



***Катедра по организация и  
икономика на фармацията***

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Economics of Pharmacy***

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**EXAM TOPICS IN SOCIAL PHARMACY AND  
PHARMACEUTICAL LEGISLATION  
IX WINTER SEMESTER ACADEMIC YEAR 2024/2025, V COURSE**

1. Main participants in the pharmaceutical industry and main functions. National characteristics and historical development of the pharmaceutical industry in Bulgaria.
2. Basic concepts in law. Fundamentals of health and pharmaceutical legislation. Concept of good practices in pharmacy.
3. Medicines policy. Components of medicines policy. Generic drug policy. Follow-up of medicines policy.
4. Health Act - purpose, scope, and structure.
5. Health Insurance Act - purpose, scope, and structure.
6. Medical Establishments Act - purpose, scope, and structure.
7. Medicinal Products in Human Medicine Act - purpose, scope, and structure.
8. Control of Narcotic Substances and Precursors Act - purpose, scope, and structure.
9. International health and pharmaceutical organizations and their role in the field of healthcare.
10. Harmonization of pharmaceutical legislation. Pharmaceutical legislation of the European Union. Role of WHO and ICH.
11. Medicinal products. Process of developing new medicines. Legislative requirements for the development of new medicines - safety, quality, and efficacy.
12. Marketing Authorization for medicinal products in the EU - legislative requirements and basic procedures.
13. Medicinal dossier - structure and main sections. Determining the regimen of prescribing and dispensing of MPs.
14. Manufacturing of medicinal products - structure of the pharmaceutical industry, legislative requirements, types of production procedures.
15. Medicines supply chain. Concept and main stages. Management of MSC.
16. Selection of drugs as an element of MSC. WHO's list of essential medicines - criteria and recommendations.

17. Quantification methods of medicinal products.
18. Delivery of medicines - stages. Methods for selection of suppliers. Contract clauses. Public procurement act.
19. Stocks - concept, meaning, types. Stock management.
20. Distribution of medicines as an element of the medicines supply process. Wholesale trade of medicines. Main functions of wholesale traders.
21. Legislative requirements for wholesale trade with medicines. Organization of work in wholesale warehouses. Good distribution practice. Parallel trade with medicines.
22. Marketing - development and definitions. Marketing strategies. Marketing tools.
23. Specific features of pharmaceutical marketing. Ethical issues in pharmaceutical marketing.
24. Retail trade of medicinal products. Structure and legal requirements for the medicines retail system. Good pharmacy practice.
25. The pharmacy - legislative status and public functions. Requirements for the structure, order and organization of work in pharmacies. Types of pharmacies.
26. Hospital pharmacy - features in the organization of work. Management of the hospital pharmacy and its place in the structure of the hospital.
27. Medicines use. Factors affecting medicines use. Rational medicines use.
28. Legislative requirements for the prescription and dispensing of medicines. Types of prescription blanks. Electronic prescription. Pharmacy software.
29. Prescribing and dispensing of medicinal products containing narcotic substances. Prescribing and dispensing of medicinal products, reimbursed by the National Health Insurance Fund (NHIF).
30. Monitoring of drug safety. Pharmacovigilance objectives. Side effects. Legal framework in the EU and Bulgaria.
31. Medicinal information and advertising - definitions, sources, types. Legal framework.
32. Requirements for the summary of product characteristics, data on the packaging and leaflets of the medicinal products.
33. Distribution of specific groups of drugs – MPs containing narcotic substances, orphan medicines, self-medication, and over-the-counter medicines.
34. Prices and pricing of medicines. Basic elements of the price of medicines. Legislative framework of pricing in the EU and Bulgaria.
35. Legislative environment of the professional organization of pharmacists. Ethical aspects of professional organizations.
36. Undergraduate and postgraduate education of pharmacists – pharmacy specialties. Pharmaceutical personnel management.

37. Financing and crediting of the activity of the pharmaceutical companies. Sources of financing and types of credits. Development of a business plan. Management of financial flows in pharmaceutical companies.
38. Accounting. Types of accounting documents. Incomes and expenses in pharmaceutical companies.
39. Inventory - organization and procedure. Types of inventories.
40. Control of the pharmaceutical system. General concepts. Legislative regulation of control. Institutions with control functions and scope of their activity.
41. Conditions and procedure for taking samples from drugs and performing laboratory tests. Terms and conditions for blocking and withdrawal of medicines from manufacturers, warehouses for wholesale trade in medicines, pharmacies, and drugstores.
42. New areas of regulation of the pharmaceutical system and the pharmaceutical profession - pharmacoepidemiology, clinical pharmacy, pharmacogenetics, and pharmacogenomics.

Approved by:  
/Head of department: Assoc. Prof. D. Kafalova, PhD/

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