State Pharmacopoeia of Ukraine and Pharmaceutical Law: State Quality Standard for Medicines for Standardization and Quality Control During Circulation in Healthcare and Pharmacy Sectors

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Abstract. The organizational, legal, scientific, theoretical, expert, educational, methodological, and practical measures to support state standards for the quality, standardization, and control of medicines during their circulation in healthcare and pharmacy are comprehensively examined. The quality requirements for medicines are summarized, and the activities are systematically categorized into organizational-legal, scientific-theoretical, and practical areas. Proposals have been developed to enhance and increase the effectiveness of the quality management system, while the components of external quality assessment in professional testing programs are carefully studied. Additionally, the document outlines the directions for scientific-expert, normative activities, and international cooperation, and it explores collaborative agreements with scientific and regulatory institutions, paving the way for innovative practices that further improve public health outcomes and safety standards. Furthermore, the research emphasizes the importance of cross-disciplinary approaches, integrating modern technological solutions and data-driven strategies to streamline regulatory processes and ensure consistent adherence to safety protocols. Stakeholder engagement, including input from healthcare professionals, pharmacists, and researchers, is considered crucial for identifying emerging challenges and best practices within the quality control landscape. Strategic partnerships with international organizations reinforce a global commitment to quality assurance, enabling comprehensive knowledge exchange and harmonization of regulatory standards. These initiatives ultimately contribute to a robust framework that safeguards public health, fosters improvement in pharmaceutical governance, and enhances system resilience in the face of challenges.

Keywords: State Pharmacopoeia of Ukraine, medicines, circulation, quality control.

Introduction. The European Union's comprehensive strategy against the illicit trafficking of falsified medicines underlines the commitment to protecting public health to maintain trust in the healthcare and pharmaceutical sectors [1, 2]. Therefore, by implementing strict legislation (Directives) and regulatory measures, innovative security measures, raising awareness among doctors and pharmacists in Ukraine and promoting international cooperation, the European Union is trying to protect patients from the dangers of falsified medicines. It is falsified medicines that pose a significant threat to public health, undermining trust in healthcare and putting patients' well-being at risk. Recognizing the seriousness of this problem, the European Union has implemented a multifaceted strategy to combat the distribution and marketing of falsified medicines in its Member States. Counterfeit medicines, according to the forensic pharmaceutical assessment criteria, are counterfeit products intentionally created to deceive consumers (doctors, pharmacists, patients) by imitating legitimate (registered for circulation) pharmaceuticals (or active pharmaceutical ingredients), containing [3-9]:

- incorrect ingredients;
- incorrect doses;
- no active ingredients at all, which poses a serious risk to the health and safety of patients;
- contribute to antimicrobial resistance;
- reduce the effectiveness of treatment, resulting in disease complications, the development of concomitant health disorders, disability, or death, in accordance with ICD-11 [10-12].

In the context of global health, the World Health Organization initiates the implementation of the 10th edition of the Compendium on Quality Assurance of Pharmaceuticals, which [13]:

- is a collection of guidelines and related materials;
- is an important resource for the healthcare sector of countries around the world, designed to strengthen pharmaceutical standards;
- plays an important role in compliance with generally accepted standards of good manufacturing practice (GMP) and inspections;
- through 46 guidelines, including 8 new and 10 revised, provides a comprehensive basis for improving regulatory systems and international standards for ensuring the quality of medicines of all clinical and pharmacological, classification and legal, nomenclature and legal groups [14].

The implementation of the European Union strategy to combat the circulation of falsified medicines is a guide for the State Service of Ukraine for Medicines and Drug Control. A seminar was held on this topic (November 27-28, 2024, Kyiv) on licensing and certification of distributors for compliance with the requirements of good distribution practice (GDP), requirements and rules for proper transportation and storage of medicines, organized with the participation of the Italian Medicines Agency (AIFA), the State Control Agency under the Ministry of Health of Lithuania, the Croatian Agency for Medicines and Medical Devices (HALMED) within the framework of the European Union's TAIEX institution-building instrument [15]. The seminar participants:

- deepened their knowledge of European Union legislation on licensing and certification of distributors for compliance with GDP requirements;
- familiarized themselves with the experience of European Union Member States on modern approaches and current international norms and rules that apply during circulation at the stage of transportation and storage of medicines;
- studied the issues of development and further implementation of regulatory legal acts and standards of the European Union in the pharmaceutical sector;
- heard the level of ensuring compliance of national legislation on the quality of medicines and medical devices with the requirements of the European Union;
- got acquainted with the procedure for implementing European Union projects within the framework of the Technical Assistance Information Exchange (TAIEX) instrument, which is an important guarantee of effective implementation of reforms in Ukraine in accordance with the provisions of the Association Agreement between Ukraine and the European Union; serves as an effective platform for exchanging best practices in the implementation and use of institution-building instruments in the countries of the European Neighborhood Instrument.

At the same time, in accordance with the European Union Directives and WHO recommendations, the 14th annual Pharmacy Summit of Ukraine was held (December 03, 2024, Kyiv). Isayenko R. (Head of the Service) and Vovk G. (Deputy Head of the Service) represented the State Service of Ukraine for Medicines and Drug Control. During participation in panel discussions on the topics “Current Challenges of Today” and “Evolution of Medicines Supply in Turbulent Times”, it was emphasized [16]:

- the number of licensees in wholesale and retail trade, import of medicines, number of pharmacies in rural areas;
- the decisions taken by the State Service of Ukraine for Medicines and Drug Control, which should contribute to ensuring stable access of the population to medicines;
- the resumption of scheduled inspections by the State Service of Ukraine for Medicines and Drug Control from January 1, 2025;

- ❖ state support measures for the opening of pharmacies in rural areas (mobile pharmacies);
- ❖ regulatory activities of the State Service of Ukraine for Medicines and Drug Control;
- ❖ understanding of current problems of the pharmaceutical industry and identifying ways to overcome them.

