАННЯ  
ТА РОЗВИТКУ ФАРМАЦЕВТИЧНИХ КЛАСТЕРІВ**

*У статті обґрунтовано організаційно-методичні засади формування та розвитку фармацевтичних кластерів, досліджено основні проблеми їх створення в Україні, запропоновано структуру фармацевтичного кластера, розроблено організаційно-економічний механізм взаємодії фармацевтичного кластера, регіону та держави, а також визначено пріоритетні напрямки розвитку фармацевтичних кластерів.*

*Ключові слова: фармацевтична галузь; організаційно-економічний механізм; кластеризація; фармацевтичний кластер.*

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**ОРГАНИЗАЦИОННО-МЕТОДИЧЕСКИЕ  
ОСНОВЫ ФОРМИРОВАНИЯ И РАЗВИТИЯ  
ФАРМАЦЕВТИЧЕСКИХ КЛАСТЕРОВ**

*В статье обоснованы организационно-методические основы формирования и развития фармацевтических кластеров, исследованы основные проблемы их создания в Украине, предложена структура фармацевтического кластера, разработан организационно-экономический механизм взаимодействия фармацевтического кластера, региона и государства, а также определены приоритетные направления развития фармацевтических кластеров.*

*Ключевые слова: фармацевтическая отрасль; организационно-экономический механизм; кластеризация; фармацевтический кластер.*

**Introduction.** The world practice shows that the success of pharmaceutical industry, high competitiveness and stable growth of the pharmaceutical industry subjects (PhIS) are provided through clusters which unite efforts in development, production and market introduction of original medicines, new production technologies of medicines and new methods of promotion, approaches to flow processes management etc. In addition, cluster becomes the point of growth for domestic pharmaceutical market, thus improving the competitiveness of the pharmaceutical industry

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in general and its integration into the global pharmaceutical market (Sahaidak-Nikitiuk and Posylkina, 2012; 2011).

**Latest research and publications analysis.** Today clustering is widespread in developed countries (Genetic Engineering & Biotechnology News, 2013). For example, there are 10 clusters in the Netherlands, 9 clusters in Finland (including health-care), 53 clusters in China (Chetyrbok, 2005; Skoch, 2007). The USA economy is the most clustered one. Cooperation between business, universities and research institutes (RI) is based on coepetition principles, according to which private funding of RI and universities varies depending on the research results (Marshall, 1981; Matusiak, 2005; Porter and Kramer, 2006; White and Srezynski, 1992). "Star Rating" of the EU countries pharmaceutical clusters can be presented as follows (Figure 1).

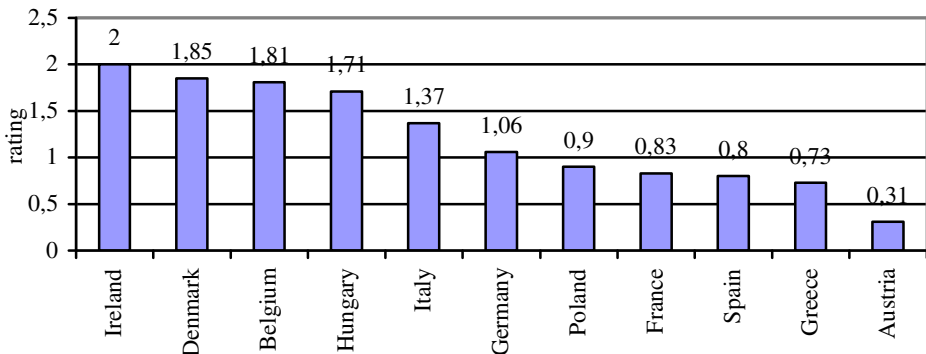


Figure 1. EU countries' pharmaceutical clusters rating in 2011  
(www.clusterobservatory.eu)

There are about 25 existing and 50 potential clusters in Ukraine today. Apparently it is not sufficient for effective industrial innovative development. Test clusters were created in 1998–2006 in Zhytomyr, Ivano-Frankivsk, Lviv, Lutsk, Rivne, Sevastopol, Kherson and Khmelnytsky (www.clusterobservatory.eu). Clustering process in Ukraine goes slowly, despite the fact that the global experience of the last two decades shows a rapid rise of the leading production sectors based on socially integrated systems, including cluster associations. Importance of pharmaceutical cluster in Ukraine is caused by: the need for timely provision of population with quality medicines in the required volumes at affordable prices; technological backwardness of domestic pharmaceutical companies (PhC) as compared to enterprises in developed countries; the need to create new workplaces and receipts to regional budgets; reducing barriers to enter the original medicines market etc.

The main challenges that hinder the creation of clusters in Ukraine are the following: distrust of entrepreneurs to each other, poor cooperation within clusters, imperfect functioning of the regulatory framework for clusters, low level of infrastructure development in regions, imperfect public, regional and local policies concerning cluster support, disparity between educational programs and business needs, the lack of qualified personnel at all levels, ineffective mechanisms for regulating prices etc. (Figure 2).

