# PROBLEMS OF PHARMACEUTICAL EDUCATION IN UKRAINE: TOPICAL ISSUES AND ELABORATION OF WAYS TO SOLVE THEM

Krychkovska A. M., Hubytska I. I., Monka N. Ya. DOI https://doi.org/10.30525/978-9934-26-430-6-20

#### INTRODUCTION

The training of professionals for the pharmaceutical industry in Ukraine for the segment of industrial pharmacy and the segment of wholesale and retail trade in medicines and medical devices (MD) in the specialty "Pharmacy, Industrial Pharmacy" is carried out by 28 higher education institutions, including Lviv Polytechnic National University (LP National University). Our previous research concerned a comparative analysis of the similarities and differences between the educational components of the educational programs of the specialty 226 "Pharmacy, Industrial Pharmacy" 1. However, with the introduction of the Specialty Standard in 2022, two separate specializations 226.01 "Pharmacy" and 226.02 "Industrial Pharmacy" were introduced within one specialty 226 "Pharmacy, Industrial Pharmacy"<sup>2</sup> . Masters in various specializations of this specialty can, at the beginning of their career, be employed at various enterprises of the pharmaceutical industry, both retail and (pharmaceutical intermediary wholesale firms, warehouses, pharmacies) and industrial pharmaceutical enterprises. However, further employment has certain differences in accordance with the principles of internship and confirmation of qualifications.

Prior to the adoption of the Standard of Higher Education of the second (master's) level of higher education in the field of study 22 "Health Care", specialty 226 "Pharmacy, Industrial Pharmacy", specialization 226.01

<sup>&</sup>lt;sup>1</sup> Krychkovska A., Lopatynska O., Hubytska I., Krvavych A., Lubenets V. (2024). The Comparative Analysis of Components of Pharmacy Education Programs in Universities of EU Countries and Ukraine. Archives of Pharmacy Practice, 15(1), 23-32. https://doi.org/10.51847/8Lt9YBxFk6.

<sup>&</sup>lt;sup>2</sup> Про затвердження Стандарту вищої освіти спеціальності 226 Фармація, промислова фармація для другого (магістерського) рівня вищої освіти: Наказ Міністерства освіти і науки України від 04 листопада 2022 року № 981 https://mon.gov.ua/storage/app/media/vishcha/osvita/zatverdzeni%20standarty/2022/11/11/226Farmatsiya.promyslova.farmatsiya.mah istr-981-04.11.2022.pdf

"Pharmacy", 226.02 "Industrial Pharmacy" in 2022, the training of higher education applicants in the specialty "Pharmacy, Industrial Pharmacy" was carried out by the Department of Technology of Biologically Active Compounds, Pharmacy and Biotechnology of Lviv Polytechnic National University under educational and professional programs (EPP) and educational and scientific programs (ESP) at three levels of higher education: first (bachelor's), second (master's), third, educational and scientific, (doctor of philosophy).

In 2023, for the first time, the NU LP enrolled in the cross-cutting EPP "Industrial Pharmacy" (300 ECTS credits) in the specialty 226.02 "Industrial Pharmacy" of the specialty 226 "Pharmacy, Industrial Pharmacy".

According to the Standard, the object of activity for students of specialization 226.01 "Pharmacy" is the development, production, quality control, wholesale and retail sale of medicines, pharmaceutical services, pharmaceutical care, and for students of specialization 226.02 "Industrial Pharmacy", respectively, the object is the development and industrial production of medicines, production technologies, quality control testing, pharmaceutical quality system. The academic rights of graduates allow them to obtain a Doctor of Philosophy degree and additional qualifications in the adult education system. For the specialization 226.01 "Pharmacy", additional training in an internship and the acquisition of a secondary pharmaceutical specialization or confirmation of a professional category are provided. In general, the organization of the educational process is regulated by the requirements for the specifics of licensing educational programs for regulated professions<sup>1</sup>. However, for the specialty 226.02 "Industrial Pharmacy", internship training with the possibility of acquiring a secondary pharmaceutical specialization is not provided by the Higher Education Standard.

The purpose of our study was to explore the possibilities of amending the Standard of Education for the specialty 226 "Pharmacy, Industrial Pharmacy", which would allow industry specialists to continue working in both wholesale and retail and industrial enterprises of the pharmaceutical industry.

The paper uses a meta-analysis of regulations on the provision of pharmaceutical education and assessment of the quality of educational services provided by higher education institutions (HEIs), a retrospective of changes within the pharmaceutical specialty, and methods of analysis and synthesis to study and solve the problems of pharmaceutical education in Ukraine.

## 1. Overview of the formation and development of the specialty 226 "Pharmacy, industrial pharmacy" of the field of knowledge 22 "health care" in Ukraine

According to the Order of the Cabinet of Ministers of Ukraine (CMU) No. 266 dated 29.04.2015 "On Approval of the List of Fields of Knowledge and Specialties for the Training of Higher Education Applicants" (as amended), Order of the Ministry of Education and Science of Ukraine No. 1151 dated 06.11.2015 "On the peculiarities of the introduction of the List of fields of knowledge and specialties for the training of higher education entrants", the specialty 15.00.01 "Drug Technology, Organization of Pharmaceutical Business and Forensic Pharmacy" was renamed to specialty 226 "Pharmacy" (Field of Knowledge 22 "Health Care"). The new specialty became the successor of the specialty 15.00.01 "Drug Technology, Organization of Pharmacy and Forensic Pharmacy" at the third educational level. The data on the correspondence of fields of knowledge and specialties according to the introduced changes for the second level of higher education are given in Table 1<sup>3</sup>

Table 1
Fields of knowledge and codes of the specialty "Pharmacy"
before 2015 and after the entry into force of the Order of the Ministry
of Education and Science of Ukraine.

Lis	st by 2015	List 2015			
Field of expertise	Code and name of the specialty	Field of expertise	Code and name of the specialty		
1202 Pharmacy	12020101 Pharmacy	22 Healthcare	226 Pharmacy		
	12020102 Clinical pharmacy	22 Healthcare	226 Pharmacy		
	12020103 Technologies of pharmaceuticals	22 Healthcare	226 Pharmacy		

Prior to the full-scale invasion of Ukraine by the Russian Federation (until 2022), 28 higher education institutions provided training of pharmaceutical professionals for the industrial pharmacy segment and the segment of wholesale and retail trade in medicines and medical devices (MD) in the specialty 226 "Pharmacy, Industrial Pharmacy", namely: Kyiv International University (KIU) (Kyiv), Interregional Academy of Personnel Management (IAPM) (Kyiv), Higher Education Institution of Ukraine "Bukovinian State Medical University" (Chernivtsi), Vinnytsia National Medical University

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 $<sup>^3</sup>$  Про внесення змін до наказу Міністерства освіти і науки України від 06 листопада 2015 року № 1151, Наказ Міністерства освіти і науки України № 419 (2016) (Україна). https://zakon.rada.gov.ua/laws/show/z0691-16#Text

named after M. Pirogov (VNMU) (Vinnytsia), State Institution "Luhansk State Medical University" (Luhansk region, Rubizhne), Dnipropetrovs'k Medical Academy (DMA) (Dnipro), Donetsk National Medical University (DonNMU) (Donetsk region, Kramatorsk), Donetsk National Medical University, Medical Faculty №3 (Mariupol), Zaporizhzhia State Medical University (ZSMU) (Zaporizhzhia), Ivano-Frankivsk National Medical University (IFNMU) (Ivano-Frankivsk), Institute of Chemical Technologies of SNU (Luhansk region, Rubizhne), Kviv Medical University (CMU) (Kviv). Kyiv), Kyiv National University of Technology and Design (KNUTD) (Kyiv), Lviv Medical Institute (LMI) (Lviv), Danylo Halytskyi Lviv National Medical University (LNMU) (Lviv), Lviv National University of Veterinary Medicine and Biotechnology (LNVM and BT) (Lviv), International Humanitarian University (Odesa), Pylyp Orlyk International Classical University (Mykolaiv), Shupyk National Medical Academy of Postgraduate Education (NMAPE) (Kyiv), Bogomolets National Medical University (NMU) (Kyiv), Lviv Polytechnic National University (Lviv), National University of Pharmacy (NUPh) (M. Kharkiv), Odesa National Medical University (ONMU) (Odesa), Odesa National Polytechnic University (ONPU) (Odesa), Ternopil Gorbachevsky State Medical University (TSMU) (Ternopil), Uzhhorod National University (UzhNU) (Uzhhorod), Ukrainian State University of Chemical Technology (USUCT) (Dnipro)<sup>4</sup>.

With the introduction of martial law and the occupation of part of Ukrainian territory by the enemy, a number of higher education institutions were evacuated and placed in other specialized higher education institutions. However, the subordination of HEIs to different ministries of the Ministry of Education and Science and the Ministry of Health of Ukraine, as well as differences in the required knowledge, level of professional training, and differences in requirements and characteristics for future employment were reflected in the HEI's educational programs and in the qualification requirements for assessing the level of success of students.

At our university, Lviv Polytechnic National University, the specialty 226 "Pharmacy" (from 2017 – "Pharmacy, Industrial Pharmacy" (according to the amendments to the List of branches of knowledge and specialties of 01.02.2017) was licensed in 2016 and implemented at the Department of Technology of Biologically Active Compounds, Pharmacy and Biotechnology (TBCPB) to train students of the first (bachelor's), second (master's) and third (doctoral) levels of higher education. These prerequisites

<sup>&</sup>lt;sup>4</sup> Krychkovska A., Hubytska I., Lopatynska O. ACTUAL ISSUES OF FORMATION OF PROFESSIONAL COMPETENCES OF FUTURE PROFESSIONALS WHEN STUDYING GOOD PHARMACEUTICAL PRACTICES. – Riga, Latvia: "Izdevnieciba "BaltijaPublishing", 2020. – 688. DOI:10.30525/978-9934-588-44-0/17

allowed us to develop new OPP, PLO and curricula for all three levels of higher education, taking into account the expectations of employers.

The standard of higher education in the specialty "Pharmacy, Industrial Pharmacy" for the second (master's) level of higher education, adopted in 2022, was introduced to improve the quality of training of future pharmacists in higher education institutions of Ukraine. It provides for the cross-cutting training of specialists, without dividing into the first and second levels of higher education, in the amount of 300 ECTS credits (for educational and professional) or 360 ECTS credits (for educational and scientific) programs. This standard covers all aspects of the pharmaceutical industry, including production, quality control, research and development of new medicines, their testing and distribution. One of the main benefits of implementing the Standard of Specialty 226 is to improve the quality of training of future pharmacists, which leads to a reduction in the number of errors and accidents in the field of pharmacy. It also allows graduates to easily engage in research, development and production of new medicines, which contributes to improving the level of medical care for the population. Another advantage of implementing the Standard of Specialty 226 is the possibility of increasing the competitiveness of the Ukrainian pharmaceutical industry in the global market. Graduates of higher education institutions with this specialty can easily engage in research and development of new medicines that meet the highest quality and safety standards. This allows to increase the production of high-quality medicines that can be exported to foreign markets, increasing the income of the Ukrainian economy. According to the Standard, the specialization 226.01 "Pharmacy" requires additional training in an internship and the acquisition of a secondary pharmaceutical specialization, or confirmation of a professional category. However, for the specialization 226.02 "Industrial Pharmacy" such training is not provided in the Education Standard. Academic rights of graduates: obtaining a doctorate degree and additional qualifications in the adult education system. Additionally, for specialization 226.01 "Pharmacy" – internship and acquisition of secondary pharmaceutical specialization.

It is worth noting that due to the study of modern technologies, quality control standards, and practical training, graduates of specialty 226 are in high demand in the labor market. Pharmaceutical manufacturing companies in Ukraine offer both advanced training courses and internships for specialists in both specializations. Graduates work at pharmaceutical manufacturing companies, pharmaceutical intermediary firms, and pharmacies. Young professionals working in pharmacies face the need to undergo pre-certification cycles (PCCs) after 5 years. However, for such an internship, it is necessary to complete an internship. It is very important to introduce an amendment to the Standard regarding the possibility of internships for masters of

specialization 226.02 "Industrial Pharmacy", or to provide for these specialists, who, due to circumstances, work in pharmacies and retail and wholesale intermediary firms, to pass the PAC without training at the internship level. Such a proposal, in our opinion, is appropriate, especially in the context of martial law in Ukraine, as well as due to the fact that future specialists in the specialty 226.02 "Industrial Pharmacy" are currently also passing the integrated test exam Krok 2 (in the testing mode)<sup>5</sup>.

Since the new Standard meets the modern requirements of the pharmaceutical industry and international standards, it requires revision and updating of educational programs, in accordance with its requirements, we have developed new educational programs in the specialty 226 "Pharmacy, Industrial Pharmacy" for the specialization 226.02 "Industrial Pharmacy". The development of new educational programs aims to provide graduates of specialty 226 with the necessary knowledge, skills and competencies to work effectively in the modern pharmaceutical industry, to include modern methods and approaches to teaching, to take into account trends and innovations in the industry, as well as to use modern technologies, to ensure the level of quality of education and graduation of qualified specialists who will be able to work effectively in the pharmaceutical industry. When creating new educational programs, we involved stakeholders – industry experts – in such cooperation, which has a positive impact on the quality of education and training of specialists for industrial pharmacy.

The Law of Ukraine "On Higher Education" provides for a change in the concept of education organization, i.e., a transition to student-centered learning. This approach also stipulates that education should be aimed at achieving specific learning outcomes, not just studying certain subjects. It emphasizes the development of competencies and skills that students acquire during their studies and defines them as an important starting point for further professional activities. Therefore, in the process of creating new educational programs, we have previously conducted research on the competencies of a future pharmaceutical specialist.

Thus, a master of specialization 226.02 "Industrial Pharmacy" must have a number of professional competencies necessary for effective work in the modern pharmaceutical industry. The most important of them include: 1. Competence in chemistry and pharmaceutical technology. The master must

<sup>&</sup>lt;sup>5</sup> Губицька І. І., Кричковська А. М., Монька Н. Я., Заярнюк Н. Л., Лубенець В. І. Актуальні питання вищої фармацевтичної освіти // Фармацевтична освіта, наука та практика: стан, проблеми, перспективи розвитку : матеріали науково-практичної конференції з міжнародною участю, присвяченої 25-річчю фармацевтичного факультету Національного медичного університету імені О. О. Богомольця, 19–20 грудня 2023 року, м. Київ. – 2023. – С. 102–105.

<sup>&</sup>lt;sup>6</sup> Закон України «Про вищу освіту» від 01.07.2014 № 1556-VII. URL: https://zakon.rada.gov.ua/laws/show/1556-18#Text

have an understanding of the processes of manufacturing medicines, know the composition and properties of active substances, as well as biopharmaceutical technologies and features of the production of biological products. 2. Competence in microbiology and immunology. The master must know the processes of growth and reproduction of microorganisms, as well as the biological mechanisms of immune response and immunological control. 3. Competence in the field of quality and standardization of medicines. The master must know the procedures for quality control of medicines, including analytical methods and documentation, standardization and certification. 4. Competence in business and management. The master must have knowledge of production and supply chain management processes, financial management and marketing in the pharmaceutical industry. 5. Competence in the field of regulation and legislation. The master must know the procedures and requirements for the regulation of medicines and medical devices, including registration, certification and compliance with health and pharmaceutical legislation. 6. Competence in research. The master must have knowledge and skills in conducting scientific research, including the development of research protocols, selection of research methods, analysis and interpretation of results, as well as publication of scientific articles. 7. Competence in ethics and social responsibility. The master must understand the ethical and legal aspects of the pharmaceutical industry, as well as have knowledge of social responsibility of business and public relations. 8. Competence in the field of information technology. The master must have knowledge and skills in the use of modern information technologies in the pharmaceutical industry, including information systems for production management and quality control, data analysis, electronic document management, etc.<sup>7</sup>.

In addition to professional competencies, a master of specialization 226.02 "Industrial Pharmacy" must also have general competencies necessary for effective work in the modern world. Such competencies may include: 1. Communication competencies. The master must have effective communication skills, both in written and oral form. This includes the ability to express oneself clearly and concisely, to listen and understand the interlocutor, and to work in a team. 2. Critical thinking and analytical skills. A master's student must have the ability to think critically and analyze the information he/she receives, as well as to find solutions based on the analysis of facts. 3. Self-organization and planning skills. The master must be able to plan his/her work and manage time in order to effectively perform the tasks that he/she faces. 4. Cultural competence. The master must understand and respect different cultural traditions and views, be able to work with colleagues

<sup>&</sup>lt;sup>7</sup> Професійний стандарт за професіями «Асистент фармацевта». https://register.nqa.gov.ua/uploads/0/491-profstandart asistent farmacevta.pdf

from different countries and cultures. 5. Competence in customer service. The master must have knowledge and skills in customer relations, including interaction with doctors and patients, as well as know the basics of marketing and sales in the pharmaceutical industry. All these competencies will help the master of specialization 226.02 "Industrial Pharmacy" to work effectively in the pharmaceutical industry and develop professionally.<sup>7</sup>.

The master of specialty 226.02 "Industrial Pharmacy" should understand the importance of ensuring the safety and quality of pharmaceuticals production, that is, the following learning outcomes can be expected from him: 1. Understanding of the scientific basis of pharmaceutical technology, including basic pharmaceutical processes and technological schemes for the production of medicines. 2. Ability to conduct research and analysis of the quality of medicinal products, including methods of analysis, validation and standardization.3. Knowledge of the regulation of the pharmaceutical industry, including requirements related to the production, quality control and development of new medicines. 4. Ability to develop technological schemes for the production of medicines, including the selection of equipment and determination of production conditions.5. Understanding the impact of the environment on the production and use of medicines. 6. Ability to work in a team and communicate with different groups, including pharmacists, engineers and managers.7. Knowledge and understanding of the ethical and legal aspects of the pharmaceutical industry, including the protection of intellectual property, responsibility to patients and compliance with international standards<sup>2</sup>.

Thus, we have reviewed the history of the specialty 226 "Pharmacy, Industrial Pharmacy" and developed general and professional competencies, program learning outcomes in accordance with the adopted Higher Education Standard, on the basis of which we have developed new educational programs for the specialty 226.02 "Industrial Pharmacy".

### 2. Problems of higher pharmaceutical education and search for ways to solve them

The Unified State Qualification Examination (USQE) is carried out in accordance with the CMU Resolution No. 334 of 28.03.2018 "On Approval of the Procedure for Conducting the Unified State Qualification Examination for Applicants for a Master's Degree in the Field of Knowledge "Healthcare" and No. 497 of May 19, 2021 "On Certification of Applicants for a Degree of Professional Higher Education and Degrees of Higher Education at the First (Bachelor's) and Second (Master's) Levels in the Form of a Unified State Qualification Examination". Thus, for the first time since 2021, the USQE Krok 2 was introduced in a test mode for graduates of the specialty 226 "Pharmacy, Industrial Pharmacy" at the HEIs subordinated to the Ministry of

Education and Science of Ukraine. The efforts of the teaching staff of the National University of Pharmacy in Kharkiv (a higher education institution subordinated to the Ministry of Health of Ukraine) created a database of questions for the EQIE. Teachers of other higher education institutions joined the work on the proper base, as all pharmacy professionals understood that there are actually two separate specialties under the name of one specialty. With the beginning of martial law in Ukraine in 2022, not all university graduates were able to pass the EQC, but in 2023, this exam was held in test mode in all universities. However, the introduction of the EDQE Step 1 and Step 2 in the HEIs subordinated to the Ministry of Education and Science of Ukraine still raises a number of questions, since the first enrollment of students in the cross-cutting educational program of specialization 226.02 "Industrial Pharmacy" took place for the first time in the HEIs subordinated to the Ministry of Education and Science only in 2023.

It is worth noting that the ECQF in the form of a system of Steps (Step 1, Step 2, Step 3) was extrapolated from the HEIs subordinated to the Ministry of Health (pharmacist) to the HEIs subordinated to the Ministry of Education and Science (industrial pharmacist). The administrations of the lowermentioned HEIs had to apply to the relevant ministries of the MES and the MoH to harmonize the transition to this new type of assessment, which was not typical for them. At the same time, the higher education institutions subordinated to the Ministry of Health (pharmacist) introduced such a form of certification of higher education students in the specialty 226 "Pharmacy, Industrial Pharmacy" as the defense of a master's thesis. The master's qualification work (MOW) involves the independent solution of the task in accordance with the requirements for the relevant qualification works. This form of certification of higher education applicants is standard for higher education institutions subordinated to the Ministry of Education and Science (industrial pharmacist). Thus, higher education students of the two specializations currently have the same form of knowledge diagnostics (Steps) and final state certification (defense of the ICR).

The introduction in 2022 by the Education Standard (as mentioned in the first section) of the division of the specialty into separate specializations allowed everyone – scientists, practitioners, research and teaching staff, students, future applicants and their parents – to make a choice about further employment: specialization 226.01 "Pharmacy" – Master of Pharmacy, specialization 226.02 "Industrial Pharmacy" – Master of Industrial Pharmacy.

In 2023, the National Qualifications Agency published professional standards for professionals and specialists in the field of pharmacy, among others:

pharmacist's assistant – a specialist whose professional activity is to provide pharmaceutical care to the population of Ukraine in compliance with the requirements and provisions set forth in the standards and legislation of Ukraine:

- Medical technology assessment expert a professional whose professional activity is to plan, organize and conduct an assessment of medical technologies (MT) in the following aspects: healthcare problem and the use of MT to solve it; description and technical characteristics of MT; safety; clinical effectiveness; costs and economic evaluation, etc;
- industrial pharmacist a professional whose professional activity is to organize the activities of a pharmaceutical company, develop, manufacture, control and manage the quality of medicines to meet the needs of health care;
- pharmacovigilance professional a professional whose professional activity is to carry out pharmacovigilance in accordance with certain standards and legislation of Ukraine in order to ensure the use of medicines, improve patient treatment and safety related to the use of medicines:
- Pharmacist a professional whose professional activity is aimed at providing the population and healthcare institutions with medicines and related products: development, production, quality assurance, sale of medicines and related products, provision of pharmaceutical care;
- Clinical pharmacist a professional whose professional activity is to provide the population and healthcare facilities with medicines and related products: development, quality assurance, sales; ensuring the rational use of medicines: clinical trials of medicines, monitoring of the effectiveness and safety of therapy, pharmacovigilance; provision of pharmaceutical care.

The professional standards were approved by the order of the NGO "Association of Employers' Organizations of the Medical and Microbiological Industry of Ukraine" dated 23.03.2023 No. 01-23. The standards will be revised in 2028.8 Since masters of specialization 226.02 "Industrial Pharmacy" (according to the Standard) do not have the opportunity to undergo an internship and are limited, respectively, to employment exclusively in the organization of pharmaceutical enterprise activities, development, industrial production, control and quality management of medicines to meet the needs of health care, we consider it inappropriate for them to have such an additional form of certification as Krok, especially in the conditions of martial law in Ukraine, when enterprises are The way to solve this problem would be to distinguish in the updated Standard the methods of assessing the level of knowledge of higher education students in the specialties 226.01 "Pharmacy" and 226.02 "Industrial Pharmacy". For the former (pharmacists), the EDCI Krok system should be retained, and for industrial pharmacists – the implementation and defense of the ICR, which involves the study and development of industrial production technology for a medicinal product with the implementation of material, technological, thermal, technical and economic calculations, development of labor protection measures, implementation of the graphic part of the project (selection and layout of main

<sup>&</sup>lt;sup>8</sup> Професійні стандарти. [https://register.nqa.gov.ua/profesijni-standarti].

and auxiliary equipment, design of a workshop plan with sections, calculation and drawing of the main apparatus, equipment and technological production scheme), etc.

In 2021, the Ministry of Education and Science of Ukraine proposed for public discussion a <u>draft Resolution of the Cabinet of Ministers of Ukraine</u> "On Amendments to the List of Fields of Knowledge and Specialties for the Training of Higher Education Applicants", developed in accordance with part three of Article 9 of the Law of Ukraine "On Higher Education", in order to improve it in line with the development of the labor market, as well as to harmonize the list of fields of knowledge and specialties with the International Standard Classification of Education. Thus, it was proposed to divide the specialty 226 "Pharmacy, Industrial Pharmacy" and transfer "Industrial Pharmacy" from Knowledge Area 22 "Health Care" to Knowledge Area 18 "Production and Technology" According to this document, position 7 was supposed to be

"18 Production and Technology" shall be amended to read as follows:

10 1 roddetion and Technology shan be amended to read as follows.					
181 Food technologies	0721	Food processing			
182 Light industry technologies	0723	Textiles (clothing, footwear and leather)			
183 Environmental protection technologies	0712	Environmental protection technology			
184 Mining	0724	Mining and extraction			
185 Oil and gas engineering and technology					
186 Publishing and printing	0211	Audio-visual techniques and media production			
	0611	Computer use			
187 Woodworking and furniture technologies	0722	Materials (glass, paper, plastic and wood)			
188 Industrial pharmacy	0588	Inter-disciplinary programs and qualifications involving natural sciences, mathematics and statistics			
	0711	Chemical engineering and processes".			

This did not take into account the fact that in industrial pharmacy, almost all legal acts regulating and governing production activities are issued by the

<sup>&</sup>lt;sup>9</sup> Обговорення проєкту змін до переліку галузей знань і спеціальностей, за якими здійснюється підготовка здобувачів вищої освіти. https://mon.gov.ua/ua/news/mon-proponuye-dlya-gromadskogo-obgovorennya-proyekt-zmin-do-pereliku-galuzej-znan-i-specialnostej-za-yakimi-zdijsnyuyetsya-pidgotovka-zdobuvachiv-vishoyi-osviti.13.08.2021

Ministry of Health of Ukraine. The long-standing subordination of pharmaceutical manufacturing companies to the Ministry of Medbioprom (Medical and Biological Industry) is now a thing of the past. This attempted change, in its time, destabilized the situation on the Ukrainian pharmaceutical market and especially caused negative perception in the higher education institutions. The production of vital human products – medicines – must guarantee their high quality and safety, and that is why the thoughtless transfer of the specialty "Industrial Pharmacy" to any other industry other than healthcare is a gross violation of any guarantees, norms and requirements governing the industrial production of pharmaceuticals.

In addition, if the proposed List of Fields of Knowledge and Specialties 2021 for higher education students at the third (educational and scientific) level is approved, i.e., if the field of knowledge is changed, all publications would become non-professional, there would be serious problems with the defense of dissertations, etc. This draft of the List of Fields of Knowledge was not supported, but was constructively criticized during the public discussion, in particular, in the part concerning the specialty 226 "Pharmacy, Industrial Pharmacy". Such decisions indicate incompetence and lack of understanding of the peculiarities of legislative regulation of the pharmaceutical sector of the national economy.

The period of existence of the Higher Education Standard for the specialty 226 "Pharmacy, Industrial Pharmacy" is currently only one year, and the pharmaceutical industry of Ukraine is expected to change again. A new List of fields of knowledge and specialties in which higher education applicants will be trained has been published (draft of March 29, 2023). The draft contains new codes for specialties by field of knowledge, as well as the corresponding names of specialties adopted in EU countries (Table 2). The Ministry of Education and Science of Ukraine has submitted for approval a draft Resolution of the Cabinet of Ministers of Ukraine "On Amendments to the List of Fields of Knowledge and Specialties for the Training of Higher Education Applicants" with a revised set of supporting documents in accordance with the decision of the State Regulatory Service of 16.02.2024 No. 47<sup>10</sup>.

<sup>&</sup>lt;sup>10</sup> Наказ МОН № 97 від 26.01.2024 «Про внесення змін до Плану діяльності Міністерства освіти і науки України та центральних органів виконавчої влади, діяльність яких спрямовується та координується Кабінетом Міністрів України через Міністра освіти і науки України, з підготовки проєктів регуляторних актів на 2024 рік».

Table 3
LIST (project) branches of knowledge and specialties in which higher education students are trained (extract)

Field of expertise		Specialty.		Relevant detailed field of the International Standard Classification of Education ISCED-2013		Levels of education at which training in the specialty is provided			
Code.	Name	Code.	Name	Code.	Name	FPO	Б	М	DF/ DM
		11	Dentistry	0911	Dental studies	+		+	+
		I2	Medicine	0912	Medicine			+	+
T Healthcare and social security		13	Pediatrics	0912	Medicine			+	+
		14	Medical psychology	0912	Medicine			+	+
	15	Nursing	0913	Nursing and midwifery	+	+	+	+	
	16	Technologies of medical diagnosis and treatment	0914	Medical diagnostic and treatment technology	+	+	+	+	
	17	Therapy and rehabilitation (by specialization)	0915	Therapy and rehabilitation	+	+	+	+	
	lthcare and	I8 Pharmacy	Pharmacy	0711	Chemical engineering and processes	+		+	+
	Неа		0916	Pharmacy					
		19	Public health	0988	Interdisciplinary programs and qualifications involving health and welfare		+	+	+
		II0 Social work and counseling	Social work and	0921	Care of the elderly and disabled adults	+	+	+	+
			counseinig	0923	Social work and counseling				

The new draft List contains one name of the specialty (Pharmacy) with a single code (I 8), which corresponds to two codes for the names of the corresponding detailed field according to the International Standard Classification of Education ISCED-2013: (0711 – Chemical engineering and processes) and (0916 – Pharmacy). Obviously, our achievements (development of new EPPs and PLOs in accordance with the Standard) may soon become irrelevant.

There are certain problems with employment of graduates of specialty 226 "Pharmacy, Industrial Pharmacy". Since in 2015-2023, there was only one specialty, and graduates of different higher education institutions (subordinated to the Ministry of Health and the Ministry of Education and Science) worked at pharmaceutical enterprises, intermediary pharmaceutical companies, and pharmacies. Having worked for 5 years, young specialists, graduates of HEIs subordinated to the Ministry of Education and Science, who

work in pharmacies, faced a problem – the need to pass pre-certification cycles (PCC), because without them, a master's degree loses its legitimacy. However, such an internship requires an internship. However, the Standard does not provide for retraining of such specialists. With the adoption of the professional standard, this problem will only get worse, since the professional qualification specified in the document on higher education is an industrial pharmacist. At the same time, pharmaceutical industrial enterprises employ specialists who are graduates of higher education institutions subordinated to the Ministry of Health of Ukraine, and after five years of employment they are offered internships and forms of advanced training. Thus, this problem needs to be addressed urgently. It should be noted that a number of long-term decisions on the regulation of the pharmaceutical industry, and especially in the sector of providing services by HEIs to students and building high-quality human resources, are made during martial law in the country and are rather spontaneous and unbalanced.

The employment of graduates of specialty 226 "Pharmacy, Industrial Pharmacy" is currently characterized by a high level of competitiveness and opportunities for a successful career in various areas of the pharmaceutical industry. An important role in the formation of professionals in the pharmaceutical industry is played by internships. Pharmaceutical manufacturing companies in Ukraine offer both advanced training courses and on-the-job training for specialists of both specializations. For example, Ukrainian Pharmaceutical Corporation Arterium regularly invites students of III-V years of study to undergo an internship at the production of medicines at Galichpharm JSC (Lviv, Ukraine). For 3-6 months, students have the opportunity to work with highly qualified specialists and professional mentors, gain valuable experience in their field and develop their professional skills<sup>11</sup>.

For example, Farmak JSC (Kyiv, Ukraine) is the organizer of the Farmak\_Lab project, which provides opportunities for students and employees to continuously improve their knowledge and skills in practice, offering lecture courses on Modern Approaches to the Development of Generic Drugs in Solid Dosage Forms and Study of Dissolution Profiles of Solid Dosage Forms, which is extremely important and useful for professionals and students<sup>12</sup>. A wide range of career opportunities in various fields — technical, clinical, educational, managerial and, in general, development opportunities — is provided to senior students and practicing

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<sup>&</sup>lt;sup>11</sup> Новини політехніки про можливості стажування в АТ «Галичфарм» для студентів Львівської політехніки. https://lpnu.ua/news/mozhlyvosti-stazhuvannia-v-halychfarm-dlia-studentiv-lvivskoi-politekhniky

<sup>&</sup>lt;sup>12</sup> Про можливості стажування на ПАТ "Фармак". http://btmb.com.ua/stazhuvannya-na-pat-farmak

pharmacists by the Pharmaceutical Firm "Darnitsa" (Kyiv, Ukraine). First of all, applicants send a resume, are interviewed and perform (if necessary) a test task and get the opportunity to intern at the company, and, in the future, to be employed<sup>13</sup>. During the meetings with the students of the NU LP, the specialists of PJSC "INDAR" insulin production familiarize them with the general structure of PJSC "INDAR", as well as with the main departments offering internships and further employment to both students and specialists. Among them are the Department of Scientific Research and Product Development, as well as the production units<sup>14</sup>. Thus, thanks to close cooperation with employers, through internships and practical training, students – future specialists in the pharmaceutical industry – acquire a wide range of knowledge and practical skills that meet the requirements of the modern labor market.

#### CONCLUSIONS

The standard of higher education of the second (master's) level of Field of Knowledge 22 "Health Care", specialty 226 "Pharmacy, Industrial Pharmacy", specialties 226.01 "Pharmacy" and 226.02 "Industrial Pharmacy" was approved and put into effect by Order No. 981 of the Ministry of Education and Science of Ukraine dated November 04, 2022.

Until 2015, higher education institutions (HEIs) subordinated to the Ministry of Health of Ukraine (MoH) trained specialists for the pharmaceutical industry with the qualification of pharmacist, and HEIs subordinated to the Ministry of Education and Science (MES) trained process engineers for pharmaceutical manufacturing plants. With the introduction of a single specialty 226 "Pharmacy" in 2016, and with the renaming of the specialty to 226 "Pharmacy, Industrial Pharmacy" in 2017, the training of specialists for the pharmaceutical industry was carried out in HEIs of different subordination (MoH and MES). The only significant difference was in the quality control of the training of higher education students. The Krok assessment system was introduced in the HEIs subordinated to the Ministry of Health of Ukraine. In the HEIs subordinated to the MES of Ukraine, higher education students performed and defended qualification works – bachelor's and master's degrees.

In accordance with the Resolution of the Cabinet of Ministers of Ukraine (CMU) on the "Procedure for the Unified State Qualification Exam for Master's Degree Applicants in the Field of Knowledge 22 "Healthcare", the Unified State Qualification Exam (USQE) in the specialty 226 "Pharmacy, Industrial Pharmacy" is currently provided for in the form of Krok. Another

<sup>14</sup> Кар'єра в компанії «Індар». https://indar.com.ua/ua/career

<sup>&</sup>lt;sup>13</sup> Кар'єра в компанії «Дарниця». https://darnytsia.ua/carrier

form of state certification of students in both specializations is the performance and defense of a master's thesis.

