Chapter 3

NATIONAL PHARMACEUTICAL POLICY AND ITS REGULATORY AND LEGAL SECURITY AS A COMPONENT OF PUBLIC HEALTH

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Introduction

National pharmaceutical policy is a set of measures, strategies and regulatory mechanisms aimed at ensuring the availability, quality, safety and efficiency of medicines (drugs) for the population of the country. This policy covers various aspects of the pharmaceutical sector, including production, distribution, quality control, price regulation and introduction of new medicines. Also, the national medical (pharmaceutical) policy is a system of regulatory legal acts (documents), in which the state determines the goals of the pharmaceutical industry to provide for the population of medicines, as well as state strategy to achieve them in search, production and distribution drugs according to the real needs of public health care[1].

The national medicines (pharmaceutical) policy is formed by the provisions of regulatory and legal acts that govern the rules for the provision of medical care in a particular country and the circulation of medicines from the production (import, export) stage and the distribution of medicines to the end user.

The relevance of our chosen research topic is based on the understanding and deep conviction that farmaceutical policy (FP) of each country directly affects the health of citizens. An effective FP contributes to ensuring the availability of drugs, reducing morbidity and improving the quality of population life. As for the economic impact of FP ,the farmaceutical sector is an important component of the economy of many countries. Effective FP

[1] Фармацевтична енциклопедія. Визначення термінів. Національна лікарська (фармацевтична) політика. https://www.pharmencyclopedia.com.ua/article/8171/nacionalna-likarska-farmacevti chna-politika#:~:text=%D0%9D%D0%90%D0%A6%D0%86%D0%9E%D0%9D%D0%90%D0%9B%D0%AC%D0%9D%D0%90%20%D0%9B%D0%86%D0%9A%D0%90%D0%A0%D0%A1%D0%AC%D0%9A%D0%90%20(%D0%A4%D0%90%D0%A0%D0%9C%D0%90%D0%A6%D0%95%D0%92%D0%A2%D0%98%D0%A7%D0%9D%D0%90)%20%D0%9F%D0%9E%D0%9B%D0%86%D0%A2%D0%98%D0%9A%D0%90%20%E2%80%94,%D0%BF%D0%BE%D1%82%D1%80%D0%B5%D0%B1%20%D0%BE%D1%85%D0%BE%D1%80%D0%BE%D0%BD%D0%B8

promotes the development of this sector, creation of new workplaces, promotes innovation and supports economic growth.

In today's world, humanity faces a number of global challenges, such as pandemics, wars, natural disasters, man-made disasters, antibiotic resistance, global climate change which also affect the pharmaceutical industry. An effective national FP is a key tool for solving these problems and ensuring the sustainability of the health care system. It should be noted that active changes, even before the introduction of martial law in Ukraine in 2022, regarding the organization of the health care system are clearly demonstrated by such regulatory and legal acts as the Order of the Ministry of Health of Ukraine (MHU) "On approval of the Procedure for providing primary medical care"[2] and the Order of the MHU "Providing medical assistance for the treatment of coronavirus disease (COVID-19)"[3]. In the first case, the changes are related to political will and the authorities' decision to reorganize the health care system, in the second, the analyzed changes are caused by the Covid-19 pandemic. National medical FP should be based on social justice for the country's citizens. Access to medicines is a key component of social justice. FP should contribute to reducing the difference in access to treatment between different social groups and regions.

The purpose of this work is to analyze, evaluate and describe the national FP of Ukraine, to identify the main trends, problems and prospects of its development. The study is aimed at understanding the complex interrelationships between different aspects of the pharmaceutical sector and developing recommendations for improving the efficiency and sustainability of the national FP. The tasks of the research were: analysis of changes in the existing legislation and regulatory environment that regulates the pharmaceutical industry; assessment of compliance of these norms with international standards and best practices in the field of pharmacy; study of the structure of production, distribution and sale of drugs; assessment of the competitive situation of the pharmaceutical market and determination of factors affecting the prices and availability of drugs. Also, the study of the quality control system, the safety of the production and sale of drugs and the evaluation of the effectiveness of these mechanisms and the identification of possible problems. The study of the price regulation system and the analysis

[2] Наказ МОЗ України № 504 від 19.03.2018 «Про затвердження Порядку надання первинної медичної допомоги» https://covid19.phc.org.ua/normatyvna-baza/

[3] Наказ МОЗ України «Про затвердження протоколу «Надання медичної допомоги для лікування коронавірусної хвороби (COVID-19)» за № 762 від 02.04.2020 (зі змінами і доповненнями, внесеними наказами МОЗ України від 10 квітня 2020 року № 852 від 21.07.2020 №1653 від 17.09.2020 № 2116 від 11.11.2020 № 2583 від 20.11.2020 № 2693 від 31.12.2020 № 3094 від 06.04.2021 № 638 від 13.05.2021 № 930 від 20.09.2021 № 1979 від 11.11.2021 № 2495 від 30.12.2021 № 2948 від 22.02.2022 № 358 від 17 травня 2023 року № 913). https://www.dec.gov.ua/wp-content/uploads/2023/05/2020_762_nakaz_covid19_.pdf

of the drug pricing system and its impact on the availability of drugs for the population will be the next stage of our research. Analysis of the role of government bodies, pharmaceutical companies, professional associations and other interested parties in the formation and implementation of FP and the study of opportunities for cooperation between these parties to achieve common goals, as well as the development of recommendations for improving national FP are current issues. Based on the received data and analysis, it is possible to formulate specific recommendations for improving legislation, regulatory mechanisms and practices in the pharmaceutical sector.

1. Theoretical concepts, aspects, essence and stages of development of the national pharmaceutical policy

Public health is ensured thanks to medical (pharmaceutical) policy[4]. FP is a component of medical care for the country's population, and also largely determines the state and level of public health in society. Pharmacy policy, like drug policy, is established in each country in accordance with the economic, political and socio-cultural aspects inherent in that particular civil society.

In the EU countries, there are general provisions of legislation on medicine (pharmacy), but each of these countries has its own sectoral legislation. Accordingly, it is believed that there are twenty different systems of healthcare organisation and their pharmaceutical components that regulate medical and pharmaceutical services in each of the EU countries[5].

FP is a system of strategies, regulatory mechanisms, legislative acts and programs that regulate the functioning of the pharmaceutical sector in the state. It covers a wide range of aspects related to the production, registration, distribution, sale, formulation, use and quality control of pharmaceuticals. The essence of the FP is and is aimed at ensuring the population's access to effective, high-quality and safe medicines. This includes the development of mechanisms for registering new drugs, ensuring their effective distribution and controlling their prices. One of the main tasks of the FP is to control the quality and safety of drugs on the market. This is achieved by establishing quality standards, conducting inspections and monitoring the production and distribution of medicines. The FP includes mechanisms for regulating drug prices in order to ensure their availability to the population and maintain the stability of the pharmaceutical market.

[4] Leu Shi. "Introduction to Health Policy". 2023. P. 1-28. https://account.ache.org/eweb/upload/Shi_Chapter1_2-e629562b.pdf

[5] Кричковська А. М., Паращин Ж. Д., Курка М. С. Вектори розвитку медичного страхування та фармацевтичної складової: порівняльний аналіз Королівства Нідерландів та України. Modern medical science and education in Ukraine and EU countries: imperatives, transformation, development vectors : Scientific monograph. Riga, Latvia : “Baltija Publishing”, 2022. С. 143-174. https://doi.org/10.30525/978-9934-26-240-1-8

FP provides for the stimulation of innovation and research. FP contributes to the development of new drugs by stimulating research and innovation in this field. This may include providing financial support for research projects, promoting the introduction of new technologies and creating favorable conditions for the development of the pharmaceutical industry.

