

## **Organization of the Pharmaceutical Business, Drug Technology and Forensic Pharmacy: Modern Trends in The Development of the Science of Pharmaceutical Law During the Covid-19 Pandemic**

**Tetiana Krasnianska**, (PhD in Pharmaceutical Sciences, Associate Professor, Ukrainian military medical academy, Ukraine)

Received: July 29, 2022  
Published: August 17, 2022

**Mykola Ponomarenko**, Doctor of Pharmaceutical Sciences, Professor, Kyiv Medical University, Kyiv, Ukraine)

\*Corresponding author: Tetiana Krasnianska

**Abstract.** The COVID-19 pandemic has affected modern trends in the training of doctors and pharmacists and their professional development. At the same time, the pandemic contributed to the development of the science of pharmaceutical law, as a basis for optimizing the legislation of Ukraine regarding the organization of pharmaceutical affairs in pharmacies and health care institutions, and thanks to modern research on the search for drug technology, it contributed to the creation of vital vaccines for the prevention of the SARS-CoV-2 coronavirus. At the same time, during the COVID-19 pandemic, the health care and pharmaceutical industry, based on the principles of medical and pharmaceutical law,

showed that specialists can minimize forensic pharmaceutical risks in the system of legal relations "doctor-patient-pharmacist-lawyer" by ensuring the access of patients, the population and health care institutions to the circulation of medicinal products of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups, in accordance with ICD-11.

**Keywords:** pharmaceutical case organization, drug technology, forensic pharmacy, pharmaceutical law, circulation, medicinal products, control regime, State Pharmacopoeia of Ukraine, evidence-based pharmacy, COVID-19.

**Introduction.** In the current conditions of the COVID-19 pandemic [1-5], pharmacy specialists play the most important role in all regions of Ukraine in ensuring patient access to the circulation of medicinal products (pharmaceuticals) of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups [6-11] in accordance with ICD-11 in health care facilities [12-13]. In such difficult conditions, we see a great dependence on the organization and competences of the work of pharmacies not only in cities, but also in rural areas in the support of patients undergoing outpatient treatment of health disorders complicated by covid, post-covid and long-covid diseases. That is, the competences of pharmacy specialists regarding the organization of the logistical work of pharmacies, simultaneous training (courses of thematic improvement, pre-certification cycles, internships, internships), quality control of vital drugs continue to play one of the main roles in the system of legal relations "doctor-patient-pharmacist-lawyer" [14-15]. It is in pharmacies that patients and citizens receive professional organizational and legal assistance and pharmaceutical care during the circulation of drugs (storage, dispensing according to a doctor's prescription, application, interaction, side effects, etc.). Therefore, research on the organization of the pharmaceutical business, drug technology and forensic pharmacy during the COVID-19 pandemic requires improvement of the control and authorization system, the control regime, and the rules for the circulation of

pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups on the basis of pharmaceutical law [16-18].

Integration processes into the European Union require the bringing of pharmaceutical legislation and regulatory acts to European standards. The organization of drug circulation in pharmacies and healthcare institutions based on the principles of pharmaceutical law will contribute to the personalization of the selection of medications to the needs of different contingents of patients, solving the problem of individual intolerance of the drug (interaction of several drugs) thanks to the possibility of dose selection, exclusion or replacement of active pharmaceutical ingredients (APIs) of drugs of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups during outpatient or inpatient treatment [19-21].

In the conditions of the pandemic of the coronavirus disease and the infectious spread of monkeypox [22, 23], the issues of correct interpretation of the terminological apparatus and the addition of the necessary terms to the legislation (for example, pharmacy, etc.) for further improvement of the rules of drug circulation remain relevant [24-29]. On the other hand, the optimization of the system of legal relations "doctor-patient-pharmacist-lawyer" as a component of the organizational-legal system of medical care for patients based on the principles of pharmaceutical law in accordance with international GxP standards [30-56] is a guarantee of the exclusion of forensic pharmaceutical risks and doctor's mistakes, provision of high-quality, timely and safe medical and pharmaceutical care, as well as further improvement of the Law of Ukraine "On Medicinal Products" as a legal basis for reforming competences in the field of health care and the pharmaceutical industry [57].

**The purpose of the work** to consider of modern trends in the development of pharmaceutical law and its impact on the improvement of the organization of the pharmaceutical case, drug technology and forensic pharmacy during the COVID-19 pandemic.

**Materials and methods.** The basis was the works of interdisciplinary research on modern European legislation and forensic pharmacy, as the basis of pharmaceutical law and their influence on the development of the control and licensing system regarding the improvement of the organization of pharmaceutical business and drug technology. The empirical method and the subject of the research work became the national legislation and regulatory legal acts regulating pharmaceutical activity during the circulation of medicinal products of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups using methods of analysis, synthesis, regulatory and comparative methods of establishing regularities and interpreting of the norms of law.

The conducted research is a fragment of the research works of the Department of Military Pharmacy of the Ukrainian Military Medical Academy, and the Department of Organization and Economy of Pharmacy of the P.L. Shupyk National Medical Academy of Postgraduate Education on the topic "Scientific and theoretical justification of the accelerated development of pharmacy, reengineering of processes and human resources from neopharmaceutical and emergent positions" (state registration number 0112U002362, implementation period 2012-2021) and the Department of Pharmacology, Clinical Pharmacology, Pathological Physiology of

Kyiv Medical University on the topic "Experimental substantiation of mechanisms of action and pharmacological effects of biologically active substances" (state registration number 0121U109202, implementation period 2020-2024).