As a result of the introduction of the Standard, from the academic year 2023-2024, all the above-mentioned higher education institutions began to train pharmacy students of the second master's level of higher education on the basis of complete general secondary education (CGE) in the specialties 226.01 "Pharmacy" and 226.02 "Industrial Pharmacy".

However, in practice, graduates of the same specialty are employed by industrial pharmaceutical companies, pharmaceutical intermediary firms and pharmacies. Accordingly, at pharmaceutical industrial enterprises, after 5 years, young specialists can undergo internships and advanced training provided by the enterprise itself. As for pharmaceutical companies and pharmacies, there is a system of pre-certification cycles (PCCs). This system of advanced training requires completion of an internship and passing the EDKI Step 3. As a result, it makes it impossible for specialists who had a different system of knowledge assessment to continue working.

We propose to bring the system of knowledge assessment, the system of postgraduate training and confirmation of qualifications of industry specialists to a single denominator. We propose to amend the current legislation and allow all specialists who have studied in the specialty 226 "Pharmacy, Industrial Pharmacy" to take the PACs.

Since the division into separate specializations of the specialty 226 "Pharmacy, Industrial Pharmacy" was introduced only by the Standard in 2022, graduates of previous years will face a no-alternative choice – a change of employment. In particular, graduates of the specialty 226 "Pharmacy, Industrial Pharmacy" in 2021 will face this problem in 2026. That is why the decision must be made in a short time.

Since the Higher Education Standard does not provide for the retraining of pharmacists graduating from HEIs subordinate to the Ministry of Education and Science, it is extremely important to introduce an amendment to the Higher Education Standard regarding the possibility of changing specialization within the same specialty.

This proposal, in our opinion, is appropriate, since future specialists in the specialty 226.02 "Industrial Pharmacy" are currently taking the EDQI Step 2 in the testing mode, and the EDQI Step 3 is not currently provided for them. At the same time, for the specialization 226.01 "Pharmacy", Step 3 is mandatory, but there is a widespread opinion among experts that it should be canceled.

#### **SUMMARY**

The monograph proves the need for and elaborates on the changes to the Standard of Education for the specialty 226 "Pharmacy, Industrial Pharmacy",

which should be taken into account and introduced into the new version of the said regulatory legal act for the proper functioning of the pharmaceutical industry of Ukraine.

The first section of the paper analyzes the main stages of formation and development of the specialty 226 "Pharmacy, Industrial Pharmacy" in Ukraine in recent years. Thus, from 2016 to the present, higher education institutions that trained students in a single specialty – 226 "Pharmacy, Industrial Pharmacy" for the industrial pharmacy segment and the segment of wholesale and retail trade in medicines and medical devices were subordinated to the Ministry of Education and Science and the Ministry of Health, respectively. With the introduction of the Higher Education Standard in Ukraine in 2022, two separate specializations 226.01 "Pharmacy" and 226.02 "Industrial Pharmacy" were introduced within one specialty 226 "Pharmacy, Industrial Pharmacy".

The second section of the research paper considers the problems of future pharmaceutical professionals that they face during their studies and employment due to the inconsistency and non-transparency of the retraining procedure – obtaining (acquiring) a related specialization within one specialties. In accordance with the Resolutions of the Cabinet of Ministers of Ukraine on the "Procedure for the Unified State Qualification Exam for Master's Degree Applicants in the Field of Knowledge 22 "Health Care" (approved by the Resolutions of the Cabinet of Ministers of Ukraine No. 334 of March 28, 2018; and supplemented by the Resolutions of the Cabinet of Ministers of Ukraine No. 351 of April 14, 2021; No. 497 of May 19, 2021), the Unified State Qualification Examination (USQE) was introduced for the specialty 226 "Pharmacy, Industrial Pharmacy" in the form of Krok. However, for the specialty 226.02 "Industrial Pharmacy" internship training with the possibility of acquiring a secondary pharmaceutical specialization is not provided for in the Higher Education Standard. Since the Standard of Higher Education does not provide for the conditions for retraining pharmacistsgraduates of higher education institutions subordinated to the Ministry of Education and Science, the authors propose to introduce an addition to the Standard of Higher Education regarding the possibility of internships for masters of specialization 226.02 "Industrial Pharmacy" and to allow specialists to graduate from previous years who are employed in pharmacies institutions and in retail and wholesale intermediary firms, the opportunity to pass pre-certification cycles without internship training.

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## Information about the authors: Krychkovska Aelita Myronivna,

Candidate of Pharmaceutical Sciences,
Associate Professor at the Department of Technology of Biologically
Active Compounds, Pharmacy and Biotechnology
Lviv Polytechnic National University
12, Stepana Bandery str., Lviv, 79013, Ukraine

#### Hubytska Iryna Ivanivna,

Candidate of Chemical Sciences, Associate Professor at the Department of Technology of Biologically Active Compounds, Pharmacy and Biotechnology Lviv Polytechnic National University 12, Stepana Bandery str., Lviv, 79013, Ukraine

#### Monka Nataliia Yaroslavivna,

Candidate of Chemical Sciences, Assistant Professor at the Department of Biologically Active Compounds Technology, Pharmacy and Biotechnology Lviv Polytechnic National University 12, Stepana Bandery str., Lviv, 79013, Ukraine