The Pharmacy Summit was an opportunity to discuss steps to strengthen the national pharmaceutical infrastructure, further improve the system of legal relations "doctor-pharmacist-patient" on the principles of medical and pharmaceutical law, guaranteeing access of the population, patients and privileged categories of citizens (participants in hostilities, disabled people of groups I and II, liquidators of the Chernobyl accident, children, etc.) to high-quality, safe, effective and economically affordable medicines of all clinical-pharmacological, classification-legal and nomenclature-legal groups [17].

In order to further improve the system of legal relations "doctor-pharmacist-patient-quality control expert-lawyer" on the eve of the seminar (27-28.11.2024, Kyiv) [15] and the Pharmacy Summit of Ukraine (03.12.2024, Kyiv) [16], within the framework of the European Union's institutional building instrument Technical Assistance Information Exchange (TAIEX) [18], the XXI International Multidisciplinary Scientific and Practical Conference "Medical and Pharmaceutical Law of Ukraine: Organization and Economics of Pharmaceutical and Medical Affairs, Drug Circulation, Technology, Safety, Efficiency, Quality Control, General, Forensic, Evidence-Based and Clinical Pharmacy and Medicine, Pharmacotherapy of Health Disorders" (14-15.11.2024, Lviv-Kyiv-Tallinn) was held. A wide range of issues were considered [19-44]:

- ➢ deepening the level of interaction between the countries of the European Union and Ukraine regarding the further implementation of European norms of pharmaceutical and medical law;
- ➢ implementation of the principles of evidence-based pharmacy and effective quality control (physicochemical, analytical, temperature regime, etc.) at all stages of circulation (storage, transportation, accounting, use, certification, standardization, quality control, prescription, administration, etc.) of medicines from development to introduction into industrial production and medical practice;
- ➢ further implementation of the State Pharmacopoeia of Ukraine in all levels of the healthcare and pharmacy sector;
- ➢ strengthening the national pharmaceutical infrastructure, further improvement of the system of legal relations "doctor-pharmacist-patient" on the principles of medical and pharmaceutical law;
- ➢ guaranteeing access of the population, patients and privileged categories of citizens (participants in hostilities, disabled people of groups I and II, liquidators of the Chernobyl accident, patients with diabetes mellitus of groups I and II) with health disorders (covid, post-covid, long-covid, cardiovascular, HIV/AIDS, addictive, psychoneurological, oncological, orphan, PTSD, comorbid, chronic, infectious, non-infectious) to high-quality, safe, effective and affordable medicines of all clinical-pharmacological, classification-legal and nomenclature-legal groups
- ➢ effective counteraction to the circulation of counterfeit medicines, elimination of medical errors, violation of the rules for the circulation of medicines, etc.

The purpose of the study was to research based on the principles of the State Pharmacopoeia of Ukraine and pharmaceutical law, to consider the level of organizational and legal, scientific and theoretical, scientific and expert, educational and methodological and practical measures implemented to support state standards for the quality of medicines, standardization and quality control of medicines during their circulation in the field of health care and pharmacy.

Materials and methods. Research period: 01.01.24-12.12.24. Research base – State Enterprise "Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicines". International and state regulatory documents on the topic of the work were used. Quality systems for providing services for certification of pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine, conducting scientific research related to the standardization and quality of medicines, are certified for compliance with the requirements of DSTU ISO 9001: 2009 (certificate UA 2.003.08911-15 dated

11.03.2015). The Pharmacopoeial Analysis Laboratory of the Pharmacopoeial Center operates in accordance with the requirements of DSTU ISO/IES 17025:2006 “General requirements for the competence of testing and calibration laboratories” (except for the requirements for the competence of calibration laboratories), the recommendations of PIC/S PH 2/95 “Recommendations on the quality system for official drug control laboratories” and the requirements set forth in the WHO recommendations “Good practices for national drug control laboratories” (WHO good practices for pharmaceutical quality control laboratories, WHO TRS No. 957, 2010).

To solve the tasks set, the following research methods were used: documentary, comparative, regulatory, retrospective, historical, forensic pharmaceutical analysis; mathematical and graphical methods; statistical evaluation and mathematical data processing were carried out using modern computer technologies.

Results and discussion. Human life and health are defined in Ukraine as the highest social value (Article 3) [45]. Therefore, the state takes care of protecting the rights and freedoms, life and health of every person and patient to access high-quality, effective, safe, and economically affordable medicines of all clinical and pharmacological, classification and legal, nomenclature and legal groups.

It is the improvement of the system of legal relations "doctor-patient-pharmacist" on the principles of pharmaceutical law and awareness of citizens and patients that contributes to their access to the circulation of high-quality medicines. As experts of the State Service of Ukraine for Medicines and Drug Control emphasize, the patient, after the doctor prescribes the medicines to him, has the right to express requirements for the quality of medicines [46]. Requirements to the quality of medicines are shown in Fig. 1.

Fig. 1. Requirements to the quality of medicines.

It is important to note that the State Service of Ukraine for Medicines and Drug Control has identified the State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products” as a structural unit subject to the requirements of the quality management system [47].

Thus, the State Enterprise “Ukrainian Scientific Pharmacopoeial Center for the Quality of Medicinal Products” is the leading scientific institution of Ukraine in the field of standardization and quality control of medicinal products.

The main organizational, legal, scientific, theoretical, and practical areas of activity have been identified [48, 49]. They are shown in Fig. 2.

