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SCIENTIFIC AND PRACTICAL APPROACHES OF FORMATION OF LOGISTIC INNOVATIVE SYSTEMS IN PHARMACEUTICAL COMPANIES

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The aim of the work is to analyze and generalize the existing scientific approaches and substantiate the mechanisms of formation of the logistics innovation system of the pharmaceutical company, which is the most important condition for creating modern effective domestic drugs under optimal use of resources and time.

Materials and methods. Studies were conducted using databases on the Internet: the State Expert Center, the Ukrainian Patent Office, scientific and metric databases. It has used retrospective, logical, graphic research methods, content analysis.

Results. The relevance of the implementation of the logistics concept of innovation management in domestic pharmaceutical companies is substantiated. A key aspect of this concept is the integration of individual parts of the innovation process through the maximum use of information exchange between participants in this process, active innovation, use of existing and creation of new knowledge, which become the main asset of innovation-oriented pharmaceutical company. The essence of the logistics innovation system of a pharmaceutical company is determined, the model of interrelations within the open logistics innovation system of a pharmaceutical company is substantiated. It is proved that with the help of a logistics innovation system it is possible to carry out planning, management, actualization of creation and implementation of innovative medicines at the optimal level of used resources and time for the implementation of relevant innovation projects. It is determined that the logistics innovation system of a pharmaceutical company is related to the management of incoming information and innovation flow (results of basic and applied research, data on clinical and preclinical study of medicines, pharmaceutical development), internal information and innovation flow (information exchange in the internal environment - resource, scientific and informational, organizational, personnel component), the initial information and innovation flow (information for government agencies, consumers, suppliers, the public, organizations interested in using the research results). These flows are integrated and relate to various aspects of the company's innovation.

Conclusions. Thus, in order to intensify and activate innovation in domestic pharmacy, it is promising to expand the scope of logistics methods for the development and implementation of innovative medicines. The purpose of the logistics innovation system is to provide the pharmaceutical company with the information necessary for completeness, relevance, reliability, timeliness at a rational cost of their provision, for effective management of material resources

Keywords: logistics innovation system, pharmaceutical company, innovative medicine, information and innovation flow

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1. Introduction

Pharmacy today is one of the most dynamic and knowledge-intensive sectors of the economy in Ukraine and around the world. The viability and prospects of economic development of pharmacy in all countries of the world are largely determined by the scale, quality and level of research and the level of used technological processes [1–3]. Prolonged lack of innovation means stagnation of pharmaceutical production, reduced quality and competitiveness of pharmaceutical products, and hence the decline in economic performance of pharmaceutical market players, on the one hand, and the threat of epidemics and pandemics due to resistance, on the other [4, 5].

In order to intensify and activation of innovation activity in domestic pharmacy, it is promising to expand the scope of logistics methods for the development and implementation of innovative medicines.

The logistics approach involves continuous improvement and optimization of existing processes, allows to organize innovation processes as a cross-cutting integrated flow, optimize time and cost of innovation projects, gain competitive advantage by optimizing material, information and other flows.

The current state of logistics development is characterized by a process approach to management, integrated logistics paradigm, based on understanding the importance of all flows and perception of logistics as a methodology for optimizing flow processes in any system, understanding the high role of information technology as a modern basis for logistics processes.

Since the late 90's in the world's leading pharmaceutical companies integrated logistics management systems for innovation has been actively creating. Under these conditions, the development and implementation of innovations turns into a continuous logistics business process.

Innovations are integrated into long-term production plans and programs of pharmaceutical companies. Creating a more flexible and comprehensive system of innovation logistics management focused on the development of highly efficient medicines, reengineering the innovation process stimulates the creation and implementation of innovations with a world level of novelty through end-to-end logistics management of innovation: from idea to implementation. All this determines the relevance of the research topic.

Innovative processes in modern conditions are considered not only as priority factors of socio-economic development as individual enterprises, industries and national economies, but also as a foundation for increasing the social welfare of the population and improving its quality of life. Considering the importance of research related to the development of new medicines, high cost and duration of innovation processes in pharmacy, logistics approaches and technologies should become an important tool for management in pharmaceutical companies.

