ANNOTATION

of PhD thesis of Tairova Karima Ermekkyzy on the topic: "Improvement of the system of normative and legal regulation of pharmaceutical production in the Republic of Kazakhstan", presented as an application for the Doctor of Philosophy (PhD) degree on the specialty 6D074800 - "Technology of pharmaceutical production"

Relevance of the research topic. The President of the Republic of Kazakhstan K.-Zh. Tokayev in his State of the Nation Address "Unity of the people and systemic reforms are a solid foundation for the Nation's prosperity" noted among the priorities of the development of the government – ensuring the improvement of the quality of medical services to full compliance with international standards.

Based on the given strategy, the relevance of the problems of regulatory support of pharmaceutical production is determined by the medical, social and economic role of the production of medicines in the life of society. In the National Project "High-quality and affordable healthcare for every citizen "Healthy Nation", approved by the Decree of the Government of the Republic of Kazakhstan dated October 12, 2021 No. 725, the third priority is affordable medicines and medical products of domestic production. The tasks for achieving this priority are designated: building scientific and human potential for the pharmaceutical and medical industries and the development of national production of medicines and medical products. At the same time, the indicators of the latter task are the share of medicines and medical products of national production in the local pharmaceutical market (in value terms), as well as the share of the purchase of medicines and medical products with local content through a unified distribution system within the framework of Guaranteed volume of free medical care and Compulsory social health insurance.

Thus, within the framework of social policy, the government aims to provide affordable and high-quality medical, including medicinal, assistance to the population. Achieving this goal is possible by solving a complex of versatile measures, among which the formation of an appropriate regulatory framework in the field of drug turnover plays an important role.

In addition to the need to ensure the rights of citizens to health protection, enshrined in the Constitution, through a balanced government policy that guarantees the safety and quality of medical care, from the point of view of the economic development of the country, the support of national pharmaceutical production is of no small importance.

In the period of market relations, ensuring competitiveness is the primary task of every pharmaceutical enterprise, the successful solution of which also depends on the appropriate legal support.

Currently, the role of special legal knowledge in ensuring any direction of human activity is rapidly increasing. This is largely due to the fact that a well-thought-out regulatory framework allows you to regulate all areas of legal relations, thereby eliminating the possibility of illegal activity. The study of criminal practice has shown that the imperfection of the legal framework creates prerequisites for illegal activities,

including in the field of pharmacy: illegal activities, non-compliance with the established rules of organization of activities, trafficking in counterfeit medicines, etc.

Another circumstance confirming the relevance of the chosen research topic is a radical change in the national criminal and administrative legislation of the Republic of Kazakhstan, which contains norms providing for liability for illegal acts in the field of pharmaceutical activity. In the updated legislation, a number of issues regulating liability for offenses in this area remained unresolved. In addition, in the recently adopted Code on the Health of People and the Healthcare System of the Republic of Kazakhstan, the section regulating issues of pharmaceutical activity, circulation of medicines and medical devices also needs further improvement.

In modern conditions, the consistent development of its own pharmaceutical industry is one of the priorities of the economic development of Kazakhstan. The organization of modern pharmaceutical production requires the integration of versatile approaches related to the comprehensive implementation of the GxP system of standards regulating various aspects of its activities.

Regulatory systems for drug circulation around the world depend on the national regulatory framework, which organizations that develop, manufacture, test, distribute and sell pharmaceuticals must adhere to.

Strict compliance with the established requirements and norms, the provision of reliable data entered into registration dossiers and other documents on which everyday regulatory decisions of pharmaceutical organizations are based, is an important component of the responsibility of pharmaceutical industry participants in terms of ensuring the safety, effectiveness and quality of medicines. Only in these conditions can the government effectively monitor the market of medicines in order to protect the health of society. All this determines the relevance of the introduction in pharmaceutical production of the Standard of Good documentation practice, which is an integral element of the quality and safety system of manufactured medicines.

Thus, the relevance of improving the issues of regulatory regulation of pharmaceutical production of medicines in the Republic of Kazakhstan is determined by the need to create an appropriate regulatory framework, the need for legal monitoring of existing regulatory legal acts, the need to improve the organizational and legal support of pharmaceutical production in the Republic of Kazakhstan within the GdocP, as well as the need to modernize and optimize certain areas of pharmaceutical activity.

The purpose of the study is to develop a scientific and methodological approach to improving the mechanisms of government regulation of pharmaceutical production. To achieve this goal , the following **research objectives** were formulated and consistently solved:

1. to conduct a comparative analysis of the international regulatory framework governing pharmaceutical activities;
2. to develop proposals to improve the current legislation in the field of pharmaceutical regulation;
3. to develop original approaches to improving the regulatory framework of pharmaceutical production of medicines;

4. to develop a draft Standard of Good documentation practice within the framework of the system of Good practices.

