LEARNING GOOD PHARMACEUTICAL PRACTICES AS A COMPONENT OF PROFESSIONAL TRAINING OF PHARMACY SPECIALISTS

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Summary

The article presents the results of the analysis of alternative methods of studying the Good Pharmaceutical Practice complex, introduced at the Lviv Polytechnic National University. The optimal structure of the curriculum for student's education by the specialty 226 "Pharmacy, Industrial Pharmacy" was determined to improve the system of training of specialists, who need understand the current pharmaceutical legislation of Ukraine and prospects for its development.

Structural-and-logical schemas based on the Guidelines of Good Pharmaceutical Practices that greatly facilitate students' perception and assimilation of all the needed information have been elaborated.

The development of such schemes by students with teacher assistance allows to improve the perception of the material and strengthen skills for independently analyzing. While performing the task, students to learn and understand certain aspects, such as the fact that the quality of the medicines is "incorporated" into the drug at the stage of pharmaceutical development, and then confirmed during preclinical and clinical research. Further, the medicine receives a "permit to life", when passing state registration. After that, the specified quality is reproduced for each series at the stage of full-scale pharmaceutical manufacturing, it is maintained unchanged at the stages of storage and distribution and, finally, it is delivered to patients in pharmacies.

The study of the possibility of mastering the discipline "Good Practices in Pharmaceutics" by students of specialty 226 "Pharmacy, Industrial Pharmacy" during the practice at the existing pharmaceutical enterprises can be considered perspective.

Keywords: pharmaceutical education, Guidelines structure, introspection.

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1. Introduction

Adaptation of Ukrainian legislation to the *acquis communautaire* of the European Union is one of the main components of the European integration policy of Ukraine. Accordingly, the regulatory systems of the EU, Member States of EU and Ukraine should be harmonized (or compatible) concerning the pharmaceutical sector as a whole and pharmaceutical education in particular. The legislation of Ukraine and the EU should include the same terminology and implement common standards. For example, the decision to register medicines or other medical product occurs in different legislative environments, using different procedures. To resolve this issue, national legislation should include references to EU law. Ukraine is not an EU member state and this creates problems for approximation of the Ukrainian legislation to the EU law. However, the European integration processes taking place in Ukraine encourage both scientists and practitioners to implement EU legislation in all fields of the national economy.

The set of Good Pharmaceutical Practices rules, especially Good Manufacturing Practice is one of the fundamental elements of quality assurance of the process of production and turnover of medicines and other medicinal products *(Pittenger, Chapman, Frail, Moon, Undeberg, Orzoff, 2016; Patel, Chotai, 2008)*. Implementation of rules of the Good Pharmaceutical Practices into the field of medicines turnover allows to guarantee their quality, to satisfy needs of the national health care system and each patient in quality medicines *(Abdellah, Noordin, Ismail, 2015; Mitroka, Harrington, DellaVecchia, 2020).* Many leading Ukrainian scientists investigate the possibility of elaboration of the Good Pharmaceutical Practices complex and structuration of the relevant legal document: *Gromovyk B., Gubin Yu., Lebedynets V., Hudz N., Kalynyuk T.* and others *(Hromovyk, Horilyk, 2013; Lebedinets, Tkachenko, Gubin, Zborovskaya, Romelashvili, Spiridonov, 2017; Hudz, Kalynyuk, Bilous, Smetanina, 2013)*. However, the possibility of step-by-step teaching at the various levels of specialist training for pharmaceutical branch and the gradual study by students of the specialty 226 "Pharmacy, Industrial Pharmacy" the whole complex of Good Pharmaceutical Practices were not studied.

The research aimed involving student audience to analyze the alternative methods of studying the complex of Good Pharmaceutical Practices, introduced for educational process at the Lviv Polytechnic National University and to determine the optimal structure of curriculum for the student's education by the specialty 226 "Pharmacy, Industrial Pharmacy" to improve the system of training of specialists, who need understanding the current pharmaceutical legislation of Ukraine and the prospects for its development.

2. Results and discussion

The object of study involves the legislation concerning whole Good Pharmaceutical Practices complex, curriculums of medical and technical higher educational establishments in Ukraine.

According to the order of the Ministry of Health care of Ukraine, the learning of the discipline "Good Practices in Pharmaceutics" is conducted by the credit-modular system for students at the fifth course of medical universities since 2013 *(Krychkovs'ka, Zayarnyuk, Bolibrukh, 2017).* The main objective of this discipline is setting in students the basic concepts of Good Pharmaceutical Practices, focusing on the main requirements of Good Practices and features of each step of the medicine life cycle: pharmaceutical development, preclinical research, clinical trials, registration (re-registration) and amendments to the registration documents, mass production, storage, wholesale and retail sale of medicines *(Koster, Schalekamp, Meijerman, 2017; Pearson, Hubball, 2012; Meijerman, Nab, Koster, 2016).*

The Good Pharmaceutical Practices complex and the list of legislative documents that regulate them in Ukraine are given in Table 1.

Table 1

Guidelines governing the Good Pharmaceutical Practices complex in Ukraine

The part of Good Pharmaceutical Practices complex	Guidelines governing the Good Practices	Definition of the certain Good Practices
Good Laboratory Practice	*Medicines. Good Laboratory Practice. Guidelines. 42-6.0:2008*	Principles and rules of the organizational processes and the conditions, under which preclinical studies of safety for people's health and environment are planned, performed, inspected recorded and reported as a report and archived.
Good Clinical Practice	*Medicines. Good Clinical Practice. Guidelines. 42-7.0:2008*	Principles and rules for designing, conducting, performing, monitoring, auditing, recording of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.
Good Manufacturing Practice	*Medicines. Good Manufacturing Practice. Guidelines. 42-4.0:2015*	Set of rules for the organization of medicines manufacturing and quality control, which is an element of the quality assurance system that provides the stable production of medicines according to the requirements of technological regulatory documentation and performance the quality control by a certain method.
Good Storage practice	*Medicines. Good Storage practice. Guidelines. 42-5.1:2011*	Set of rules and requirements, that ensure the quality of medicines and other medicinal products during storage and transportation at all stages of their turnover.
Good Distribution Practice	*Medicines. Good Distribution Practice. Guidelines. 42-5.0:2014*	Set of rules and requirements, that ensures the quality of medicines during management and organization of their wholesale distribution at all stages.
Good Pharmacy Practice	*On approval of the Guidelines "Good Pharmacy Practice. Pharmacy service quality standards". Order Ministry of Health care of Ukraine, No 455, 30.05.2013*	Set of rules and requirements for pharmacy professional's activity to promote public health and prevent disease, dispense and use of prescribed medicines, self-medication, as well as recommendations concerning medicines prescribing and administration.

Lviv Polytechnic National University according to the Law of Ukraine "On Education" provides the specialists training by the three-cycle system: bachelor – master – Ph.D. student. Students training occurs by the educational-and-qualification characteristics (EQC) and educational-and-professional (EPP) and educational-and-scientific (ESP) programs, which provide theoretical, practical and scientific training, including independent research activity under the supervision of a scientific advisor and consultants from research institutes or industrial laboratories by mutual agreement on scientific cooperation and student's practical training *(Hromovyk, Horilyk, 2013)*. The educational process of future pharmacists is carried out by the curriculum for the specialty 226 "Pharmacy, Industrial Pharmacy" approved by Lviv Polytechnic National University and provides three-cycle training, namely: 240 ECTS credits for education at the first (bachelor) cycle, 90 ECTS credits at the second (master's) cycle and 60 ECTS credits at the third (educational-scientific) cycle for the degree of Doctor of Philosophy.