**Results and their discussion.** In recent years (2011–2022), the activation and productivity of rule-making processes contributed to the improvement of most laws to EU standards and the preparation of new normative legal acts, in particular, the preparation of a new edition of the Law of Ukraine "On Medicinal Products". The work carried out contributed to the optimization of the system of legal relations "doctor-patient-pharmacist-lawyer" during the circulation of pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups on the basis of pharmaceutical law [58, 59].

Determining the affiliation of laws and regulations to the pharmaceutical industry is relevant because of the following:

- **firstly**, it has not only general theoretical knowledge, but also a practical point of view, because such clarification serves as the basis for solving urgent problems of pharmaceutical legislation and makes it possible to improve the rule-making process in a specific sphere of social relations, for example, replenishing the terminological apparatus of the Law of Ukraine "On Medicinal Products";
- **secondly**, the solution to the problem of separating the criteria of one branch of law from another in legal theory was, is and remains in the zone of heated discussions (for example, theories of the state and law, criminal legislation, administrative legislation, etc.);
- **thirdly**, to define the field of law – pharmaceutical law, as a relatively independent set of legal norms that regulates a qualitatively homogeneous sphere of social relations by a specific method of legal regulation;
- **fourthly**, the general legislative properties of the system of legal relations "doctor-patient-pharmacist-lawyer", i.e., systems that are not statutory and are not identified, but are specified according to the sectoral pharmaceutical law;
- **fifthly**, the criteria for the division of law; consist of legal institutes built in the field of law according to their own subject and method of legal regulation; relatively independent from other associations of legal norms in the pharmaceutical law system;
- **sixthly**, the place of pharmaceutical law in the state administrative and delict authority is determined by several factors, namely: Ukraine's integration into the European and world economic society, global revolutionary processes in the domestic economy, the existing state of circulation – provision of the population (sick) with medical care, etc.
- **seventh**, the outdated system of legal relations and the creation of a modern legal array, which acts as a legislative regulator for the analysis of the reasons and conditions that inhibit the improvement of legal relations in the medical and pharmaceutical sectors of Ukraine;
- **eighthly**, the subject of the state administrative tort of legal regulation is social relations, which objectively require actual regulation with the help of generally recognized specific and relevant legal norms (-participation in scientific research work; -participation in the preparation of regulatory and legal acts);
- **ninthly**, the subject of legal regulation is primarily social relations. Undoubtedly, these relations are strong-willed and purposeful, because they are the embodiment of

the internal conviction of all participants of the pharmaceutical market in the fulfillment of current legal relations regarding their rights and obligations, that is, the patient exercises his right to receive drugs, the pharmacist – to engage in pharmaceutical activities in accordance with the obtained specialty and circulation of drugs registered on the territory of Ukraine;

- **tenth**, the element of the subject of legal regulation is "focus on the patient", the ultimate goal of which is to provide the population with effective, safe, high-quality, and affordable drugs, consideration and discussion of the draft and adoption of the Law of Ukraine "On Pharmaceutical Activity";

- **eleventh**, ensuring the circulation of pharmaceuticals as a type of activity of the pharmacy regarding production (manufacturing), accounting, storage, dispensing, transportation, sale, disposal, destruction of pharmaceuticals, accounting of prescriptions, etc.;

- **twelfth**, ensuring control over the quality of drugs during circulation in a pharmacy (detection of falsified drugs) and development of legal relations in the chain "pharmacist-drug quality control-lawyer-law enforcement agencies";

- **thirteenth**, execution by all participants who are on the pharmaceutical market of the State Pharmacopoeia of Ukraine;

- **fourteenth**, organization, holding, discussion and generalization of proposals at scientific and practical conferences, for example, November 17-18-19, 2022, the annual XIX Multidisciplinary scientific and practical conference "Medical and pharmaceutical law of Ukraine: organization of pharmaceutical business, general, forensic and clinical pharmacy, pharmacotherapy of health disorders" in the conditions of the coronavirus pandemic (interdisciplinary relations of medical and pharmaceutical law in the field of health care and the pharmaceutical industry in the conditions of the COVID-19 pandemic; State Pharmacopoeia of Ukraine; evidence pharmacy and evidence-based medicine) [60].

**Table 1.** Results of participation in research work and in the preparation (improvement) of laws and regulatory acts.

No.	Participation in research work: carried out in the following directions	Participation in the preparation (improvement) of laws and regulatory acts: carried out in the following directions
1.	Methodological substantiation of the strategy and tactics of systemic measures for the optimization and effective development of the domestic production of medicinal products.	Prepared additions, changes and carried out an analysis of the main state factors of pharmaceutical law of Ukraine, adapted and implemented to European provisions.
2.	Scientific, practical, and theoretical substantiation of systemic measures to ensure pharmaceutical law in the sphere of circulation, promotion of	Some cross-sectoral legal acts and orders of the Ministry of Health of Ukraine, which were amended and