The object of the study within the framework of the formulated tasks was the totality of public relations in the field of pharmaceutical activity.

The subject of the study was the norms of law regulating public relations in the field of pharmaceutical activity, law enforcement practice in the field of drug turnover, the activities of pharmaceutical entities, departmental legal acts regulating pharmaceutical production.

Research methodology. The basis of the research methodology was the dialectical method as a general scientific method of cognition of various events, processes, phenomena in their numerous interrelations and relationships.

Research methods:

- general legal methods: comparative legal analysis of normative legal acts; retrospective historical and legal analysis of legal norms;
- sociological methods: questioning of law enforcement officers, pharmacists, citizens; semi-structured interview of pharmaceutical sector employees;
- organizational methods: SWOT analysis;
- statistical methods: standard statistical methods of digital data processing used in pharmaceutical statistics using computer technology with a package of relevant statistical programs (SPSS, Excel).

Research materials for:

- general legal methods: laws and other regulatory legal acts of the Republic of Kazakhstan, individual CIS countries, international legal acts; law enforcement practice;
- sociological methods: questionnaires; questionnaires for conducting semi-structured interviewing;
- organizational methods: standard operating procedures of pharmaceutical production;
- statistical research: digital data obtained at the request of government bodies (the Committee on the legal statistics and special accounts of the state office of public prosecutor of Republic of Kazakhstan, SK-Pharmacy, etc.) and data obtained during the conducted research.

Empirical base of the study:

- historical and legal analysis of the norms of law and comparative legal analysis of laws and other regulatory legal acts of the Republic of Kazakhstan and individual CIS countries, as well as the practice of their application over the past 7 years;
- a survey was conducted:

a) law enforcement officers (243 respondents: investigators, interrogators) in order to identify problems of countering offenses in the field of drug trafficking;

b) citizens – patients of polyclinics, pharmacies (45 respondents) in order to identify the main types of violations committed by employees of pharmacy organizations;

c) semi-structured interviewing and questioning of pharmaceutical sector employees (120 respondents) in order to study the practice of using regulatory legal acts regulating pharmaceutical activities;

- an analysis of threats and opportunities, strengths and weaknesses (SWOT) of regulatory legal acts regulating pharmaceutical production in the Republic of Kazakhstan was carried out;

- the analysis of threats and opportunities, strengths and weaknesses (SWOT) of pharmaceutical production in the Republic of Kazakhstan was carried out;

- 162 sources of literature were used, including scientific publications on topical issues of pharmaceutical activity, regulatory legal acts, dissertations, etc.;

- foreign experience of the practice of proper documentation and document management in pharmaceutical production in accordance with the Standards of Good Practices of GxP was studied.

The scientific novelty of the study is that:

- based on a comprehensive comparative analysis of the regulatory framework regulating pharmaceutical activities and the responsibility of individuals and legal entities for offenses in the field of drug trafficking in the Republic of Kazakhstan and certain CIS countries, proposals have been developed to improve the current national legislation;

- based on the SWOT analysis of pharmaceutical production in the Republic of Kazakhstan at the present stage, original approaches to improving the regulatory framework of pharmaceutical production of medicines have been developed;

- the scientific and methodological justification of the implementation, the main provisions and principles of Good Documentation Practice pharmaceutical production processes in accordance with GxP standards have been developed;

- a draft Standard of Good Documentation Practice and methodological recommendations for practitioners on the proper documentation of production processes have been developed.

Statements of the thesis to be defended:

1. Proposals for amendments and additions to the current national legislation: The Code of the Republic of Kazakhstan on the Health of People and the Healthcare System; The Code of the Republic of Kazakhstan on Administrative Offenses; The Criminal Code of the Republic of Kazakhstan.

2. Methodology for improving the normative and legal regulation of pharmaceutical production, based on the results of legal monitoring.

3. Draft Standard of Good Documentation Practice and methodological recommendations for its implementation in pharmaceutical production in accordance with the requirements of GxP.

The theoretical significance of the research is to improve the general concept of regulatory support for pharmaceutical activities, taking into account the established pharmaceutical and law enforcement practice. The results of the study can serve as a theoretical basis for further developments on the use of legal knowledge in pharmaceutical production, as well as pharmaceutical special knowledge in law and law enforcement. Theoretical provisions can be useful in the preparation of educational, methodological and scientific works, as well as in the educational process of educational organizations.

The practical significance of the research results lies in the implementation into the practical activities of government bodies, the scientific activities of a number of

educational institutions and the practical activities of a number of organizations, which is confirmed by the acts of implementation in:

- Majilis of the Parliament of the Republic of Kazakhstan (Act of implementation dated 15.05.2020);
- Kharkiv Medical Academy of Postgraduate Education of Ukraine, Kharkiv (Act of implementation dated 02.01.2019);
- Association for the Support and Development of Pharmaceutical Activities of the Republic of Kazakhstan (Implementation Act dated 01.03.2022);
- Association of Pharmaceutical and Medical Organizations of South Kazakhstan region "DAMU" (implementation act dated 21.12.2020);
- Nur-May LLP (implementation act dated 17.05.2020);
- Sultan LLP (implementation act dated 04.14.2022);
- The Police Department of the Kyzylorda region (act of implementation dated 09.14.2020);
- Almaty Academy of the Ministry of Internal Affairs of the Republic of Kazakhstan named after M. Esbulatov (act of implementation dated 17.03.2022).

Approbation of the results of the study.

The main conclusions and provisions of the dissertation research were reported at international scientific and practical conferences:

- Austria, Vienna - III International Scientific Congress of European Scientists within the framework of the III International Scientific Forum of Scientists "East-West" (Austria, Russia, Kazakhstan, Canada, Ukraine, Czech Republic), January 11, 2019;
- Kazakhstan, Almaty – International Scientific and Practical Conference "Law Enforcement system of Kazakhstan in the new global reality: government, reforms, development", February 28, 2019;
- Ukraine, Kharkiv – V Scientific and practical Internet Conference "Social Pharmacy: government, problems and prospects", April 25-26, 2019;
- USA, New YorkYork – 9th International Youth Conference "Perspectives of Science and Education", May 10, 2019;
- Kazakhstan, Almaty – International scientific and Practical conference dedicated to the memory of Professor R. Dilbarkhanov "Formation and prospects of development of the scientific school of pharmacy: continuity of generations", Almaty, 2019;
- Kazakhstan, Shymkent - International scientific and practical Conference "Modern aspects of medicine and pharmacy: education, science and practice", dedicated to the 40thto the anniversary of the establishment of the South Kazakhstan Medical Academy, Shymkent 2019;
- Kazakhstan, Almaty – II annual International scientific and Practical conference on the occasion of the 60th anniversary of Doctor of Law, Professor, Honored Worker of the Ministry of Internal Affairs of the Republic of Kazakhstan, retired Justice Colonel Akimzhanov T.K. "Actual problems of legislation and law enforcement practice in the Republic of Kazakhstan and foreign countries", December 20, 2019;
- Kazakhstan, Almaty – International Scientific and Practical conference "Law Enforcement system of Kazakhstan in the new global reality: government, reforms, development", February 28, 2020;

- Kazakhstan, Almaty - III International Scientific and Practical Conference dedicated to the memory of Professor R. Dilbarkhanov "Formation and prospects of development of the scientific school of Pharmacy: continuity of generations", October 16, 2020.

Conclusions.

Based on the comparative analysis of the regulatory framework of the Republic of Kazakhstan and individual CIS countries, the main directions for improving the current legislation of the Republic of Kazakhstan are determined.

Proposals for amendments and additions to the national legislation of the Republic of Kazakhstan have been developed.

Based on the study of the features and SWOT analysis of pharmaceutical production in the Republic of Kazakhstan, an algorithm for regulatory support of pharmaceutical production has been developed.

Based on the SWOT analysis of the current Standards of good practices of the GxP of the Republic of Kazakhstan from the point of view of the regulation of the documentation system, a scientific and methodological justification for the implementation and the main provisions of the Good Documentation Practice pharmaceutical production processes in accordance with the GxP standards have been developed.

A draft Standard of Good Documentation Practice GdocP has been developed as an element of the quality and safety assurance system for manufactured medicines.

Publications.

The main provisions of the dissertation are reflected in 17 scientific publications, including: 1 publication in an international journal included in the Scopus database, 1 publication in the materials of other foreign international journals, 4 publications in publications recommended by Committee for Quality Assurance in the Sphere of Education and Science of the Ministry of Education and Science of the Republic of Kazakhstan, 9 publications in the materials of international scientific and practical conferences, 2 teaching aids.

The author's personal contribution consists of conducting a comprehensive interdisciplinary dissertation research, independent formation of research directions, direct participation in all stages of research, collection and systematic analysis of domestic and foreign literary data on the topic of the work, in conducting a comprehensive comparative analysis of the regulatory framework of the Republic of Kazakhstan and foreign countries. The author conducted a sociological study among law enforcement officers, employees of the pharmaceutical sector, citizens and statistical processing of the data obtained. The results are summarized and presented in the form of dissertation chapters, articles and methodological recommendations.

The volume and structure of the dissertation. The dissertation consists of an introduction, four chapters, a conclusion, a list of references and appendices. The content and scope of the work are determined by the purpose and objectives of the study.