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History of formation and development of legal guaranteeing of Pharmacia in Ukraine

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Abstract

The purpose of the article was to characterize the processes related to the genesis of the legal guarantee of the Ukrainian pharmacy. The methodological basis meant a set of general scientific and special legal methods of scientific knowledge, the use of which was determined by the purpose, objectives and specifics of the subject. It has been concluded that the emergence and formation of the legal guarantee of pharmacy has ancient origins, but its development is taking place at the present time, as new standards of Ukrainian pharmacy are still being formed. Four stages in the formation of pharmaceutical relations have been distinguished. It has been emphasized that the current state of the legal guarantee of pharmacy begins its development from the moment when Ukraine gained independence. That led to the emergence of new forms of economic management within the pharmacy, which affected its formation of legal guarantee. In particular, it was necessary to create the system of state control over the quality of medicines. The processes of globalization of the markets of production and sale of medicines required the updating of technologies for the production of drugs by domestic manufacturers.

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Keywords: pharmaceutical area; pharmaceutical business; pharmaceutical legal relations; health sector; legal guarantee.

Historia de la formación y desarrollo del soporte legal de la farmacia en Ucrania

Resumen

El propósito del artículo fue caracterizar los procesos relacionados con la génesis de la garantía legal de la farmacia ucraniana. La base metodológica significó un conjunto de métodos científicos generales y legales especiales del conocimiento científico, cuyo uso estuvo determinado por el propósito, los objetivos y las especificidades del tema. Se ha llegado a la conclusión de que el surgimiento y la formación de la garantía legal de la farmacia tiene orígenes antiguos, pero su desarrollo se está produciendo en la actualidad, ya que todavía se están formando nuevos estándares de la farmacia ucraniana. Se han distinguido cuatro etapas en la formación de las relaciones farmacéuticas. Se ha enfatizado que el estado actual de la garantía legal de la farmacia comienza su desarrollo desde el momento en que Ucrania obtuvo la independencia. Eso llevó al surgimiento de nuevas formas de gestión económica dentro de la farmacia, lo que afectó su formación de garantía legal. En particular, era necesario crear el sistema de control estatal sobre la calidad de los medicamentos. Los procesos de globalización de los mercados de producción y venta de medicamentos requirieron la actualización de las tecnologías para la producción de fármacos por parte de los fabricantes nacionales.

Palabras clave: área farmacéutica; negocio farmacéutico; relaciones jurídicas farmacéuticas; sector salud; garantía jurídica.

Introduction

Pharmaceutical activities have a long history. It is due to the fact that Pharmacia is a systemic entity that covers phenomena of different content. In particular, we are talking about the development and manufacture of medicines, their sale through specialized institutions, the training of pharmacists, pharmaceutical science and pharmaceutical legislation.

Therefore, the formation and development of Pharmacia as a legal phenomenon includes such phenomena as the actual occurrence of medicines, their use and the processes of legal regulation of pharmaceutical

relations, the formation of the system of state government agencies in the pharmaceutical sector.

One of the first pharmaceutical reference books that pointed to the independence of pharmaceutical activity was Sushruta Samhita, an Indian Ayurvedic treatise of the VI century B.C. There were also Sumerian cuneiform clay tablets (end of the VI century B.C. – early II century B.C.) containing recipes for medicine (History of pharmacy, 2021). Pharmaceutical activity actively developed in the Ancient Egypt. The papyri found testify to the development and use of medicines. For example, the Ebers Papyrus describes 811 recipes for medicinal products, where many of them consist of 5-13 components, and one recipe includes 37 ingredients (Guzev, 2017).

Pharmaceutical activity was developed even more intensively over time, and the ancient Roman physician Dioscorides Pedanius was the first to single out medicinal substances as a separate area of medical knowledge in the I century A.D. At the same time, he provided a complete description of all known medicines in his work “Hospital Remedies”. The physician and philosopher Claudius Galen (131-201 A.D.) also made a significant contribution to the emergence of pharmacia.

He was the first who pointed out that a pharmacia is a place where medicines are both stored and produced (Ohar *et al.*, 2011). Despite the scientific approach to the discovery and use of medicinal products, this area of activity was one of the most mysterious for human beings. Therefore, both alchemists and monks, who opened pharmacies at monasteries, were involved in that activities.

Pharmaceutical specialty was first singled out in 1178 in France. It was from this time that the first pharmacies began to open. At the same time, the pharmacist simultaneously performed the function of a therapist and a pharmacist. Pharmaceutical education emerged in the XIV century in European countries. The first public pharmacies emerged in 1490 on the territory of modern Ukraine, and the first private pharmacies appeared in 1578 in Lutsk.

Their legal regulation raised simultaneously with the actual formation of pharmaceutical relations, in particular, the Herbalist’s Charter adopted in 1543 in England (Flannery, 2001). This indicates the relevance of the research of scientific issues in the field of pharmacia, which are directly related not only to the development of a segment of the state economy, public administration of the pharmaceutical sector, but also to the fundamental human right to life and health care (Teremetskyi and Khovpun, 2020).

The *purpose* of the article is to study and characterize the processes related to the emergence, formation and development of legal guaranteeing of pharmacia in Ukraine. The main *objective* is to reveal the genesis of the legal guaranteeing of pharmacia in Ukraine and its role in improving the

provision of the country's population with affordable and most necessary medicines in the course of implementing the medical reform.

1. Methodology of the study

Theoretical basis of the article is the scientific achievements of national and foreign scholars in various branch and related sciences. The empirical basis was certain provisions of the Constitution of Ukraine, the Association Agreement between Ukraine and the EU, international legal acts and legislation of Ukraine regulating relations in the healthcare sector in general and pharmacia in particular.

The methodological basis of the article is a set of general scientific and special legal methods of scientific cognition, whose use is determined by the purpose, objectives, specifics of the subject matter and object of the research.

Thus, the dialectical method was used to clarify the current status of legal regulation of relations in the field of pharmacy, as well as to determine the perspectives for its further development and improvement. The historical and legal method was used to study the origin, formation and development of legal guaranteeing of pharmacia in Ukraine.

Theoretical provisions of the article were formulated with the help of the formal and logical method. The comparative and legal method, as well as the method of structural and functional analysis made it possible to distinguish and analyze the various stages for the formation and development of legal relations that arose in the field of pharmacia in Ukraine.

The application of the method of legal modeling allowed developing a number of suggestions aimed at improving scientific views on the optimization of legal relations in the field of pharmacia. The axiological method was used in determining the importance and value of legal regulation of pharmacia for the vital activity of Ukrainian society, as well as the formation of new standards for the development of Ukrainian pharmacia in the context of European integration. Generalization and forecasting methods were used to formulate the conclusions to the article.

2. Results and Discussion

2.1. Origin of legal guaranteeing of Ukrainian pharmacia

We believe that it is advisable to consider pharmacia as a legal phenomenon not from ancient times, but from the moment of the

emergence of systemic pharmaceutical activity, which led to the need for its legal regulation. Moreover, legal guaranteeing of pharmacia in Ukraine has a long retrospective.

Thus, the pharmacy ordination “Lekta digna” was introduced in Lviv in 1609. This document defined the rights and obligations of pharmacists. The King Sigismund III approved the Charter of the Lviv Pharmacy Workshop (Perfumery Workshop) in February 1611, which, in particular, determined responsibility and limited competition in the pharmacy business (Fedushchak, 2011).

The indicated facts emphasize that legal guaranteeing of Ukrainian pharmacia was formed along with the development of pharmacology, the formation of a pharmacist profession. It is due to the fact that the free functioning of pharmaceutical activities without an element of public provision is practically impossible, since pharmacia is directly related to human life and health.

Legal guaranteeing of pharmacia has gradually expanded with the development of human civilization. It is evidenced by the following historical facts. Thus, the foundations of pharmacological science in Ukraine were laid at the Kiev-Mohyla Academy in 1682-1817. A graduate of this Academy N. Ambodyk wrote the first textbook on pharmacology and pharmacognosy called “Medical Speech, or Description of Medicinal Plants”, where he systematized information about medicinal plants.

The pharmacist H. Ventsel started the first private pharmacy in 1810 in Kharkiv, which was included in the “Russian Medical List”. Its activities were regulated by the Pharmaceutical Charter of 1789. It is noteworthy that permission to work in a pharmacy was granted by the Minister of Internal Affairs after passing the exam by a pharmacist at the Department of Medical Speech, Pharmacy and Medical Literature of Kharkiv University. Due to a systematic approach to the development of legal guaranteeing of pharmacia in Ukraine there were 1067 pharmacies as of 1913, including 714 rural and 353 urban ones, and there were already 1096 pharmacies in 1927 (Borishchuk *et al.*, 2014).

A professional direction – pharmaceutical activity has begun to be formed along with the opening of pharmacies. There was a tendency at the end of the XIX century in increasing the number of people wishing to receive a pharmaceutical education. Thus, the Department of Pharmacology at Academician O.O. Bohomolets Kyiv Medical Institute was founded in 1842, where the general problems of pharmacology were studied. It was opened at St. Volodymyr University under the title “Medical Veshchestvosloviie with a Recipe”.

Not more than 5 people per year received the title of pharmacist and 10-15 people became pharmacy assistants at Kharkiv University in the 1860s.

Kharkiv University trained 30 pharmacists and 31 pharmacy assistants in 1872, in 1874 – 32 pharmacists and 26 pharmacy assistants, in 1877 – 16 pharmacists and 38 pharmacy assistants. 700 pharmacists were trained on the basis of the pharmaceutical laboratory of Kharkiv University in 1916 (Prokopenko *et al.*, 2015).

2.2. Stages of formation and development of pharmacia on the territory of modern Ukraine

Two interrelated processes took place simultaneously in the Soviet period of the formation of pharmacia (1920-1923): the withdrawal of the private sector of pharmacies from civil circulation (by nationalization on the basis of the Decree of the Council of People's Commissars of the Ukrainian SSR "On the nationalization of the pharmacy business" in 1920) and the development of legal guaranteeing for pharmaceutical activities (the Pharmacy Department was created under the People's Commissariat of Health of the Ukrainian SSR, which was in charge of the pharmacy personnel and the pharmaceutical subdivision of the Health Department of the provincial executive committee including the management of the pharmacy warehouse, as well as the control and analytical laboratory).

The activity for the production of medicines arose directly from the moment of the formation of management activity. "Krasnaya Zvezda" Chemical Pharmaceutical Plant was launched in Kharkiv in 1923, the branch of the Ukrainian Institute of Experimental Endocrinology was founded in Kyiv in 1930, which began to produce medicines since 1932 (today it is the well-known pharmaceutical company "Darnitsa"). The Kyiv Vitamin Plant has begun its work since 1937. The artel named after Kirov was registered in 1947, which was transformed into the Borshchahovskiy chemical-pharmaceutical plant in 1957 (Illiashenko, 2016).

Due to the systematic development of the pharmaceutical industry Ukraine, among other Soviet Republics, was second in terms of drug production. The country produced about 30% of all pharmaceutical products in the state, which represented 800 types of drugs. Despite this situation, industrial production had difficulties after Ukraine gained independence. "Enterprises experienced an acute shortage of raw materials in the middle of 1992. Production of more than 50 items of vital medicinal products was discontinued. The level of provision of medical institutions and the population with them was decreased to 35%" (Chernykh, 2002).

In order to overcome the critical state that arose in the pharmaceutical industry in 1992, the Comprehensive Program for the Development of the Medical, Veterinary and Microbiological Industry, Improvement of Providing the Population and the Needs of Livestock Farming with Medicinal Products was approved by the Resolution of the Cabinet of Ministers (hereinafter referred to as the Cabinet of Ministers) of Ukraine.

The enterprises for the manufacture of medicinal products were re-equipped according to this Program, and the production of semi-finished products was launched. The Pharmacological and Pharmacopeial Committees, the State Inspectorate for Quality Control over Medicinal Products were formed.

That contributed to the renewal of the pharmaceutical sector of the economy. "In particular, the production of 120 drugs and prophylactic agents that were not previously produced in Ukraine was mastered from 1992 to 1996, where 10 of them were fundamentally new" (Chernykh, 2002: 3). Thus, the system of public administration entities in the field of circulation of medicinal products was created during this period.