Problems of the innovative paradigm of logistics have been studied in the works of some foreign scientists – Ron Adler, James F. Morore, D. Suruvka-Marshalek, I. Svyatovets and others [6, 7]. Among domestic scientists who have studied the implementation of logistics approaches in the management of innovation processes, it has been identified the work of M. Yu. Grigorak, E. V. Krykavsky, and others [8, 9]. Their works also considered the problems of the evolution of the paradigm of the logistics concept of management, analyzed them, explored the main features of innovative and intelligent logistics.

The monograph of Posylkina O. V., Sahaidak-Nikitiuk R. V., Hromovyk B. P. [10] is devoted to the study of one of the most pressing problems facing domestic pharmacy in market conditions: optimal resource management. The broad factual material shows the dependence of the efficiency of pharmaceutical companies, their financial well-being on the state and strategy of resource management. Methodological bases of formation of effective system of management of resources of the pharmaceutical enterprises, tools and methods of an estimation of efficiency of its functioning and directions of improvement are considered.

Dorokhova L.P. et al. considered the problems of interaction of participants in innovation development at the regional level, proposed mathematical approaches and formulations for modeling [11].

The implementation of innovation strategy in modern conditions is seen as a network integrated process, which is carried out through a single, but interconnected transactions of knowledge and experience between all stakeholders. The object of management in innovation logistics is the flow of innovations – the directed movement of discoveries, inventions, innovation proposals, patents, know-how, etc. In high-tech, science-intensive industries, including pharmacy, the parameters of cost and time become determinants of integrated management of the innovation flow in the development of new pharmaceutical products. Today, companies focus not only on creating high value products in the eyes of consumers, but also the development cost, as well as

optimizing the time required to develop, manufacture and product launch. In pharmacy, the timely completion of the innovation process, its acceleration and timely medicine launch is not only important economically, but also socially.

Innovation activity is accompanied by the same logistics flows as activities in other areas: material, information and financial flows. At the same time, the peculiarities of logistics management are connected with the peculiarities of specific stages and types of innovation processes. Effective innovation management requires effective organization of appropriate logistics processes, which would take into account their features [12].

Conducted studies have shown that currently there is no unified scientifically-based methodology for the formation of a logistics innovation system of a pharmaceutical company. Solving this problem is an important area of research.

The aim of the work is to analyze and generalize the existing scientific approaches and substantiate the mechanisms of formation of the logistics innovation system of the pharmaceutical company, which is the most important condition for creating modern effective domestic medicines under optimal use of resources and time.

2. Planning (methodology) of the research

The following research plan has been developed:

- analyzed and generalized theoretical and scientific-practical approaches to the use of a logistical approach to the management of innovation flows;
- substantiation of scientific and practical approaches to the use of logistics information system in pharmacy;
- construction of a logistics information system for a pharmaceutical company.

3. Materials and methods

Studies were conducted using databases on the Internet: State Expert Center, Ukrainian Patent Office, scientific and metric databases. It has used retrospective, logical, research methods, content analysis.

4. Results of the research

The development of integration processes at different levels of innovation management has led to the ineffectiveness of traditional approaches to the organization of the innovation process as a closed, focused mainly on the internal environment and resources of the company. Today the main task of the enterprise innovative activity is not so much the formation of an innovative idea, but the rapid implementation of this idea in the form of an innovative product (process) and obtaining economic and / or social effect. Under these conditions, the concept of open innovation is received more and more recognition. According to G. Chesborough (founder of open innovation), “open innovation – is the use of targeted input and output flows of knowledge to accelerate innovation” [13].

The reasons for shifting the emphasis towards open innovation, according to experts, are:

– development of the knowledge economy, which led to the active dissemination of knowledge and information among the participants of the innovation process;

– development of the intellectual property market;

– development of innovation infrastructure and institutional environment, which contributed to a more active transformation of intellectual property into intellectual capital;

– formation of chains of creation of streams of value of innovative products and expansion of sphere of commercialization of scientific researches, developments and technologies.

Today, the effective organization of scientific and innovative activities is not possible without effective management of material, financial, information, service flows [14, 15]. And this is the reason to activate implementation of innovative logistics in the activities of pharmaceutical companies, research institutions, higher education institutions that deal with the development of new medicines and technologies for their production.