The result of the conducted analysis of our curriculum showed that considerable attention is paid to the study Good Pharmaceutical Practices complex throughout the training period of future specialists for pharmacy and industrial pharmacy. Primarily, at the first (bachelor) cycle of higher education, the problems of regulatory pharmaceutical practice and distribution are considered in such disciplines as *"Pharmacy Drug's Technology"* (issues of Good Pharmacy Practice and Good Storage Practice), *"Management and Marketing in Pharmacy"* and *"Legal Regulation of Pharmaceutical Companies Activity"*. Disciplines *"Clinical Pharmacy"* and *"Laboratory and Functional Diagnostics"*, *"Quality Control of Medicines"*, accordingly, address issues of Good Clinical Practice and Good Laboratory Practice. The questions on Good Manufacturing Practice have an important place when learning such disciplines as *"Designing Chemical-and-Pharmaceutical Manufactures"*, *"Industrial Pharmaceutical Technology"* and *"Modeling and Design of Chemical-and-Pharmaceutical Enterprises in GMP System"*. The various types of practices (technological, pre-degree, research) at domestic enterprises where Good Manufacturing Practice rules are implemented (*"Arterium"* Corporation, a pharmaceutical company *"Darnytsia"*, PJSC *"Pharmak"*, Ltd. *"Ternopharm"*, etc.) are important for the professional and practical training of pharmacists.

However, the curriculum exactly for the third (educational-and-scientific) cycle includes a complex professional-and-oriented discipline *"Good Practices in Pharmaceutics"*, which aims to form an integrated view on the conception of Good Practices in quality assurance of medicines; pharmaceutical development; medicines preclinical and clinical investigation; medicines registration in Ukraine; drugs manufacturing in accordance with the requirements of Good Manufacturing Practice; storage and distribution of medicines by the requirements of Good Storage Practice and Good Distribution Practice; retail trade by the requirements of Good Pharmacy Practice, etc. Consequently, the graduate of the Lviv Polytechnic National University of the third (educational-and-scientific) cycle has sufficient knowledge concerning Guidelines of Good Practices.

However, first and second cycle students need an awareness of the generalized structure. A teacher assistance in modeling approximate fundamentals for further mastering of educational materials a huge information field such as separate issues, guidelines, orders of the Ministry of Health care of Ukraine, reference book, etc. is important especially for them.

Often, the authors of the educational literature suggest to students such a principle of material presentation as simulation and scaling material, diagrams and structures for better discipline perception. Typically, each scientist offers its structure a more accessible material submission.

In Lviv Polytechnic National University, students when studying the discipline *"Good Practices in Pharmaceutics"*, independently elaborate schemes of current regulatory documents that establish certain Good Practices. Fig. 1-3 show examples of Guidelines structures developed by students of specialty 226 "Pharmacy, Industrial Pharmacy" of the second cycle higher education program.

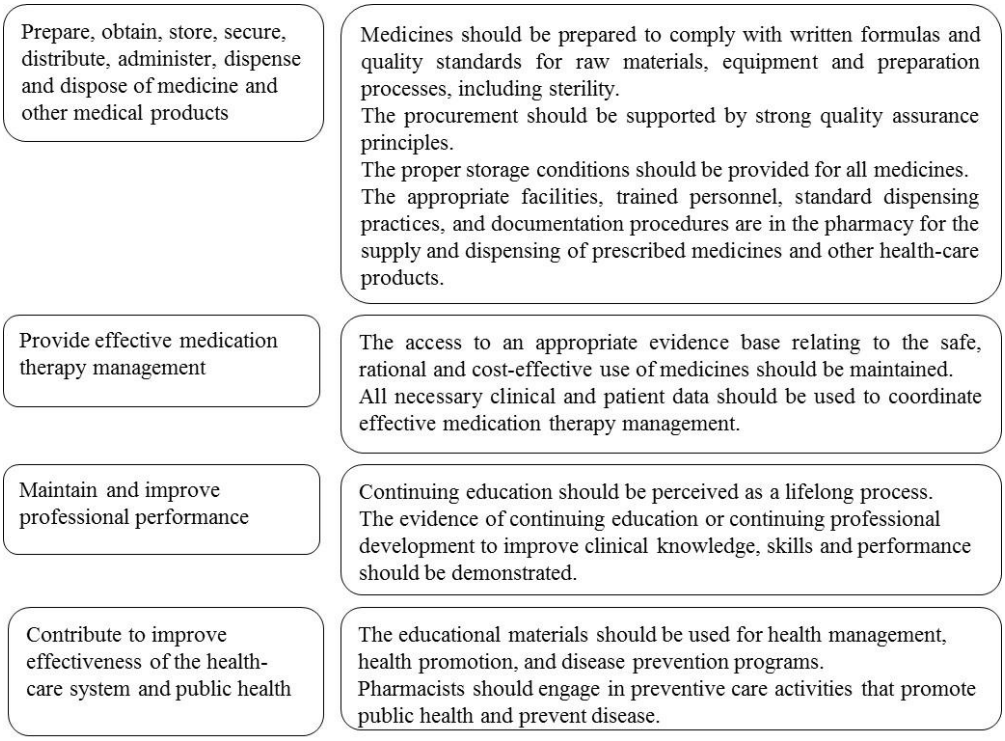

Fig. 1. Structure of Guidelines "Good Pharmacy Practice" developed by a student of second cycle of education program Rak H.

The development of such schemes by students with teacher assistance allows to improve the perception of the material and strengthen skills for independently analyzing, determining the essential elements and formulating conclusions about the necessary (possible) information, which is fundamental for the performance of the professional activity. While performing the task, students to learn and understand certain aspects, such as the fact that the quality of the medicines is "incorporated" into the drug at the stage of pharmaceutical development, and then confirmed during preclinical and clinical research. Further, the medicine receives a "permit to life", when passing state registration. After that, the specified quality is reproduced for each series at the stage of full-scale pharmaceutical manufacturing, it is maintained unchanged at the stages of storage and distribution and, finally, it is delivered to patients in pharmacies. Appropriate Good Practices are obligated for implementation to maintain the quality of medicines at all specified stages of drug turnover *(Law, Bader, Uzman, Williams, Bates, 2019; Ten Cate, Scheele, 2007).*

The pharmaceutical manufacturing requires Good Manufacturing Prctice compliance, which enables the achievement of appropriate quality, efficacy, and safety of the medicines, that laid down during pharmaceutical development and proven in preclinical and clinical trials.