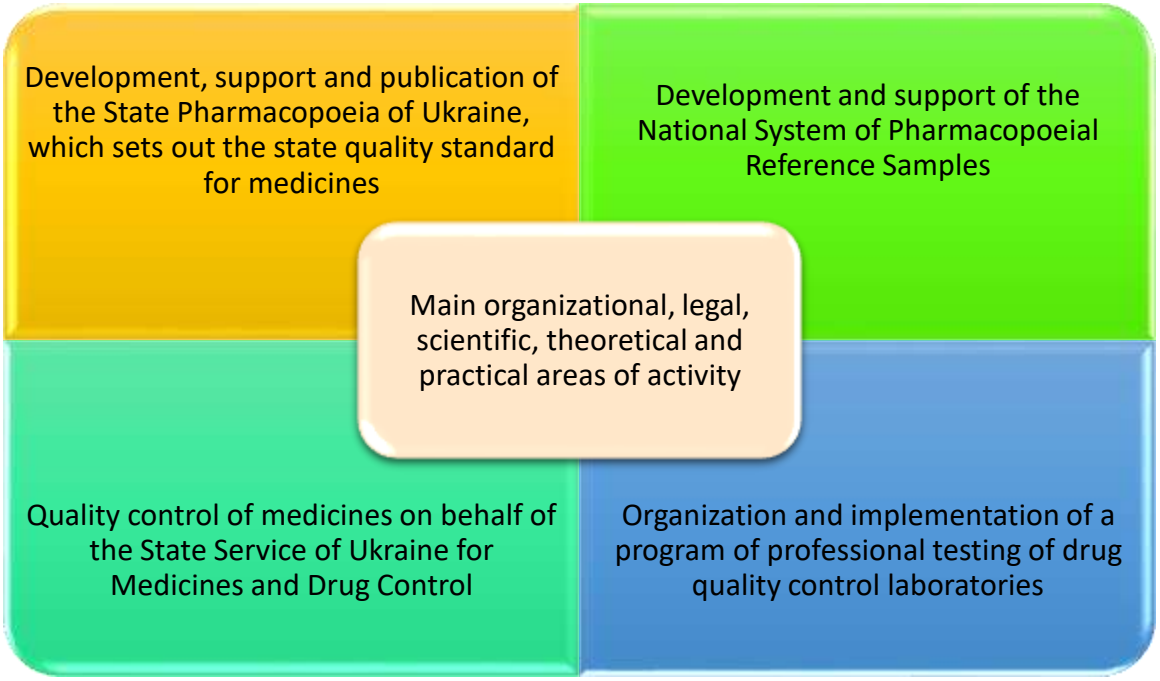

Fig. 2. Main organizational and legal, scientific, and theoretical and practical areas of activity.

According to the results of the documentary analysis, it was established that in 2024, organizational and legal, scientific, and theoretical research at the state enterprise "Ukrainian Scientific Pharmacopoeia Center for the Quality of Medicines" (hereinafter referred to as the Pharmacopoeia Center) was carried out in the following areas.

Development of the State Pharmacopoeia of Ukraine

The State Pharmacopoeia of Ukraine was systematically updated as a component of the system for standardizing the quality control of drugs, its harmonization with the European Pharmacopoeia, the American Pharmacopoeia (USP), the development and introduction into the State Pharmacopoeia of texts and articles on the validation and statistics of medicinal plant raw materials, for biological testing, and the update of the article "Medicines manufactured in pharmacies".

Amendment 7 to the State Pharmacopoeia of Ukraine in 2 volumes was put into effect by order of the Ministry of Health of Ukraine dated May 2, 2024 No. 754) [50].

The development and editing of texts for the State Pharmacopoeia of Ukraine, which were initiated in previous supplements to the State Pharmacopoeia of Ukraine, 2nd edition, continued.

Formation of a base of quality standards for biological medicinal products for veterinary medicine

Developed: 6 articles on biological tests; 3 articles on biological methods of quantitative determination; 4 articles on general texts on microbiology; 6 articles on general texts on biological medicinal products; 2 articles on monographs on dosage forms; 9 articles on monographs on vaccines for use in veterinary medicine; 1 article on suture materials for human use.

Formation of a base of quality standards for medicinal plant raw materials and medicinal plant preparations

Developed: 16 new monographs on medicinal plant raw materials, of which 8 are national monographs, including the monograph "Standardized Cannabis Extract N". 19 monographs on medicinal plant raw materials were revised; 3 articles on pharmaco-technological tests.

Formation of a database of quality standards for radiopharmaceuticals

Developed: 1 article on new texts.

Formation of a database of quality standards for homeopathic preparations

Developed: 1 article on new texts.

Formation of a database of quality standards for pharmaceutical preparations manufactured in pharmacies

Developed: 2 new monographs.

Revision of existing texts in accordance with the current edition of PhEur

Developed: 1 section on materials and containers; 2 sections on reagents; 18 articles on analysis methods; 3 monographs on substances.

Harmonized versions were prepared:

- ✓ general articles of the State Pharmacopoeia of Ukraine on the topic "Chemical precursors for radiopharmaceuticals";
- ✓ general text of recommendations on the use of tests for bacterial endotoxins;
- ✓ general monograph "Radiopharmaceuticals";
- ✓ monograph on dosage forms "Parenteral drugs";
- ✓ reviewing the general text 2.2.55. "Peptide mapping".

The Pharmacopoeial Analysis Laboratory is engaged in quality control of drugs. Fig. 3 shows quantitative indicators of quality control in the areas: state control at the direction of the State Service of Ukraine for Medicines and Drug Control; analysis at the request of the customer and technical assistance; development and validation of biological methods; quality analysis by biological indicators; development of microbiological methods; quality analysis by chemical and physicochemical indicators.