The State Committee of Ukraine for the chemical, petrochemical industry and medicinal products was established in 1991, which was the central government agency subordinated to the Cabinet of Ministers of Ukraine.

Its activities were aimed at organizing an independent chemical cycle in Ukraine, which assisted in producing drug ingredients. The Pharmacopoeia Center was established in 1992, whose task was to develop national standards for medicinal products.

The State Committee for the Medical and Microbiological Industry was established in 1993, whose powers include: performing tasks aimed at improving the provision of the population and the needs of animal agriculture with medicinal products, medical and veterinary equipment; solution of issues of providing the industry with material and technical resources; implementation of a unified scientific, technical and investment policy and coordination of foreign economic activity in the field of medical and microbiological industries.

The enterprises and organizations of the national form of ownership, which were part of the liquidated concern "Ukrmedbioprom", were transferred to the sphere of its management. The system of legal guaranteeing for pharmacia was developed due to its activities, in particular, the system for managing the pharmaceutical industry and the sale of medicines.

Ukraine adopted the fundamental law of the pharmaceutical sector "On Medicinal Products" in 1996. This law established legal regulation of relations associated with the creation, registration, production, quality control and sale of medicinal products, defined the rights and obligations of enterprises, institutions, organizations and citizens, as well as the powers of state authorities and officials in this area (On Medicinal Products, 1996). It was also determined that the management of pharmacy was entrusted to the Ministry of Health of Ukraine, the State Committee of Ukraine for the Medical and Microbiological Industry and specially authorized state agencies.

Summarizing it should be noted that the next stage of the formation and development of legal guaranteeing of pharmaceutical legal relations was formed in 1991-1996, which we offer to name: “The emergence of independent Ukrainian state agencies for legal guaranteeing of pharmaceutical legal relations and the creation of the pharmaceutical sector in the economy of independent Ukraine”.

The next stage in the formation and development of legal guaranteeing of pharmacia was marked by the adoption of the Comprehensive Program for the Development of the Medical Industry for 1997-2003 approved by the Resolution of the Cabinet of Ministers of Ukraine in 1996, which determined the development of medical equipment and the production of medicinal products.

The Program fixed the directions and financing for the development of production bases for the finished medicinal products and their substances. Pharmaceutical production was expanded in the state due to the implementation of that Program. Thus, about 800 types of medicinal products were produced in 1992, then more than 4000 were produced in 2005 (Almakaieva, 2011).

The Resolution of the Cabinet of Ministers of Ukraine “On streamlining the activities of pharmacies and approving the Rules for the retail sale of medicinal products” was adopted in 1997. According to that Resolution, the Ministry of Internal Affairs, the Licensing Chamber, the State Tax Administration, the State Committee for Standardization, Metrology and Certification, the State Inspectorate for Quality Control of Medicinal Products, the Council of Ministers of the Autonomous Republic of Crimea, the regional, Kyiv and Sevastopol city state administrations were charged with the obligation to strengthen control over the sale of medicinal products.

To take measures on preventing trade in places not specified in the license, to prosecute persons violating the rules for the sale of medicinal products in accordance with the law. Having analyzed the content of that Resolution, one can argue that there was a practice of distributing medicinal products outside pharmacies at the time of its adoption, as well as massive falsification of medicines. Overcoming those violations became possible due to the active development of legal guaranteeing of pharmacia.

At the same time, agencies for monitoring the quality of medicinal products were created. Thus, the State Inspectorate for Quality Control of Medicinal Products of the Ministry of Health (hereinafter referred to as the Ministry of Health) of Ukraine began its functioning in accordance with the Decree of the Cabinet of Ministers of Ukraine “On State Control over the Quality of Medicinal Products”.

The process of providing medicines has received a new development due to that direction. The order of the General Directorate of Health,

Pharmacy Association “On the regulation of free and preferential provision of medicinal products on physicians’ prescription in case of outpatient treatment” was adopted in 1999. It laid the foundation for the existence of the system of affordable medicinal products for the population.

There were also changes in the system of pharmaceutical legal relations management in 1999, in particular, the Resolution of the Cabinet of Ministers of Ukraine “Issues of the Committee for the Medical and Microbiological Industry” was adopted. It allowed the Committee for the Medical and Microbiological Industry to have 5 deputies, including one first deputy chairman and deputy chairman of the Committee – the director of the state enterprise “Expert Center of the Committee of the Medical and Microbiological Industry”, as well as the board of eleven people.

The National Agency for Controlling the Quality and Safety of Food, Medicinal Products and Medical Devices was established in the same year, as a result of which the Coordinating Expert Committee on Food Quality and Safety, the Committee on Hygienic Regulation, the Committee on Immunobiological drugs, the Committee for New Medical Technology, the Pharmacopoeia Committee, the Bureau of Registration of Medicines and the State Inspectorate for Quality Control of Medicines were liquidated. The above indicates the ongoing development of the pharmacia management system and the optimization of the management of the pharmaceutical sector.

The Decree of the President of Ukraine of 2000 approved the Concept for the Development of Public Health in Ukraine, which determined the priority of the development of medical and pharmaceutical industries. The Health Departments of regional state administrations were entrusted with control over the quality and sales of medicinal products and medical devices. It was also determined that the public health care sector should provide the population with the most necessary medicinal products (Concept for the Development of Public Health in Ukraine, 2000).

2.3. Development of pharmaceutical activity and formation of special state agencies in this area

The legal guaranteeing of pharmacia continued to be formed along with the development of pharmaceutical activities, in particular, through the formation of special state agencies in this area. Thus, the Resolution of the Cabinet of Ministers of Ukraine “On the formation of the State Department for Quality Control, Safety and Production of Medicinal Products and Medical Devices” was adopted in 2000.

The Department managed and controlled the quality, safety and production of medicinal products including active substances, excipients, medicinal plant materials and medical cosmetics, immunobiological

preparations, biomaterials, medical equipment and medical products (On the approval of the Provisions on the State Department of Control, 2020).

The State Pharmacopoeia of Ukraine has launched its activities in Ukraine since the beginning of October 2001 – the first national pharmacopoeia among the CIS countries, which had been developed since 1998. That document established national standards for the development, manufacture of medicinal products, their testing and quality compliance. The quality control system of medicinal products has received the basis for further development in the direction of the safety of using medicines due to this, and hence the support of public health.

Summing up the results of the development of pharmacia from 1997 to 2003 within the framework of the implementation of the Comprehensive Program for the Development of the Medical Industry for 1997–2003, it is advisable to single out another stage in the formation of legal guaranteeing of pharmaceutical legal relations in 1997–2003 and name it as “Comprehensive development of pharmaceutical production and control over the quality and safety of medicinal products”.

The next stage in the formation and development of legal guaranteeing of pharmacia began in 2003. The State Program for the Development of Industry for 2003-2011 was adopted in July of the same year, which was approved by the Resolution of the Cabinet of Ministers of Ukraine. It laid down the mechanisms for the formation of competition among the entities of production, in particular, in the pharmaceutical sector of the economy.

Achieving this became possible due to the principles laid down for the modernization of existing enterprises, the development of new technologies for the development of medicinal products, changes in the product certification system and production standards. The basis for that was both changes in ideas, business standards and the renewal of legal guaranteeing of pharmacia, which began to be transformed from a control system into a support system and creation of favourable conditions for the development of the pharmaceutical sector of the economy.

The State Service for Medicinal Products and Medical Devices was established in 2003, which became the successor of the State Department for Quality Control, Safety and Production of Medicinal Products and Medical Devices. It should be noted that constant changes in the pharmacy management system lead to destabilization of legal guaranteeing statics.

The procedures for the sale of medicinal products are improved simultaneously with the renewal of the pharmacia management system. Thus, new Rules for the sale of medicinal products in pharmacies approved by the Resolution of the Cabinet of Ministers of Ukraine have come into effect since 2004 (Rules of trade in medicinal products in drugstores, 2004). Wholesale and retail trade in medicinal products without a license was

prohibited according to these Rules. Only medicines registered in Ukraine could be sold. The provisions of these Rules have established additional requirements for entrepreneurial activities in the field of pharmacia, as well as for the quality of medicines.