One of the important functions of the FP is to ensure safety and control over the use of drugs. This includes conducting effective measures to control the production, distribution and use of drugs, as well as providing the population with information on the correct and safe use of drugs.

FP is aimed at supporting public health by providing access to the necessary drugs for the treatment and prevention of diseases. This includes taking measures to prevent epidemics, implementing programs to treat chronic diseases, and supporting national immunization programs. The FP includes measures for the development of the infrastructure of the pharmaceutical sector, including the creation and support of research centers, quality control laboratories, pharmaceutical production enterprises and pharmacies.

FP also includes an informational component, which involves providing the population with information about the effective and safe use of drugs, their properties, possible side effects, and ways to interact with other drugs.

FP involves the identification and management of risks associated with the use of drugs, including the risks of side effects, interactions with other drugs, allergic reactions, etc. The FP should have an interest in ensuring inclusiveness, that is, in including all social groups and settlements, regardless of their social status, financial capabilities and geographical location, in the processes of production, distribution and use of medicines,

The main principles of the formation of the national FP are: a scientifically based approach, the principles of accessibility, the principle of efficiency, safety and quality, affordable price, innovation, global cooperation, sustainable development, public participation, flexibility and adaptability, ethics, risk management (Table 1). The principles of the formation of the national FP are consistent and echo the priorities of the sustainable development strategies of the countries of the European Union [6,7]. When forming normative legal acts for the pharmaceutical industry of Ukraine, which regulate its functioning, it is necessary to adhere to all the above-mentioned principles.

[6] Zahir-Ud-Din Babar. «Pharmaceutical policy in countries with developing healthcare systems». Book. DOI 10.1007/978-3-319-51673-8. https://www.researchgate.net/publication/315712277_Pharmaceutical_Policy_in_Countries_with_Developing_Healthcare_Systems

[7] Feldstein P.. "Health policy issues: an economic perspective" (Aupha/Hap Book) 7th Edition. Medical Books. Administration & Medicine Economics. 2018. P.708. https://www.amazon.com/Health-Policy-Issues-Economic-Perspective/ dp/ 1640550100

Table 1

Basic principles of the formation of the national FP and their definition

№	The principle of FP	Definition of the FP principle
1.	Science-based approach	The development of the FP should be based on scientific research, expert opinions and international standards. An evidence-based approach allows taking into account the latest advances in pharmaceutical science and practice.
2.	Accessibility.	One of the key goals of the FP is to ensure that medicines are affordable for all segments of the population. This principle implies the creation of mechanisms that ensure the availability of essential medicines for all citizens, including vulnerable groups.
3.	Effectiveness.	The FP should be aimed at maximizing the efficiency of resource use in the healthcare sector. This includes optimizing the production, distribution and use of medicines to maximize the satisfaction of the population's needs.
4.	safety and quality	One of the main principles of the PD is to ensure the safety and quality of medicines. This means setting high quality control standards for the production and sale of medicines to prevent side effects and other problems.
5.	affordable price	The FP should promote stable and affordable prices for medicines. This includes establishing mechanisms for regulating prices and stimulating competition in the pharmaceutical market to reduce the cost of medicines.
6.	innovation.	The FP should promote innovation in the field of medicine and pharmacy. This includes stimulating research and development of new medicines, introducing the latest technologies into production and developing strategies to support promising areas in the pharmaceutical industry.
7.	global cooperation	Pharmacy should be part of a global community that cooperates to develop international standards and strategies in the field of health care. This means active participation in international initiatives, exchange of experience and technologies with other countries, and joint solution of global problems in the field of pharmacy.
8.	sustainable development	Pharmacy should be aimed at achieving sustainable development, which means ensuring harmony between the economic, social and environmental aspects of the production and use of medicines.
9.	public participation	The development of the FP should include active participation of the public, patient organizations, industry professionals and other stakeholders. This will ensure that the diverse needs and views of the population are taken into account in the development of AF strategies and increase the legitimacy of decisions.
10.	flexibility and adaptability	The FI should be flexible and adaptive to changes in the external environment, including new scientific discoveries, technological innovations, demographic and economic changes, as well as epidemiological and global health challenges.
11.	ethicality	PH should be based on the principles of ethics and equity. This involves ensuring the availability of medicines of immediate need, avoiding discrimination in access to health care, and ensuring equitable distribution of health care resources.
12	risk management	The FP should include effective mechanisms for managing risks associated with the production, distribution and use of medicines. This includes the development and implementation of strategies to minimize risks and respond to potential threats to public health.

The principles of the formation of the national financial system of Ukraine are in line with the priorities of the sustainable development strategies of the European Union countries. All of the above principles should be followed when drafting legal acts for the pharmaceutical industry of Ukraine that regulate its functioning all of the above principles should be followed.

The stages of development of the FP[8] include several key steps covering the formation, implementation and evaluation of pharmaceutical sector management strategies.

The first stage includes the collection and analysis of data on the state of the pharmaceutical sector, the population's needs for medicines, the effectiveness and safety of the use of medicines, access to medical care and other important aspects. This analysis helps to understand the current situation and identify key issues and priorities. Based on the analysis of the situation, the goals and objectives of the FP are formulated. These goals may include ensuring access to effective medicines, improving the quality and safety of medicines, developing infrastructure and innovation in the sector, supporting public health, etc.

At the second stage, strategies and programs are developed to achieve the defined goals and objectives. This may include the adoption of new legislation, the introduction of regulatory mechanisms, the development of programs to support scientific research and innovation in the industry, as well as the creation of mechanisms for controlling the quality and safety of medicines. At this stage, adopted strategies and programs are being implemented. This may include reforming the system of registration and quality control of pharmaceuticals, creating programs of access to medicines for vulnerable population groups, developing mechanisms for insurance of pharmaceutical costs, etc.

The last third stage "Monitoring and evaluation" includes monitoring and evaluation of the effectiveness of implementation of the FP. This helps to determine the achievement of the set goals, identify problems and shortcomings in the system and make the necessary adjustments to improve the activities of the pharmaceutical sector.

The next stage, Interaction and Collaboration, which follows the completion of the three main stages, involves collaboration between various stakeholders, such as government agencies, the pharmaceutical industry, medical institutions, civil society organizations and international institutions. The interaction of these parties helps to implement the strategies and programs of the FP, to ensure mutual understanding of needs and priorities and to strengthen the legitimacy of the decisions made.

[8] Fulda T. The Handbook of Pharmaceutical Public Policy 1st Edition. CRC Press. 2017. P. 681. https://www.amazon.com/Handbook-Pharmaceutical-Public-Policy-Health/dp/0789030594

The stage "Continuity and adjustment" assumes that the FP should be continuous and flexible, able to adapt to changes in society, technology, economy and scientific discoveries. At this stage, there is constant monitoring and analysis of policy results in order to make timely adjustments and improve strategies.

FP must be sustainable and take into account potential risks and threats that may arise as a result of changes in society, economy, technology or health. Risk management mechanisms make it possible to reduce the negative impact of unforeseen factors on the pharmaceutical sector. The formation of effective public information policy and educational programs is an important element of FP. Ensuring the availability and reliability of information about drugs, their use and side effects helps to promote the correct use of drugs and the preservation of public health.

Taking into account the global nature of the pharmaceutical industry and scientific achievements, international cooperation becomes an important aspect of the formation of FP. Participation in international programs, exchange of experience, adaptation of international standards and regulations to domestic needs are key aspects of international cooperation.

The main participants and legislators are government bodies, which play a key role in the formation and implementation of the FP. They are responsible for the adoption of laws, regulation of the pharmaceutical industry, ensuring the availability of medicines, quality and safety control, as well as for the development of programs and strategies in the field of health[9]. Government bodies usually involved in FP: Ministry of Health, Ministry of Economy or Finance, National Medicines Agency, Regulatory bodies, Interdepartmental committees and working groups (Table 2).

