

ANNOTATION
to the dissertation work of Bukatov Yerik Berikovich
on the topic: «Government control for the medicine circulation in the
Republic of Kazakhstan»,
presented for the doctor of philosophy degree (PhD)
by specialty «6D051000 – State and local government»

Topicality of the research topic. In the President Kassym-Jomart Tokayev's State of The Nation Address "A Fair State. One Nation. Prosperous Society" dated September 1, 2022, in the third direction of the reforms "Strategic Investment in The Country's Future" it is said that the main value of the country is a person. By ensuring the population with quality healthcare services and thereby improving the health of citizens it is possible to achieve a developed harmonious society. Therefore, the Head of State pays close attention to the development of an effective healthcare system, issues of financing the healthcare system, as well as building a modern system of public administration in healthcare. It is worth noting that the national healthcare system of Kazakhstan also has high expectations to achieve the UN Sustainable Development Goals. The sphere of medicines circulation is an integral part of the healthcare system and largely determines its effectiveness. The COVID-19 pandemic has confirmed the strategic importance of medicines in the healthcare system and the impact of medicines on the country's national security. More organized national healthcare systems with a well-functioning medicines circulation and effective government administration, developed and received the necessary medicines and vaccines for coronavirus infection more quickly.

Medicines are an important element in the realization of the right to health of every citizen of Kazakhstan, and the effectiveness of interactions between participants in the pharmaceutical market to provide the population with high-quality and safe medicines largely depends on public administration. The state plays a central role in the pharmaceutical market, it determines the legal and organizational mechanisms of interaction. In the event of a "pharmaceutical market fiasco" the state creates and purchases goods and services to ensure social equality among all citizens.

The sphere of medicines circulation consists of many stages. Each stage is regulated by the state to varying degrees. Starting from the development stage and ending with the disposal stage, public administration is aimed at providing the population with safe and high-quality medicines. In many ways, the effectiveness of treatment, health, life expectancy and standard of living of a person depend on medicines. Spending on medicines is growing every year in all countries of the world. In low and middle-income countries, the share of medicines can reach up to 70% of total health care spending. It is the high social significance of medicines that sets the state the task of effectively managing the sphere of circulation of medicines. The head of state in his message "Unity of The People and Systemic Reforms are a Solid Foundation for The Nation's Prosperity" drew attention to the medicines safety of the country, the development of the pharmaceutical market and the attraction of

investments in pharmaceutical production. The COVID-19 pandemic has shown the country's dependence on imported medicines and vaccines, and also revealed the problems of public administration in the field of medicines circulation. In Kazakhstan, by 2025, the task was set to increase the share of domestic medicines to 50% in the pharmaceutical market, thereby reducing dependence on imports. With effective government management, the pharmaceutical industry can achieve these indicators and become the driver of the Kazakhstani economy, which in turn will provide the population with safe and affordable medicines.

The degree of scientific development of the research topic. Theoretical and legal issues of public administration in the sphere of circulation of medicines are presented in the works of domestic and foreign scientists: Shertaeva K.D., Utegenova G.I., Mokhova A.A., Aksenova-Sorohtey Y.N., Baranovskaya E.A., Zanina I.A., Lavrova N.N., Putilo N.V., Volkova N.S., Tsomartova F.V., Mironova T.K., Olefira Y.V., Schiavetti B., Vinendaele E., De Spiegeleer B., Wirtz W.J., Hogerzeil H.W., Gray A.L., Bigdeley M., De Jonchira K.P., Ewen M.A., Gyans-Lutterodt M., Okoroha J., Leonardo Alves T., Bloom G., Mintsy V., Bloom D., Henson S., Peters D.H. and etc.

The issues of state management of quality control, efficiency and safety in the sphere of circulation of medicines were considered in the works of: Smetova G.G., Shopabayeva A.R., Zhakipbekov K.S., Temergaliev K.T., Sydykov S.B., Mukanov A. B., Nabirov D., Shmid G., Yusupov R., Alotaibi N., Overton S., Hadjou M., Krech L., Kelesidis T., Rafailidis P., Weigmann K., Nayyar G.L., Breman J.G., Tadege H., Berhane J., Buckley G.B., Gostin L.O., Bocheneka T., Abilov V., Davida I., Pisani E., Viana T., Raufu A., Angeli D.G., Trezzy K., Singha S., Mohan B., Shiera J.G., Rubina K.S., Zoler M.L., Kavilanz P., Huluz F., Kiger S., Hasnid A., Saez S. and etc.

Among domestic specialists in the issues of socio-economic analysis of the problems of public administration in the sphere of circulation of medicines are: Shopabaeva A.R., Ramazanov A.E., Dyusembinova G.A., Kanushin M.A. The development of the pharmaceutical market of the Republic of Kazakhstan was considered by: Datkhaev U.M., Erzhanova R.B., Blatova R.M., Zhakipbekov K.S., Kasymbaeva A.Z., Piskunova L.P., Sannikova Y.A., Suleeva B.B., Kishtibaeva A. and others. The issues of irrational use of medicines are reflected in the works of: Zhusupova G.K., Zhaldybaeva S.S., Satmbekova D.K., Shakarova A.M.

The issues of the quality of medicines are considered in the works of: Musinov S.R., Tulegenova A.U., Mukhanova S.K. The issues of patent law and public procurement were considered in the works of: Alseitov K., Kaibagarova M., Shamakhanova A. Actual problems of private health care costs were considered in the works of: Zagidullina G.N., Omirbayeva B.S., Srirama S., Khan M. The issues of price regulation for medicines are considered in the works of: Orazbayev S.K., Suliotis K., Papageorgiou M., Politi A., Vogler S., Zimmermann N. The problems of the medicines and health insurance market are considered in the works of: Spankulova L.S., Chulanova Z.K., Kerimbaev A.R., Nuruly E., Isaev Z.S.

The issues of integration of the pharmaceutical markets of the EU, OECD and EAEU countries are considered in the works of Spanov M.U., Orynbet P.Z.,

Omelyanovsky V.V., Maksimova L.V., Tatarinov A.P., as well as in regulatory legal acts, programs and analytical reports of EU, OECD and EAEU countries.

It should be noted that the scientific elaboration of the issues considered in the dissertation on external reference pricing in the Republic of Kazakhstan is not well reflected in domestic research. The problems of external reference pricing were considered in the foreign works of the following scientists: Tumi M., Remuzat S., Vater A.L., Urbinati D., Kavalets P., Tesar T., Vostalova L., Robinson J.S., Panteli D. , Espin J., Rovir J., Tirgil A. and etc.

The goal of the dissertation is to explore and develop the theoretical and methodological foundations of public administration in the sphere of circulation of medicines and, in the process of complex analysis, develop proposals for improving the management system in the bodies and in the sphere of circulation of medicines.

To achieve the goal, the following **tasks** were set and solved:

- to explore the sphere of circulation of medicines as an object of public administration;
- reveal the essence of state management of quality control, efficiency and safety in the sphere of circulation of medicines;
- to generalize the foreign experience of public administration in the field of circulation of medicines and to study the possibilities of applying foreign experience in public administration in the field of circulation of medicines in Kazakhstan;
- analyze the market of medicines in Kazakhstan and determine the subjects and objects of the sphere of circulation of medicines;
- to characterize the regulation of relations in the field of medicines circulation;
- reveal the features of state management of the pricing process for medicines in Kazakhstan;
- to determine the optimal criteria for the formation of a reference basket of countries for Kazakhstan;
- investigate the problem of high household expenses on medicines;
- to propose recommendations for improving the management system in the governing bodies in the field of medicines circulation;
- to propose recommendations for improving the interaction between the state and participants in the pharmaceutical market in the field of circulation of medicines.

The object of the dissertation research is the public administration of the sphere of circulation of medicines as an important part of the health care system of the Republic of Kazakhstan.

The subject of the study is the socio-economic relations in the field of circulation of medicines that arise in the process of public administration.

Theoretical and methodological significance of the study. The theoretical basis of the study was the scientific works of leading foreign and domestic scientists in the field of public administration in the sphere of circulation of medicines. The study used recognized scientific research methods, general scientific methods (systemic and integrated approach, political and cultural approach, structural and functional analysis, comparative analysis, institutional method, historical method) and empirical research methods (sociological, economic-mathematical, statistical).

The empirical base of the study is legislative and regulatory legal acts, analytical materials, official publications, statistical collections and reviews of the WHO, EU, OECD, EAEU, the Ministry of Health of the Republic of Kazakhstan, the National Center for Expertise of Medicines and Medical Devices, the National Scientific Center for Health Development named after Salidat Kairbekova, the Bureau of National statistics of the Agency for Strategic Planning and Reforms of the Republic of Kazakhstan. In addition, the content of the messages of the President of the Republic of Kazakhstan, state strategies, programs and national projects are reflected in the dissertation work. The study analyzed information from the official websites of state and quasi-state bodies, international organizations, pharmaceutical companies and public associations. The dissertation work used data from an online sociological survey of medicines consumers in the Karaganda agglomeration.