The Procedure for the state registration (re-registration) of medicinal products and the amount of the fee for their state registration (re-registration) approved by the Resolution of the Cabinet of Ministers of Ukraine as of May 26, 2005 was additionally adopted in order to implement these Rules (On the approval of the Procedure of state registration (re-registration) of medicinal products, 2005).

The state registration of a medicinal product according to this Procedure is carried out by the Ministry of Health of Ukraine on the basis of an application and the results of an examination of registration materials for such a product, carried out by the State Expert Center of the Ministry of Health of Ukraine. This provision was justified, it made it possible to improve the quality of medicinal products, to establish the system for ensuring pharmaceutical activities.

An important Resolution of the Cabinet of Ministers of Ukraine “On Measures to Stabilize Prices for Medicines” was adopted in October 2008. The state according to that Resolution establishes the system for stabilizing prices at the pharmaceutical market, in particular, it determines marginal supply and marketing allowances in the amount of not more than 10% charged to wholesale selling price, taking into account taxes and fees, and marginal trade (retail) allowances (On measures to stabilize the prices for medicinal products, 2008).

Price stabilization is one of the most important forms of legal guaranteeing for pharmacia, since it is aimed at creating the system of access to medicines for the population with the purpose to ensure the public health of the country’s population.

The State Inspectorate for Quality Control of Medicinal Products under the Ministry of Health of Ukraine has begun its work since 2010. Control over the quality of medicines was carried out by checking the compliance by business entities with the requirements of the legislation on the quality of medicinal products by using laboratory analysis of the quality of medicines, visual control, verification of related documents. In general, regulation on the selection of medicine samples to check their quality has been introduced since 2010.

Summing up, we should define that the stage of formation of legal guaranteeing of pharmaceutical legal relations from 2003 to 2011 can be named as “The formation of legal guaranteeing of pharmacia and stabilization of prices in the pharmaceutical market”.

A new stage in the formation and development of legal guaranteeing of pharmaceutical legal relations has begun to be formed since 2011, which was associated with providing the population with affordable medicines as part of implementing medical reform. Thus, the Ministry of Health of Ukraine announced in 2011 the publication of the draft Concept of the state target-oriented program “Development of import-substituting industries in Ukraine and substitution of imported medicinal products with domestic ones including biotechnological drugs and vaccines for 2011-2021” (Draft Concept of the State Target-Oriented Program, 2011). The above Concept testified to an attempt of creating an import-substituting production of medicines in Ukraine, which would make it possible to make medicines more accessible to the population.

The Government of Ukraine approved in 2013 the Concept of the National Target-Oriented Economic Program for the Development of Industry for the period up to 2020, the purpose of which is:

A comprehensive solution of problematic issues for the functioning of the industrial sector of the Ukrainian economy by developing an organizational and economic mechanism and attracting resources to implement the tasks of structural and technological modernization of domestic industry in the direction of increasing the share of high-tech activities in the volume of production and exports, meeting the needs of the domestic market for products of own production, increasing employment and thereby improving the well-being of the population (The Cabinet of Ministers of Ukraine, 2013: 06).

National producers received tax benefits and the opportunity to introduce science-intensive technologies as innovations due to the adoption of this Concept.

The drug quality control system continues to be improved along with the support of the national pharmaceutical manufacturers. Thus, an updated Procedure for quality control of medicinal products during wholesale and retail trade was approved in 2014. The conduct of input state control and quality control of medicinal products by business entities having licenses to carry out economic activities for the wholesale and retail trade in medicinal products has been determined in accordance with that Procedure.

The purpose of this control is to detect trade in low-quality medicinal products, unregistered drugs in Ukraine, narcotic drugs, etc. (On the approval of the Procedure to control over the quality of medicinal products, 2014).

2.4. Impact of medical reform on legal provision of pharmacia in Ukraine

The medical reform began in Ukraine in 2016, which was directly related to the legal guaranteeing of pharmacia. In this regard the Cabinet

of Ministers of Ukraine approved the Concept for the Development of the Public Health System, the expected result of which (among others) was the increase in the medical literacy of the population by counteracting the uncontrolled and irrational use of medicinal products.

