



Medical And Pharmaceutical Law: Deepening the Cooperation Between the LMI, KhMAPE* and Estonian Scientific Publishing House SSP OÜ, as Part of the System of Ukraine's Integration into the European Community

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Abstract. Deepening cooperation between the LMI, KhMAPE and the Estonian scientific publishing house SSP OÜ will be part of the system of Ukraine's integration into the European Community by building pharmaceutical companies for the production of domestic drugs. Integration of pharmaceutical production can take into account the problems and risks that arose

during the creation of the common economic zone "Yavoriv" on the basis of state guarantees.

Keywords: medical law, pharmaceutical law, integration, EU, Ukraine, cooperation, organization and economics of pharmacy, drug technology, forensic pharmacy, state guarantees.

Introduction. Optimizing the level of cooperation between Ukraine, Estonia, and other European Union (EU) countries in the pharmaceutical production of medicines is an important element of the country's future EU membership, which requires the candidate countries to comply with the fundamental principles enshrined in the Washington Treaty on Democracy and Freedom human [1]:

- rule of law and protection of human and civil rights;
- development of international cooperation in the field of improving and strengthening democratic institutions, rights, freedoms and maintaining stability;
- support for peace, good neighborly relations, and conflict resolution at the diplomatic level;
- introduction of the European model of control over the domestic armed forces.
- Therefore, we believe that it is necessary to study the experience related to the reform of the pharmacy business in Estonia (started in 2015; completed in April 2020) [2].

The essence of the reform lies in two main aspects:

- Pharmacy service providers should be separated from pharmaceutical manufacturers and distributors (vertical integration ban);

- The ownership of pharmacies should be transferred only to professional pharmacists.

Experts believed that these conditions guarantee the quality of pharmacy services and increase free competition between pharmacies. The reform is based on the fact that without the influence of wholesale networks, pharmacists are free for professional development and free from the commercial interests of pharmaceutical companies. Although increased competition is one of the goals of the reform, the Office of Competition mentioned possible obstacles to free competition as a result of the reform.

Therefore, the main questions that still need to be answered remain, namely:

- Are pharmacists interested in owning and managing a business with all the additional responsibilities and potential responsibilities other than their professional responsibilities (forensic risks)?
- Are pharmacists willing to take on the financial risks and economic obligations of an independent company? The interest of pharmacists in purchasing existing pharmacies was really not very great.

Professional pharmacists were surprised by the assumption that if they did not own pharmacies, their level of service would be lower, more efficient, and professional, or not in the interests of patients in the doctor-patient-pharmacist / pharmacist chain.

According to the State Medicines Agency, currently about 68% of Estonian pharmacies do not meet the new requirements for the Law on Medicinal Products. Most pharmacies in Estonia are owned by four large networks of wholesale pharmaceutical companies.

After the reform, 469 pharmacies remained in Estonia [3], of which 25 pharmacies were closed, but five were later reopened. At the same time, three new pharmacies appeared in places where they did not exist before; three of them are closed due to repair work. That is, the total number of existing pharmacies is 474. The study of the experience of leading EU countries can be useful for the integration of the pharmaceutical business of Ukraine in the global pharmaceutical market.

The purpose of the study was to study the possibility of deepening cooperation between LMI, KhMAPE and the Estonian scientific publishing house SSP OÜ, as part of the system of Ukraine's integration into the European Community on the principles of medical and pharmaceutical law, organization and economics of pharmacy, drug technology and forensic pharmacy in order to optimize legal relationship between the “doctor – patient – pharmacist – advocate”.

Materials and methods. Information and analytical basis of the study were scientific papers on the topic of the work. It should be noted that the review of scientific sources of literature was conducted taking into account the recommendations of the Cochrane Society for PICO. The research methods used are normative and legal, documentary, retrospective, comparative, systemic, tabular, forensic, and pharmaceutical and graphic. Microsoft Excel 2010 (descriptive characteristics: minimum and maximum value, average value) was used to process the results and determine the consistency between the studied parameters.

The study of the article is a fragment of research work of LLC "Lviv Medical Institute" on "Improving the circulation of drugs in pharmacotherapy on the basis of evidence and judicial pharmacy, organization, technology, biopharmacy and pharmaceutical law" (state registration number 0120U105348, deadline 2021-2026); Kharkiv Medical Academy of Postgraduate Education on "Improving the organizational and legal procedure for providing patients with drugs from the standpoint of forensic pharmacy, organization and management of pharmacy" (state registration number 0116U003137, deadline 2016-2020) and "Pharmaceutical and Medical Law: integrated approaches to systems of drug circulation from the standpoint of forensic pharmacy and organization of pharmaceutical business" (state registration number 0121U000031, deadline 2021-2026).

Results and discussion. A study of the experience of reforms in the pharmaceutical industry in Estonia, which is part of the EU, showed that there are three levels of circulation of drugs [3]:

- 1st level of drug circulation – circulation of drugs in the system of legal relations "drug manufacturer-distributor of drugs";
- 2nd level of drug circulation – drug circulation in the system of legal relations "distributor of drugs-pharmacy-health care institution";
- 3rd level of drug circulation – drug circulation in the system of legal relations "doctor-patient-pharmacist".

Analysis of the pharmaceutical market (the 1st level of drug circulation) – production (for example, the 15 largest pharmaceutical companies in the world) in 2021 showed that there is a steady growth with global revenue of about 1.4 trillion US dollars in revenue from drug sales, namely [4]:

- ✓ 15th place in rank – Novo Nordisk (Denmark) – \$21.00 billion;
- ✓ 14th place in the ranking – Gilead Sciences (USA) – \$24.70 billion;
- ✓ 13th place in the ranking – Amgen Inc (USA) – \$26.00 billion;
- ✓ 12th place in rank – Takeda (Japan) – \$26.28 billion;
- ✓ 11th place in the rank – Eli Lilly (USA) – \$28.30 billion;
- ✓ 10th place in the ranking – GlaxoSmithKline plc (UK) – \$32.10 billion;
- ✓ 9th place – Sanofi SA (France) – \$36.55 billion;
- ✓ 8th place – AstraZeneca plc (UK) – \$37.4 billion;
- ✓ 7th place in the ranking – Merck & Co., Inc (USA) – \$42.74 billion;
- ✓ 6th place – Bristol-Myers Squibb (USA) – \$46.4 billion;
- ✓ 5th place – Hoffmann-La Roche AG (Switzerland) – \$48.47 billion;
- ✓ 4th place – Novartis International AG (Switzerland) – \$51.60 billion;
- ✓ 3rd place in rank – Johnson & Johnson (USA) – \$52.80 billion;
- ✓ 2nd place in the ranking – AbbVie Inc (USA) – \$56.20 billion;
- ✓ 1st place – Pfizer Inc (USA) – \$81.30 billion.

At the same time, the Verkhovna Rada of Ukraine considered (22.05.2022) the draft Law on Amendments to the Law of Ukraine "On Medicinal Products" to restrict the circulation of medicinal products manufactured in the Russian Federation or the Republic of Belarus (No. 7313) [5]. This Law defines [6, 7]:

- tightening restrictions on the import of drugs produced in Russia and Belarus to Ukraine;
- the right of the Ministry of Health of Ukraine to refuse to register drugs, if at least one of its components or stage of production (circulation) was carried out at plants in these two countries;
- the right of the Ministry of Health of Ukraine to refuse to register a drug if it is established that the applicant or his representative is directly or indirectly related to economic entities that are directly or indirectly involved in the production of drugs in the aggressor state (Russia or the Republic of Belarus). The established norm allows international pharmaceutical companies to refuse to register drugs even if the drugs are manufactured in other countries;
- permission to cancel the state registration of drugs, if the applicant or his representative is associated with Russian pharmaceutical companies;
- the right of the Cabinet of Ministers of Ukraine for the period of martial law in Ukraine to temporarily suspend the export of drugs in case of failure to meet the needs of the health care sector of Ukraine in such drugs in full.

Among the companies that will not be able to supply medicines to Ukraine, in particular, are pharmaceutical companies KRKA (Slovenia), Menarini (Italy), Servier (France), Acino Pharma, Novartis, GSK, Sanofi, Takeda, Dr. Reddy`s, Abbott, SUN, AstraZeneca, Novo Nordisk, Hetero.

In our opinion, it is the leadership of Ukraine that should offer and guarantee favorable conditions for the construction of 15 modern pharmaceutical plants (enterprises) with appropriate infrastructure (houses, shops, schools, kindergartens, etc.) in the regions of Ukraine (Kyiv, Lviv, Vinnytsia, Ivano-Frankivsk, Ternopil, Rivne). To achieve this goal, to involve under state guarantees the 15 largest pharmaceutical companies in the world in 2021 (USA, UK, Switzerland, Japan, France, Denmark) [4], as well as KRKA (Slovenia), Menarini (Italy), Servier (France), Acino Pharma, Novartis, GSK, Sanofi, Takeda, Dr. Reddy`s, Abbott, SUN, AstraZeneca, Novo Nordisk, Hetero.

Good Manufacturing Practice (GMP) standards require special attention to risk assessment and verification procedures [8], and it is important to identify the validation measures needed to demonstrate critical aspects of the control of specific operations. Significant changes to installations, equipment and processes that may affect the quality of pharmaceutical products must be confirmed. A risk assessment procedure should be used to determine the scope and degree of validation.

The master validation plan serves to ensure that all equipment, procedures that may affect the quality, integrity or performance of the product have been validated; it contains the general principles to be followed during the validation task and the action plans to be implemented to that end.

On behalf of the General Director of the Lviv Medical Institute (LMI), Doctor of Medical Sciences, Associate Professor Ihor Hayduchok, 12.05.2022 held a working meeting of the rector of LMI, Doctor of Medical Sciences, prof. Mykhailo Reheda with a representative of the Kharkiv Medical Academy of Postgraduate Education (Acting Rector – Doctor of Medical Sciences, Professor Oleh Korop),

Doctor of Pharmaceutical Sciences, Professor Viktoriia Shapovalova and technical editor of the Electronic multidisciplinary scientific and practical journal "Actual problems of medicine and pharmacy", editor-in-chief of the journal "SSP Modern Law and Practice", Doctor of Pharmaceutical Sciences, Professor, Attorney-at-law, Professor Valerii Shapovalov concerning the deepening cooperation between LMI, KhMAPE and the Estonian scientific publishing house SSP OÜ, as part of the system of Ukraine's integration into the European Community on the basis of medical and pharmaceutical law.

During the work, prof. Mykhailo Reheda summed up the work of the international multidisciplinary scientific and practical conference "SSP Conference on the Relationship between Doctor and Patient in a Pandemic" (SSP Conference on communication between doctor and patient in a pandemic), which took place online on April 16, 2022 (registration numbers of the event No. 240217, ACA729970).

It was noted that the organizers of the conference were:

- Lviv Medical Institute (General Director of the Lviv Medical Institute (LMI), Doctor of Medical Sciences, Associate Professor Ihor Hayduchok), Department of Anatomy, Physiology and Pathology (Head of the Department - Ph.D., Assoc. prof Olha Ryabukha, <https://orcid.org/0000-0001-6220-4381>); Department of Internal Medicine No. 2 (Head of the Department – Candidate of Medical Sciences, Assoc. Prof. Tsisnetska A.); Dean of the Faculty of Pharmacy Ph.D., Assoc. Soronovich I. (Head of the Department of Pharmaceutical Chemistry, Pharmacognosy and Botany with Resource Studies of Medicinal Plants); Department of Organization and Economics of Pharmacy, Drug Technology and Biopharmacy (Head of the Department, Candidate of Economic Sciences, Acting Associate Professor Baida B.);
- Kharkiv Medical Academy of Postgraduate Education (Acting Rector – Doctor of Medical Sciences, Professor Oleh Korop), Department of Medical and Pharmaceutical Law, General and Clinical Pharmacy (Head of the Department – Doctor of Pharmaceutical Sciences, Professor Viktoriia Shapovalova);
- Estonian scientific publishing house SSP OÜ (<https://ssp.ee/>) with the participation of the Ukrainian public organization “Association of Medical and Pharmaceutical Law” (<https://medinstytut.lviv.ua/wp-content/uploads/Zaproshehnyya-2021.pdf>);
- It was noted that the participants of the conference were very interested in the reports of prof. Viktoriia Shapovalova, Candidate of Pharmaceutical Sciences Alina Osyntseva, Assoc. prog. Anatolii Derkach, prof. Viktoriia Shapovalova, Assoc. prof. Olha Ryabukha, and others. concerning ICD-11, which was posted on the websites of journals [9-14], namely:

However, Doctor of Medical Sciences, Professor Mykhailo Reheda drew the attention of those present to address the following issues, namely:

- ❖ registration of the Electronic Multidisciplinary Scientific and Practical Journal "Actual Problems of Medicine and Pharmacy" in the Ministry of Education of Ukraine, on its inclusion in the list "B" of professional

publications in medical and pharmaceutical sciences (responsible for registration – Deputy Editor-in-Chief, Doctor of Medical Sciences, Professor Mykhailo Reheda);

- ❖ motivating the teaching staff of LMI to publish articles in international journals (Scopus, Web of Science, PubMed, Google Scholar, CrossRef, National Library of Estonia, Copernicus Index, ISSN National Center, Microsoft Academic, Open Ukrainian Citation Index, International Committee of Medical Journal Editors (ICMJE);
- ❖ conducting organizational, legal, and preparatory work in LMI on the opening of the department "Training of specialists in medicine and pharmacy in medical and pharmaceutical law, technology and safety of drugs, organization and economics of pharmacy, forensic, clinical pharmacy, biopharmacy and quality control, specialization (internships) pharmacists-interns ". Also, the peculiarities of specialization for pharmacists-interns who are graduates of higher education institutions in the specialties "Pharmacy" and "Industrial Pharmacy", regardless of the form of study – budget/contract) on the basis of internships [15];
- ❖ strengthening the work of the teaching staff of the LMI on R&D. State registration number: 0120U105348. Open R&D, registration date: 09-12-2020 "Improvement of the drug circulation system during pharmacotherapy on the basis of evidence and judicial pharmacy, organization, technology, biopharmacy and pharmaceutical law" (<https://medinstytut.lviv.ua/wp-content/uploads/pdf/Dovidka-pro-zatverdzhennya-temy-LMI.pdf>). Execution of research work on candidate and doctoral theses in medical and pharmaceutical sciences (specialty: 15.00.01 – drug technology, organization of pharmaceutical business and forensic pharmacy) with the participation of scientists LMI and on clinical bases KhMAPE (acting rector – Doctor of Medical Sciences, Professor Oleh Korop). Examples of publications on the topic [16-34];
- ❖ optimization of preparatory work on the plan on the basis of LMI together with KhMAPE (acting rector – Doctor of Medical Sciences, Professor Oleh Korop), SE "Ukrainian Scientific Pharmacopoeial Center for Quality of Medicines" (director – Doctor of Chemical Sciences, Professor Olexandr Grizodub) and other institutions (November 17-19, 2022) Register of congresses, congresses, symposiums and scientific-practical conferences to be held in 2022, agreed in the NAMS of Ukraine and approved by the Ministry of Health of Ukraine and the "Testing Center" p.p. for No. 656 and No. 665) XIX multidisciplinary scientific-practical conference "Medical and pharmaceutical law of Ukraine: organization of pharmaceutical business, general, judicial and clinical pharmacy, pharmacotherapy of health disorders" (<https://drive.google.com/file/d/13-JfmYg5tm5GEinacZkSOyf2HOur-wub/preview>). Responsible – Vice-Rector for Research of the LMI – Head of the Department of Internal Medicine No. 1, Doctor of Medical Sciences,