Scientific novelty of the dissertation research. Measures to reform government bodies and methods for improving public administration in the field of medicines circulation were proposed in the dissertation research:

1. a scheme of interaction between state and quasi-state bodies regulating the sphere of circulation of medicines was drawn up;
2. recommended measures to improve the pricing system for medicines, based on the generalization of scientific data, clarified the definitions of "external reference pricing" and "reference pricing";
3. developed proposals for the disposal of unnecessary (low-quality, expired) medicines;
4. recommended measures to improve public administration in the field of circulation of medicines;
5. Directions for reducing household spending on medicines are outlined.

The main provisions of the dissertation research submitted for defense:

1. Proposed structural changes in government bodies and quasi-state bodies in the field of medicines circulation, based on the concept of development of public administration of the "Human-centric" model - "People First";
2. Author's substantiation of the system of external reference pricing and the principles of compiling a basket of reference countries for Kazakhstan;
3. Proposal for the formation of a state policy for the disposal of unnecessary medicines in Kazakhstan;
4. Recommendations for improving public administration in the area of medicines circulation, taking into account the COVID-19 pandemic;
5. The necessity of introducing medicines insurance, improving the system of compulsory medical insurance and increasing the financing of the healthcare system, including medicines provision of the population, is substantiated.

The practical significance. The results of the study can be included in the disciplines: "Public Administration of the Social Sphere" and "Public Administration of the Healthcare System" of the educational program "State and Local Administration". The proposals made were taken into account by the Committee for Medical and Pharmaceutical Control of the Ministry of Health of the Republic of Kazakhstan. The principle of compiling an external reference basket of countries considered in the study can be applied in determining pricing for original

medicines. Recommendations on the development of a state policy for the disposal of unnecessary medicines will reduce the level of environmental pollution, and reduce the level of poisoning from expired medicines.

Approbation and implementation of research results. The results of the dissertation research were published in 8 scientific papers: 1 article in an international scientific journal, 3 articles in scientific publications of far abroad countries and presented at international scientific conferences, 3 articles in publications recommended by the Committee for Quality Assurance in the Sphere of Education of the Ministry of Education of the Republic of Kazakhstan, 1 article in a journal from the list of the Scopus database.

The structure and scope of the dissertation. The dissertation work consists of normative references, designations and abbreviations, introduction, 3 chapters, conclusion, list of references and applications. The main text of the dissertation is presented on 144 pages, the research work contains 30 tables, 44 figures and 22 appendices. The list of references contains 202 sources.

In the first chapter of the dissertation "Theoretical Foundations of State Administration in the Sphere of Medicines Circulation", the sphere of medicines circulation is considered as an object of public administration. The experience of public administration in the sphere of medicines circulation in Australia and Canada is analyzed. International and national standards for the quality of medicines have been identified as an important element of state management in the sphere of medicines circulation.

Medicines are a boon, medicines are used by people in everyday life, they, as part of the healthcare system, are a criterion for the value orientations that exist in society, access to medicines should be equal and fair for all members of society. The sphere of circulation of medicines is an important element in the healthcare structure, on which the health of the population and the national security of the country depend, therefore the state exercises closer regulation and supervision in this area. The state, through management tools, regulates "market failures" in the field of medicines circulation.

Public administration of the sphere of circulation of medicines is an important part of the state policy in the field of healthcare. The scope of circulation of medicines should include all stages of the life path of a medicines.

Public administration should be aimed at all stages of the sphere of circulation, while using the paradigms of public administration "Good Governance", "New Public Management". The state must ensure that the public uses genuine, safe, effective and high-quality medicines produced by licensed manufacturers. The management process should be understandable for pharmaceutical market participants, while the management process should be guided by the principles of protecting and promoting human rights, public health, sustainable development and safety.

The experience of Australia and Canada contributes to a better understanding of the pros and cons of public administration in the area of medicines circulation for the healthcare system in Kazakhstan. At the same time, the experience of Australia and Canada shows the development of the "New Public Management" and "Good

Governance" paradigms in public administration in the field of medicines circulation in these countries. Given the high social significance of medicines, government intervention in the sphere of circulation in these countries is significant, while if the market can independently regulate any function, then government intervention is minimal. For example, in the field of medicines advertising, the state trusts advertising agencies and companies, while remaining in the role of an observer. It is also worth noting that in Australia and Canada, communication between the state and the population in the field of medicines circulation has been effectively established through various institutions. It would be interesting to apply the experience of these countries in the state administration of the sphere of circulation of medicines in the conditions of Kazakhstan.

The main government authorities in the sphere of medicines circulation, which are directly responsible for the quality and safety of medicines, were analyzed. Thus, the activities of the National Center for Expertise of Medicines and Medical Devices were considered. The reasons for the appearance of low-quality and counterfeit medicines were analyzed. As world experience shows, a well-developed system for managing the sphere of medicines circulation makes it possible to provide the population with high-quality and safe medicines. Kazakhstan regulators must effectively address the main problems that contribute to the production and distribution of substandard and falsified medicines, address the problems of medicines availability, inefficient public administration and weak technical capacity. Representatives of civil society, patients, pharmaceutical companies, etc. should be involved in the regulatory process.

In the second chapter "Assessment of public administration in the sphere of circulation of medicines in the Republic of Kazakhstan" the market of medicines in the Republic of Kazakhstan and the impact of public administration on the pharmaceutical market are analyzed. The features of public administration in the field of circulation of medicines in Kazakhstan are revealed. Household expenditures on health care and medicines are analyzed.

In Kazakhstan, during the years of independence the main participants in the pharmaceutical market have been formed. With a large number of participants, in each market segment there are 5-6 companies that occupy a leading position and determine the development of the market. Over the years, leading companies such as Stopfarm, Medservice Plus were recognized as participants in unfair competition. In 2017, SK-Pharmacy was fined 1.3 billion tenge for creating monopoly conditions for Stopharm in 2010-2015.

The global COVID-19 pandemic has shown the presence in the Kazakh pharmaceutical market among the participants of cartel agreements and monopolies. Only 6 out of 34 manufacturers together produce 77% of all medicines in Kazakhstan. The leading Kazakhstani manufacturers include: Chimpharm JSC, Nobel Almaty Pharmaceutical Factory, Karaganda Pharmaceutical Complex LLP, Abdi Ibrahim LLP, Kelun-Kazpharm LLP, DOSFARM LLP. During the pandemic, Kazakh companies produced medicines worth 138.3 billion tenge, the real growth in medicines production was 47%. At the same time, the share of imports increased, if in January 2020 Kazakhstan imported medicines in the amount of 72.1 million

USD, then in January 2021 this figure increased to 423 million USD. In 2019, the volume of imports amounted to 1.146 billion USD, during the pandemic, imports increased to 1.229 billion USD. In many ways, dependence on imports contributes to medicines shortages and price exposure.

The state needs to create equal conditions for all participants in the pharmaceutical market. Lobbying the interests of any companies should be unacceptable. Fair competition forces pharmaceutical companies to improve the quality of work and reduce prices for their services and products. In the midst of the COVID-19 pandemic, many companies took the initiative and tried to quickly resolve force majeure situations that arose due to a shortage of medicines. Additional logistics services were provided by the distribution company "INKAR", the leading Kazakhstan medicines manufacturers further increased the production of pharmaceutical products. The COVID-19 pandemic has shown how important it is to have many strong pharmaceutical companies in the pharmaceutical market.

Public administration in the field of medicines circulation is a complex process and consists of many elements. The state is the main player at all stages of the sphere of circulation of medicines, effective interaction with other participants in the sphere of circulation of medicines depends on the state policy: the population, medicines manufacturers, distributors, pharmacies, medical institutions, etc. Effective public administration at all stages of the sphere of circulation of medicines allows the state to provide the population with high-quality and safe medicines.

The Republic of Kazakhstan has set itself the task of reducing the costs of Kazakhstanis from 42% to 30% by 2025 on healthcare, including the cost of medicines. According to WHO recommendations, the share of public spending on health care should not exceed 20% of total spending. The health care systems of countries where population spending on health care does not exceed 20% are considered sustainable. The consequences of the global COVID-19 pandemic and inflation have had a painful impact on the spending of Kazakhstanis. During the pandemic, the expenses of Kazakhstanis for medicines, medical devices and equipment increased by 63%. In 2020, on average, each household spent 47.1 thousand tenge on medicines, medical products and equipment.