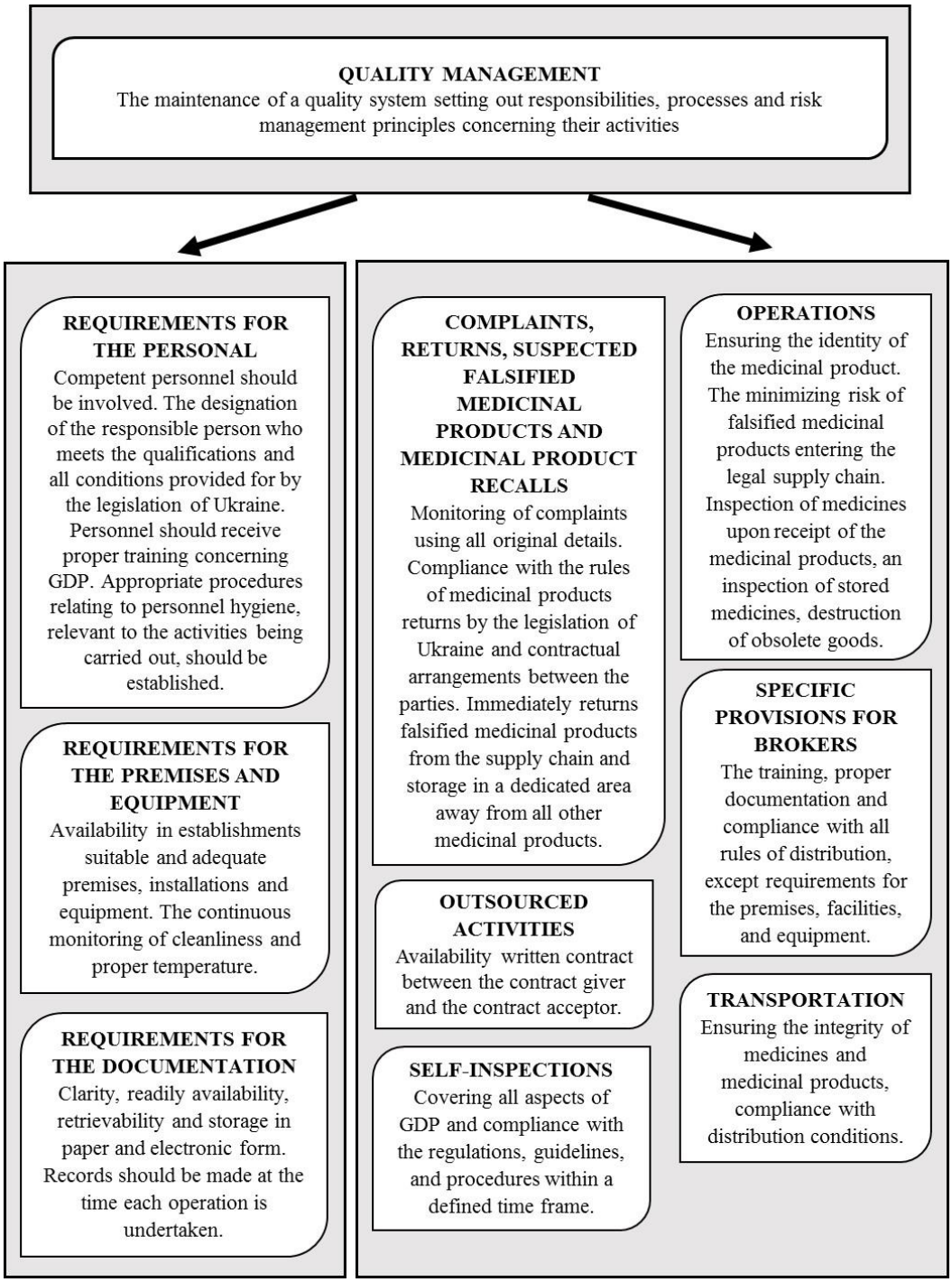

Fig. 2. Structure of Guidelines "Medicines. Good Distribution Practice. 42-5.0:2014", developed by a student of second cycle of education program *Dedyk L.*