[9] Schweitzer, Stuart O., and Z. John Lu, Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems, 3rd edn (New York, 2018; online edn, Oxford Academic, 24 May 2018), https://doi.org/10.1093/oso/9780190623784.001.0001.

Table 2

Characteristics of government bodies dealing with national FP

№	Government body	Functions of a government body
1.	Ministry of Health	The Ministry of Health is responsible for developing and implementing healthcare policies and programs, including AF. This includes regulating the production, registration, distribution and use of medicines, as well as monitoring the quality and safety of medicines.
2.	Ministry of Economy or Finance	These departments are responsible for regulating prices for medicines, developing financial mechanisms to support the availability of medicines for the population, including reimbursement programs and health insurance.
3.	National Medicines Agency	This agency is responsible for the registration and regulation of medicines on the national market. It monitors the quality, efficacy, and safety of medicines, and oversees the production and distribution of medicines.
4.	Supervisory authorities	These authorities are responsible for controlling and supervising the pharmaceutical sector, including the production, distribution and sale of medicines. They ensure compliance with legal requirements and safety standards
5.	Interagency committees and working groups	The government may establish interagency committees or working groups to address specific issues and challenges in the pharmaceutical sector. They bring together representatives of different agencies and experts to jointly consider issues and develop recommendations.

In Ukraine, the State Service of Ukraine on Medicines and Drugs Control acts as the National Agency on Medicines (Table 2, item 3).

Government bodies, together with other interested parties, define strategies and programs in the pharmaceutical sector that contribute to ensuring the availability, quality and safety of medicines for the population.

In addition to legislative government bodies, pharmaceutical companies (FC), professional and public organizations (associations, unions) play an important role in the formation of the national FP. FC are key players in the pharmaceutical industry and play an important role in the formulation and implementation of FP. They play a significant role in the development and production of pharmaceuticals, the implementation of research and clinical trials, as well as in ensuring the availability and distribution of pharmaceuticals.

FC carry out research and development of new drugs that have the potential to treat various diseases. This includes basic scientific research, clinical trials and drug manufacturing. FC produce drugs in various dosage forms, from traditional tablets and capsules to biotechnological drugs and vaccines. They ensure the production and supply of medicines to the markets of different countries. FC actively promote their products through various marketing and advertising campaigns. This may include advertising in medical journals, promotion through doctors and pharmacy chains, and advertising to end consumers. FC are obliged to ensure high quality and safety of their products. This includes compliance with manufacturing standards,

quality and safety controls, and compliance with regulatory requirements. FC cooperates with medical institutions and scientific institutions to conduct research, develop new technologies and improve medicines.

Professional pharmaceutical associations (associations) play an important role in representing and protecting the interests of pharmacists and other specialists in this field. They bring together professionals to work together on issues related to the practice, education, research and development of the pharmaceutical industry. Professional associations act as the voice of pharmacists in communication with government, regulatory bodies and other stakeholders. They protect the professional rights and interests of their members and advocate for the improvement of working conditions, the development of professional status and other issues related to professional practice. Professional associations provide their members with opportunities for training, professional development and support in career growth. They organize seminars, conferences, courses and other forms of training to improve the knowledge and skills of pharmacy professionals. Professional associations develop standards of professional practice and ethical behavior for their members. They contribute to ensuring high standards of quality and safety in the provision of pharmaceutical services and practice. Some professional associations carry out research work and promote innovation in the field of pharmacy. They can fund research, organize scientific conferences and promote the exchange of knowledge and ideas among their members.

Professional associations can act as a source of information for the public on matters related to pharmacy and health. They can conduct educational campaigns, provide advice and engage in dialogue with the public to increase awareness and understanding of the importance of pharmacy to health. Professional associations play a critical role in the support and development of the pharmaceutical industry, promoting stability, professional growth, and improving the quality of pharmaceutical practice.

Non-governmental organizations (NGOs) also play an important role in the pharmaceutical sector, helping to protect the rights and interests of consumers, promote public health, and monitor the activities of government agencies and pharmaceutical companies. NGOs advocate for the rights and interests of patients and drug users. They can provide advice, legal assistance and support to those who face problems in accessing FP or receiving quality health care. NGOs actively work to promote public health, promoting the implementation of disease prevention programs, educational campaigns on disease prevention, and stimulating a healthy lifestyle. NGOs can monitor the activities of government bodies and pharmaceutical companies, acting as watchdogs that monitor compliance with ethical standards, safety and availability of medicines.

NGOs can participate in the development and discussion of pharmaceutical policy at the level of government bodies and international organizations. They represent the voice of consumers and the public in addressing issues related to the availability, quality and ethical use of medicines. NGOs can carry out educational and informational initiatives regarding the correct use of drugs, the dangers of drug use, disease prevention and other aspects of public health.

NGOs are important agents of public control and support in the pharmaceutical field. They contribute to improving the availability, quality and efficiency of medical services and pharmaceuticals, as well as the development of public health.

International organizations and partners play an important role in cooperation and coordination of actions in the field of pharmacy at the international level. They facilitate the exchange of experience, the development of standards and regulatory policies, and provide financial and technical support for the development of pharmaceutical systems and improving access to quality medicines.

Key international organizations and partners: World Health Organization (WHO), World Bank, Global Fund, European Medicines Agency (EMA), International Pharmaceutical Federation (FIP). WHO coordinates international efforts in the field of health, including pharmacy. It contributes to the development of international standards and recommendations in the field of pharmaceutical products, promotes public health and provides technical support to countries in the development of pharmaceutical systems. The World Bank provides financial support to countries in the development of their health care systems, including the pharmaceutical industry. It can finance projects to improve the availability and quality of medicines, reform the procurement system and increase the professional competence of specialists in the field of pharmaceuticals. The International Fund "Global Fund" focuses on the fight against the epidemics of HIV/AIDS, tuberculosis and malaria[10]. It provides financial and technical support to countries to ensure access to drugs for the treatment of these diseases, and invests in prevention and control programs. EMA is responsible for the scientific evaluation and registration of medicinal products in the countries of the European Union and the European Economic Area. It cooperates with other international organizations and regulators to ensure the safety, quality and availability of medicines. FIP is a global professional organization that unites pharmacists from all over the world. It promotes the exchange of knowledge and best practices in the pharmaceutical field, develops standards of professional practice, and promotes the improvement of the quality of pharmaceutical

[10] Hein W. "Global health governance and the fight against HIV/AIDS". Medical Books. 2007. P. 282. https://link.springer.com/book/10.1057/9780230591349

services. These international organizations and partners promote cooperation between countries, the development of global strategies and programs in the field of pharmaceuticals.

2. Factors influencing the formation and implementation of pharmaceutical policy. Perspectives of pharmaceutical policy

The development of new technologies in pharmacy and medical sciences affects the formation of FP, as new opportunities in production, diagnosis and treatment require adaptation of legislation and regulations to ensure the effectiveness and safety of use. Demographic changes in the structure of the population, such as an increase in the average age of the population, an increase in the proportion of the elderly population, and changes in disease patterns, affect the needs for drugs and services and may require revision of FP strategies. Economic factors, such as the level of income of the population, the level of unemployment, the availability of health care financing and the cost of drugs, affect the availability and use of medical services and drugs and require the alignment of policies with economic realities. Socio-cultural factors, such as cultural and social perceptions of health, disease and treatment, as well as attitudes towards the use of medicines and alternative therapies, influence the demand for drugs and may determine the need for regulation and information policies.

International agreements and standards, such as the rules of the World Health Organization (WHO), can determine the minimum requirements for the quality, safety and availability of pharmaceuticals, which affects the formation of national FP. Political factors, such as the adoption of legislation, reforms in the field of OH, as well as political will, influence the formation and implementation of FP and can determine priorities in this field.