Analysis and settlement of complaints, claims, analysis, and implementation of proposals from employees, customers (if any)

Claims from customers are resolved in the working order. Proposals from employees who come to the quality management group of the pharmacopoeial analysis laboratory are resolved in the working order.

Feedback from customers (positive and negative, if any)

During 2024, positive feedback was received from 10 Ukrainian drug manufacturers. Refusals from testing are also recorded in cases where small enterprises (individual entrepreneurs, small suppliers of plant raw materials, etc.) do not agree to use the laboratory's services due to the high cost of testing for these customers.

Functioning of the laboratory quality management system

During the analysis of the effectiveness and efficiency of the quality management system, assessment of the possibility of its improvement, the need for changes, as well as subsequent adoption of appropriate decisions, the results of external and internal audits of the laboratory quality management system were processed. Customers conducted 10 external audits: 3 on-site audits (with a review of the laboratory by the customer's auditors) and 7 audits in the form of a remote questionnaire. Internal audits of the quality management system were conducted as planned.

Feedback from customers, including complaints, measures taken to resolve them

Complaints are received orally (by telephone). They are resolved as they are received in a working order. Complaints (appeals) from customers mostly concern the timing of receiving analysis results.

Processed data from tests with results outside the specifications, causes of non-conformities

All tests with results outside the OOS specifications are investigated in accordance with CPM 2-1.006. No laboratory errors were detected. All non-conformity analysis results are related to the quality of the samples provided.

Assessment of the functioning of the quality management system processes

All processes of the quality management system that depend on laboratory employees' function properly in accordance with the procedures described in internal documents. Providing the laboratory with material resources depends on the financial capacity of the enterprise.

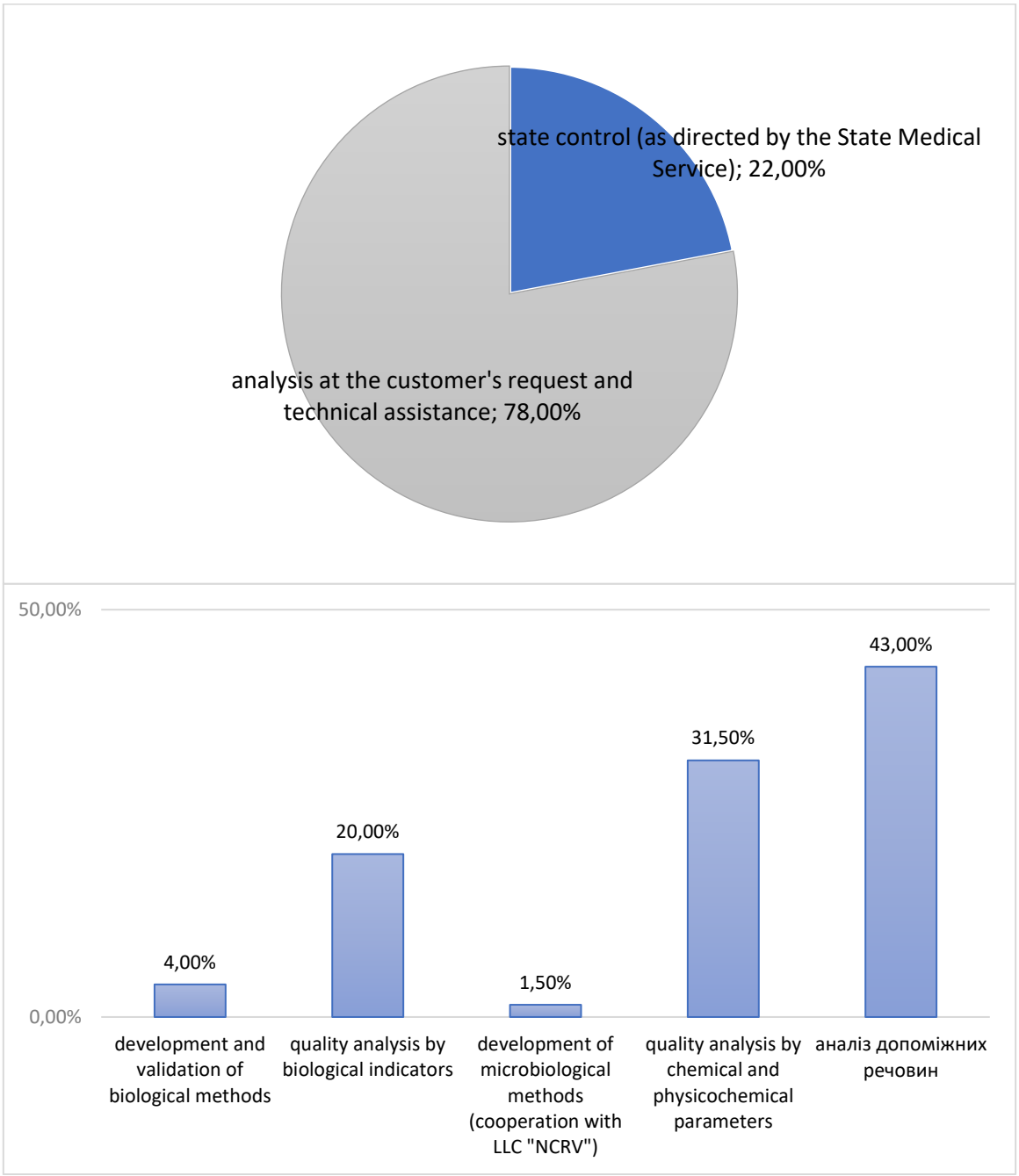

Fig. 3. The ratio of the number of batches submitted for laboratory quality analysis.

Changes in the field of certification:

The following methods have been added to the certification of the pharmacopoeial analysis laboratory:

- quantitative determination of cardiac glycosides by the in vivo method;
- identification by the coagulological method in low molecular weight heparins;

- quantitative determination of heparin.

Biological methods of analysis

Development of general articles of the State Pharmacopoeia of Ukraine for biological tests. For the first time in Ukraine, a set of works was carried out on the implementation and verification of the most modern method for determining pyrogenic contamination using recombinant protein. A monograph of the State Pharmacopoeia of Ukraine on the topic "Tests for bacterial endotoxins using recombinant factor C" was developed.

Proposals for improving and increasing the effectiveness of the quality management system

Proposals for improving and increasing the effectiveness of the quality management system were developed (Fig. 4).

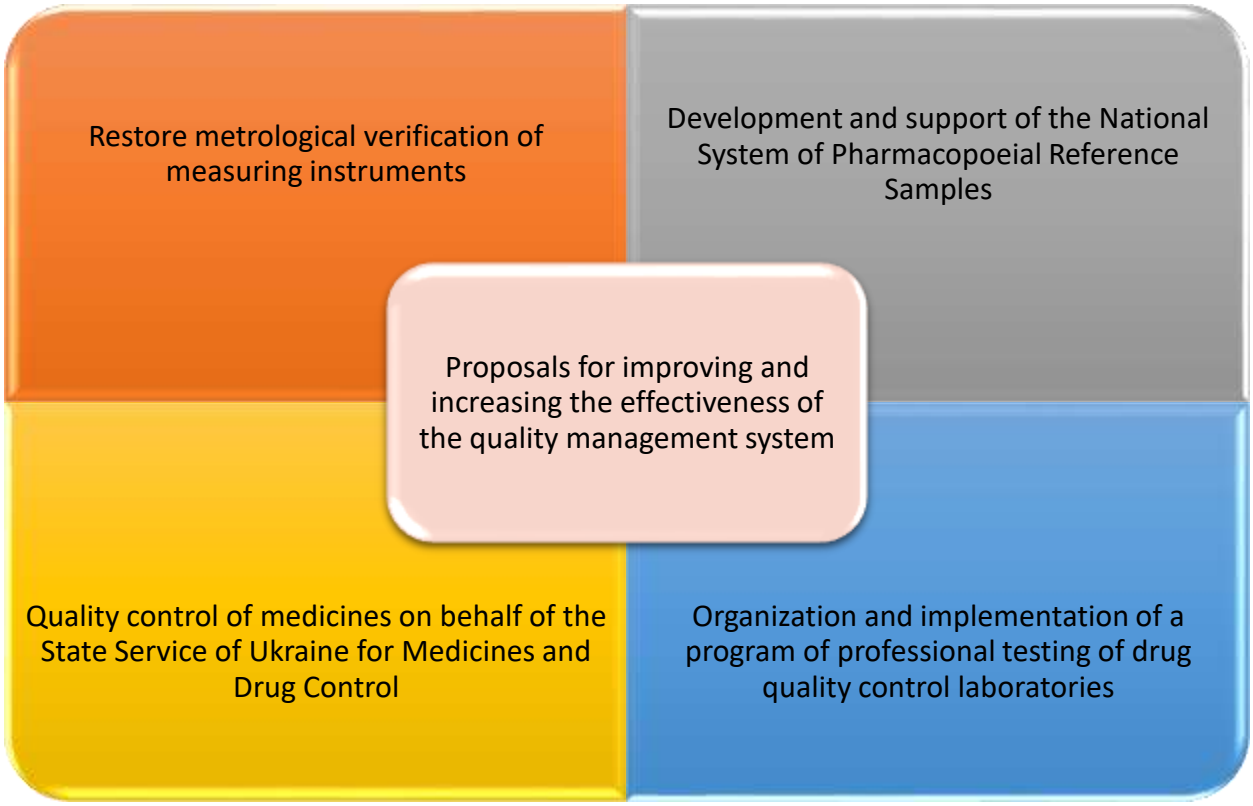

Fig. 4. Proposals for improving and increasing the effectiveness of the quality management system.

Experimental support sector for the development of monographs on medicinal plant raw materials

Main areas: development, certification, implementation of pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine of plant origin, quality control of medicinal plant raw materials. Preparation of a dossier for each type of medicinal plant raw materials in accordance with CPM 4-1.004 "Procedure for the development of national monographs and/or monographs with a national part on medicinal plant raw materials for inclusion in the State Pharmacopoeia of Ukraine".

Developed:

- Procedure for developing pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine on medicinal plant raw materials
- Procedure for purchasing, storing, and disposing of medicinal plant raw materials

Revised:

- “Procedure for developing national monographs and/or monographs with a national part on medicinal plant raw materials for inclusion in the State Pharmacopoeia of Ukraine”.

Development of draft monographs for the State Pharmacopoeia of Ukraine:

- ❖ 20 new monographs on medicinal plant raw materials, including 7 national monographs
- ❖ 19 monographs on medicinal plant raw materials in accordance with EuPh 11.7
- ❖ 5 general monographs

Educational and methodological activities. Professional Testing Programs

Professional testing programs for pharmaceutical quality control laboratories train personnel to perform standard analytical procedures [51, 52]. External assessment of the quality of analytical results is shown in Fig. 5.

Analyst's work with a volumetric flask, evaluation of analyst's work with volumetric flasks, providing participants with the necessary information to identify problems and improve their work with measuring vessels, providing participants with recommendations on criteria for evaluating analyst's qualifications when working with volumetric flasks

Quantitative determination of analytes in solution by liquid chromatography, evaluation of the work of analytical laboratories for quality control of medicinal products when conducting quantitative tests by liquid chromatography, providing participants with the necessary information to identify problems and improve their work when conducting quantitative tests by liquid chromatography

Fig. 5. External assessment of the quality of analysis results.

Statistical assessment of the level of qualification of analysts when working with a volumetric flask was carried out according to the approaches of the State Pharmacopoeia of Ukraine. The acceptance criterion calculated for the maximum permissible level of unsatisfactory results of 5% adopted in analytical practice is 8.1. According to the results of the statistical assessment, the level of qualification of analysts when working with a volumetric flask in the industry is unsatisfactory. Laboratories that showed unsatisfactory results require further training of personnel.

In the task “Quantitative determination of the analysis in solution by liquid chromatography” an integral test was used to assess the test participants, which assesses the correctness of the functioning of the components of the analytical system. The correctness of the test was assessed according to the main and additional acceptance criteria, as follows:

- 41 analysts (98% of the total number of participants) received satisfactory results when assessed according to the main acceptance criterion;
- 38 analysts (90% of the total number of participants) received satisfactory results when assessed according to the additional acceptance criterion.

Laboratories that received unsatisfactory results require staff training and, possibly, verification of the correct functioning of the components of the analytical system.

Scientific and expert, international cooperation

Scientific and expert, international cooperation is shown in Fig. 6.

Fig. 6. Scientific and expert, international cooperation.

Among the organizational and legal measures, it is necessary to indicate the instruction of the Minister of Health of Ukraine Lyashko V. dated December 29, 2023 No. DM64/6-23 and the order of the State Service for Medicines and Drug Control dated August 19, 2024 No. 1268. Experts of the

Pharmacopoeia Center studied, developed, and revised draft regulatory legal acts to implement the Law of Ukraine dated July 28, 2022 No. 2469-IX “On Medicines” [54]. The areas of regulatory activity are shown in Fig. 7.

Fig. 7. Areas of regulatory activity.

The results of the work of the working group on the development of regulatory legal acts for the implementation of the Law of Ukraine “On Medicinal Products” No. 2469-IX [58] are shown in Fig. 8.

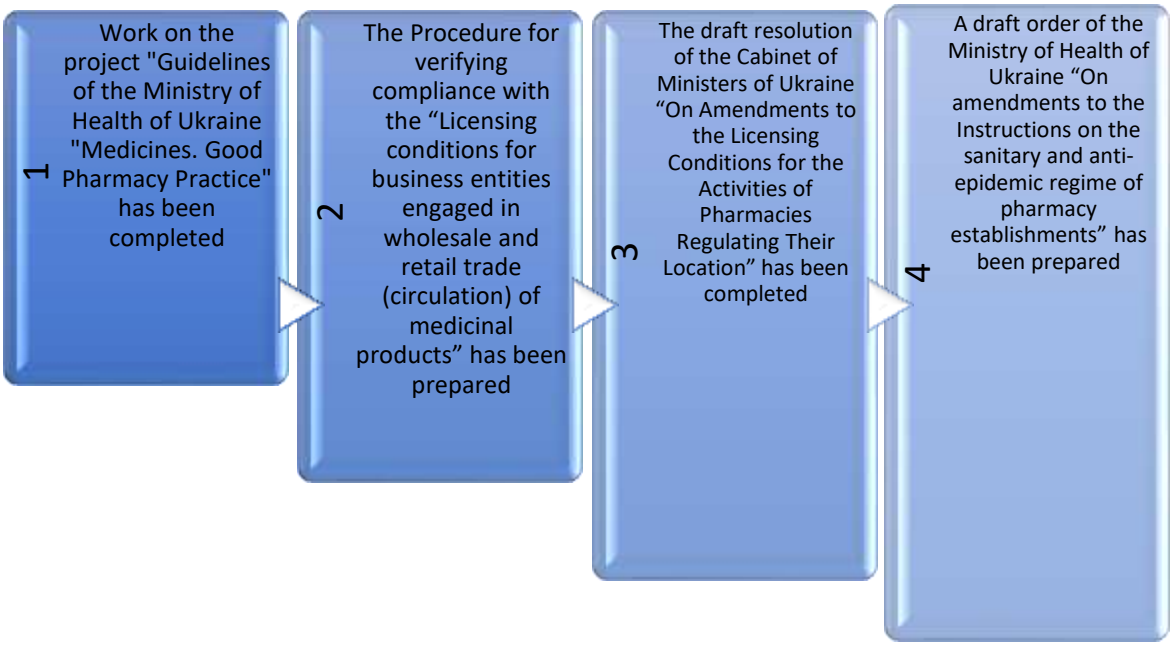

Fig. 8. Developments in the development of regulatory legal acts for the implementation of the Law of Ukraine "On Medicinal Products" No. 2469-IX

Scientific and expert employees of the Pharmacopoeia Center ensured the implementation of the agreements stipulated in the Memorandum of Understanding signed between the US Pharmacopoeia Convention and the State Service for Medicines and Drug Control, the European Union, and the Ministry of Health of Ukraine (Fig. 9).

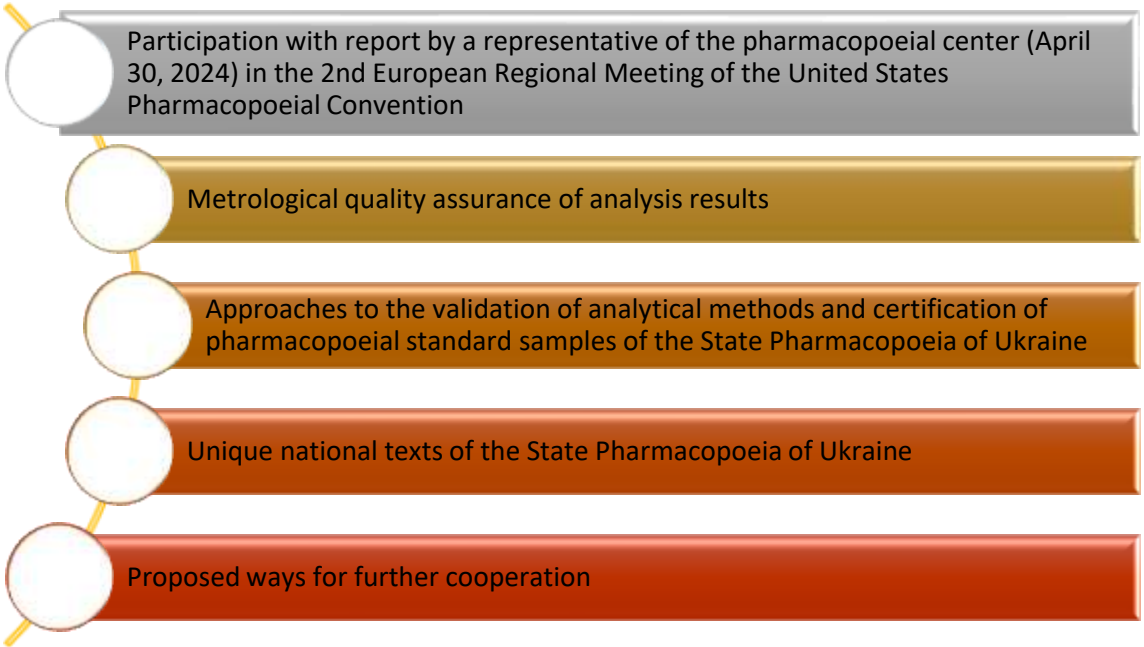

Fig. 9. Agreements in the Memorandum of Understanding.

Participated (18.04.2024) in the explanatory session of the European Commission on consumer protection and health protection. It took place within the framework of the official EU screening, dedicated to Chapter 28 "Consumer protection and health protection" [59]. The implementation of Chapter 28 "Consumer protection and health protection" [59] is shown in Fig. 10.

Fig. 10. Implementation of Section 28 "Consumer Protection and Health Care" [59].

Among the important practical measures to improve the level of work of the Pharmacopoeia Center, important cooperation agreements have been concluded [60-62].

A cooperation agreement has been concluded with the Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law" (Fig. 11).

At the joint initiative of the Pharmacopoeia Center and the State Service for Medicines and Drug Control in the Kharkiv Region, a Memorandum of Cooperation was concluded (Fig. 12).

At the joint initiative of the Pharmacopoeia Center and the Kharkiv Regional State Laboratory of the State Service of Ukraine for Food Safety and Consumer Protection, a Memorandum of Cooperation was concluded with the aim of:

- ✓ ensuring cooperation in the exchange of experience and expanding professional knowledge;
- ✓ effective interaction, development of long-term partnerships to maintain the high reputation of leading institutions in the state and at the international level;
- ✓ providing advisory support in key areas of further cooperation, strengthening cooperation, which opens new prospects for both organizations, which is especially relevant in difficult conditions of war and other challenges (pandemic, monkeypox virus, post-covid syndrome, circulation of counterfeit medicines), to ensure pharmaceutical and medical security in Ukraine.

