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INTEGRATION INTO THE EUROPEAN UNION: CURRENT STATE AND PROBLEMS OF PHARMACEUTICAL EDUCATION IN UKRAINE

ІНТЕГРАЦІЯ В ЄВРОПЕЙСЬКИЙ СОЮЗ: СУЧАСНИЙ СТАН ТА ПРОБЛЕМИ ФАРМАЦЕВТИЧНОЇ ОСВІТИ В УКРАЇНІ

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According to the Resolution 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 (MES) No. 1151 dated 06.11.2015 “On the peculiarities of introducing the list of fields of knowledge and specialties for the training of higher education entrants”, the specialty 15.00.01 “Technology of drugs, organisation of pharmaceutical business and forensic pharmacy” was renamed to specialty 226 “Pharmacy, industrial pharmacy” of Field

of Knowledge 22 “Healthcare”. In fact, according to the new list of fields of knowledge, the specialty “Technology of Pharmaceuticals” was also included in the same specialty [1]. However, in Ukraine, 28 higher education institutions (HEIs) of different subordination provide training of professionals for the pharmaceutical industry in Ukraine for the industrial pharmacy segment and the segment of wholesale and retail trade in medicines and medical devices (MDs) in the speciality “Pharmacy, industrial pharmacy”: Ministry of Health (MoH) and Ministry of Education and Science (MES). The purpose of this paper is to identify certain problems and inconsistencies in the regulatory and legal acts governing the acquisition of higher education by applicants for the specialty 226 “Pharmacy, Industrial Pharmacy”. In the recent past, a number of problems arose, as the standards for educational levels and educational components of educational, professional and scientific programmes differed significantly under the same name of the speciality and the same field of knowledge [2]. The approaches to assessing the level of knowledge and qualifications of students were particularly different. Applicants who received a speciality in an HEI Subscribe to DeepL Pro to edit this document. Visit www.DeepL.com/pro for more information. subordinated to the Ministry of Health must undergo a graduated system of knowledge assessment: Step 1, Step 2, Step 3. Before the adoption of the 2022 Education Standard [3], pharmacists in the specialty “Pharmacy, Industrial Pharmacy” were trained in HEIs subordinate to the Ministry of Health of Ukraine at three levels of higher education: first (bachelor’s), second (master’s), third, educational and scientific (PhD). The Standard for the specialty 226 “Pharmacy, Industrial Pharmacy” is a regulatory document that sets out the requirements for the educational programme and the graduate of the relevant specialty. However, with the introduction of the Standard, two separate specialisations 226.01 “Pharmacy” and 226.02 “Industrial Pharmacy” were introduced within the same speciality 226 “Pharmacy, Industrial Pharmacy”. Specialists with different specialisations can, at the beginning of their career, be employed at various pharmaceutical companies – both industrial and wholesale and retail. However, further employment has certain differences in terms of internships and qualification confirmation [4]. According to the Standard, the object of activity for students of specialisation 226.01 “Pharmacy” is the development, production, quality control, wholesale and retail sale of medicines, pharmaceutical services, pharmaceutical care, and for students of specialisation 226.02 “Pharmacy, 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 the degree of Doctor of Philosophy and additional qualifications in the adult education system.

For the specialisation 226.01 “Pharmacy”, additional training in an internship and the acquisition of a secondary pharmaceutical specialisation or confirmation of a professional category are provided. In general, the organisation of the educational process is regulated by the requirements for the specifics of licensing educational programmes for regulated professions [4]. However, for specialisation 226.02 “Industrial Pharmacy” such training is not provided for in the Education Standard. The most important professional competences for the Master’s degree in 226.02 “Industrial Pharmacy” are those necessary for effective work in the modern industrial pharmaceutical industry. The most important of them include: 1. Competence in chemistry and pharmaceutical technology. The master must 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 the immune response and immunological control. 3. Competence in the field of quality and standardisation of medicines. The master must know the procedures for quality control of medicines, including analytical methods and documentation, standardisation 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 regulating 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, and others. These competences will help the master of specialisation 226.02 “Industrial Pharmacy” to work effectively in the pharmaceutical industry and develop professionally. In addition to professional competencies, a master’s degree in 226.02 “Industrial Pharmacy” must also have general competencies necessary for effective work in the modern

world. Such competences may include: 1. Communication competences. 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 analyse the information he or she receives, as well as to find solutions based on the analysis of facts. 3. Self-organisation and planning skills. The master must be able to plan his/her work and manage time in order to effectively perform the tasks he/she faces. 4. Cultural competence. The master must understand and respect different cultural traditions and views, be able to work with colleagues 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. These competences will help the master of specialisation 226.02 "Industrial Pharmacy" to be successful in work and develop as a professional in the modern global economy [3]. Two new regulations are also important for the European integration of both the Ukrainian pharmaceutical industry and the educational process: the new Draft "List of Fields of Knowledge and Specialties for Training of Higher Education Applicants" of 2023 and the Conceptual and Reference Framework for Digital Competencies of Healthcare Workers and Ensuring Digital Culture, Digital Literacy (Digital Education), Cybersecurity and Cyberspace Hygiene of Healthcare Workers of 06 October 2023 [5; 6]. The new Draft proposes to divide the single speciality "Pharmacy" into three codes that correspond to the European Classification Framework: Pharmacy, Chemical Engineering and Processes, and Multidisciplinary Pharmacy. However, it will be problematic to implement this in Ukraine, as all current legislative regulations are issued by the Ministry of Health of Ukraine and apply to the pharmaceutical industry. With regard to the digitalisation of the pharmaceutical industry in particular and the healthcare system of Ukraine in general, this is a timely decision that has already been implemented in practice and covered in scientific publications [5; 6]. Thus, many steps have already been taken in Ukraine for European integration, but understanding the problems and inconsistencies in the regulatory framework of the pharmaceutical industry encourages scientists and practitioners to find the best solution.

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