**The research objective** is to elaborate organizational and methodological framework for pharmaceutical clusters formation and development.

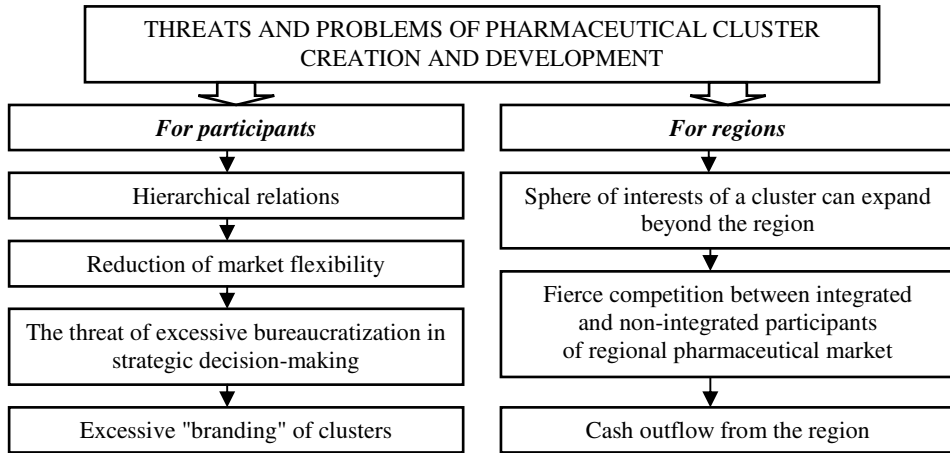


Figure 2. Threats of pharmaceutical clusters creation and development in Ukraine, authors' development

The research methods are content and structural analysis, system method, statistical and sociological methods.

**Key research findings.** Pharmaceutical cluster is a voluntary association of sectoral territorial research centers, industrial (pharmaceutical plants – PhP, pharmaceutical factories – PhF) and distribution companies, pharmacy institutions, suppliers of substances, basic and auxiliary materials, equipment and specialized services, medical facilities and specialized laboratories (bases for clinical and preclinical studies), infrastructure and other entities that complement each other, working closely with RI, other sectors, public organizations and local authorities to create, produce and sell medicines to improve the competitiveness of each participant of pharmaceutical cluster as a whole, making available quality pharmaceutical products (PhP) at affordable prices and promoting socioeconomic development and the improvement of ecological state of the region and the country. Thus, pharmaceutical cluster is an association of units engaged in production, distribution and medicines sale, science and education, providing purposeful activity at domestic and foreign markets basing on the mechanisms of public-private partnership.

Full-fledged pharmaceutical clusters at the regional level contribute to the dissemination of new drugs production technologies, compliance of standards and technologies of the pharmaceutical industry, promote science and education. So, pharmaceutical clusters creation in Ukraine are increasing the competitiveness of PhIS and of pharmaceutical industry in general. So, the purpose of pharmaceutical clusters creation in Ukraine can be defined as competitiveness increase of individual clusters and the pharmaceutical industry in general.

The distinctive feature of the cluster approach in pharmacy, on the one hand, is the development of innovative medicines and putting them into production, which, on the other hand, is a global goal of domestic pharmaceutical industry in general, so pharmaceutical clusters should serve as the points of growth for the domestic market at the regional and national levels at all stages of the life cycle of PhP, thus becoming the basis for improvement of foreign economic activities of the pharmaceutical indus-

try. Among potential participants of the pharmaceutical cluster are the following: research institutions (development of innovative drugs, creation and reproduction of substances etc.); analytical laboratories, preclinical and clinical bases; higher education institutions (the system of training of qualified personnel – pharmacists, medical representatives of PhC, logistics managers etc.); venture companies; pharmaceutical distributors; pharmaceutical manufacturers; drugstores; transportation companies, warehousing services; pharmaceutical waste recycling centers; infrastructure sector, insurance, information (marketing, information and advertising agencies), economic, legal and audit services, leasing, outsourcing and consulting; manufacturers of medical equipment, substances, packaging materials and auxiliary materials; authorities (regional state administration, local authorities); pharmaceutical and logistics associations; specialized enterprises, veterinary hospitals, beauty and dental salons etc.). We show the pharmaceutical cluster structure in Figure 3.

Cluster management and cooperation of participants should be based on the common approach to quality requirements of drugs, the provision of benefits and pharmaceutical clusters information. Selection of participants for a cluster must be carried out on the basis of their development prospects with the research and importance of the range and volume of manufactured PhP. Cluster leadership is exercised by the Council of the cluster, which is responsible for informing all participants about the promising directions of cluster development, effective drugs implementation in medical practice, capacity building and provision of RI and universities with material and technical resources. To protect the interests of cluster participants and providing certain guarantees, the Council must follow a single approach to contractual relations and implementation of development projects, PhP production and sales.

Priority directions for pharmaceutical clusters in Ukraine today include:

- in industrial technologies – manufacturing of medicines, biomedical safety, recycling, wastewater treatment;
- in pharmacy – genomic and post-genomic medicines technology, protein engineering, modelling the effects of drugs, synthetic (peptide) medicines, development of new generation vaccines, modern methods of drug delivery to destinations in human body etc.;
- in medicine – development, implementation and commercialization of domestic medical technologies, system treatment of infectious diseases, medical technology transfer from abroad;
- in bioinformatics – database modelling in medicine and pharmacy, computer design of medicines patterns etc.

**Conclusions.** The world practice experience shows that pharmaceutical industry success, high competitiveness and stable growth of PhIS are provided through clusters creation. Cluster in that case is the point of growth of the domestic pharmaceutical market and for its integration into the world market.

The paper identifies the key problems of pharmaceutical clusters today, the essence of the notion "pharmaceutical cluster" in Ukrainian conditions, along with determining the list of its potential participants. A structure of pharmaceutical cluster has been offered. Organizational economic mechanism of interaction inside a pharmaceutical cluster, involving regional authorities and the state is developed. Priority areas for pharmaceutical clusters development are identified.

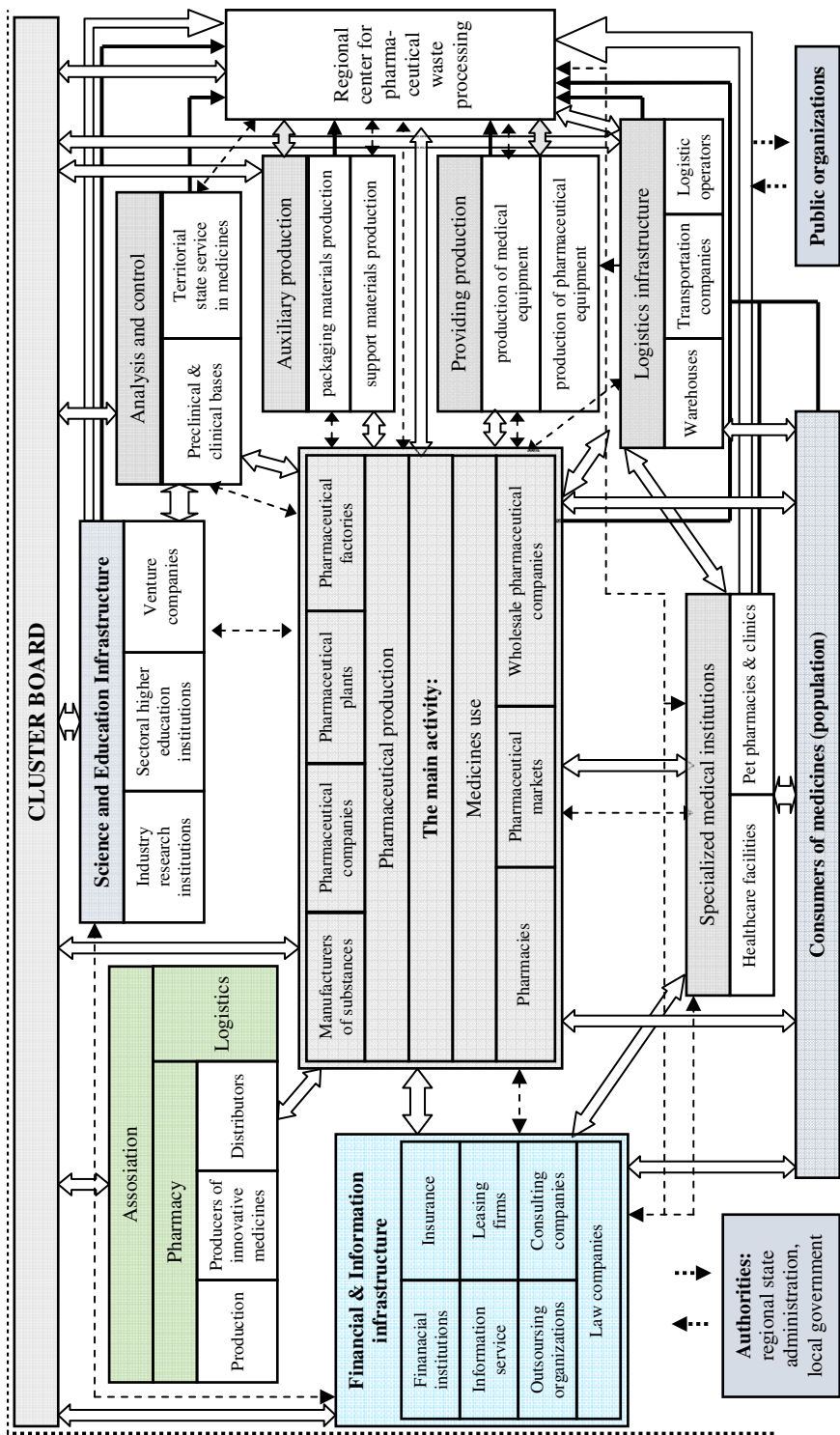


Figure 3. Diagram of the pharmaceutical cluster structure, authors' development

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