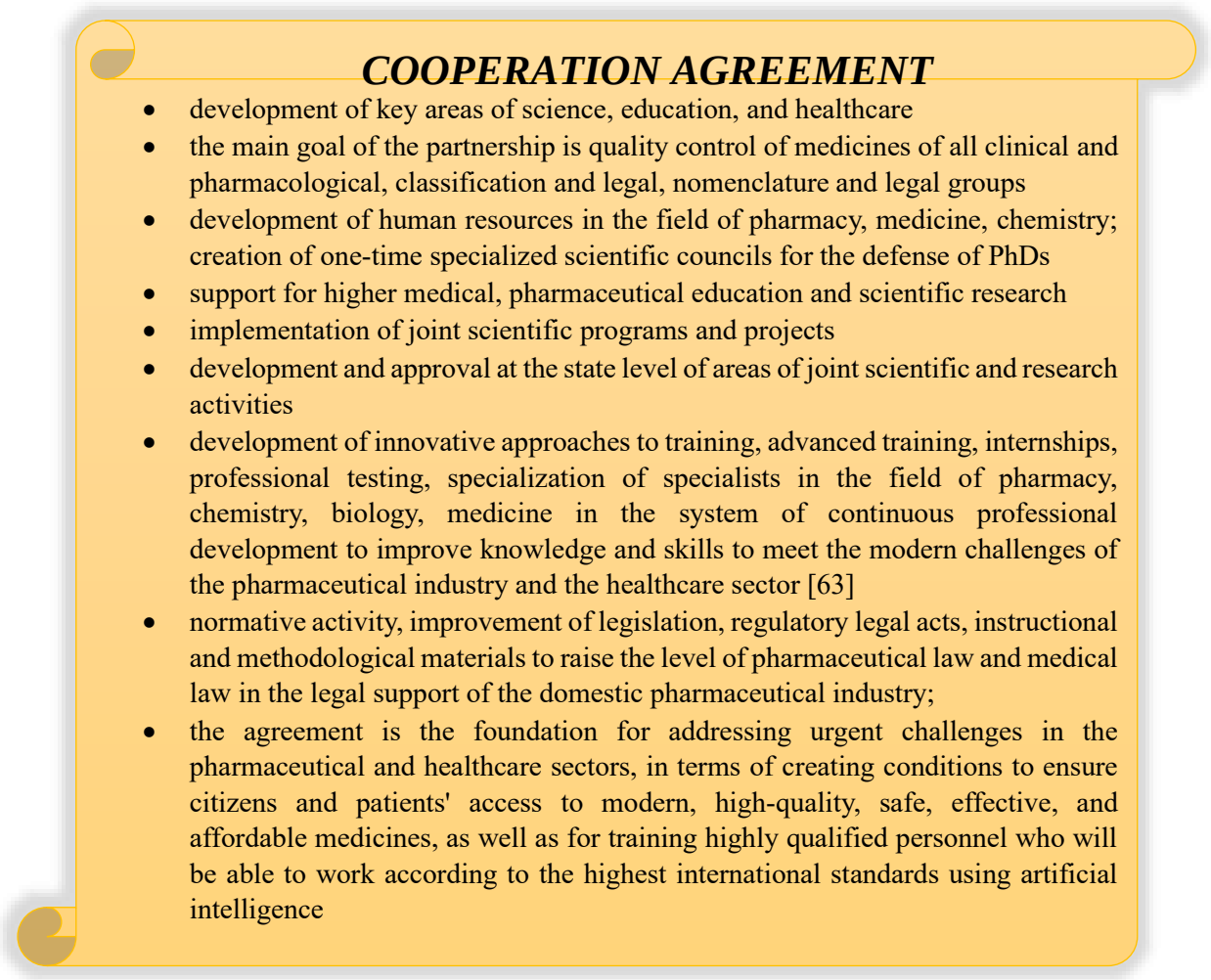

Fig. 11. Cooperation Agreement with the Private Scientific Institution "Scientific and Research University of Medical and Pharmaceutical Law".

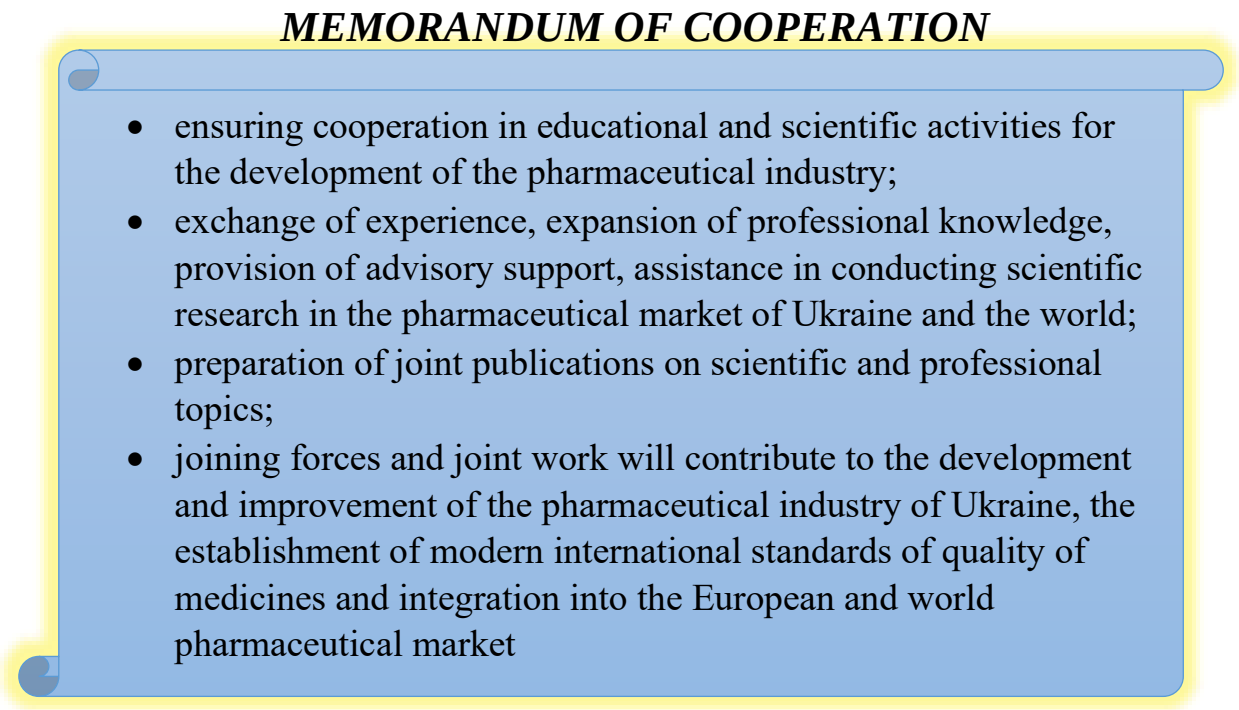

Fig. 12. Memorandum of Cooperation between the Pharmacopoeia Center and the State Service for Medicines and Drug Control in Kharkiv Region.

Thus, based on the State Pharmacopoeia of Ukraine and pharmaceutical law, the level of organizational, legal, scientific, expert, educational, methodological, and practical measures implemented during 2024 by expert and scientific specialists of the Pharmacopoeial Center to support state quality standards for medicines, as well as standardization and quality control of medicines during their circulation in the field of healthcare and pharmacy was considered.

Conclusions. The strategy of the World Health Organization on the implementation of the 10th edition of the Compendium on Quality Assurance of Pharmaceuticals was considered. The levels of interaction between the countries of the European Union and Ukraine on the further implementation of European norms of pharmaceutical and medical law were analyzed. The directions of organizational, legal, scientific, theoretical, and practical measures of the Pharmacopoeial Center were studied (certification of pharmacopoeial standard samples of medicines; quality control of medicines, professional laboratory testing programs; scientific activity).

Declaration of conflict interest. The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article. The authors confirm that they are the authors of this work and have approved it for publication. The authors also certify that the obtained data and research were conducted in compliance with the requirements of moral and ethical principles based on medical and pharmaceutical law, and in the absence of any commercial or financial relationships that could be interpreted as potential conflict of interest.

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Data availability statement. The datasets analyzed during the current study are available from the corresponding author on reasonable request.

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