

SYLLABUS ON STATE EXAM ON

SOCIAL PHARMACY AND PHARMACEUTICAL LEGISLATION

The State Examination in Social Pharmacy and Pharmaceutical Legislation consists of a main written part followed by an oral interview with the State Examination Committee. Students are asked two questions to be developed in writing. The topics must be developed in detail, in pharmaceutical and terminologically correct language

1. Regulatory area for functioning of the pharmaceutical system. Main health and pharmaceutical normative acts and regulations, connection between them and the objects of regulation.
2. Bulgarian pharmaceutical legislation – Health law, Health establishments law, Health insurance legislation – structure and basic definitions. Attitude to the pharmaceutical activities.
3. Bulgarian pharmaceutical legislation – