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## IMPROVING STATE REGULATION OF INNOVATIVE DEVELOPMENT OF THE HEALTHCARE SECTOR

**Abstract.** Improving the accessibility and quality of healthcare services for the population, which is one of the key objectives of the healthcare reform strategy, requires improvement of social policy aimed at ensuring a high standard of living for citizens and high-quality implementation of reforms that will increase the economic, technical and informational accessibility of healthcare services. The article proves that scientific, technical and innovative activities in the field of medical industry development are one of the driving forces for continuous improvement of the quality of medical services, their adaptation to rapidly changing living conditions and ensuring a high level of human development. The article examines the main directions and trends of innovations in the medical sector implemented in Ukraine, namely: organisational innovations, which involve a comprehensive re-engineering of the organisational and institutional mechanisms of the system aimed at the gradual transformation of the medical sector from a socially costly model to a socially investment model focused on intensive development and intersectoral growth on the principles of market competition; digitalisation of the healthcare system, introduction of new diagnostic and treatment technologies in the medical sector.

**Key words:** state regulation, healthcare sector, innovative development, accessibility of medical services, digital technologies.

**JEL classification:** O18, O21, R11

## Introduction

Reforming Ukraine's healthcare system is one of the key areas of government policy that requires constant attention and improvement. A significant share of the gross domestic product is allocated to healthcare services, but per capita spending in Ukraine remains lower than in most developed countries. At the same time, other countries demonstrate high life expectancy and lower mortality rates with comparable expenditures. This demonstrates the importance of effective state regulation of the healthcare system, which determines its organisational and financial potential.

Despite numerous attempts at reform, the Ukrainian healthcare system has not yet reached the desired level of efficiency, which necessitates a detailed analysis of existing management mechanisms and tools. Given the rapid socio-economic changes and the growing need for quality healthcare services, innovation and scientific and technological activities in this area are becoming critically important. It is the driving force behind improving the quality of healthcare services, adapting them to modern challenges and ensuring high standards of human development. Thus, the study of mechanisms and instruments of state regulation of the healthcare system is relevant and necessary to improve management approaches and increase the overall efficiency of the healthcare industry.

Most scholars consider regulation from the legal point of view, with little attention paid to the state one. However, if we consider the healthcare sector, the formation of the philosophy of the concept of "regulation" will be carried out at the state level, i.e. we will refer to it as "state regulation".

Ye. Kulhinskyy believes that "one of the aspects of the administrative use of the concept of regulation is to ensure the degree of centralisation of power. On the one hand, the national government may be interested in maintaining absolute control over the system, requiring that all decisions made within the system be approved by it. On the other hand, the gover-

nment may resort to decentralisation by devolving decision-making to lower levels of the system" (Kulhinsky 2015).

Instead, Z. Hladun interprets regulation more broadly, namely, "in the public health system, regulation by the state involves the establishment of general principles and procedures for the implementation of medical activities, including the provision of care, responsibility for compliance with these rules, and includes the influence of public authorities on the activities of health care institutions. The regulatory process must be based on an officially recognised social development strategy, state medical programmes, standards and a mechanism for their mandatory implementation, state control and administrative and legal enforcement (Hladun 2007).

According to O. Petrukh, "innovations in the healthcare sector are the result of innovative activities implemented in the form of modernisation of the material and technical base, introduction of the latest progressive means and methods of treatment, medical technologies, medical devices and medicines, improvement of existing methods of diagnosis and treatment (medical innovations), development of software tools for information processing, creation of new models of healthcare and personnel development (Petrukh 2018).

The purpose of the article is to analyse the existing mechanisms and instruments of state regulation of the healthcare system of Ukraine, to assess their effectiveness in the context of current socio-economic challenges, and to develop recommendations for improving the management and financing processes in the healthcare sector in order to improve the quality of medical services, adapt to rapidly changing conditions of life and ensure sustainable development of the healthcare system.

## 1. Methods

The theoretical and methodological basis of the article is the main provisions of economic science, scientific works of Ukrainian and foreign scholars on the problems of theory and practice of management and state regulation of the healthcare sector.

In the course of the study, to achieve this goal, the following methods were used: theoretical generalisation and systematisation - for a comprehensive description of the organisational and managerial principles of healthcare regulation; classification, grouping, systemic economic analysis - to substantiate the mechanism of healthcare system development in transformational conditions, etc.

## **2. Results and discussion**

Let's consider the basic principles of healthcare regulation and their impact on ensuring an adequate level of quality of life (Figure 1).

The main principles are defined: a guaranteed package of medical services that is universally available to every citizen; compliance with national and international standards of quality and professionalism; respect between patients and healthcare professionals; cooperation and collaboration of various sectors of the economy, services, organisations in the interests of patients, communities and the population; ensuring the price-quality ratio with the most efficient, fair and sustainable use of resources; the multi-faceted healthcare economy and its multi-channel financial system.

V. Shevchuk defines the basic principles of forming a mechanism for implementing the state policy in the field of healthcare system development, based on the results-based management methodology. These include: customer orientation and introduction of competitive relations, which contributes to improving the quality of services; systematic approach and continuous improvement of processes, products and services; development of management and control tools; leadership and active involvement of employees in the implementation of management decisions. Considerable attention is paid to the creation of an information environment and the use of modern technologies, as well as compliance with the principles of programme and project management. Other areas of focus include strategic and operational planning, the use of logistics approaches in cooperation with suppliers, improving financial management and implementing a system for measuring results that characterise customer satisfaction and

achievement of strategic goals. This approach ensures a comprehensive improvement of healthcare management (Shevchuk 2014).

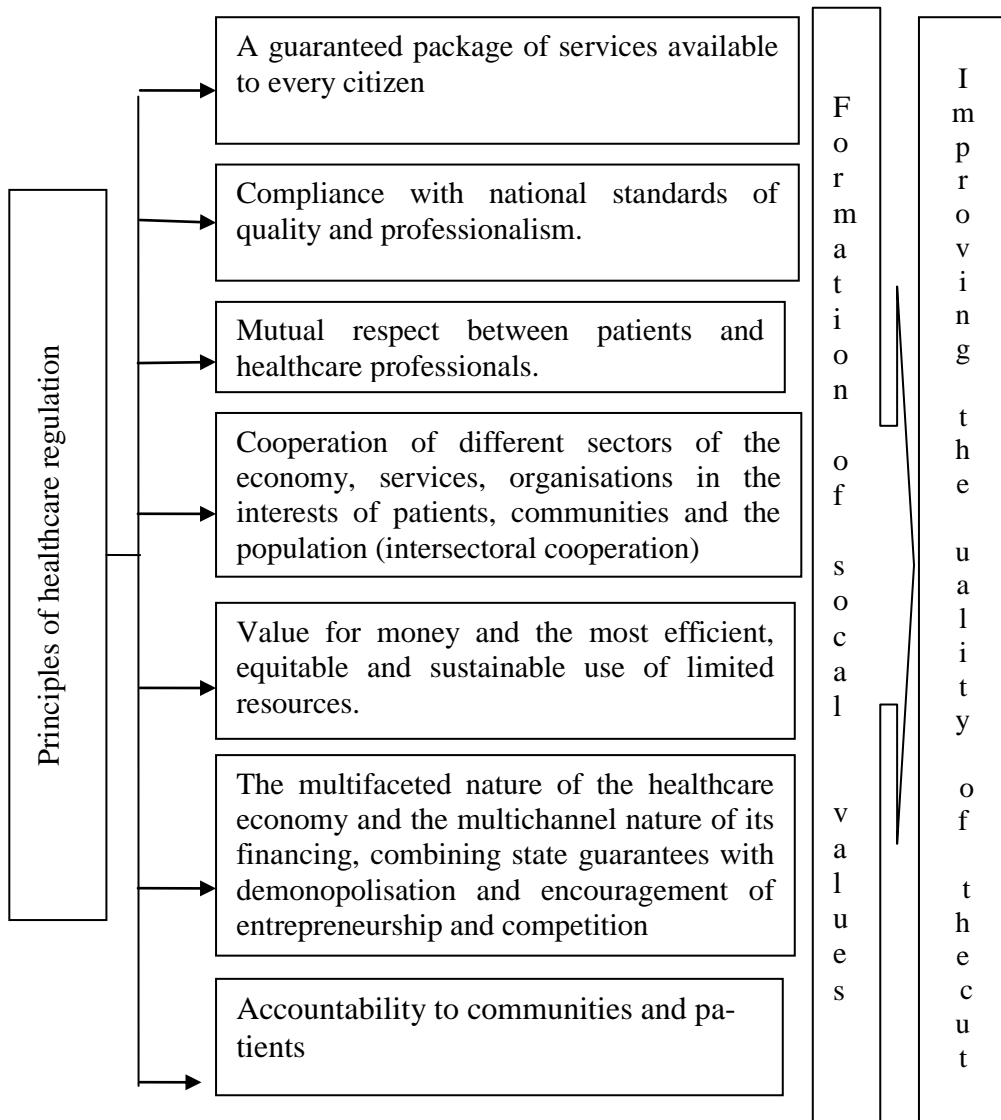


Figure 1: **Impact of healthcare regulation principles on the quality of life**

Source: compiled by the author

An important component in the regulation of the healthcare sector is the development of its effective mechanism. O. Krasnova and T. Pluzhnikova emphasise that the main objectives of the mechanism of state regula-

tion in the healthcare sector are to ensure the quality of medical services to citizens, free medical care guaranteed by the state, as well as financing of healthcare institutions and equipping them with the latest technologies. Particular attention is paid to improving the system of organisation and management of healthcare, raising the level of qualification of medical personnel, developing preventive activities and modernising the legal framework. In addition, the need to create competitive relations in the medical market and adapt the existing healthcare system to constantly changing conditions in order to increase its efficiency and meet modern challenges is highlighted (Krasnova, Pluzhnikova 2018).

V. Pashkov determined that "the basis of the policy of development of the national health care system should be the regularity of creation of reliable legislation and regulatory and legal support of medical services for the population. The consistency of the content of legal acts also implies a certain commonality of their methodological composition and axiological orientation. The indisputable factors in this direction should be: observance of national interests, ensuring the level of national economic security and proper health of the nation, etc. These factors are universal in nature, but it is clear that the implementation of health care policy involves not only its own specific factors, but also factors common to them" (Pashkov 2006).

Domestic scholars consider the mechanism of state regulation separately at the economic, financial, social, legal, motivational, institutional, administrative, and economic levels, and therefore it does not provide for systematic approach.

Thus, Z. Hladun notes, "in the healthcare sector, state legal regulation is aimed at creating favourable organisational and financial conditions for the activities of healthcare institutions. Its starting point is the recognition of the main links of the system medical and pharmaceutical institutions, as independent and equal participants in the market of medical care and medical services. Such regulation does not provide for state interference in their organisational and professional activities, except as expressly provided by law" (Hladun 2007).

We agree with the opinion of Y. Berezhna that "the concept of state regulation of the healthcare sector in Ukraine, which describes its purpose and tasks, the peculiarity of which is the definition of its directions and based on the application of the cluster approach, i.e. using the tools of state regulation that ensures the functioning of the national healthcare cluster, motivating the interaction of its economic entities in interconnected markets of this sector as the reasons for the success of the intended consequences of state regulation. Creating an adequate level of national security in the healthcare system requires improving the tools for regulating the healthcare sector, taking into account the regularity of ensuring the functioning of the national healthcare cluster and in order to implement the potential for sustainable development of socio-economic relations in all interconnected markets of this sector" (Berezhna 2014).

In our opinion, there is a need to generalise and improve the mechanisms for improving the regulation of the healthcare sector. We propose to consider three components of the mechanisms: organisational and administrative, socio-economic, and institutional and legal (Figure 2).