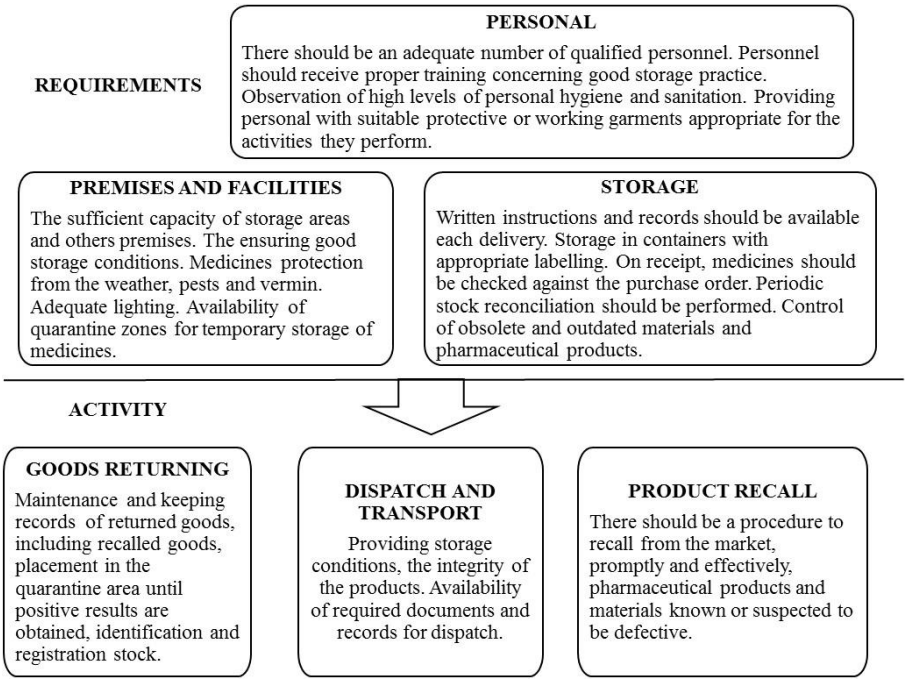

Fig. 3. Structure of Guidelines "Medicines. Good Storage Practice. 42-5.1:2011", developed by a student of second cycle of education program *Nos N.*

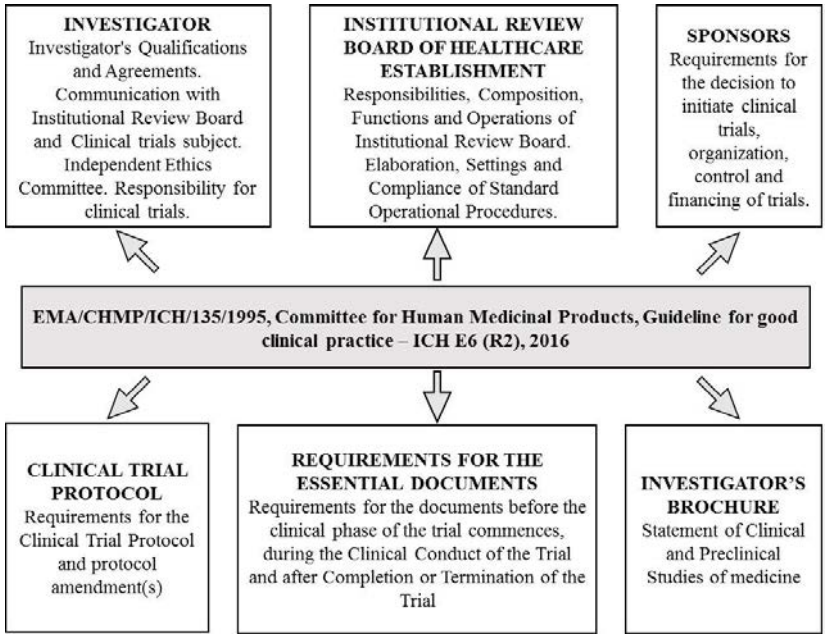

Fig. 4. Structure of Guidelines "Medicines. Good Clinical Practice. 42-7.0:2008", developed by a student of second cycle of education program *Spreys D.*

3. Conclusion and suggestions

1. A retrospective review of the curriculum has been carried out; the current educational process for specialty 226 "Pharmacy, Industrial Pharmacy", which takes place at the Lviv Polytechnic National University, has been analyzed.

2. The discipline "Good Practices in Pharmaceutics" includes the whole range of practices, so it is proposed at the Lviv Polytechnic National University for study at the third (educational-scientific) level.

3. Structural-and-logical schemas based on the Guidelines of Good Pharmaceutical Practices that greatly facilitate students' perception and assimilation of all the needed information have been elaborated.

4. The study of the possibility of mastering the discipline "Good Practices in Pharmaceutics" by students of specialty 226 "Pharmacy, Industrial Pharmacy" during the practice at the existing pharmaceutical enterprises can be considered perspective.

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