The development of innovative logistics in the pharmaceutical industry has to base on the following principles:

– management of streaming processes oriented on the factors of the current and internal environment and using of all the available information;

– systematization in making management decisions related to the management of flow processes at all stages of the innovation process;

– decision-making on the basis of economic compromises taking into account the interests of various stakeholders and participants in the innovation process;

– attitude to logistics as a tool to improve innovation management.

Information logistics in pharmacy is a universal tool for managing innovation in order to increase the efficiency of the processes of creation and implementation of new medicines.

Logistics innovation system in pharmacy is a communication environment that allows streaming to receive, generate, analyze information about objects and subjects (participants) of innovation, to model the most effective combinations of resource use, to predict risks and costs, which are associated with the unpredictability of the results of scientific processes and research related to the creation of new medicines (Fig. 1). The construction of such systems can significantly increase the productivity of innovation and reduce the cost of its administration.

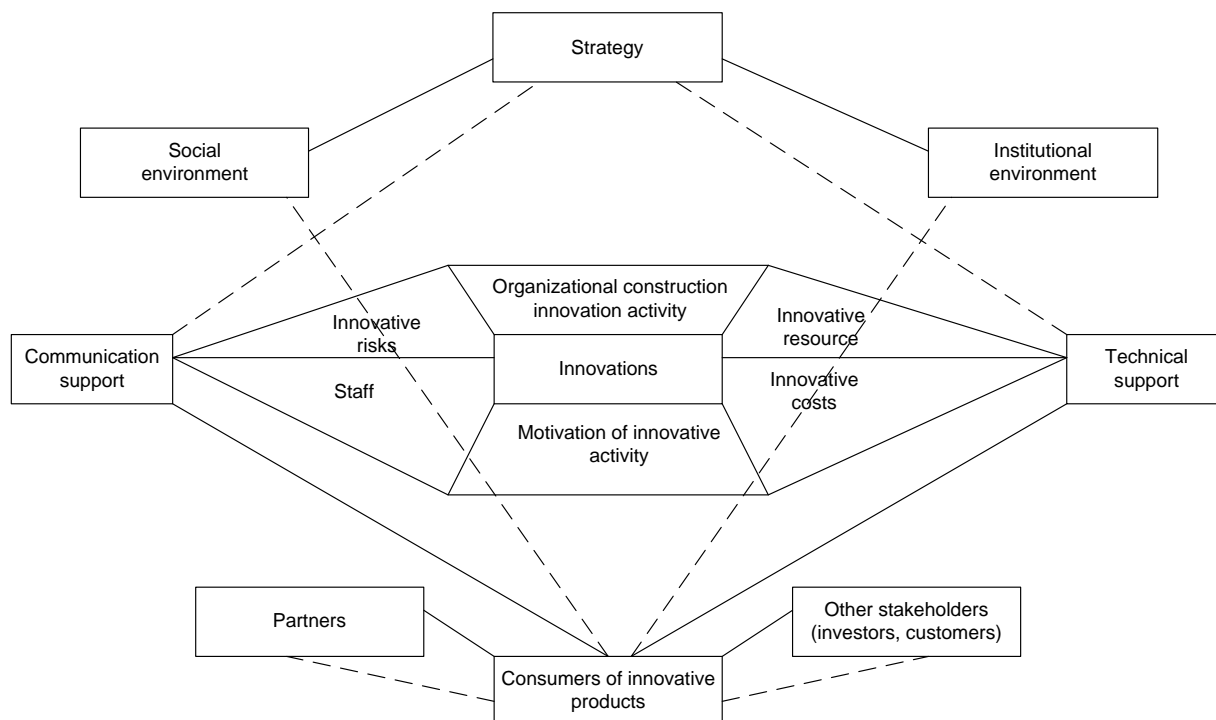


Fig. 1. Model of relationships within the open logistics innovation system of a pharmaceutical company

5. Discussion of the results

The modern pharmaceutical company in general can be represented as a converter of its incoming information and innovation flows: data from scientific and experimental research of drugs, “open innovations”, the results of scientific activities on pharmaceutical development, intellectual property created at different stages of the scientific process and can be successfully commercialized, materials of registration medicines on drugs, etc. (Fig. 2).