It is proposed that the organisational and administrative mechanism should take into account the development of a strategy for decentralised management of the healthcare system and self-governance of medical institutions associated with the creation of "planned regulated markets" with a combination of the decentralisation model and inevitable autonomy, which are complemented by the main parts of accreditation, licensing and inter-sectoral cooperation; mutual coordination of central and local public authorities, local self-government and other legal entities used in the process of implementing healthcare policy, in accordance with their powers and relations between them and other entities.

According to the authors of the article, "the main directions of the country in regulating the healthcare system should be to improve the existing process of providing financial resources to the industry and to search for new financial resources, in the future, voluntary health insurance and health funds. Attracting additional financial resources in the healthcare sector will contribute to the development of the healthcare insurance system".

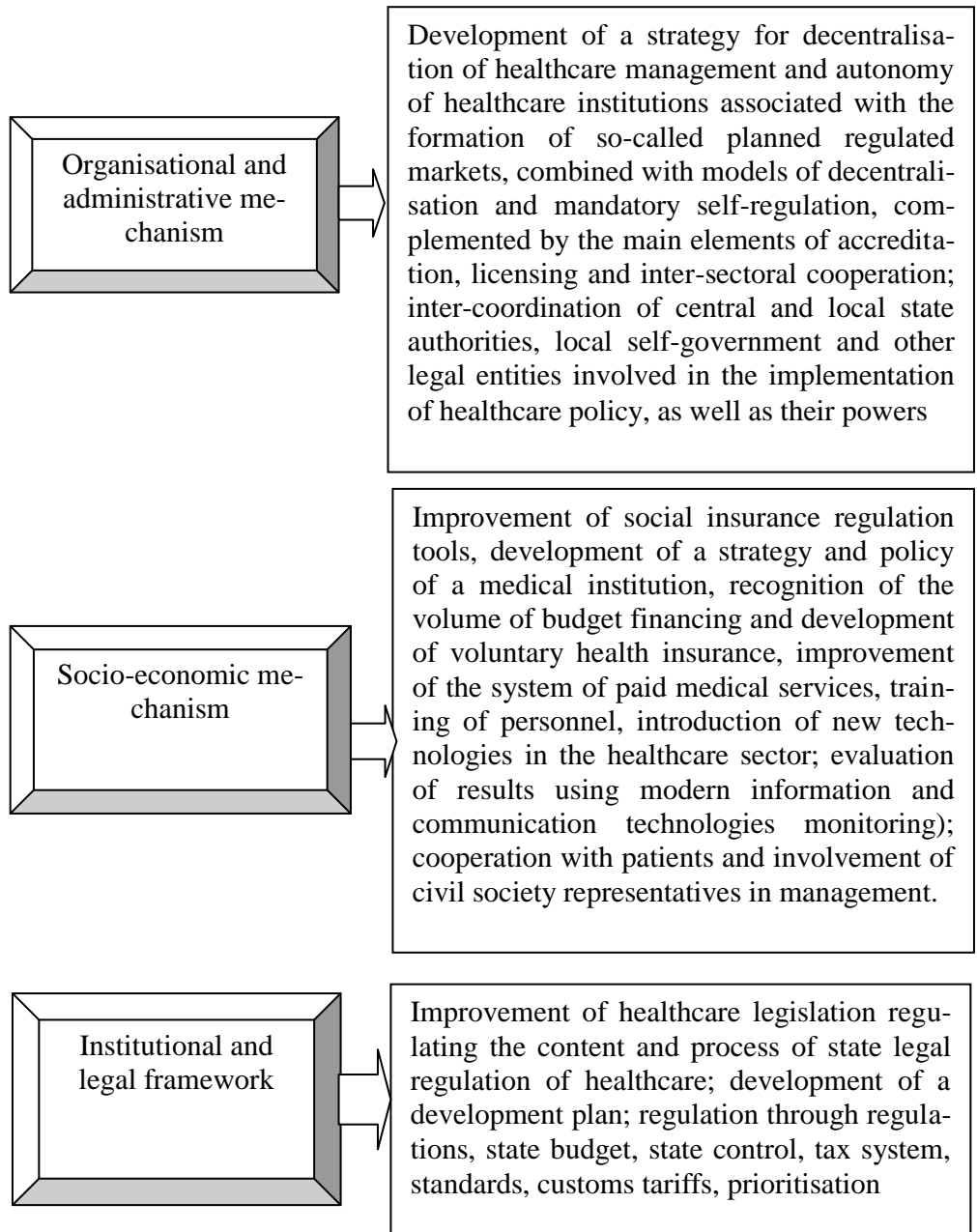


Figure 2: **Mechanisms for improving healthcare regulation**

Source: improved by the author

Therefore, the socio-economic mechanism must necessarily include the improvement of social insurance regulation tools, development of a strategy and policy of a medical institution, recognition of the amount of



budget funding and prospects for the introduction of voluntary health insurance, improvement of the procedure for providing paid medical services, effective staff training, introduction of innovative technologies in the healthcare system; evaluation of results using modern information and communication technologies; cooperation with patients and involvement of public representatives in management.

When developing a socio-economic mechanism, V. Shevchuk necessarily identified the need to use monitoring tools. "In the irreconcilably modern conditions of society's development, the management of the healthcare system must meet not only the current paradigm of innovative growth, but also the framework for the use of management technologies, the latest principles of organising public healthcare. The author emphasises the use of an intersectoral approach to healthcare, the State's responsibility for the demographic security of the nation, the interest of the population in improving personal health, and the benefits of preventive measures and primary healthcare. State regulation of innovative healthcare development should include monitoring of resources and performance of the healthcare system, management within the systems of "centralisation - decentralisation", "state regulation and self-management", "methods and tools of regulation, government and market mechanisms, "departmental, state and individual healthcare systems", "interaction of the intersectoral public healthcare system" (Shevchuk 2014).

Budget policy is an important means of state regulation of financing the national healthcare system. However, in today's environment, the budgeting system can no longer be limited to the analysis of income and expenditure items, but must take into account development goals and an assessment of the potential value of efficiency. The healthcare budget policy itself, if it is not focused on social outcomes, may have a number of negative features (Zubenko 2013):

- lack of information on the degree to which the needs of service users are met;
- Lack of support for the development of a competitive healthcare system;
- the threat of a proportionate reduction in funding as a result of the

budget crisis.

The content of the institutional and legal mechanism involves improving the legislative framework for healthcare, regulating the nature and process of state legal regulation of medicine; development of a development programme; intervention through regulations in the state budget, control, tax system, standards, customs tariffs, and priority setting.

Thus, the article proves the need to improve the mechanism of regulation of the healthcare system as a key component of the competitiveness of the national economy and a formative vector of the quality of life of the population. The basic principles and tools of the State's regulation of the health care system are presented, which form the system of innovative development of the entire sphere.

In this context, the innovative development of the healthcare sector can be viewed as a qualitatively defined dynamic process of structural, technical, technological and product improvement of the system and its individual elements based on the introduction of new knowledge and the latest achievements in science and technology, which contributes to the preservation of health and longevity, improvement of the quality and effectiveness of medical care and the standards of living of society.

The fundamental area of innovation in the healthcare sector in Ukraine is the healthcare reform, which is based on the introduction of organisational innovations aimed at gradually transforming the healthcare sector from a socially costly model to a socially invested model focused on intensive development and cross-sectoral growth based on the principles of market competition. The main innovative changes are as follows:

1) Reorientation from a linear-functional to a matrix management model based on the allocation of separate operational processes for the development of which it is possible to develop independent development strategies, criteria for assessing the efficiency of functioning and financing strategies;

2) Reorganisation of the system of training, motivation and evaluation of medical personnel with elements of competitive analysis and transition

from simple hourly remuneration to hourly piecework. That is, remuneration will be based not only on the position held, but will also depend on the amount of work performed;

3) Changing the principles of financing medical institutions from the cost-based approach to an approach that is based on the quantity and quality of services provided;

4) Introduction of new organisational forms of management in the sector (private, communal), which will have the right to provide medical services on a par with state institutions and facilities and provide state guarantees for patients;

5) Digitalisation of management, counselling and healthcare services;

6) Diversification of sources of investment in the development of the healthcare sector through public-private partnerships, raising funds from insurance and other funds and community funds;

7) Empowerment of the management of medical institutions and organisations on the basis of autonomy, which will allow them to make decisions on staffing, areas of financial resources and their distribution.