Besides, the reform of medicine also meant providing the population with access to medicinal products and medical care. It is to achieve this result the Resolution of the Cabinet of Ministers of Ukraine “On ensuring the availability of medicinal products” was adopted in March 2017 (On ensuring the availability of medicinal products, 2017). Patients with cardiovascular diseases, bronchial asthma or type II diabetes were able to receive free of charge medicines or with a small additional payment.

The Ministry of Health of Ukraine in order to implement this project has developed the Register of affordable medicines. In this case two factors were taken into account: the prevalence of the disease among the population and the production of medicines by national manufacturers. That approach led to the receipt of state assistance to citizens and pharmaceutical manufacturers.

In addition to the drug availability program, the program of state guarantees of medical care for the population began to be formed, which also provided a list of medicinal products, where the state guarantees to patients the full payment for their provision at the expense of the State Budget of Ukraine according to the tariff for the prevention, diagnosis, treatment and rehabilitation related to diseases, injuries, poisonings and pathological conditions, as well as in regard to pregnancy and childbirth (On State Financial Guarantees of Medical Care for the Population, Art. 1).

The content of the activity of drug sales establishments has also been changed as a result of the implementation of the medical reform. Thus, the provisions of the 2001 WHO Guidelines for the Development and Implementation of Standards of Good Pharmacy Practice (Pharmaceutical Services) – GPP began to be implemented in pharmaceutical practice. In particular, the pharmaceutical establishment should help to ensure the correct use of prescribed drugs and medical products, as well as to prevent self-medication.

To achieve a positive effect from the implementation of medical reform, it was necessary to amend the legal guaranteeing of pharmacia. The Pharmaceutical Directorate has been established in the structure of the Ministry of Health of Ukraine since 2018 for this purpose. It includes the Expert Group on Market Admission of Medicinal Products, which ensures the formation and implementation of the state policy in the field of creation, production, quality control and sale of medicinal products, medical immunobiological preparations, in the field of narcotic drugs, psychotropic substances circulation (Regulations on the Expert Group, 2018).

Changes in the administrative and legal guaranteeing of pharmacia in 2020 were due to the fight against the COVID-19 pandemic. One of the directions was the development of the possibility of electronic retail trade in medicinal products. The Resolution of the Verkhovna Rada of Ukraine “On the adoption of the draft Law of Ukraine on amending the Art. 19 of the Law of Ukraine “On Medicinal Products” as a basis regarding the implementation of electronic retail trade in medicinal products” was adopted for this purpose. The Law was eventually adopted.

Conclusion

Summarizing the above, we note that the formation and development of legal guaranteeing of pharmacia has ancient origins. It has been established that the systemic pharmaceutical activity was formed, its legal regulation was formalized, state management of the pharmaceutical sector was launched in Ukraine in the XVIII century. The current status of legal guaranteeing of pharmacia begins its retrospective development from the moment Ukraine gained independence.

That led to the emergence of new forms of economic management in pharmacia, which affected the formation of its legal guaranteeing. In particular, there was a need to create the system of state control over the quality of medicinal products. Globalization processes at the markets for the production and sale of medicinal products required updating the technologies for the production of medicines by domestic manufacturers. All that influenced the development of the legal guaranteeing of pharmacia.

It has been emphasized that the state policy, as well as the model of implementation of pharmaceutical legal relations available in the country plays an important role in the process of establishing the legal guaranteeing of pharmaceutical legal relations. The formation and development of the specified relations is characterized by the gradual emergence of medicines, pharmacies, the production of medicines, state regulation of the pharmacy business.

We believe that the formation of the legal guaranteeing of pharmaceutical legal relations continues due to the formation of new standards for the development of Ukrainian pharmacia. Based on the foregoing, we can suppose the following stages for the formation and development of legal guaranteeing of pharmacia:

1. from 1991 to 1996 – the emergence of independent Ukrainian state agencies for legal guaranteeing of pharmaceutical legal relations and the creation of the pharmaceutical sector in the economy of independent Ukraine;

2. from 1997 to 2003 – comprehensive development of pharmaceutical production and control over the quality and safety of medicinal products;
3. from 2003 to 2011 – the formation of legal guaranteeing of pharmacia and the stabilization of prices at the pharmaceutical market;
4. from 2011 to the present day – the formation of legal guaranteeing for the availability of medicinal products for the population of Ukraine.

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