It is obvious that the prospects of scientific achievements and commercial attractiveness of medicines are determined in the early stages of pharmaceutical development by the number of scientific results, publications and citation index, patent applications, reports at professional conferences and participation of certain projects in exhibitions.

Incoming information flow is a set of data that allows you to objectively justify the decision in the logistics information innovation system of pharmaceutical

companies about the development of innovation. It should contain the following local flows: determination of the world level and directions of active pharmaceutical ingredient development, main markets and competing firms and directions of medicines commercialization, information about basic and applied research of active pharmaceutical ingredients, preclinical and clinical research of medicines, pharmaceutical development, comparison of technical and economic indicators with analogues etc.

Information logistics at the stage of basic research takes special place. The main part of basic

research is information on new data, theories, hypotheses, patterns. The purpose of applied research is to find, research and develop principles and methodologies for solving certain practical problems. The methodology of rational assessment of future medicines should include its place in the range of existing medicines. It is necessary to predict the strengths and weaknesses of the medicine and in the early stages of the study to strive to expand the range of its application, to the preventive focus of pharmacotherapy based on a clear knowledge of clinical manifestations, complications and consequences of the disease.

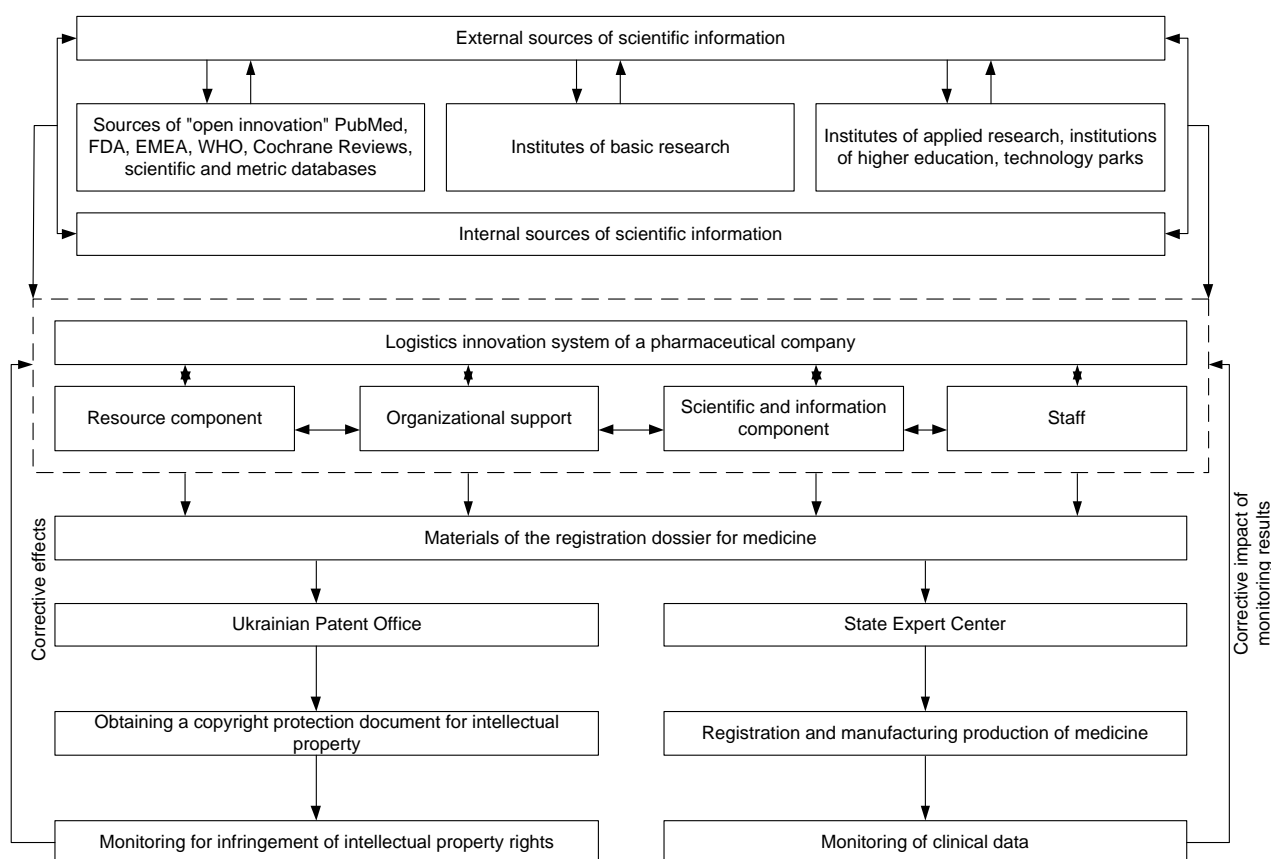


Fig. 2 Pharmaceutical company as a converter of information and innovation flows

Internal information flow, as a set of data that connect with each other and allow effective interaction of all structural units of the organization – participants in the development of innovative medicines, should be formed as a system of direct and feedback, the common goal of which is registration and marketing of new innovative medicines.