Implementation of institutional and organisational innovations in the healthcare sector in Ukraine requires a long period of transformation and transition from declarative documents to real actions, development of reform projects and evaluation of their effectiveness at each stage of implementation, as well as consolidation of not only governing bodies and public administration at all levels, but also the public, academia and business.

Digital technologies are currently one of the leading trends in the development of global healthcare. In particular, according to experts, the global healthcare market may exceed USD 10 trillion by 2022. Gross investments in medical digital products and technologies will increase to USD 280 billion by this time. At the same time, the rapid spread of viral diseases (as exemplified by Covid 19) and the potential emergence of other dangerous viruses will significantly strengthen these trends and create demand for active implementation of digital technologies in the industry. The main priority for the development of digital technologies is diagnostics and counselling.

The priority and main directions of digitalisation of the healthcare sector as one of the conditions for its effective modernisation and development in the current environment are emphasised in the Concept of Development of the Digital Economy and Society of Ukraine for 2018-2020. In particular, the document states that "digital medicine should guarantee interaction between healthcare professionals, patients and institutions with the assistance of communication and digital technologies. Transition of medical records into electronic format is one of the main tasks of digital medicine. The creation of a full-fledged digital healthcare platform is an important step towards the digitalisation of medical and related services, as well as the interaction of operators in this area. A digital healthcare platform is a set of dynamic, systematic electronic indicators on the health status of an individual patient, which guarantees information exchange between participants in the process of consumption and production of healthcare services" (Cabinet of Ministers of Ukraine 2018).

Another government policy document, the Digital Agenda of Ukraine, also assigns an important role to the digitalisation of the healthcare sector. The document states that an important condition for the digital transformation of the healthcare system in Ukraine is the creation of an Electronic Health Record (EHR) as a national system with a characteristic set of dynamic and systematic electronic data on the health status of patients, medical personnel, services provided, institutions and organisations, which will simplify administration and significantly affect the level of accessibility and quality of medical services.

At the present stage, information technology is becoming increasingly widespread in the healthcare sector and includes a wide range of services and information systems, including:

- Creating and maintaining electronic medical records that allow accumulating patient data, which improves the quality of health diagnostics, increases the efficiency of prescribing treatment or preventing diseases and avoids unnecessary bureaucratic procedures;
- Electronic prescriptions, which allow for prompt changes in prescriptions depending on the state of the disease, create opportunities

for automatic transfer of prescriptions from a doctor to a pharmacy, and control of the circulation of medicines;

- Promoting healthy lifestyles, informing the public about innovations and new opportunities in healthcare and medical care, creating call centres for prompt response to the sanitary and epidemiological situation in localities and urgent emergency calls;

- Virtual conferences of specialists to make a diagnosis or discuss other problems that require different consultations (for example, web conferences);

- Specialised software that systemises medical institution data and facilitates scheduling of patient appointments, creating electronic queues, managing patient data, creating specialist work schedules, and organising document flow;

- Telemedicine, which involves consulting patients without the need for a personal visit to a doctor, providing psychological assistance and preliminary diagnosis for referral to specialists, monitoring the condition of patients undergoing outpatient treatment, etc.

The healthcare sector currently has a number of state innovation programmes funded from the state budget, including the following:

- The project "Stop the Epidemic of Cardiovascular Diseases", under which leading specialists in the regions conduct examinations and consultations with patients to prevent and diagnose cardiovascular diseases in a timely manner;

- The programme is aimed at improving the system of paediatric, neonatal, cardiological and cardiac surgery care within the framework of the European Health Strategy 2020 project;

- The State Programme for the Promotion of Family Medicine, aimed at implementing the Resolution of the Cabinet of Ministers of Ukraine "On Comprehensive Measures for the Introduction of Family Medicine into the Health Care System" (No. 989 of 20.06.2000);

- The State Programme "Quality Assurance of Medicinal Products", which provides for bringing the circulation of medicinal products in line with the requirements of good manufacturing, distribution, laboratory and clinical practice, its harmonisation with the requirements and directives of

the EU and WHO aimed at re-equipping pharmaceutical companies with modern high-performance equipment.

The effectiveness of these programmes depends primarily on the organisation of their implementation on the ground, transparent allocation of funds for their implementation and the availability of feedback from patients involved in the programme. Unfortunately, the effectiveness and efficiency of the implementation of government programmes of innovation, innovative measures in the field of medicine, and innovative activity of healthcare institutions cannot be clearly analysed and monitored due to the lack of appropriate criteria for assessing and statistically recording innovative activities in the field of services, including healthcare. In this regard, the digitalisation of the healthcare sector is an important innovative direction that will create the basis for accounting, analysis and reporting in the healthcare system.

The experience of developed countries shows that an important role in the development of the healthcare sector is played by industries specialising in the production of medical goods and products, pharmaceuticals, and information technologies. However, as noted by scholars Z. Yurynets and O. Petrukh, "The industrial sector of the national economy, which developed and produced innovations in the field of healthcare, medical technologies and was focused on innovation processes, is now either destroyed or forced to reorient to other activities and is forced to survive in the market without any state incentives. And the activities of enterprises engaged in the production of medical products and technologies are characterised by imitation orientation" (Yurynets, Petrukh 2018). Thus, the low level of innovative development of the industry is largely due to the general trends in the innovative development of the national economy in the absence of an effective investment and innovation policy.

Funding for the development of science and technology in the medical sector in Ukraine is provided mainly from the state budget, as this industry is recognised as fundamental and is one of the priorities of state innovation development and technology transfer.

Important indicators of the development of innovation in the healthcare

sector are not only the development of innovative technologies, but also the state of their implementation in medical and treatment practice, an increase in the proportion of medical institutions using technological innovations, the latest approaches to treatment and diagnosis, updating of medical equipment, etc. Taking this into account, we agree with the opinion of A. Svintsitsky and O. Vysotska that "to assess the real innovative development of practical healthcare institutions, it is advisable to focus not on the generally accepted indicators of basic research performance (number of patent applications and granted patents, index of publication activity of employees, etc (Svintsitsky, Vysotska 2015).

One of the problems that hinder scientific and technological progress in the medical sciences is the reduction of scientific personnel potential, significant "aging" of scientific personnel in the industry and emigration of the best specialists abroad as a result of the decline in the prestige of this speciality, lack of material and technical base for research and limited funding.

The priority steps to improve the staffing of innovation activities in the medical sector are to raise the prestige of the status and speciality of researchers, to develop effective incentive systems that include economic and social components, to review the system of selection and training of scientific personnel, and to create conditions for research activities.

Improvement of the system of state support for innovative development of the medical sector requires defining a system of priorities, state guarantees, incentives and mechanisms to stimulate innovation at all stages of the innovation process, as well as establishing effective links between individual stages of the process. In the field of medicine, innovation is manifested in the fact that the innovation process is a sequential chain of events that transforms an innovation from an idea into a meaningful product (new equipment, drugs, vaccines, software), technology (new methods, standards, treatment and diagnostic procedures) or service, their testing and implementation in the practical activities of medical institutions. That is why the development and intensification of innovation in the healthcare sector requires the development and support of government programmes aimed at supporting

the development of innovations at all stages:

1. Initiation of innovations - creating demand for the development of innovative products and technologies in line with the state priorities for the development of the healthcare sector by placing a state order, attracting international organisations, creating a venture capital fund, etc.

2. Directly the process of organising scientific research, which should correspond to the concept of health improvement, which includes the subject and object of research.