To reduce the high expenses of the population on medicines, it is necessary to use alternative pricing methods. Following the example of the OECD countries, mixed pricing methods can be used, since each method has its own advantages and disadvantages. Within the framework of a single pharmaceutical market, it will be beneficial for the EAEU countries to jointly purchase medicines, such as orphan medicines. Joint purchases will help to reduce prices for medicines. In addition, in order to reduce public spending on health care by up to 20%, the state needs to increase funding for the health care system to the level of OECD countries. Undoubtedly, the introduction of mechanisms for medicines and medical insurance, the mechanism of co-payments will reduce the level of spending by the population, but without increasing public funding it will be problematic to achieve the necessary WHO indicators.

In the third chapter of the dissertation work "Improving the state management of the sphere of circulation of medicines in the Republic of Kazakhstan" the author

proposes mechanisms for improving the management system in state governments and quasi-state bodies in the sphere of circulation of medicines. The ways of improving the state management in the sphere of circulation of medicines are proposed.

Kazakhstan needs to reduce import dependence on foreign medicines. During the COVID-19 pandemic, Kazakhstan failed to ensure medicines safety, producing only 17% of medicines (in monetary terms). During this period, more than 20 countries and a number of international organizations sent humanitarian aid in the form of medicines to Kazakhstan. Therefore, the state needs to create favorable conditions for both Kazakhstani and foreign medicines manufacturers. It is also necessary to attract companies from "Big Pharma" to localize production in Kazakhstan. It is worth considering the option of providing Kazakh companies with tax holidays and preferential loans. It is necessary to encourage Kazakh companies using "Kazakh raw materials", "contract manufacturing" and to simplify unnecessary bureaucratic procedures. For example, to recognize clinical trials conducted not only in ICH countries, but also in countries with the fourth level of regulation. It is also necessary to simplify the examination and registration procedure for socially important medicines produced according to GMP standards in priority countries. In addition, medicines manufactured under GMP standards do not have to undergo a quality assessment procedure.

During the global COVID-19 pandemic, medicines prices continued to rise. Scientific studies and foreign experience show that the inclusion of high-income countries in the reference basket will increase prices. If a country includes countries with lower incomes in its reference basket, prices will decrease. Therefore, it is advisable to revise the countries in the reference basket, for example, add Armenia and Kyrgyzstan, with these countries Kazakhstan has a single pharmaceutical market. World experience shows that the developed countries of the world use external reference pricing as one of the methods for determining prices or as an addition during negotiations to determine prices for medicines.

The state needs to carry out a balanced pricing policy for medicines, foreign experience shows that in the case of a strict pricing policy, there is a risk of shortage and disappearance of medicines. So already in January 2021, residents of Almaty began to complain about the lack of high-demand medicines in the retail pharmacies of the city. For example, the medicines "Cardiomagnyl", "Kipferon", etc. have become scarce. For the uninterrupted provision of the population with the necessary medicines, the state needs to deliberately take administrative measures to curb the prices of medicines.

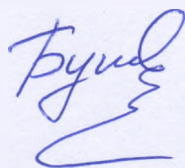
There is a need to revise the structure of the governing bodies in the sphere of medicines circulation. Poor implementation of reforms in the field of healthcare and circulation of medicines creates the need to analyze the reforms at the initial stage and a more detailed analysis of foreign experience. To solve this problem, we propose to create on the basis of the "department of strategy and development" and the "department of medicines policy" of the Ministry of Health of the department for reforms in the field of health care and in the field of medicines circulation. It is necessary to assign to the "National Scientific Center for Health Development" the

functions of information and educational work in the field of health care and the circulation of medicines. The Center should act more actively as a dialogue platform between the population, the state, subjects and objects of the pharmaceutical market.

We also propose to transfer the storage and logistics functions of SK-Pharmacy to a competitive environment, the functions of purchasing medicines and medicines provision to the Mandatory Health Insurance Fund, and functions related to information systems to the Republican Center for Electronic Health. It is necessary to expand the number of members of supervisory boards, management bodies of the sphere of circulation, by inviting independent experts and public figures from private, professional and public organizations that are directly related to the sphere of circulation of medicines. Functions for the examination of advertising, the transfer of packages and the destruction of medicines must be transferred to a competitive environment. We offer various management solutions at each stage of the sphere of medicines circulation. For example, recognition of clinical trials conducted according to GCP standards in priority countries. The considered proposals for improving the state management of the sphere of circulation of medicines should improve the management system and provide the population with high-quality, safe and effective medicines.

Based on the foregoing, a well-built public administration system can solve emerging urgent problems that have developed as a result of force majeure situations or pandemics. Timely solution of emerging problems will have a positive impact on the population, since medicines play an important role in the life of a person, society and the state.

Dissertation candidate



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