Characterization of efficiency, productivity, reliability and flexibility of the logistics information innovation system of pharmaceutical company is proposed to be carried out using resource, research and information, organizational and personnel subsystems.

The initial information flow in the logistics information innovation system connects the organization with the key elements of its external environment. It should include such local information flows as: information for state authorized bodies (State Expert Center, Ukrainian Patent Office), information for consumers, information for suppliers, information for the public, scientific and

technical information for organizations interested in using research results.

Upon registrationa medicine, the applicant (pharmaceutical company) must indicate the grounds for choosing the type of medicine to which the set of available registration documents must correspond. The applicant must submit a registration form of the medicine according to the order of the Ministry of Health of Ukraine dated 23.07.2015 No. 460 [16]. Details of the innovation flow of pharmaceutical company are shown in Fig. 3.

It should be noted that the national departmental health authority of any country (for example, in Ukraine – the State Enterprise “State Expert Center” of the Ministry of Health of Ukraine) registers medicines in establishing their pharmacological efficacy, health safety and quality. The registration certificate is a permit for medical use, which provides for the industrial manufacturing of medicins, their promotion on the market and sale.

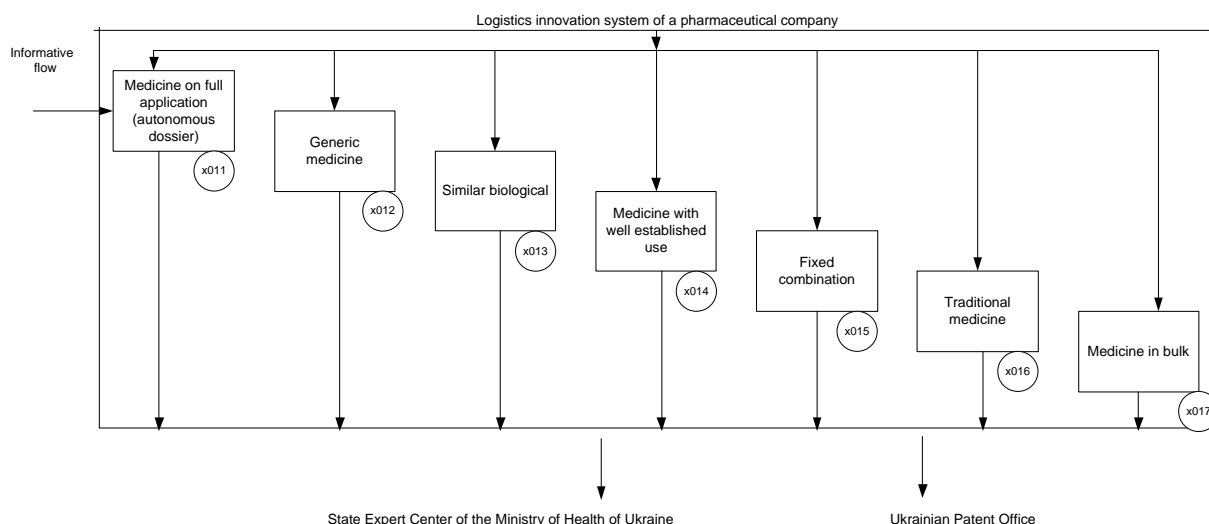


Fig. 3 Detailing of the information flow in the logistics innovation system of pharmaceutical company

However, the registration certificate gives its owner only positive rights to a particular medicine, i.e. the right to use it in commercial circulation. These rights are not exclusive, namely: the holder of the certificate has no right to prohibit other persons from using the developed medicine without his permission, namely to prohibit other manufacturers to use the same brand of medicine, produce it in the same way, use similar packaging and so on.