3. Formation of future production. At this stage, prototypes of medical technologies are created, tested and approved.

4. Production of an innovative product (service) - small-scale, serial and mass production.

5. Commercialisation of innovations implies penetration (creation of a market for a new product, technology or drug).

6. Promotion of innovations - dissemination of new medicines and services among partners (medical institutions, pharmaceutical companies) and the public.

7. Monitoring the effectiveness of the implementation process and the results of use.

The current development of research and innovation in the healthcare sector in Ukraine faces a number of obstacles that limit its effectiveness. Among the main barriers are the low level of funding for research and development and the imperfect regulatory framework that does not take into account the potential to attract various forms of investment, such as private funds, donor contributions, venture capital and household savings. A significant problem is the shortage of qualified personnel, their increasing migration abroad, and the insufficient development of research infrastructure, including modern equipment, laboratories, and information resources. In addition, there is a lack of certainty in the protection of intellectual property, a lack of effective incentives to invest in innovation, and an inefficient structural and organisational model of the healthcare system, which hampers innovation and improves the level of healthcare services.

The innovative development of the healthcare sector depends on a



number of key factors, including ensuring the functioning of resource-saving policies and the rational use of human and material resources, as well as the introduction of advanced technologies into medical practice. An important aspect is the improvement of economic relations aimed at developing the market for innovative products and services in healthcare, stimulating employees' interest in achieving high results and creating a system of mutually beneficial economic relations between medical institutions, citizens and businesses. A special role is played by the policy of equal opportunities for different forms of ownership in the healthcare sector, promotion of the expansion of the market for medical technologies and services, and development of public-private partnerships that increase the investment attractiveness of the industry for private investors.

To ensure the sustainable development of the healthcare industry, it is necessary to create an innovative model that takes into account the unity of medical science, active participation in international projects of the system, continuous medical education and the formation of sustainable partnerships with leading research centres, the creation of effective mechanisms for protecting intellectual property and state guarantees for innovative investments, the development of public-private partnerships and effective communications in the consumer-state-science-business quadrant.

Analysing the experience of the European Union and world leaders in the field of medical innovation, a number of effective forms of state incentives for innovative investments in healthcare can be identified. These forms include the creation and development of clusters that bring together interconnected enterprises and research institutes within the same territory, as well as the joint establishment of enterprises by scientific institutions and businesses. An important tool is the introduction of tax incentives at the national level for innovative enterprises operating in priority sectors of state and public security. The development of public-private and municipal-private partnerships, as well as the creation of specialised investment funds, are powerful mechanisms for stimulating innovation and attracting investment in the healthcare sector.

### 3. Conclusions

Thus, ensuring further development of medical science, increasing the effectiveness of R&D and the level of introduction of new technologies into the activities of medical institutions requires improvement of state regulation of innovative development of the healthcare sector in the following areas:

- improving the regulatory framework for the development of scientific and technical activities and intellectual property;

- creating a favourable investment climate in the sector by expanding opportunities for attracting various forms of investment in innovation, providing state guarantees for investment protection and effective tools to stimulate investment and innovation activity in the healthcare sector (fiscal, administrative, credit);

- Continuing to modernise the innovative infrastructure of the healthcare sector's scientific potential, creating centres for specialised, interdisciplinary research and research and production complexes;

- Improving the social status and motivation of medical researchers, creating favourable working conditions that will help rejuvenate the human resources and reduce the outflow of qualified specialists;

- development of the information environment of the medical sector and intensification of the implementation of information and communication technologies;

- further reform of the healthcare system with the definition of investment responsibility, appropriate resources and instruments of state incentives for the created structures to implement productive innovations that meet national and regional priorities in the sector;

- intensification of international cooperation and scientific and technical integration in the medical sector, including the production and testing of medicines, medical equipment and medical devices, and the introduction of the latest approaches to the treatment and prevention of diseases;

- Improving the information database of research results, highlighting key medical, social and economic indicators and the corresponding statistical support system.

The development of relevant programmes and identification of tools for their implementation at different levels of government correspond to the main directions of the innovation strategy, which is an important supporting component of the strategic concept of healthcare system development, the effectiveness of which determines the quality and pace of reforms.

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