	medicinal products and parapharmaceutical products.	supplemented in 2008-2021, were analyzed.
3.	Scientific and practical substantiation of the rational use, training, and placement of pharmaceutical personnel.	Amendments were made to 14 licensing and regulatory documents of the State Medical Service of Ukraine.
4.	Complex scientific and theoretical substantiation of the regularities of the development of the system of medical provision of the population of Ukraine from the neo-pharmaceutical and emergent positions.	A practical position has been developed regarding the systematization of the structural-analytic array and the analysis of changes made to legislative and regulatory factors (2007-2021).
5.	Scientific and methodical approaches to the implementation of the formulary system of pharmaceutical provision of health care institutions. In 2015-2020, the scientific school carried out the initiative and research scientific work "Scientific-theoretical substantiation of the accelerated development of pharmacy, reengineering of processes and human resources from neopharmaceutical and emergent positions" (state registration number 0112U002362, implementation period – 2012-2021). The scientific leader of the scientific work is Doctor of Pharmaceutical Sciences, Professor M.S. Ponomarenko.	A unified retrospective analysis of the pharmaceutical human resources of the pharmacy network from 2009 to the present in Ukraine. There were 94 proposals to 82 legislative and normative legal acts on improvement of pharmaceutical activity introduced and adopted. A new version of the 2 <sup>nd</sup> Edition of the Law of Ukraine "On Medical Products" was proposed (the drafts were sent to the Verkhovna Rada of Ukraine), the draft Resolution of the Cabinet of Ministers of Ukraine "On Personnel Certification" was sent to the Ministry of Health of Ukraine.

Using the capabilities of the European Committee regarding the compliance of the situation with the provisions of the "European Social Charter", as of 2013, problematic issues regarding the pharmaceutical provision of the population of Ukraine were identified in Ukraine. The organizational and legal measures of state influence on the reform and modernization of the health care sector on the basis of pharmaceutical and medical law are defined. It was noted that clarifying the norms of medical and pharmaceutical law, implementing the principles of medical and pharmaceutical legislation, forensic pharmacy, evidence-based medicine, and evidence-based pharmacy in the practical activities of pharmacy specialists and doctors will contribute to the formation of a highly educated specialist in the field of health care. Pharmacy specialists have theoretical foundations and practical skills regarding: clinical-pharmacological, classification-legal and nomenclature-legal classification of drugs; legislative, regulatory and instructional-methodical documents regulating the legal circulation of drugs; rational and safe use of drugs; safe self-medication; licensing of

certain types of economic activity; problems associated with falsification of pharmaceuticals; circulation systems of prescription and over-the-counter drugs; control regime and organization of quality control of pharmaceuticals in pharmacies and health centers of all forms of ownership. It is proposed for introduction into the undergraduate and postgraduate forms of education of bachelors, masters, students of thematic improvement cycles (pharmacists, pharmacist assistants, masters of pharmacy, doctors, nurses), pharmacist-interns, master's students, postgraduates, employees of law enforcement, control, advocacy bodies and structures, whose activities are related to the circulation of drugs.

Needs to note that at the meeting of the 72<sup>nd</sup> World Health Assembly held in May 2019, the WHO countries undertook to recognize patient safety as one of the priority tasks in the field of health care and to take all necessary measures to reduction of harm caused to patients in medical institutions. The World Health Assembly approved the establishment of World Patient Safety Day, which will be celebrated every year on September 4, 2019 (Decree of the President of Ukraine No. 648/2019 on the annual observance of "Patient Safety Day"). International conferences are held every year, in particular, on November 17-19, 2022, the XIX Multidisciplinary scientific and practical conference "Medical and pharmaceutical law of Ukraine: organization of pharmaceutical business, general, forensic and clinical pharmacy, pharmacotherapy of health disorders in the conditions of the coronavirus pandemic" will be held (Invitation, <https://medinstytut.lviv.ua/invitation-to-the-xix-multidisciplinary-scientific-and-practical-conference/>) [60]. The conference program includes three main directions: 1 – interdisciplinary relations of medical and pharmaceutical law in the field of health care and the pharmaceutical industry in the conditions of the COVID-19 pandemic; 2 – state control over circulation of pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups, State Pharmacopoeia of Ukraine; 3 – evidence-based pharmacy and evidence-based medicine (Table 2).

**Table 2.** Three main directions of the international conference: A. Interdisciplinary relations of medical and pharmaceutical law in the field of health care and the pharmaceutical industry in the conditions of the COVID-19 pandemic; B. State control over the circulation of pharmaceuticals of all pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups, State Pharmacopoeia of Ukraine; C. Evidence-based pharmacy and evidence-based medicine.

<p><b>A. Interdisciplinary relations of medical and pharmaceutical law in the field of healthcare and the pharmaceutical industry in the conditions of the COVID-19 pandemic</b></p>	<p><b>B. State control over the circulation of pharmaceuticals of all pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and</b></p>	<p><b>C. Evidence-based pharmacy and evidence-based medicine.</b></p>
--	---	---

	<b>classification and legal groups, State Pharmacopoeia of Ukraine</b>	
<p>State regulatory policy;  - UN Conventions; - decisions of the WHO;  -European, International and National legislation: conventions, directives, analytics; - Healthcare management and pharmaceutical management and marketing, organization and economics of pharmacy, development and technology of new medicines (based on known pharmacological substances), nanotechnology, pricing; - Solving problematic issues regarding the circulation of vaccines, antibiotics and other medicines; - Accessibility of the population to medical and pharmaceutical care; - Licensing of medical and pharmaceutical activities; - Labor relations; - Quality, life expectancy and social protection of patients, family doctors, doctors of other specialties and pharmacists;</p>	<p>Analytical chemistry. State control over the quality, safety, effectiveness, and availability of medicinal products of all clinical-pharmacological, nomenclature and legal, and classification and legal groups; counterfeit, falsified, low-quality, substandard means and substances; - Legal guardianship in the system of legal relations "doctor - patient - pharmacist". Controlling, law enforcement, prosecutor's office, judicial, advocacy, expert, and forensic institutions. Protection of the rights, freedoms, life, and health of patients (persons in institutions of the penitentiary system); - Forensic chemical-pharmaceutical examination (chemical, biological, cytological, toxicological, medical, psychiatric, narcological, forensic, physical-</p>	<p>Government programs (Resolutions of the Cabinet of Ministers of Ukraine), pilot projects (hypertensive disease, diabetes, bronchial asthma, COVID-19); - Dental care; - Pharmaceutical correction for HIV/AIDS, tuberculosis, hepatitis, oncological diseases, etc.; - Benefits for medicinal products (participants and veterans of hostilities, liquidators of the consequences of the Chernobyl nuclear power plant accident, disabled persons of the I and II groups, and other categories); - State policy in the field of combating the narcotization of society and the accessibility of patients to vitally necessary medications in the treatment of pain of various genesis and the provision of palliative and hospice care; - Rare (orphan) diseases (spinal muscular atrophy, cystic fibrosis, mucopolysaccharidosis, tyrosinemia, Gaucher, Pompe, Fabry, pituitary dwarfism, autism, hemophilia, cancer, systemic autoimmune diseases, etc.); - State pharmacovigilance. Quality control of medicines (fighting against falsified medicines). Safety of medicinal products (creation of original pharmaceuticals, combined pharmaceuticals, innovative pharmaceuticals, generic pharmaceuticals, preclinical and</p>

<ul style="list-style-type: none"> <li>- Bookkeeping;</li> <li>- Patent science;</li> <li>- Composition and production technology of cosmetology products (ointments, creams, cologne, paint, etc.).</li> </ul>	technical, handwriting, DNA, documentary, accounting, explosive-technical, fire-technical, dactyloscopic, etc.); Lawyer, pharmacist-criminologist, pre-trial and forensic investigation.	clinical trials of pharmaceuticals) in accordance with ICD-11. Adverse drug reactions (registration and re-registration of drugs, vaccines, etc.). Addictive health disorders. Safe self-medication. The formulary system of Ukraine, the USA, Germany, Israel, etc. countries (state, regional and local formularies) and the international classification of primary medical care (ICPC-2)
---	--	--

In the following, the experience of the teaching staff of the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy of the KhMAPE, Ukrainian Military Medical Academy and Kyiv Medical University regarding the educational process during the quarantine period caused by the acute respiratory disease COVID-19 due to the SARS-CoV-2 coronavirus were summarized. On the example of cycles of professional development of medicine and pharmacy specialists using distance learning technologies. It is noted that anti-epidemic measures are being taken at the KhMAPE in order to prevent the spread of acute respiratory disease COVID-19 in the educational process. The Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy successfully conducts courses for doctors and pharmacists using distance learning technologies. The positive feedback from doctors and pharmacists about the organization of distance learning by the Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy of the Khmapo Polytechnic University (95% of students were satisfied with the completed advanced training courses) is emphasized.

It should be noted that the day before (July 28, 2022), the Verkhovna Rada of Ukraine adopted the final version of the relevant project of the Law of Ukraine No. 5547 "On Medicinal Products" proposed by the Committee on National Health, Medical Care and Medical Insurance in the repeated second reading as a whole as law. The proposed new version of the Law of Ukraine "On Medicinal Products" defines [61-65]:

- the law will come into force in 2.5 years from the date of adoption by the Parliament and how long it will take the Ukrainian Farm Industry to retool production in accordance with EU requirements, i.e., after the end of martial law (2D coding, which was planned to be introduced from January 1, 2028, will be introduced after 5 years after the end of martial law;
- circulation conditions (creation, pharmaceutical development, preclinical research, clinical trials (research), state registration of pharmaceuticals;
- circulation conditions (production, manufacture) in the conditions of pharmacy, appointment, use, import, wholesale and retail trade, distance trade, quality control, pharmacovigilance of drugs;

- the rights and obligations of legal entities and individuals, as well as the powers of state authorities and officials in the relevant field;
- creation of conditions for the development of the pharmaceutical industry, formation of a favorable investment climate, overcoming technical barriers in the international trade (circulation) of drugs.

However, the harmonization of the medical field and the pharmaceutical industry to the requirements of the EU Directives (laws) is based on the components of medical and pharmaceutical law, namely medical legislation, pharmaceutical legislation, forensic pharmacy, evidence-based medicine, evidence-based pharmacy, the drug control regime, quality control and the safety of drugs of all pharmaceuticals of all clinical and pharmacological groups, nomenclature and legal groups and classification and legal groups, which indicate the control regime in the system of over-the-counter and prescription drug circulation.

Thus, during the Covid-19 pandemic, modern trends contributed to the development of the science of pharmaceutical law, as a basis for optimizing the legislation of Ukraine (approval of the new version, corresponding to the project of the Law of Ukraine No. 5547, "On medicinal products"), the organization of pharmaceutical affairs in pharmacies and health centers, and thanks to modern research on the search for drug technology, it contributed to the creation of vital vaccines for the prevention of the SARS-CoV-2 coronavirus, as well as to the minimization of forensic pharmaceutical risks in the system of legal relations "doctor-patient-pharmacist-lawyer".

**Conclusions.** Based on the analysis of the points of view of representatives of the theory of law, as well as scientists of pharmacy, we made a conclusion, namely: 1. Pharmaceutical law as a set of legal norms has the characteristics of a branch of law, namely, its subject, that is, social relations that arise during the implementation of pharmaceutical activity. As well as the method of legal regulation as methods, methods and means of legal regulation of social relations established by the norms of law related to the subject of pharmaceutical law. 2. The main ways of regulating relations in pharmaceutical law are permission, obligation, and prohibition. 3. The well-founded criteria for the existence of pharmaceutical law make it possible to move on to the consideration of other independent features - the existence of science, the field of legislation, issues of the complex sectoral nature of the field, as well as the relationship of pharmaceutical law with other tangential branches of law, primarily with medical, constitutional, administrative, and criminal law.

