IMPLEMENTATION OF EUROPEAN REGULATORY EXPERIENCE AND MANAGEMENT OF THE PHARMACEUTICAL SECTOR OF THE HEALTH CARE INDUSTRY IN UNIVERSITY EDUCATION

SCIENTIFIC RESEARCH GROUP:

Voskoboinikova H.L.  
Prof., D. of Ped. Sc., PhD in Pharm.  
Department of Pharmacy  
Kyiv International University, Farmak JSC, Kyiv, Ukraine

Dovzhuk V. V.  
PhD in Pharm, Association Prof.  
Ukraine

Dovzhuk N.S.  
PhD in Ped.  
Ukraine

Konovalova L.V.  
PhD in Ped., Association Prof.  
Department of Organization and Economic of Pharmacy, Ukraine

Summary: The article is devoted to the implementation the experience of the pharmaceutical sector of the EU countries. The strategy of reforms of the pharmaceutical sector of the EU countries are being analyzed. Authors give their view to solving the problems, among them is the development of a strategy to ensure the quality of training of masters of pharmacy in university education.

Keywords: European experience, implementation of European regulatory, pharmaceutical sector, university education

Introduction. New challenges and demands of the European labor market determine the improvement of the system of professional training of masters of pharmacy in university education.

The integrated implementation of ISO international standards and the Guidelines of Good Practices in Pharmacy requires international cooperation of the
State System for Quality Assurance of Medicines and international (WHO, FDA) and European organizations (EMA) in matters of quality management, pharmaceutical development to ensure the quality of production, quality control of medicines [1-3].

The purpose of the study: to determine the conceptual foundations, normative and regulatory framework of the implementation of the European experience of managing the pharmaceutical sector of the EU health care industry in university education.

Research methods: comparative analysis of the legislative and regulatory framework, scientific sources, systematization of research in the pharmaceutical sector of EU countries and university education.

Research results and their discussion.

In order to harmonize the legislative and regulatory framework of the EU to ensure the quality of medical care for the population in Ukraine, it is necessary to:

- implementation of the Complex of good practices in pharmacy;
- attestation and independent audit of the conditions of drug development and production;
- licensing of all types of pharmaceutical activity;
- state registration of drugs;
- harmonized functioning of the State System of Quality Control of Medicinal Products.

The implementation of the basic modern concepts of the functioning of the State system of quality control of medicinal products in the conditions of European integration includes: quality management is the basis of the modern Concept of product quality assurance with the implementation of international standardization ISO 9001; a technological concept based on forecasting the quality of products based on the application of a complex of good practices in pharmacy: GLP, GCP, GMP, GDP, GPP, GSP, the "6 Sigma" system [4; 5], which determines the professional development of specialists in the pharmaceutical sector from university education throughout professional activity.

The main direction of the implementation of the experience of university pharmaceutical education in the countries of Central and Eastern Europe is to ensure the quality of the educational process of master's training in Ukraine, the implementation of a quality assurance system in higher education institutions.

The system of ensuring the quality of masters of pharmacy is based on the following principles: compliance with European and national quality standards of higher education; maximum satisfaction of society's requests and expectations regarding the professional training of masters of pharmacy in higher education institutions; the development of university autonomy, which is responsible for ensuring the quality of educational activities and the quality of higher education; democratic principles of leadership and personal responsibility of managers of educational processes; openness of information at all stages of ensuring the quality of the educational process; transparency and logic of decision-making processes; academic integrity and scientific ethics; an integrated combination of system and process approaches to the processes of educational activity and higher education; professional development and competence of employees; constant monitoring and improvement of the quality of educational activities and the quality of higher education; student-centered training based on a competency approach;
involvement of higher education seekers, employers and other interested parties in the process of quality assurance and implementation of aspects of dual education in the practical training of masters of pharmacy.

In turn, ensuring the quality of training of masters of pharmacy in university education requires the introduction of a number of measures: development of a strategy for ensuring the quality of educational activities and higher education; designing the organization of the educational activity quality assurance system; revision and modernization of educational programs with a certain periodicity and constant monitoring; formation of a system of responsibility of all structural divisions and employees for quality assurance; involvement of master's level applicants in quality assurance; independent evaluation of higher education applicants, scientific and pedagogical workers and pedagogical workers and regular publication of the results of such evaluations; ensuring professional development of pedagogical, scientific and scientific-pedagogical workers; ensuring the availability of the necessary resources for the organization of the educational process in accordance with the educational program; ensuring the availability of information systems for effective management of the educational process; ensuring publicity of information about educational programs; implementation of policy in the field of quality, its monitoring of the educational process.

Conclusions. It is promising to implement the experience of the pharmaceutical sector of the EU countries, namely: the introduction of a self-regulation system that allows relevant organizations to take an active part in the development and implementation of important regulatory and legal documents, to increase the level of pharmaceutical care in accordance with the needs of the population and to protect the interests of pharmaceutical industry specialists.

The strategy of reforms of the pharmaceutical sector of the EU countries is aimed at the maximum satisfaction of patients' needs for quality medicines and safety of use, promotion of availability of medicines and responsible use of medicines in view of cost and efficiency and introduction of a system for ensuring the quality of pharmaceutical care.

Therefore, the main strategic orientation is the development of a strategy to ensure the quality of training of masters of pharmacy in university education.

References: