



FACULTY OF PHARMACY MEDICAL UNIVERSITY SOFIA

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Approved from the Faculty council with protocol: No 3/04.05.2022 г

DEAN:

/prof. Al.Zlatkov, DSc/

DEPARTMENT “ORGANIZATION AND ECONOMICS OF PHARMACY”

SYLLABUS

of

Social pharmacy and pharmaceutical legislation

INCLUDED IN “PHARMACY” EDUCATION CURRICULUM

DEGREE OF EDUCATION: “**MASTER**”

CREDITS (ECTS): **12**

ANNOTATION

Medicines and pharmaceutical regulation is constantly evolving. In recent years, the scope of legislative and regulatory authority has gradually expanded in response to the increasing complexity of the pharmaceutical system and the public's need for rapid access to quality, effective and safe medicines. Social Pharmacy and Pharmaceutical Legislation is a two-semester, compulsory course for the MSc in Pharmacy and teaches the basic elements of the drug supply process, national medicines policy and all the important aspects of ensuring activities for access to quality, efficacious and safe medicines at affordable prices (manufacturing of medicines, marketing authorization, clinical trials, classification of medicines, wholesale and retail of medicines, price regulation and reimbursement,

pharmaceutical marketing, etc.). The basic requirements of pharmaceutical marketing, financial management of the pharmaceutical system, business accounting, inventory management and control are also covered. The aim of teaching the course is to form theoretical knowledge of drug and pharmaceutical regulation, to create practical skills of students to work with regulatory documents, to carry out activities related to drug supply, proper record keeping, to prepare for professional realization, competence and capacity for patient consultation, teamwork and compliance with good practices.

The course also focuses on the development of EU law on medicines and medicines activities, digital transformation, crisis management, supply chain recovery, e-health, pharmaco-economics, pharmaceutical care and clinical pharmacy as new areas for professional development, competencies and skills of future Master Pharmacists. The course curriculum prepares future pharmacists to be competitive in the job market with knowledge of the overall health and drug supply system that will be useful to them regardless of their field of practice.

During the practical exercises of the discipline, students work with case studies and documents on the main requirements of the European Medicines Agency and the Medicines Executive Agency, public registers, databases and sources concerning regulatory market access, authorisation of the manufacture, use, wholesale and retail of medicines and other health-related goods, pricing, reimbursement, advertising, responsible self-medication, etc.

At the end of the course, students should be able to know the main legislative documents that regulate the work of pharmacists, be able to apply them, carry out analyses of drug supply, control and pharmaceutical practice, know the main procedures and processes in the marketing of medicines, authorization of production, wholesale and retail of medicines, accountability, legislative and professional control of the activities of pharmacists.

Type of control and evaluation: The evaluation of students is based on an examination of overall preparation, participation in the process of knowledge acquisition during the two semesters, independent work and ongoing control through two colloquia.

English language training

SYLLABUS

1. Pharmaceutical system as a part of the health care system.
2. Basic concepts in law .
3. Law of the European Union. Institutions relevant to medicines regulation in the EU.
4. Basic laws in the health care system in Bulgaria - Health Act, Health Care Act, Health Insurance Act.
5. Purpose and structure of basic laws in pharmacy – Law on medicinal products in human medicine.
6. International and national regulation of control of narcotic drugs and precursors - Act on Control of Narcotic Drugs and Precursors.
7. Process of development of new medicines. Clinical trials.
8. Regulatory access of medicinal products to the European market.
9. Protection of intellectual property and data in the dossier of medicinal products.
10. Manufacturing of medicines.
11. Wholesale trade. Good distribution practice, basic elements and application.
12. Retailing of medicines. Good pharmaceutical practice. Pharmacy - legislative status and public functions.
13. Hospital pharmacies.
14. Economic accounting and financial management of the pharmaceutical system.
15. Legislative environment of professional association of pharmacists. Recognition of professional qualifications.
16. Pharmaceutical supply - types of pharmaceutical supply systems. Drug supply process. Selection of medicines.
17. Supply and distribution of medicines as elements of the drug supply process.
18. Medicines utilization as an element of the drug supply process. Factors influencing medicines use. Legislative requirements for prescribing and dispensing medicines.
19. Management of medicines during health crises.
20. Self-medication - nature, requirements and opportunities.
21. Distribution of costly and life-saving medicines - legislative requirements and organisation of supply. Medicines for the treatment of rare diseases.
22. Marketing of medicines. Ethical foundations of pharmaceutical marketing.
23. Pharmaceutical information and advertising. Information and advertising - definitions. Planning and creation of advertising.
24. Pharmacovigilance.
25. Legislative framework of pricing in the EU and Bulgaria.
26. Financing and control of medicines affordability. Health insurance as a system to improve accessibility of medicines.
27. Digital transformation of healthcare.
28. Control of the pharmaceutical system. Legislative and administrative oversight of pharmaceutical system operations. Institutions with control functions and scope of activities. Procedures for control of pharmaceutical sites and activities. Verification and SESPA.

29. Areas for development and regulation of the pharmaceutical system, profession, science and practice. Pharmacoeconomics. Pharmaceutical care. Clinical pharmacy.

30. Social Pharmacy and Pharmaceutical Legislation - Place, role and relevance to the practice of the Master Pharmacist, opportunities for upgrading and development.

Date

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