Professor Yurii Fedorov, Doctor of Pharmaceutical Sciences, Professor Valerii Shapovalov;

- ❖ creation of a vivarium of rats and mesh at LMI for conducting preclinical trials of drugs of all classification-legal and clinical-pharmacological groups on its basis;
- ❖ the leadership of Ukraine should offer and guarantee favorable conditions for the construction of 15 modern pharmaceutical plants / enterprises (residential buildings and infrastructure for pharmaceutical specialists) in Ukraine (Kyiv region, Lviv region, Vinnytsia region, Ivano-Frankivsk region), Ternopil region, Rivne region) pharmaceutical companies KRKA (Slovenia), Menarini (Italy), Servier (France), Acino Pharma, Novartis, GSK, Sanofi, Takeda, Dr.Reddy`s, Abbott, SUN, AstraZeneca, Novo Nordisk , Hetero.

Therewith, prof. Mykhailo Reheda acquainted the audience with the publications edited by him, namely manuals, reference books, textbooks, monographs, etc., used by the teaching staff during the training of medical students and students-pharmacists in most universities of Ukraine (<https://regeda.org.ua/annotation.htm>) [35-39].

During the exchange of views between prof. Viktoriia Shapovalova and prof. Valerii Shapovalov noted that Ukraine produces about 30 percent of vital drugs that are in circulation on the shelves of pharmacies and municipal non-profit enterprises-health care institutions and proposed the INITIATIVE (previously, for 2 years and 6 months, prof. Valerii Shapovalov tries to bring attention of the General Director of the Lviv Medical Institute (LMI), Doctor of Medical Sciences, Associate Professor Ihor Hayduchok) about the need to find sites and on its basis the construction of three modern pharmaceutical companies in Lviv (together with EU countries – Poland, Germany, Slovakia, the Czech Republic, Estonia, Denmark, etc., as well as the United States, Canada, Great Britain), which in the future could employ graduates not only LMI, but also Lviv National Medical University named after Danylo Halytsky (Rector, Academician of the National Academy of Medical Sciences of Ukraine, Ph.D., Prof. Zimenkovsky B.), which would produce not only original drugs, but also in-bulk, generics, combined drugs for all categories of citizens (patients) [40-46] of Ukraine (disabled I and II groups, participants in hostilities, liquid initiators of the Chernobyl accident, patients with cardiovascular disease, circulatory system, tuberculosis, type 1 and 2 diabetes, cancer patients, HIV/AIDS, Covid-19, SARS, orphan diseases, drug addiction, etc.), i.e. in accordance with the Resolution of the Cabinet of Ministers of Ukraine of August 17, 1998 No. 1303 "On streamlining free and preferential dispensing of medicines on prescription in the case of outpatient treatment of certain groups and certain categories of diseases" (<https://zakon.rada.gov.ua/laws/show/1303-98-%D0%BF#Text>).

Construction of modern pharmaceutical enterprises in Lviv could take place (for example) within the special economic zone and "Truskavets Resort" and "Yavoriv" (SEZ "Yavoriv") / for the period up to 1.01.2020 within the administrative and territorial boundaries of Yavoriv district of Lviv oblast, except for the territories

of the military range and military units), which was established in accordance with the Law of Ukraine (On the Yavoriv Special Economic Zone, <https://zakon.rada.gov.ua/laws/show/402-14#Text/>).

It should be noted that SEZ "Yavoriv" was created to attract investment to: create new jobs and ensure employment of employees of Yavoriv State Mining and Chemical Enterprise "Sulfur". A special legal regime of economic activity established by the Law of Ukraine "On General Principles of Establishment and Functioning of Special (Free) Economic Zones" (Vidomosti Verkhovnoi Rady Ukrainy (VVR), 1992, No. 50, p. 676) is established and operates on the territory of SEZ Yavoriv (<https://zakon.rada.gov.ua/laws/show/2673-12#Text>) taking into account the features established by this Law.

Unfortunately, investments in Special Economic Zones in Lviv Region were significantly declining every year. Foreign investor expects to restore tax and other benefits in special zones (Stadnyk G., Kanevsky D. Special economic zones of Lviv region are of less and less interest to investors // DW, 23.03.2011 (<https://www.dw.com/uk/a-14939477>, <https://p.dw.com/p/10gRJ>)).

Thus, the deepening of cooperation between LMI, KhMAPO and the Estonian scientific publishing house SSP OÜ, as part of the system of Ukraine's integration into the European Community should take into account the problems that arose during the establishment of SEZ "Yavoriv" and under state guarantees The Council of Ukraine of the relevant laws, and at the level of the Lviv Regional State Administration - the adoption of the necessary regulations of regional content on the basis of medical and pharmaceutical law.

Conclusions. The possibility of deepening cooperation between LMI, KhMAPO and the Estonian scientific publishing house SSP OÜ as part of the system of Ukraine's integration into the European Community on the principles of medical and pharmaceutical law, organization and economics of pharmacy, drug technology and forensic pharmacy to optimize the system of patient-doctor relations pharmacist-lawyer ". According to the results of the study, the urgency of creating favorable conditions for state guarantees for the construction of 15 modern domestic pharmaceutical plants in Ukraine together with the world's leading pharmaceutical manufacturers has been proved.

References.

1. Mashtalir M., Leskiv S. Integration of Ukraine into the European Union as a basis for building civil society. *Theory of state and law*. 2017. No. 6. pp. 163–166. URL: <http://pgp-journal.kiev.ua/archive/2017/6/37.pdf>.
2. Lahevee M. Estonian pharmacy market heading towards controversial reform. *Bnt*. 13.09.2019 URL: <https://bnt.eu/legal-news/estonian-pharmacy-market-heading-towards-controversial-reform/>
3. Pharmacists just getting used to post-pharmacy reform situation. *ERR.ee*. 10.07.2020. URL: <https://news.err.ee/1111675/pharmacists-just-getting-used-to-post-pharmacy-reform-situation>.

4. What are the top 15 pharmaceutical companies in the world in 2022 ranked by revenue from pharmaceutical drug sales? *GetReskilled*. 2022. March. URL: <https://www.getreskilled.com/pharmaceutical-companies/>.
5. Roll-call vote on inclusion in the agenda of the session of the draft Law on Amendments to the Law of Ukraine "On Medicinal Products to Restrict the Circulation of Medicinal Products Manufactured in the Russian Federation or the Republic of Belarus" (No. 7313). 05/03/2022 URL: http://w1.c1.rada.gov.ua/pls/radan_gs09/ns_golos?g_id=19533.
6. More than 10 international pharmaceutical companies will not be able to import European-made drugs to Ukraine due to restrictions on the circulation of drugs from Russia and Belarus. *Interfax-Ukraine*. 31.05.2022. URL: <https://interfax.com.ua/news/pharmacy/836100.html>.
7. Ukraine has banned the circulation of drugs produced in Russia and Belarus. *Minfin*. 22.05.2022. URL: <https://minfin.com.ua/ua/2022/05/22/85858097/>.
8. Turnkey Projects: A turning point for biopharmaceutical industry. *Bram-Cor*. 15.05.2022. URL: <https://www.bram-cor.com/en/en-pharmaceutical-turnkey-projects>.
9. 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>.
10. Osyntseva A. Forensic and pharmaceutical, organizational and legal study of the problem of formation, development and spread of polydrug addiction in modern conditions. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.2. P.1-18. URL: <https://doi.org/10.53933/ssppmpm.v2i2.49>.
11. Shapovalova V., Shapovalov V., Shapovalov V. 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>.
12. Hayduchok I., Shapovalov B. Covid-19: multidisciplinary researches of forensic and pharmaceutical risks and causal relationships of unqualified medical care for patients during pandemic.. 2022. *SSP Modern Law and Practice*. Vol.2. N.1. P.1-25. URL: <https://doi.org/10.53933/sspmlp.v2i1.39>.
13. Ryabukha O. COVID-19 Pandemic encourages to deepen the study of the thyroid gland: correlation portraits as a means of research in different directions of follicular thyrocytes activities. *SSP Modern Pharmacy and Medicine*. 2022. Vol. 2. N.1. P.1-21. URL: <https://doi.org/10.53933/ssppmpm.v2i1.40>.
14. Ryabukha O. COVID-19: multidisciplinary studies on the thyroid activity during the pandemic and post-covid processes. *Actual Problems of Medicine and Pharmacy*. 2022. Vol.3. N.1. P.1-25. URL: <https://doi.org/10.52914/apmp.v3i1.39>.
15. Features of specialization for interns on the basis of internships. *Ministry of Health of Ukraine*. 02.06.2022. URL: <https://moz.gov.ua/article/news/osoblivosti-prohodzhennja-specializacii-dlja-likariv-interniv-na-bazah-stazhuvannja->

16. 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>.
17. Shapovalov (Jr.) V., Gudzenko A., Shapovalova V. et al. Forensic and pharmaceutical study of the presence of a causal link between the degree of alcohol abuse and qualification level of the respondentsю. *Pharmacia*. 2017. Vol. 66. N.3. P.31–39. URL: <http://bsphs.org/wp-content/uploads/2017/11/Shapovalov.pdf>.
18. 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>.
19. Shapovalov V.V.(Jr.), Zbrozhek S.I., Shapovalova V.O. et al. Organizational and legal evaluation of availability of medicines' circulation for cancer patients. *Pharmacia*. 2018. Vol. 65, N. 2. P. 17-22. URL: <http://bsphs.org/?magazine=organizational-and-legal-evaluation-of-availability-of-medicines-circulation-for-cancer-patients>.
20. Shapovalova V.O., Shapovalov V.V., Shapovalov V.V. (Jr.) et al. Forensic pharmaceutical evaluation of polydrug addiction with concomitant use of psychoactive substances. *Likars'ka sprava*. 2018. No. 1-2 (1146). Pp. 171–177. DOI: 10.31640/JVD.1-2.2018(29).
21. Shapovalov (Jr.) V., Gudzenko A., Shapovalova V. et al. Forensic and pharmaceutical analysis of addictive morbidity because of the use of narcotic psychoactive substances in Ukraine (retrospective aspect). *International Journal of Pharmaceutical Sciences and Research*. 2018. Vol.3. Is.3. P.22-25. URL: <http://www.pharmacyjournal.net/archives/2018/vol3/issue3>.
22. 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.
23. Shapovalova V.O., Mykhailov V.S., Shapovalov V.V. The characteristics of the development of cataleptic phenomena during the action of a new Ukrainian neuroleptic--a butyrophenone derivative--in experiments on mice. *Fiziologichnyi zhurnal*. 1999. Vol.45. N.3. P 114–117.
24. Shapovalova V.O., Shapovalov V.V. Spasmophilia in children and the anticonvulsant properties of a new Ukrainian preparation containing a pyrimidine derivative. *Fiziologichnyi zhurnal*. 1998. Vol.44. N.5-6. P. 102–105.
25. 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.
26. Chuiev Y., Shapovalova V. Integrated ABC/VEN-analysis of drug prescriptions in pharmacotherapeutic schemes for relief of drunken forms of alcohol dependence. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.1. P.1-14. URL: <https://doi.org/10.53933/ssppmpm.v2i1.35>.

27. Hayduchok I., Tukhar I., Shapovalov V. Chronic pancreatitis, comorbid with alcohol addiction: epidemiology, causes, developmental features, symptoms and supportive pharmaceutical therapy. *SSP Modern Pharmacy and Medicine*. 2022. Vol.2. N.2. P.1-13. URL: <https://doi.org/10.53933/sspmmpm.v2i2.46>.
28. Shapovalov V.V., Gudzenko A.A., Zbrozhek S.I. et al. Forensic and pharmaceutical analysis of addictive morbidity because of the use of psychotropic psychoactive substances in Ukraine (retrospective aspect). *Annals of Mechnikov Institute*. 2018. N.3. P.41–44. DOI: 10.5281/zenodo.1456544. URL: http://www.imiamn.org.ua/journal/3_2018/PDF/9.pdf.
29. Shapovalov V.V., Gudzenko A.A., Shapovalova V.A. et al. Forensic and pharmaceutical analysis of addictive morbidity because of the use of psychoactive substances in Ukraine. *Clinical Informatics and Telemedicine*. 2020. Vol.15. Iss.16. P. 125-128. URL: <http://kit-journal.com.ua.doi.org/10.31071/kit2020.16.02>.
30. Gudzenko A., Shapovalov V., Shapovalov V., Shapovalova V. Forensic pharmacy: analysis of complaints about the pharmaceutical provision for privileged categories of patients in Ukraine (experimental research). *Science Review*. 2021. Vol. 2. Iss.37. P.1–6. DOI: https://doi.org/10.31435/rsglbal_sr/30042021/7517.
31. 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/sspmmpm.v1i2.32>.
32. 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>.
33. 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>.
34. 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. 2021. *SSP Modern Law and Practice*. Vol. 1. N.1. P.1–22. URL: <https://doi.org/10.53933/sspmplp.v1i1.20>.
35. Reheda M.S., Gaiduchok IG Pulmonology. Lviv: Spolom, 2000. 436 p.
36. Urgent conditions: a textbook. M.S. Regeda, V.J. Kresyun. Fright and others. View. second, ext. and processing. 2003. 891 p.
37. Regeda M.S., Fedorov J.-R.M., Hayduchok I.G. etc. Diagnosis and emergency medical care in the clinic of internal medicine. Lviv, 2013. 237 p.
38. Reheda M.S. Pleurisy. Lviv, 2013. 129 p.
39. Reheda MS, Boychuk T.M., Bondarenko Y.I. et al. Inflammation is a typical pathological process. Lviv, 2013. 149 p.

40. Shapovalova V.A., Zbrozhek S.I., Shapovalov V.V. et al. Coronavirus disease pandemia 2019: growth of epidemic dangers. *Acta scientific pharmaceutical sciences*. 2020. Vol. 4. Iss. 7. P. 61–68. URL: <https://www.actascientific.com/ASPS/ASPS-04-0559.php>.
41. Zbrozgek 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. No. 2. P. 1-32. URL: <https://doi.org/10.53933/sspm.v1i2.31>
42. 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.
43. Shapovalova V., Shapovalov V., Negretsky S. Forensic and pharmaceutical problems concerning circulation of cannabis: perspectives of state control, medical and narcological health effects. *Actual problem of medicine and pharmacy*. 2020. Vol. 1 No. 1-2. URL: <https://apmplmi.com/index.php/apmp/article/view/17>.
44. Shapovalova V.O., Shekera O.H., Gudzenko A.O. et al. Rezhym kontroliu likarskykh zasobiv dlia farmakoterapii khronichnoho pankreatytu: informatsiinyi lyst pro novovvedennia. K.: Ukrmedpatentinform MOZ Ukrainy, 2018. №289–2018. 6 p.
45. Shapovalov V.V., Shapovalova V.O. Modern state support drug patients in rural areas: analysis of complaints of citizens on principles of medical and pharmaceutical law. E-Journal: *Research Bulletin SWorld «Modern scientific research and their practical application»*. 2013. P.93-96. URL: <https://www.elibrary.ru/item.asp?id=28873229>
46. Shapovalov V.V., Shapovalova V.O., Shapovalov V.V. et al. Medychne ta farmatsevytchne pravo: navch. posib. dlia dodyplomnoi ta pisliadyplomnoi formy navchannia. Seriia «Medychne ta farmatsevytchne pravo». 4-e vyd. zi zminamy ta dopovnenniamy. Kharkiv – Ivano-Frankivsk: KhMAPO, 2020. 128 s.