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SYLLABUS

for the state exam

in "Social pharmacy and pharmaceutical legislation"

1. Medicines policy. Components of medicines policy. Generic medicines policy. Follow-up of medicines policy.
2. Legal environment of functioning of the pharmaceutical comapanies. Basic concepts in law. Fundamentals of health and pharmaceutical legislation. Concept of good practices in pharmacy.
3. Health Act, Health Insurance Act, Medical Establishments Act – purpose, scope, structure.
4. Medicinal Products in Human Medicine Act – purpose, scope and structure.
5. Control of Narcotic Substances and Precursors Act – purpose, scope and structure.
6. Medicinal products of the European Union. Role of WHO and ICH.
7. Medical products. Process of developing new medicines. Legislative requirements for the development of new medicines – safety, quality and efficacy.
8. Marketing authorization of medicinal products in the EU – legislative requirements and basic procedures. Medicinal product dossier – structure and main sections. Determining the regime of prescribing and dispensing drugs.
9. Manufacturing of medicinal products – structure of the pharmaceutical industry, legal requirements, types of production procedures.
10. Medicines supply chain. Nature and main stages. Types of management of drug supply systems. Selection of drugs as an element of LSP. WHO's list of essential medicines – criteria and recommendations. Methods for calculating the required quantities of drugs.
11. Delivery of medicines – stages. Methods for selection of suppliers Conclusion of contracts. Contract clauses. Public procurement law.
12. Stocks – nature, meaning, types. Control of stocks and methods for their management.
13. Distribution of medicines as an element of the drug supply process. Wholesale of medicines. Main functions of wholesalers. Legislative requirements for wholesale trade in medicines. Organization of work in wholesale warehouses. Good distribution practice. Parallel trade in medicines.
14. Marketing – development and definitions. Marketing strategies. Marketing tools. Specific features of pharmaceutical marketing. Ethical foundations of pharmaceutical marketing.
15. Retail sale of medicinal products. Structure and legal requirements for the drug retail system. Good pharmacy practice. Pharmacy – legislative status and public functions. Requirements for the structure, order and organization of work in pharmacies. Types of pharmacies for outpatients and citizens.

16. Hospital pharmacy – features in the organization of work. Management of the hospital pharmacy and its place in the structure of the hospital.
17. Medicinal use. Factors affecting drug use. Rational drug use.
18. Legislative requirements for the prescription and dispensing of medicines. Types of prescription blankss and legal requirements. Prescription work. Electronic prescription. Pharmacy software.
19. Drug safety monitoring. Pharmacovigilance objectives. Side effects. Legal framework in the EU and Bulgaria.
20. Drug information and advertising - definitions, sources, types. Nature of pharmaceutical and drug information and advertising. Legislative framework. Requirements for the summary of product characteristics, data on packaging and leaflets of medicinal products.
21. Distribution of specific groups of medicines - narcotic medicines, orphan medicines, self-medication and over-the-counter medicines.
22. Prices and pricing of medicines. Basic elements of the price of medicines. Legislative framework of pricing in the EU and Bulgaria.
23. Legislative environment of the professional organization of pharmacists. Ethical aspects of professional organizations. Undergraduate and postgraduate education of pharmacists. Pharmaceutical personnel management.
24. Financing and crediting of the activity of the pharmaceutical sites. Sources of financing and types of credits. Development of a business plan. Management of financial flows in pharmaceutical sites.
25. Accounting. Types of accounting documents. Classification of revenues and expenses of pharmaceutical sites.
26. Inventory – organization and procedure. Types of inventory.
27. Control of the pharmaceutical system. General concepts. Legislative regulation of control. Institutions with control functions and scope of their activity.
28. 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.
29. Pharmacoeconomics – nature and types of pharmacoeconomic analyzes.
30. Pharmaceutical care – nature, prerequisites, purpose and tasks. Place of pharmaceutical care in modern pharmaceutical practice and basic steps in its implementation.

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