**Conflict of interest.** The authors declare that the study was conducted in the absence of any commercial or financial relationships that could be considered a potential conflict of interest.

**Funding.** This study was not funded by any public or private institutions.

## References.

1. Lyashko V. The outbreak of COVID-19 began in Ukraine. *Ministry of Health of Ukraine*. 20.01.2022. URL: <https://moz.gov.ua/article/news/v-ukraini-pochavsja-spalah-covid-19---victor-ljashko>.

2. Operational information on the spread and prevention of COVID-19. *Ministry of Health of Ukraine*. 19.01.2022. URL: <https://moz.gov.ua/article/news/operativna-informacija-pro-poshirennja-koronavirusnoi-infekcii-2019-cov19>.
3. Operational information on the spread and prevention of COVID-19. *Government portal*. 18.01.2022. URL: <https://www.kmu.gov.ua/news/operativna-informaciya-pro-poshirennya-ta-profilaktiku-covid-19-18012022>.
4. Shapovalova V. An Innovative multidisciplinary study of the availability of coronavirus vaccines in the world. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.2. P.1–17 URL: <https://doi.org/10.53933/ssppmpm.v2i2.45>.
5. Shapovalova V., Shapovalov V., Shapovalov Valentyn et al. The COVID-19 pandemic (strains "Delta", "Omicron"): particularities of study on the thematic cycle "General Pharmacy based on pharmaceutical law". *Actual problems of medicine and pharmacy*. 2022. Vol.3. N.1. P.1–18. URL: <https://doi.org/10.52914/apmp.v3i1.36>.
6. Ponomarenko M.S. et al. Justification of the creation of a normatively defined assortment of drugs in accordance with the protocols of the pharmacist and clinical protocols of medical care for family pharmacy pharmacies and general type pharmacies at family medicine institutions. *ScienceRise*. 2016. No. 4/4 (21). P. 17-19.
7. Alekseeva I.M., Knysh M.S., Ponomarenko M.S. et al. To the issue of improving the regulatory and legal basis of pharmaceutical activity. *Zaporozhye Medical Journal*. 2009. Vol. 11. No. 6. P. 87-90. URL: [http://nbuv.gov.ua/UJRN/Zmzh\\_2009\\_11\\_6\\_27](http://nbuv.gov.ua/UJRN/Zmzh_2009_11_6_27).
8. Ponomarenko M.S., Solovyov O.S. Legislative novels on pharmaceutical law. Formation of the national medical policy under the conditions of the introduction of medical insurance: issues of education, theory and practice; the mother III All-Ukrainian of science - practice conference, Kharkiv, March 12, 2015, pp. 176-177.
9. Shapovalov V.V., Shapovalov Valentin V. (Jr.), Shapovalova V.A. *Pharmaceutical and medical law: textbook. allowance (series: Pharmaceutical law)*. Kharkov: Publishing House "Scorpion", 2011. 208 p.
10. Shapovalov V.V., Shapovalov Valentin V. (Jr.), Shapovalova V.A. Introduction to medical, pharmaceutical law and forensic pharmacy. "Law and Ethics of Biomedical Activity in Russia and Abroad". 2014. No.3. pp.186-194.
10. Shapovalova V.O., Vasina Yu.V., Shapovalov V.V. et al. Study of the circulation system of extemporaneous medicines in Ukraine on the basis of pharmaceutical law. *Pharmaceutical journal*. 2016. No. 1. P. 77-85.
11. Galatsan O.V., Shapovalova V.O., Shapovalov V.V. Pharmaceutical law in the state system of minimizing legal and pharmaceutical risks in the circulation of medicinal products in rural areas. *Ukraine Journal of Psychoneurology*. 2013. T. 21. Issue 2 (75). P. 96-100. URL: <https://uvnnpn.com.ua/arkhiv-nomeriv/2013/tom-21-vipusk-2-75/farmatsevtichne-pravo-v-derzhavn-y-sistem-m-n-m-zats-sudovo-farmatsevtichnikh-rizik-v-pri-ob-gu-l-ka>.
12. Shapovalova V. The ICD-11 for the twenty-first century: the first view from the organizational, legal, clinical and pharmacological aspects. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.1. P.1-13. URL: <https://doi.org/10.53933/ssppmpm.v2i1.37>.

13. Ivanishyn-Hayduchok L., Shapovalova V., Shapovalov V. ICD-11: Organizational and legal, medical and pharmaceutical, social and economic issues of implementation of the program of state guarantees of medical care in 2022 in Ukraine, based on the fundamental principles of the European Union. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.2. P.1–14. URL: <https://doi.org/10.53933/ssppmp.v2i2.53>.
14. Shapovalova V., Shapovalov V., Shapovalov Valentyn et al. Experience of the department of medical and pharmaceutical law, general and clinical pharmacy of the Kharkiv medical academy of postgraduate education concerning the educational process during the quarantine period caused by COVID-19. *Actual problems of medicine and pharmacy*. 2021. Vol.2. N.2. P.1–20. URL: <https://doi.org/10.52914/apmp.v2i2.33>.
15. Hayduchok I., Shapovalov V., Shapovalov Valentyn. Organizational and legal study and implementation by administrative staff of higher education of licensing conditions for educational activities in Ukraine during COVID-19 pandemic. *Actual problems of medicine and pharmacy*. 2022. Vol. 3. N.1. P.1–30. URL: <https://doi.org/10.52914/apmp.v3i1.38>.
16. Grizodoub O. Twenty years of the state pharmacopoeia of Ukraine: the experience of establishing the first national pharmacopoeia in the post-soviet area. *SSP Modern Pharmacy and Medicine*. 2021. Vol.1. N.2. P.1–20. URL: <https://doi.org/10.53933/ssppmp.v1i2.22>
17. Hryhoruk Yu.M., Ponomarenko M.S., Solovyov O.S. Chronometric analysis of unfinished legislative initiatives on pharmaceutical law. Formation of the national medical policy under the conditions of the introduction of medical insurance: issues of education, theory, and practice; the mother III All-Ukrainian of science - practice conference, Kharkiv, March 12, 2015. P. 28-39.
18. Shapovalov V., Shapovalova V., Andrieieva V. et al. Analysis of healthcare expenditures in countries of the world. *Recipe*. 2019. Vol. 22, N. 5, P. 712-719.
19. Zbrozhek S. I., Shapovalova V. A., Shapovalov V.V. et al. Organizational and legal research of indicators of incidence and prevalence of diabetes mellitus in countryside areas. *Annals of Mechnikov Institute*. 2017. N.1. P. 44–53. URL: [http://www.imiamn.org.ua/journal/1\\_2017/zmist1\\_2017.html](http://www.imiamn.org.ua/journal/1_2017/zmist1_2017.html).
20. Shapovalova V.A., Sosin I.K., Butenko G.M. et al. Pharmaceutical law in narcology. H.: "Fact", 2004. 800 p.
21. Shapovalov V.V., Shapovalova V.O., Shapovalov V.V. et al. Medychne ta farmatsevtychne pravo: navch. posib. dlia dodyplomnoi ta pisliadyplomnoi formy navchannia. Seriia «Medychne ta farmatsevtychne pravo». 4-e vyd. zi zminamy ta dopovnenniamy. Kharkiv –Ivano-Frankivsk: KhMAPO, 2020. 128 s.
22. Shapovalova V. O., Zbrozhek S. I., Shapovalov V. V., Shapovalov V. V. Coronavirus disease pandemic 2019: growth of epidemic dangers. *Acta scientific pharmaceutical sciences*. 2020. Vol.4. Iss.7. P.61–68. URL: <https://doi.org/10.31080/ASPS.2020.04.0559>.
23. Shapovalova V. Monkeypox virus – new challenges of modernity: experimental organizational and legal, clinical and pharmacological studies. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.3. P.1–15. URL: <https://doi.org/10.53933/ssppmp.v2i3.54>.

24. Ponomarenko M.S., Alekseeva I.M., Solovyov O.S. and others. Subject and method of pharmaceutical law. *Pharmaceutical journal*. 2015. No. 2. P.87-95.
25. Hayduchok I., Shapovalov V. Organizational and legal measures of state control of reforming and modernizing the health care on principles of pharmaceutical and medical law. *Actual problem of medicine and pharmacy*. 2020. Vol. 1 No. 1-2. URL: <https://apmplmi.com/index.php/apmp/article/view/11/6>.
26. Hayduchok I., Shapovalov V. Forensic pharmacy and medicine: risks for pharmacotherapy of addiction and countering of illegal circulation of psychoactive substances in the COVID-19 pandemic. 2021. *SSP Modern Pharmacy and Medicine*. Vol.1. N.2. P.1-28. URL: <https://doi.org/10.53933/ssppmpm.v1i2.32>.
27. Boryshchuk V.O., Solovyov O.S., Krasnyanska T.M. et al. State administrative-legal tort on issues of optimization of the organization of provision of medicines to the rural population. *Pharmaceutical journal*. 2015. No. 4. P.9-15. URL: [http://nbuv.gov.ua/UJRN/pharmazh\\_2015\\_4\\_3](http://nbuv.gov.ua/UJRN/pharmazh_2015_4_3).
28. Zbrozhek S.I., Shapovalova V.O., Shapovalov V.V. (Jr.) et al. Processing of the control regime of medicines for pharmacotherapy of chronic pain syndrome in the field of palliative aid. *Likars'ka sprava*. 2019. N.5-6. P.111-118. doi: 10.31640/JVD.5-6.2019 (15).
29. Varchenko V.G. Ponomarenko M.S., Syatinya M.L. et al. Draft Law of Ukraine "On Pharmaceutical Activity". *Medicines of Ukraine*. 2001. No. 3 (11). P.2.
30. Shapovalov V.V., Shapovalova V.O., Shapovalov V.V. et al. Medychne ta farmatsevytchne pravo: navch. posib. dlia studentiv dennoi ta zaochnoi formy navchannia. *Seriia «Medychne ta farmatsevytchne pravo»*. 3-ye vyd. zi zminamy ta dopovnenniamy. Kharkiv -Kyiv: KhMAPO, 2020. 128 s.
30. Shapovalova V., Shapovalov V., Osyntseva A. et al. Organization of the pharmaceutical business, industrial pharmacy and forensic pharmacy concerning the competences of quality management during the circulation of medical products: GxP standards. *Actual problems of medicine and pharmacy*. 2022. Vol.3. N. 2. P.1–20. URL: <https://doi.org/10.52914/apmp.v3i2.44>.
31. Zbrozhek S. Reform of the healthcare system as a basis for streamlining the organization of circulation and availability of medicines for patients in the context of the COVID-19 pandemic. *SSP Modern Pharmacy and Medicine*. 2021. Vol. 1. N.2. P.1-32. URL: <https://doi.org/10.53933/ssppmpm.v1i2.31>.
32. Haiduchok I.H., Shapovalova V.O., Shapovalov V.V. et al. Rezhym kontroliu likarskykh zasobiv dlia farmakoterapii koronavirusnoi khvoroby (COVID-19) u khvorykh na systemni zakhvoriuvannia. *Informatsiinyi lyst pro novovvedennia v sferi okhorony zdorovia*. Kyiv, 2020. No 225 –2020. 8 s. URL: <https://medinstytut.lviv.ua/wp-content/uploads/pdf/Informatsiynyy-lyst.pdf.30>.
33. Zbrozhek S. Medical and pharmaceutical legislation: normative and legal regulation of healthcare specialists' activities in Finland. *SSP Modern Pharmacy and Medicine*. 2021. Vol.1. N.1. P.1-8. URL: <https://doi.org/10.53933/ssppmpm.v1i1.5.31>.
34. Shapovalov V., Butko L., Shapovalov V. Organizational and legal study of quarantine restrictions in the spread of coronavirus disease in Ukraine. *SSP Modern Pharmacy and Medicine*. 2021. Vol.1. N.2. P.1–12. URL: <https://doi.org/10.53933/ssppmpm.v1i2.23>.