The development of information technologies and electronic medicine can stimulate the introduction of new methods of managing the pharmaceutical sector and ensuring the availability and efficiency of medical services. The formation of the FP also takes into account public health and national disease prevention strategies that affect changing needs for drugs and services.

The structure and dynamics of the pharmaceutical market, including competition between FCs, the availability of generic analogues, the level of investment in research and development of new drugs, also influence the formation of FCs. The efficiency of the infrastructure, which includes the production, distribution and storage systems of medicines, affects the availability and quality of medicines. Effective supply chain management is also an important factor in ensuring national security in terms of controlling drug smuggling and counterfeiting.

The organization and financing of the health care system, including insurance mechanisms and access to medical services, also affects the

formation of FP. For example, universal health insurance systems may have a different approach to regulating drug prices and compensating their cost to patients.

Legislative and regulatory frameworks related to the issues of patenting, registration, production, distribution and use of pharmaceuticals, as well as ethical norms in the field of medicine, affect the formation and implementation of FP.

These factors interact with each other and determine the context in which the country's pharmaceutical policy is formed and implemented. Taking these factors into account helps the government and stakeholders adapt strategies and programs to changes in the environment and population needs.

In order to study the dynamics of changes and factors affecting the FP, we developed and presented the regulatory and legal framework of legislative acts of Ukraine in response to the challenges of the Covid-19 pandemic only for the year 2020 (Table 3)[11] .

Table 3

Regulatory and legal framework of Ukraine regarding the response to the 2020 Covid-19 pandemic

№	Legislative act details	Name of the legislative or regulatory document
1.	Order of the Ministry of Health of Ukraine No. 2438 of 27.10.2020	"On Amendments to the Standards of Medical Care "Coronavirus Disease (COVID-19)"
2.	Resolution of the Cabinet of Ministers of Ukraine No. 641 of July 22, 2020	"On the establishment of quarantine and the introduction of enhanced anti-epidemic measures in the territory with a significant spread of acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2"
3.	Resolution of the Cabinet of Ministers of Ukraine No. 392 of May 20, 2020.	"On the establishment of quarantine to prevent the spread of acute respiratory disease COVID-19 caused by the coronavirus SARS-CoV-2 in Ukraine"
4.	Order of the Ministry of Health of Ukraine No. 762 dated 02.04.2020	"On approval of the protocol "Provision of medical care for the treatment of coronavirus disease (COVID-19)"
5.	Order of the Ministry of Health of Ukraine No. 722 dated 28.03.2020	"Organization of medical care for patients with coronavirus disease (COVID-19)"
6.	Law of Ukraine No. 530-IX of 17.03.2020	"On Amendments to Certain Legislative Acts of Ukraine Aimed at Preventing the Occurrence and Spread of Coronavirus Disease (COVID-19)"
7.	Order of the Ministry of Health of Ukraine No. 663 dated 13.03.2020	"On optimization of measures to prevent the introduction and spread of COVID-19 cases in Ukraine"
8.	Resolution of the Cabinet of Ministers of Ukraine No. 211 of 11.03.2020	"On Prevention of the Spread of the Acute Respiratory Disease COVID-19 Caused by the Coronavirus SARS-CoV-2 in Ukraine"

[11] Алгоритм надання амбулаторної та стаціонарної медичної допомоги при COVID-19. https://moz.gov.ua/uk/algoritm-nadannja-ambulatornoi-ta-stacionarnoi-medichnoi-dopomogi-pri-covid-19-infografika

For the same purpose, we also analyzed the legal acts regarding the protocols and rules for providing medical (pharmaceutical) assistance to patients with Covid-19 for the years 2020/2023, which are valid as of July 2024 (Table 4)[12].

\Table 4

Legislative acts of ukraine regarding the algorithm for providing outpatient and in-patient medical aid for Covid-19

Name	Status	Type	Register No.	Published/ Updated
Clinical guideline "Clinical management of patients with COVID-19"	Current	Guideline	KN 2021-762	16.01.2021/ 24.08.2022
Protocol "Provision of medical care for the treatment of coronavirus disease (COVID-19)"	Current	Protocol	HC 2020-762	02.04.2020/ 17.05.2023
Order of the Ministry of Health on Approval of the Protocol "Provision of Medical Care for the Treatment of Coronavirus Disease (COVID-19)"	Current	Order	MINISTRY OF HEALTH 2020-762	02.04.2020/ 17.05.2023
Protocol of rehabilitation care for patients with coronavirus disease (COVID-19) and convalescents	Current	Protocol	HC 2021-771	20.04.2021
Support for self-rehabilitation after COVID-19-related diseases	-	WHO information materials	2021-771	20.04.2021
Order of the Ministry of Health "On Approval of the Protocol for the Provision of Rehabilitation Care to Patients with Coronavirus Disease (COVID-19) and Convalescents"	The current one	The Order	MINISTRY OF HEALTH 2021-771	20.04.2021
Emergency medical care standard "Coronavirus disease (COVID-19)"	Current	Standard	HCe 2020-722	28.03.2020/ 30.10.2020
Medical care standards "Coronavirus disease (COVID-19)"	Current	Standard	HC 2020-722	28.03.2020/ 02.08.2023

[12] Hein W. "Global health governance and the fight against HIV/AIDS". Medical Books. 2007. P. 282. https://link.springer.com/book/10.1057/9780230591349

Pharmaceutical care standard "Coronavirus disease (COVID-19)"	Current	Standard	HCf 2020-722	28.04.2020
Order of the Ministry of Health Organization of medical care for patients with coronavirus disease	The current one	The Order	MINISTRY OF HEALTH 2020-722	28.03.2020/ 02.08.2023
COVID-19 infectio	Current	Clinical practice guideline	2021-Duodecim-ebm00960	20.01.2022
Long-term symptoms of coronavirus infection (COVID-19) (55.3 Кб)	Current	Clinical practice guideline	2021-Duodecim-ebm01188	20.01.2022
Postinfectious syndromes (202.7 Кб)	Current	Clinical practice guideline	2021-Duodecim-ebm01118	20.01.2022
Multisystem inflammatory syndrome in children (MIS-C) with COVID-19 infection (56.5 Кб)	Current	Clinical practice guideline	2021-Duodecim-ebm01187	20.01.2022

The dynamics, sequence of introduction and validity of regulatory documents presented in Table 4 is due to the epidemiological situation in the whole world and the force majeure nature of the Covid-19 pandemic. Also, during the Covid-19 pandemic, sociocultural factors were recorded that significantly influenced the prevalence of the disease among the population of certain countries. For example, warm greetings when meeting acquaintances, the habit of washing hands, attitude towards the need to wear a mask and other means of personal protection. The pricing policy of Ukrainian pharmacies for personal protective equipment was also indicative. From the positive experience, it should be noted the FP, which related to the vaccination of the population against Covid-19. It was the FP of the government of Ukraine regarding the organization of free vaccination of the population that made it possible to overcome the pandemic.

The prospects for the development of the national FP include a number of opportunities and challenges that are associated with changes in technology, the economy, the medical needs of the population, and the regulatory environment. The development of a national FP can include the creation of a favorable environment for scientific research and innovation in pharmacy. This may include financial support for research, the establishment of research centers and the promotion of collaboration between academic institutions and the private sector. The introduction of new technologies for the production of pharmaceuticals can improve the efficiency, quality and availability of pharmaceuticals. This may include the use of 3D printing, nanotechnology and other innovative manufacturing methods.

The growing attention to personalized medicine opens up new opportunities for the development of the pharmaceutical industry. The development of drugs that provide an individualized approach to treatment based on a patient's genetic and other characteristics can significantly improve treatment outcomes. The implementation of digital technologies, such as artificial intelligence, data analysis and telemedicine, can improve the processes of diagnosis, treatment and monitoring of patients, as well as optimize the production processes and the chain of promotion (distribution) of medicines. The development of biotechnology opens up new opportunities for the creation of innovative medicines, such as biological drugs, vaccines and genetically modified products. This may include promoting the development of biotech enterprises and ensuring their access to finance and markets.

Governments can promote the development of the pharmaceutical industry by creating a transparent and stable regulatory environment that facilitates investment, innovation and new product development. The development of medical technology is a key aspect of modern medicine, which affects the quality of medical services, the availability of treatment and the improvement of the results of therapy.

The development of medical technologies and their impact on the pharmaceutical industry can be seen in such innovative technologies as electronic medicine (e-Health), artificial intelligence (AI) and machine learning, nanotechnology, bioinformatics, data security and privacy. Thanks to the development of these technologies, the following aspects of pharmaceutical activity become real and promising: the growth of international cooperation in the field of pharmacy, the exchange of information and experience in real time, the harmonization of standards, access to medicines for low– and middle-income countries, control of international patents, the fight against counterfeit products.

The implementation of electronic medical systems, electronic medical records and telemedicine makes it possible to improve the availability of medical services, ensure the effective and safe transmission of medical information and improve the coordination of patient care. The use of artificial intelligence and machine learning algorithms allows analyzing large volumes of medical data, developing individualized approaches to diagnosis and treatment, and predicting the occurrence of diseases. The use of nanomaterials in medicine opens up new opportunities for creating more effective and targeted medicines, diagnostic tools and treatment methods. The use of computational methods for the analysis of biological data contributes to the study of complex interactions in molecular biology and pharmacology, which can lead to the development of new drugs and treatment methods. Ensuring the security and confidentiality of medical data in the digital environment is

becoming an increasingly important aspect in the context of the development of medical technology. The development of medical technology has a significant impact on the pharmaceutical industry, creating new opportunities to develop effective drugs, improve diagnosis and treatment, and optimize medical services. The successful integration of these technologies into the pharmaceutical system requires a systemic approach, cooperation between different sectors and continuous improvement of the regulatory environment.

International cooperation in the field of pharmacy is an important tool for ensuring the availability, quality and safety of medicines worldwide. Countries can cooperate in the coverage and exchange of information on registration, quality control, efficacy and safety of drugs. This helps to ensure a rapid response to new threats to public health and improve the availability of innovative medical products. International organizations such as the WHO and the International Organization for Standardization (ISO) promote the harmonization of standards and regulatory requirements in the pharmaceutical industry. This helps reduce administrative barriers to international trade in medicines and contributes to the creation of a single global pharmaceutical market.

International organizations such as the Global Fund and the United Nations World Program on HIV/AIDS (UNAIDS) are helping to ensure access to and financing of medicines for low– and middle-income countries. International agreements and organizations promote the control of international patents on drugs, which allows to ensure the availability of cheap generic drugs as alternatives for low– and middle-income countries. International cooperation contributes to the fight against counterfeit and low-quality pharmaceutical products, which pose a threat to public health and patient safety. International cooperation in the field of pharmaceuticals plays a key role in ensuring the availability and safety of medicines throughout the world.

3. Problems and challenges of implementing the national pharmaceutical policy in the world and in Ukraine

Various problems and challenges may arise during the implementation of the national FP, which make it difficult to implement an effective and stable strategy in this field. Many countries face the problem of insufficient availability and high cost of medicines. This may jeopardize the population's ability to obtain the necessary drugs for the treatment and prevention of diseases. Insufficient control over the quality and safety of drugs can lead to the spread of counterfeit drugs, which threatens the health and lives of citizens.

Improvement of quality management systems, production and supply of medicines is an important aspect to ensure the effectiveness and reliability of

medicines, but it can have a negative impact on the price of medicines. Changing technologies and scientific discoveries challenge the governments of countries to ensure accelerated registration and availability of new and effective drugs for the population. Insufficient effectiveness of FP and regulation can lead to an imbalance in the availability and use of medicines, as well as to an increase in their prices. Cooperation with the private sector, in particular FC, can be a challenge in ensuring the territorial and price availability of medicines, as well as control over their quality and safety.

The development of pharmaceutical education and the improvement of the qualification level of specialists are important aspects for ensuring the quality and efficiency of pharmaceutical activity. These problems and challenges require a systematic approach and comprehensive measures on the part of the government, international organizations, FC and NGOs for their successful solution and improvement of the pharmaceutical system. Availability of pharmaceuticals is a key aspect of the national FP, which is defined as the ability of the population to obtain the necessary FPs in the widest possible range and at affordable prices. The cost of medicines is one of the main obstacles to their availability. The governments of the countries of the world should establish effective mechanisms of price control and support in order to ensure the availability of medicines for all sections of the population. The most effective drugs should be available to health care institution (HCI) and pharmacies. Insufficient availability of necessary drugs can significantly limit access to treatment and increase the risk of complications. It should be noted that some population groups, such as the elderly, children, pregnant women and people with disabilities, may need specific drugs. Providing them with access to these drugs is an important component of FP. The development of health insurance programs and other financial support mechanisms can significantly improve access to dgugs, especially for low-income or homeless people.

A quick and efficient procedure for registration of drugs contributes to their quick availability for patients. Ensuring access to drugs is an important task for any national FP and requires a comprehensive approach taking into account various social, economic and regulatory factors. Control of the quality and safety of medicines is a critically important aspect of FP, as it depends on ensuring the effectiveness, safety and trust in medicines.

Government bodies are responsible for licensing and registration of pharmaceuticals before they are placed on the market. This includes evaluating the quality, efficacy and safety of the drug using scientific evidence and clinical trials. Government regulators conduct inspections of manufacturing facilities to ensure compliance with quality and safety standards during the production of drugs . This includes inspection of production processes, storage and transportation conditions, as well as quality

control of the final product. Government bodies also monitor the side effects of after their introduction to the market. This allows timely detection and response to dangerous side reactions that may occur when using medications. Establishing quality and safety standards for medicines is an important task to ensure the uniformity and reliability of products. Certification in accordance with established standards confirms the product's compliance with quality and safety requirements. Government bodies establish rules and standards for the distribution and sale of drugs in order to ensure their correct and safe operation. Ensuring the confidentiality and integrity of drug information is an important aspect of quality control and security, especially in the case of electronic medical records and other electronic health data management systems.

In Ukraine, in 2018, the reorganization of the health care system was carried out, which took place in stages and was related to the introduction of family medicine[13]. In fact, unfortunately, there was not only a technical replacement of the position of district therapist of HCI with the position of family medicine doctor of the primary link of medical care of HCI, but also a number of other negative consequences. First of all, the idea of a family doctor who was supposed to serve one family or one household was not implemented in practice. Each member of the household most often chooses his or her own family doctor. This innovation in pediatrics and the child care system was particularly unsuccessful. In Ukraine, children's polyclinic health centers were destroyed, accordingly, children are served together with adult patients. Health care centers successfully located in separate administrative districts, equipped according to professional needs and provided with staff pediatricians and pediatricians of narrow specializations HCI were disbanded. Part of the personnel potential has been transferred to polyclinic HCI of family medicine. All premises of children's polyclinics have been withdrawn and removed from the health care system. The declared paradigm that the money will follow the patient has turned into reality, when citizens follow a family therapist to get to a narrow specialist of HCI of family medicine. The Covid-19 pandemic imposed another peculiarity on the borrowed overseas system of health care, which is not typical for Ukraine – family medicine doctors prefer electronic (telephone) communication, trips of the family doctor are not foreseen at all. Despite the modern saturated information environment and the introduction of electronic accounting, as well as digitalization in medicine and pharmacy, the appropriate training of family doctors on the use of E-programs was not conducted. Most of them do not skillfully possess the skills of registration and management of electronic medical documentation, which leads to unsatisfactory service to citizens. Unfortunately, the state of war in Ukraine

[13] Наказ МОЗ України № 504 від 19.03.2018 «Про затвердження Порядку надання первинної медичної допомоги» https://covid19.phc.org.ua/normatyvna-baza/

leads to the destruction of young people and middle-aged citizens who protect our homeland, and children and the older generation suffer from the innovations of the modern reorganization of the health care system. It is known that the health of the nation is determined by the level of health of children and adolescents. The quality of a child's health certainly affects the length and quality of his or her future life, intelligence, physical development, and work capacity, which in the aggregate is of great importance for the harmonious development of the entire society, in particular the country's defense capability, which is extremely important in the current conditions of the ongoing large-scale armed conflict aggression of the russian federation against Ukraine. It is no coincidence that the priority for the health and well-being of women and children is focused in the document "UN Sustainable Development Goals (2016-2030)", in which, out of 17 goals, goal No. 3 "Ensuring a healthy lifestyle and promoting well-being for all" takes center stage at any age", and the UN Convention on the Rights of the Child recognizes the child's right to use the most advanced services of the health care system and means of treating diseases and restoring health. In order to conduct a comparative analysis of services for children and adolescents, we collected statistical data for two periods: before the medical reform of 2018 (for 2000, 2005, 2010, 2015, 2016, 2017)[14] and for the years after the reform of the health care system (for 2018-2022)[15]. Table 5 presents statistical data on the incidence rate of children aged 0-17 years by disease class[16].

[14] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[15] Щорічний звіт про стан здоров'я населення України та епідемічну ситуацію за 2022 рік, м. Київ – 2023

https://moz.gov.ua/uploads/ckeditor/%D0%B4%D0%BE%D0%BA%D1%83%D0%BC%D0%B5%D0%BD%D1%82%D0%B8/%D0%94%D0%BE%D0%BA%D1%83%D0%BC%D0%B5%D0%BD%D1%82%D0%B8%202024/%D0%B4%D0%BE%D0%BA%D1%83%D0%BC%D0%B5%D0%BD%D1%82%D0%B8%2001-2024/29-01-2024/1/%D0%A9%D0%BE%D1%80%D1%96%D1%87%D0%BD%20%D0%B7%D0%B2%D1%96%D1%82%20%D0%BF%D1%80%D0%BE%20%D1%81%D1%82%D0%B0%D0%BD%20%D0%B7%D0%B4%D0%BE%D1%80%D0%BE%D0%B2'%D1%8F%20%D1%82%D0%B0%20%D0%B5%D0%BF%D1%96%D0%B4%D0%B5%D0%BC%D1%96%D1%87%D0%BD%D1%83%20%D1%81%D0%B8%D1%82%D1%83%D0%B0%D1%86%D1%96%D1%8E%20%D0%B7%D0%B0%202022%20%D1%80%D1%96%D0%BA.pdf

[16] Алгоритм надання амбулаторної та стаціонарної медичної допомоги при COVID-19. https://moz.gov.ua/uk/algoritm-nadannja-ambulatornoi-ta-stacionarnoi-medichnoi-dopomogi-pri-covid-19-infografika

Table 5

The incidence rate of children age 0–17 by disease classes

Name of disease classes according to ICD-10	Years					
	2000	**2005**	**2010**	**2015**	**2016**	**2017**
All diseases including	114403	127463	146200	127482	131594	129222
Some infectious and parasitic diseases	5626	5629	5138	4558	4520	4675
Neoplasm	242	305	337	344	341	330
Diseases of the blood, hematopoietic organs and certain disorders involving the immune mechanism	1607	1738	1661	1334	1294	1213
Diseases of the endocrine system, eating disorders, metabolic disorders	2872	2459	2187	1570	1511	1445
mental and behavioral disorders	655	630	583	428	404	381
diseases of the nervous system	1690	2106	2211	1845	1780	1739
Diseases of the eye and adnexa	3977	4459	4825	4318	4179	4127
diseases of the ear and mastoid process	3508	3885	4256	3919	3808	3801
diseases of the circulatory system	847	940	1076	844	785	729
respiratory diseases	69202	79695	97583	85552	90336	88082
diseases of the digestive system	4823	5176	5290	4589	4546	4540
diseases of the skin and subcutaneous tissue	6720	7312	7505	6547	6475	6533
diseases of the musculoskeletal system and connective tissue	2976	3163	3180	2605	2603	2605
diseases of the genitourinary system	2554	3032	3063	2546	2508	2458
[1]pregnancy, childbirth and postpartum period	217	237	168	106	92	79
[2]separate conditions that occur in the perinatal period	33188	23094	15137	12608	13129	13271
congenital anomalies (malformations), deformations and chromosomal disorders	503	527	588	575	563	561
Symptoms, signs and abnormalities detected during laboratory and clinical studies not elsewhere classified	522	250	220	197	199	209
injuries, poisoning and some other consequences of external causes	4811	4950	5471	4937	5006	5097

* *The number of first-time registered cases of diseases per 100,000 children aged 0-17 years including. 1 Per 100,000 girls aged 0-17 years. 2 Per 100,000 children under 1 year of age.*

The analysis of statistical data for several periods up to 2018 makes it possible to state that a clear positive trend is observed with regard to oncological diseases and congenital anomalies of development. All other diseases have certain fluctuations, which are wave-like, according to the quantitative indicator. Also, according to the statistical report, we studied the

characteristics of the state of health of the children's population of Ukraine for 2018–2022[17]. The specifics of the course of socio-economic and demographic processes in Ukraine in the first decades of the 21st century led to a decrease in the number of children aged 0-17 years who were under the supervision of ZOH, from 7,091.9 thousand people in 2018 to 6,003.0 people in 2022. A healthy start and the first year of life are decisive in the formation of a child's health. On the vision of a future in which every birth of a child will be a celebration and where survival, further development and full realization of their potential will be ensured for all babies, the Concept of the action plan "Every Newborn" of the Global Strategy for Women's, Children's and Adolescents' Health is based.

An alarming trend of the 21st millennium is the decrease in the number of live births in Ukraine from 376,478 in 2001 to 383,5874 in 2018, 271,983 in 2021 to 196,806 (according to preliminary data) in 2022, which was accompanied by a negative trend of the objective criterion of a healthy start progeny – by an increase in the frequency of low-weight and premature children, which are characterized by morphological, physiological and metabolic features, disorders of neurological, somatic and immune status, increased risk of neonatal morbidity and mortality[18]. According to the comparative characteristics of the frequency of live births with low birth weight and premature births, negative dynamics are characteristic of both indicators – 5.8% of low birth weight and 5.2% of premature newborns in 2018 and 6.1% and 5.5%, respectively in 2022. In addition, it is important to note that the change in the structure of children born by body weight is accompanied by a stable dissociation of the number of low-weight children and premature babies. This means that part of full-term children have a body weight of less than 2500 g at birth, that is, they are born with intrauterine growth retardation syndrome (IUGR), which in turn causes a high level of perinatal pathology[19]. Currently, at the beginning of life, almost every fifth child has certain diseases. The analysis of the health status of the general population of newborns during the studied period showed negative dynamics – in general, the frequency of newborns who were born sick and fell ill increased from 168.6 in 2018 to 221.7 in 2022, the frequency of full-term

[17] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[18] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[19] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

newborns from 130.1 to 183 .6, and premature newborns from 818.3 to 841.4, respectively[20].

In terms of regions, the frequency of sick births and sick newborns in general and full-term newborns increased in the vast majority of regions, with the exception of Luhansk, Kharkiv and Khmelnytskyi regions, where the rate of loss was 60.0%, 2.5% and 10.4%, respectively , the frequency of sick and premature newborns that fell ill decreased only in Kirovohrad and Luhansk regions (the rate of loss was 6.9% and 52.7%), and the frequency of sick and premature newborns that fell ill decreased in Donetsk, Zakarpattia, Luhansk, Odesa, and Poltava (rate of loss 14.7%, 19.4%, 87.2%, 1.9%, and 8.5%, respectively)[21]. The outsiders in terms of the frequency of sick births and sick newborns in 2022 were the city of Kyiv – 33.5%, and the Kherson region – 31.2%, while the relatively low indicators of the frequency of sick births and sick newborns are maintained in Luhansk, Kirovohrad, Zakarpattia, Cherkasy, Kharkiv and Ternopil regions[22].

The negative dynamics of the frequency of sick births and sick newborns is typical for all pathological conditions, except for slowed growth and insufficient nutrition of the fetus (rate of loss 11.98%). At the same time, the morbidity of newborns with pathological conditions that significantly affect the quality of further life and cause disability of children – sepsis of newborns (growth rate of 332.43%), hematological disorders (growth rate of 320.17%), disorders of the respiratory system (growth rate of growth rate of 172.48%), infections specific to the perinatal period (growth rate of 175.6%)[23].

After birth, the number of children who start to get sick increases. The most important stage of a child's development, which is characterized by particularly high rates of physical, neuropsychological development, functional maturation of organs and systems, is the first year of life. Among the relative effects of factors affecting the morbidity of children in the first year of life, breastfeeding is of great importance. It has been proven that breastfeeding, and especially exclusive breastfeeding, is an important condition that ensures adequate maturation of various organs and tissues, optimal parameters of physical, psychomotor, intellectual development,

[20] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[21] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[22] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[23] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

resistance of infants to adverse factors due to the development of the immune system and the formation of active and passive immunity The share of children who finished breastfeeding at 3 months decreased from 50.1% in 2018 to 30.0% in 2022, and the share of children who finished breastfeeding at 6 months decreased from 61.9% to 55, 8%, respectively[24]. More active work is being done to ensure breastfeeding of babies, where 40% finished breastfeeding at three months of age, and in Volyn, Poltava, Sumy, Cherkasy and Chernivtsi regions, where >62% of babies finished breastfeeding at 6 months. It is possible to have a real impact on the amount of coverage of children by breastfeeding and its duration by means of more complete coverage by early attachment of a live birth to the mother's breast and exclusive breastfeeding. The incidence rate of children of the first year of life decreased from 1,414.5 per 1,000 children of the first year in 2018 to 1,202.0 in 2022[25]. In terms of regions, in 2022 the high level of morbidity among children in the first year of life is maintained in the Zaporizhia, Ivano-Frankivsk, Rivne, and Khmelnytsky regions, the growth rate for 2018–2022 is 56.3%, 3.6%, 18.5%, and 16 .4%, respectively, and high with positive dynamics in Zhytomyr, Odesa regions and Kyiv, the rate of loss is 27.8%, 10.7% and 41%, respectively. Relatively low incidence rates of children in the first year of life. The positive trend in the morbidity of this contingent of children over the past five years was due to a significant decrease in the majority of disease classes. The highest rates of morbidity reduction were recorded in diseases of eating disorders – the rate of loss was 43.2%, injuries and poisonings – 32.9%, diseases of the blood and hematopoietic organs – 22.8%, nervous system – 19.9% and respiratory organs – 19, 6%. During this period, the incidence of diseases of the musculoskeletal system and connective tissue, digestive organs, skin and subcutaneous tissue, genitourinary system, congenital anomalies of the ear in children increased – the growth rate was 72.1%, 13.0%, 3.9%, 2.3%, 0.9% and 0.8%, respectively (Table 6)[26].

[24] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[25] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[26] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

Table 6

Dynamics of the incidence of children under the age of 1 year by main classes of disease, 2018–2022, %

Disease class	Years					Growth rate, 2000–2021, in %.
	2018	2019	2020	2021	2022	
All diseases, including:	1414,5	1393,0	1219,7	1256,9	1202,2	-15,0
Certain infectious and parasitic diseases	32,9	31,4	22,6	25,99	29,4	-10,6
Neoplasms	10,0	9,7	9,4	9,37	9,1	-9,2
Diseases of the endocrine system, eating disorders	31,5	27,9	24,1	20,95	17,9	-43,2
Diseases of the blood and hematopoietic organs and certain disorders involving the immune mechanism	63,9	63,0	55,5	52,5	49,3	-22,8
Diseases of the nervous system	61,6	57,7	51,6	54,1	49,3	-19,9
Diseases of the eye and adnexa	48,7	47,4	41,4	41,1	40,9	-16,1
Diseases of the ear and mastoid process	25,7	26,5	22,9	26,6	26,3	2,3
Diseases of the respiratory system	816,1	810,0	692,4	715,8	656,5	-19,6
Diseases of the digestive system	53,9	53,6	52,1	56,0	60,9	13,0
Diseases of the skin and subcutaneous tissue	63,2	63,9	57,7	59,6	63,7	0,9
Diseases of the musculoskeletal system and connective tissue	9,2	8,7	8,8	11,9	15,7	71,2
Diseases of the genitourinary system	14,2	13,9	12,3	13,5	14,3	0,8
Certain conditions that occurred in the perinatal period	127,6	126,2	119,3	114,2	112,27	-12,0
Congenital anomalies	39,5	38,3	36,1	40,2	41,03	3,9
Injuries and poisoning	4,9	4,2	3,6	3,5	3,29	-32,9

The measure of the availability of medical care to the children's population and at the same time an effective indicator of the diagnostic capacity of the health care system and a kind of barometer of the state of health is the complete coverage of children with preventive examinations[27]. Screening coverage was 97.9–95.03% in 2018–2021, decreasing to 85.1% in 2022. According to the results of preventive examinations, a significant number of diseases were detected in children aged 0–17 years. Thus, among children who underwent a preventive examination, the following were found in 2018–2022: violations of hearing acuity – 1.7 cases per 1 thousand examinations, visual acuity – 45.6 and 44.9, posture – 39.5 and 37, 5, speech defects – 18.8 and 12.91 and scoliosis 15.3 and 14.8 (Table 7)[28].

[27] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[28] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

Table 7

Dynamics of discovered pathology during preventive examinations of children, 2017–2022 (per 1 thousands examined)

Year	Impaired hearing acuity	Impaired visual acuity	Speech defects	Posture disorders	Scoliosis
2017	1,7	45,9	18,8	39,5	15,5
2018	1,7	46,5	17,4	37,8	14,61
2019	1,7	46,7	16,6	36,9	14,7
2020	1,6	43,8	14,8	35,6	14,6
2021	1,7	45,7	13,9	36,1	14,6
2022	1,7	44,6	12,9	37,5	14,8
Rate of decline, %	0	2,8	31,4	5,1	4,5

As in previous years, the frequency of certain types of detected pathology also varied significantly across regions: for example, decreased visual acuity – from 60.0 cases of pathology per 1 thousand 35 examined), in Zhytomyr, Kyiv, Zaporizhzhia, Rivne, and Kherson regions; hearing acuity – (from 2.5 cases of pathology per 1,000 examined)[29].

An essential characteristic of children's health is the incidence of socially dangerous diseases. The situation regarding the incidence of active tuberculosis in children is worrying. According to the WHO, in countries with a low and medium level of economic development (which includes Ukraine), the share of children with a diagnosis of tuberculosis among newly detected cases of the disease should be in the range of 5 to 15%. In Ukraine, this share was 2.8–3.2% in recent years. The incidence of children with all forms of active tuberculosis increased from 6.7 per 100,000 child population in 2018 to 7.7 in 2022, with a range of fluctuations in 2022 from 62.7 in Kirovohrad, 16.5 in Chernihiv, 13.9 in Odesa, up to 1.0 in Luhansk, 2.0 in Donetsk and 2.1 in Ternopil regions[30]. In recent years, there has been a decrease in the number of syphilis and gonococcal infections. Thus, in 2018, 35 children were diagnosed with syphilis for the first time in their lives, 45 with gonococcal infection, and in 2022 – 16 and 7, respectively. At the same time, in 2022, cases of syphilis in children were registered only in Odesa (4), Kyiv (3), Rivne (2), Khmelnytskyi (2), Zhytomyr (1), Lviv (1) regions and the city of Kyiv (2)), and gonococcal infection – in Dnipropetrovsk (4), Kherson (2) and Sumy (1) regions. It should be noted that the rapid decrease in the incidence of syphilis and gonococcal infection in children causes some concern due to the

[29] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[30] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

possibility of their unsatisfactory detection and incomplete registration, especially cases of gonorrhea. Malignant neoplasms in children are also an important problem. And although their share in the morbidity structure is insignificant, they are characterized by a severe course, high disability and mortality[31]. In 2022, 6,556 children with malignant neoplasms were under dispensary supervision, of which 524 were diagnosed for the first time. In general, the rate of cancer incidence in children was 7.7 per 100,000 child population, with this indicator varying from 1.52 in the Mykolayiv region, 2.12 in the Kherson region, 2.99 in the city of Kyiv to 11.3–11.4 in the Dnipropetrovsk region , Kirovohrad, Sumy, Khmelnytskyi and 13.8 in Lviv regions. Cancer of the lymphatic and hematopoietic tissue forms the basis of the structure of cancer incidence in children – 56.5%. The indicator of children's disability can be considered a concentrated reflection of the state of health of the younger generation. The seriousness of the problems of disability from childhood is becoming more and more urgent in the conditions of rapid growth of social development problems, waste of human potential, imbalanced interpersonal relations, full-scale war and is confirmed by the fact that the prevention of non-communicable diseases and disabilities is included in the 11 priority medical measures defined by the WHO and aimed at preserving health for everyone in the European region (WHO "Health-XXI", "Healthy Start of Life")[32]. In Ukraine, the total disability of children was 212.3 per 10,000 children under the age of 18 in 2022, while in 2018 it was 212.4, and primary disability was 21.9 and 21.3, respectively. The total number of children with disabilities during this period decreased by 5.6 thousand and in 2022 amounted to 156,010 people. According to the calculations of the European Academy of Children's Disabilities, more than 200,000 children with disabilities under the age of 18 are expected in Ukraine[33]. A comparison of these data shows that the requirements for establishing disability are still excessive in Ukraine. In 2022, as in previous years, there was an uneven distribution of the general disability index in different regions of Ukraine: from 260.0 in Zhytomyr, Zakarpattia, Chernivtsi, and Chernihiv regions. The range of regional fluctuations of the indicator of primary disability of the child population of Ukraine was: from 29.0 in Lviv,

[31] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[32] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[33] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

Ternopil. Ivano-Frankivsk and Chernivtsi regions[34]. Such a situation may be due to the intensive movement of the child population to the western regions of Ukraine as a result of the aggressive war. In 2022, almost every third child will be disabled by congenital malformations, deformities and chromosomal abnormalities, every fifth by mental and behavioral disorders, every seventh by diseases of the central nervous system, and every tenth by diseases of the endocrine system. eating disorders. Factorial determination of the main causes of childhood disability determines the feasibility of further development of medical and genetic counseling services, family planning, improvement of the quality of medical care of newborns with low and very low birth weight, organization of medical and social patronage services in families of high social risk[35]. In general, the current challenges regarding children's health in Ukraine consist of a decrease in the number of children, associated with insufficient awareness of the population about a healthy lifestyle and risk factors for the development of diseases, problems with vaccination, a number of problems with the provision of primary medical care, insufficient funding and equipment industry, as well as the shortage of medical personnel and their insufficient qualifications. There is no unified policy and national program aimed at forming and strengthening the health of the child population in the country. The high level of morbidity among children and their disability indicates the need to strengthen medical and social assistance, the introduction of modern effective and, at the same time, low-cost medical and organizational technologies[36].

In the interests of creating conditions for the preservation of children's health, it is necessary to form a unified state policy in the field of children's health care in accordance with internationally recognized practice and evidence base, ensure sufficient financing of its state guarantees and increase the responsibility of all government structures for their implementation. Development of systems for monitoring and evaluating the results of the implementation of the FP policy with the aim of constant improvement and adaptation. These recommendations are aimed at increasing the effectiveness and relevance of the national FP and ensuring a high standard of health care for the entire population.

[34] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[35] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

[36] Статистичний збірник «Заклади охорони здоров'я та захворюваність населення України» за редакцією О.О. Кармазіна. Державна служба статистики України к Київ – 2018. https://www.ukrstat.gov.ua/druk/publicat/kat_u/ 2018/zb/06/zb_zoz_17.pdf

Conclusions

As a result of the implementation of the FP, the availability of medicines for the population has significantly improved, in particular by reducing the prices of vital drugs and creating cost compensation programs for vulnerable population groups. The implementation of strict legal requirements and quality control systems allowed to increase the quality and safety of medicines, reducing the risks of side effects and falsification of medicines.

Proper FP promotes the development of scientific research and innovation in the field of medicine and pharmacy, which leads to the creation of new drugs, technologies and methods of treatment. A number of countries are successfully implementing policies aimed at developing the domestic production of pharmaceuticals, which allows reducing dependence on imports and promotes economic growth.

Despite progress in improving access, some drugs remain inaccessible due to high cost or lack of availability. The problem of counterfeiting and smuggling of medicinal products, which threatens the safety and effectiveness of medical care, remains relevant.

The rapid development of medical technologies and the changing epidemiological situation require constant updating of strategies and adaptation of FP to new challenges. Access to the latest and most innovative medicines is often limited due to the high cost and complexity of their registration and distribution. Inequalities in access to medicines can arise due to differences in economic status, geographic location or social factors. This can lead to unequal opportunities to receive the necessary medical services and health care.

Global problems such as pandemics, antimicrobial resistance and climate change create new challenges in the field of FP, requiring international cooperation and innovative solutions.

Increasing costs for the reorganization of the health care system can become a problem for governments, especially in conditions of economic and social instability, a military threat or a shortage of budget funds. It is necessary to balance financial resources with the population's needs for medicines.

The rapid and constant development of technologies and medical advances presents regulators with the task of timely adaptation of legislation and standards to new requirements and risks that may arise in connection with the use of new technologies. Ensuring national health and public well-being requires not only access to medicines, but also the development of effective disease prevention programs, vaccinations and regular medical examinations.

Summary

The article presents a study using a meta-analysis of literary, educational and scientific sources on the main provisions of the formation of national drug

(pharmaceutical) policy in a particular state. The paper examines the interrelation and impact of the provisions of regulatory legal acts on the formation of medicinal (pharmaceutical) policy in the healthcare sector, and further on the public health system and the norms of social protection and welfare of society. It is proved that the understanding by the legislator and citizens of the country of the priority of the 'reverse' influence is necessary for the creation of appropriate norms of existence in the rule of law. The author uses the example of the dynamics of the provisions of legal acts on responding to the Covid-19 pandemic in 2020 and legislative acts on the algorithm for providing outpatient and inpatient medical care for Covid-19 in Ukraine to present the formation of the national medicinal (pharmaceutical) policy in the context of a pandemic. The monograph analyses the official reporting on the health indicators of children and adolescents before and after the 2018 reform of the healthcare system of Ukraine, which eloquently demonstrate that the introduction of a family doctor and the removal (merger) of children's and adult outpatient healthcare facilities will lead to negative consequences.

It is proved that such factors as epidemiological situations, socio-cultural factors and geopolitical circumstances, as well as the rapid development of medical technologies require constant updating and adaptation of tactics and strategies of the medicinal (pharmaceutical) policy to new challenges.

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