The Patent Office grants the owners of copyright protection documents (patents for inventions, utility models, industrial designs; certificates for marks for goods and services) the monopoly right to certain intellectual property.

Thus, the information and innovation flow in the implementation of innovative medicines is directed to both the State Expert Center and the Ukrainian Patent Office.

It should be noted that information on scientific development is first submitted as part of the registration dossier at the time of medicine registration, and then updated when new knowledge is obtained during the life cycle of the medicine. Thus, the information flow, which is associated with the introduction of medicines on the market, circulates after registration of the medicine [15].

Thus, information support is a key process of innovation activity of pharmaceutical company, which largely consists in the formation of arrays of source data, their use to produce new information (data on innovative medicines) and in bringing new information to all authors involved in the creation of medicines. When building the process of information support of innovation, it is advisable to consider separately such areas as obtaining information from the external environment (open and closed innovations), creating information and information exchange in the internal environment and transferring information to the external environment – authorized state bodies (State Expert Center, Ukrainian Patent Office).

The concept of logistics approach to information support of innovative activity of the company provides an active role of logistics in setting and solving problems of determining the composition and movement of information and is based on the following provisions:

- the movement of information used in innovation activities has a streamlined nature, which allows you to apply logistics tools to it and determine its qualitative and quantitative parameters;

- regularity (discreteness) of information flows is determined by the content of innovation activities and the type of necessary information and is normatively established by the subject of management;

- the content of information flows should fully and objectively reflect the whole set of data that characterize the various aspects of decision-making and implementation necessary for the organization of the innovation process.

The proposed logistics innovation system takes into account the peculiarities of information and innovation flow depending on the type of registration of medicines by the pharmaceutical company: medicines with a full registration dossier, generic medicines, hybrid medicines, medicines with well-established medical use, fixed combination, traditional medicines, medicines in products bulk. The information and innovation flow for all the above types of medicines, regardless of their nature and other features, must meet the general requirements for the materials of the registration dossier (in the format of the General Technical Document).

Limitations of the research. The article does not consider special requirements for information and innovation flows with accelerated approval of priority medicines.

Prospects for further development of this field. The use of the proposed logistics innovation system in the development of innovative medicines of different pharmacotherapeutic groups is promising.

6. Conclusions

1. The relevance of the implementation of the logistics concept of innovation management in domestic pharmaceutical companies is substantiated. A key aspect of this concept is the integration of individual parts of the innovation process through the maximum use of information exchange between participants in this process, active implementation of innovations, use of existing and creation of new knowledge, which become the main asset of innovation-oriented pharmaceutical companies.

2. The essence of the logistics innovation system of pharmaceutical companies is determined, the model of interrelations within the open logistics innovation system of pharmaceutical companies is substantiated. It is proved that with the help of logistics innovation system it is possible to plan, manage, implement the creation and implementation of innovative medicines at the optimal level of resources used and time for the implementation of relevant innovative projects.

3. It is determined that the logistics innovation system of a pharmaceutical company is related to the management of incoming information and innovation flow (results of basic and applied research, data on clinical and preclinical study of medicines, pharmaceutical development), internal information and innovation flow (information exchange in the internal en-

vironment – resource, scientific and informational, organizational, personnel component), the initial information and innovation flow (information for government agencies, consumers, suppliers, the public, organizations interested in using the research results). These flows are integrated and relate to various aspects of the company's innovation. The purpose of the logistics innovation system is to provide the pharmaceutical company with the information necessary for completeness, relevance, reliability, timeliness at a rational cost of their provision, for effective management of material resources.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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