35. Gudzenko A., Shapovalov V., Shapovalov V. et al. Forensic pharmacy: analysis of complaints about the pharmaceutical provision for privileged categories of patients in Ukraine (experimental research). *Science Review*. 2021. V.2. Iss.37. P.1–6. doi: [https://doi.org/10.31435/rsglbal\\_sr/30042021/7517](https://doi.org/10.31435/rsglbal_sr/30042021/7517).
36. Ponomarenko M.S., Solovyov O.S., Krasnyanska T.M. et al. The main stages of standardization and streamlining of training and use of the pharmaceutical personnel resource base. *Current issues of pharmaceutical and medical science and practice (ZDMU)*. 2016. No. 2 (21). P.1 10.
37. Ponomarenko M.S., Kabachna A.V., Solovyov O.S. et al. Systemic approaches in creating the necessary assortment of medicines for family pharmacy pharmacies and general type pharmacies at family medicine institutions. *Pharmaceutical journal*. 2016. No. 2. P.54-60.
38. Avtorske svidotstvo 69821, Ukraina. Oryhinalni ta henerychni likarski zasoby: navchalno-metodychnyi posibnyk dlia samostiinoi roboty / V.O. Shapovalova, V.V. Shapovalov, A. . Osyntseva. No. 70614; opubl. 17.01.2017.
39. Shapovalova V. O., Shapovalov V. V., Shapovalov V. V. (mol.) et al. Farmatsevychna korektsiia: metod. rek. Kh., 2019. 20 s.
40. Zbrozhek S.I. Medical and pharmaceutical law: the issue of availability of palliative care for drug-addicted women with HIV infection in Ukraine. *Actual problems of medicine and pharmacy* 2020. Vol. 1. No. 1-2. 6 p. URL: <https://apmplmi.com/index.php/apmp/article/view/21/16>.
41. Gudzenko A. O., Osyntseva A. O., Shapovalov V. V. et al. Doslidzhennia obihu spyrtovykh likarskykh zasobiv: metod. rek. Kh., 2018. 28 s.– 1(2). – P. 1–32. <https://doi.org/10.53933/ssppmp.v1i2.31>.
42. Gudzenko A. Substantiation of components of the national list of medicines of domestic production for pharmaceutical provision of affected persons in conditions of the special period in Ukraine. *SSP Modern Pharmacy and Medicine*. 2021. Vol.1. N.1. P.1–6. URL: <https://doi.org/10.53933/ssppmp.v1i1.15>.
43. Alekseeva I.M., Ponomarenko M.S. et al. Formation of legal awareness as a component of professional competence of pharmaceutical workers in the countries of the European Union (experience of the Czech Republic). *Current issues of pharmaceutical and medical science and practice (ZDMU)*. 2016. No. 2(21). P. 96 – 101.
44. Ponomarenko M.S., Solovyov O.S., Krasnyanska T.M. et al. The main stages of standardization and streamlining of training and use of the pharmaceutical personnel resource base. *Current issues of pharmaceutical and medical science and practice (ZDMU)*. 2016. No. 2(21). P. 110.
45. Shapovalova V. System of drugs circulation based on medical and pharmaceutical law. *Actual Problems of Medicine and Pharmacy*. 2021. Vol.1. N.1-1. URL: <https://apmplmi.com/index.php/apmp/article/view/1>.
46. Shapovalov (Jr.) V., Gudzenko A., Komar L. et al. Concerning the importance of forensic and pharmaceutical researches to improve patients' accessibility to medicinesю. *Pharmacia*, 2017. Vol.65. N.2. P.23–29. URL: <http://bsphs.org/wp-content/uploads/2017/07/Shapovalov.pdf>.

47. Shapovalova V. O., Chernykh V. P. The physiological properties of the action of a new analgesic and antipyretic preparation. *Fiziologichnyi zhurnal*. 1997. Vol.43. N.1-2. P. 117–121.
48. Shapovalov (Jr.) V., Gudzenko A., Shapovalova V., Osyntseva A., Shapovalov V. Forensic and pharmaceutical study of the presence of a causal link between the degree of alcohol abuse and qualification level of the respondents. *Pharmacia*. 2017. Vol.66. N.3. P.31–39. URL: <http://bspchs.org/wp-content/uploads/2017/11/Shapovalov.pdf>.
49. Shapovalov (Jr.) V., Zbrozhek S., Gudzenko A. et al. Organizational and legal analysis of the pharmaceutical provision for the most common diseases of society. *International Journal of Pharmaceutical Sciences Review and Research*. 2018. Vol.51. N.1. P.118-124. URL: <http://globalresearchonline.net/journalcontents/v51-1/18.pdf>.
50. Shapovalov V.V. (Jr.), Zbrozhek S.I., Shapovalova V.O., Shapovalov V.V. Organizational and legal evaluation of availability of medicines' circulation for cancer patients. *Pharmacia*. 2018. Vol. 65. N.2. P.17-22. URL: <http://bspchs.org/?magazine=organizational-and-legal-evaluation-of-availability-of-medicines-circulation-for-cancer-patients>
51. Osyntseva A. Forensic and evidence pharmacy: features of medical, pharmacological and pharmaceutical correction. *Actual problem of medicine and pharmacy*. 2020. Vol.1. N.1-2. URL: <https://apmplmi.com/index.php/apmp/article/view/19>.
52. Shapovalova V.A., Shapovalov V.V. The clinical efficacy of the combined drug agent Valcophen in children *Likars'ka sprava*. 1999. N.1. P.124–126.
53. Ponomarenko M.S., Kabachna A.V., Shelkova E.V. et al. Implementation of the professional and educational function of the formulary system in the educational process of the Department of Organization and Economy of Pharmacy of P.L. Shupyka Coll. of science works of cooperation NMAPE 2016. P. 609 – 614.
54. Ponomarenko N.S., Solovyov A.S., Augunas S.V. et al. Generalized analysis of the weighted average indicator of the pharmacy staff in Ukraine 1913 - 1991 Recipe. 2016. Vol.19. Number 3. pp. 408-413.
55. Shapovalov V.V. (Jr.), Shapovalova V.A., Shapovalov V.V. Forensic and pharmaceutical research on the impact of drugs on the safety, life, and health of road users within the organization of pharmaceutical business, drug technology, pharmaceutical and medical law in Ukraine. *Health of Society*. 2021. Vol. 10. N. 4. P.127-132. DOI: <https://doi.org/10.22141/2306-2436.10.4.2021.246355>.
56. Hayduchok I., Shapovalov B. Covid-19: multidisciplinary researches of forensic and pharmaceutical risks and causal relationships of unqualified medical care for patients during pandemic. *SSP Modern Law and Practice*. 2022. Vol.2. N.1. P.1-25. URL: <https://doi.org/10.53933/sspmlp.v2i1.39>.
57. Law of Ukraine "On Medicinal Products". *Verkhovna Rada of Ukraine*. 1996., №22, ст.86 (стаenom на 08.06.2022) URL: <https://zakon.rada.gov.ua/laws/show/123/96-%D0%B2%D1%80#Text>
58. Shapovalov V.V. (Jr.), Shapovalova V.A., Shapovalov V.V. Development of forensic and pharmaceutical researches within the organization of pharmaceutical business, drug technology and pharmaceutical law in Ukraine concerning the turnover

- of controlled drugs and substances. *Health of Society*. 2021. Vol. 10. N. 3. P. 98-106. DOI: <https://doi.org/10.22141/2306-2436.10.3.2021.246351>.
59. Shapovalova V., Zakharchenko I. Organizational and legal approaches to reforming of the law enforcement system of Ukraine: illegal circulation of psychoactive substances and addictive dependence. *SSP Modern Law and Practice*. 2021. Vol. 1. N.1. P.1–22. URL: <https://doi.org/10.53933/sspmlp.v1i1.20>.
60. Invitation to the XIX Multidisciplinary scientific and practical conference "Medical and pharmaceutical law of Ukraine: organization of pharmaceutical business, general, judicial and clinical pharmacy, pharmacotherapy of health disorders". URL: <https://medinstytut.lviv.ua/invitation-to-the-xix-multidisciplinary-scientific-and-practical-conference/>.
61. Parliament adopted a new law "On medicinal products" (updated). *Apteka.ua*. 28.07.2022. URL: <https://www.apteka.ua/article/641850>.
62. Draft Law of Ukraine "On Medicinal Products". *Apteka.ua*. 15.12.2021. URL: <https://www.apteka.ua/article/621487>.
63. Pharmacists will be punished for dispensing prescription drugs in pharmacies without a prescription. *Debit-Credit*. 02.08.2022. URL: <https://news.dtki.ua/law/liability/77759-farmaceutiv-budut-karati-za-vidpusk-v-aptekax-recepturnix-likiv-bez-receptu>.
64. Draft Law on Amendments to Article 42-4 of the Code of Ukraine on Administrative Offenses regarding the strengthening of liability for violations of the established procedure for the sale (issuance) of medicinal products (No. 7445 dated 06.08.2022). *Verkhovna Rada of Ukraine*. 08.06.2022. URL: <https://itd.rada.gov.ua/billInfo/Bills/Card/39754>.
65. Shapovalova V.O., Zbrozhek S.I., Shapovalov V.V. (Jr.) et al. Content analysis of pharmacies in Ukraine, which produce extemporaneous drugs. *Public health*. 2017. T.6. N.3–4. P.77–83. DOI: 10.22141/2306-2436.6.3.2017.123498.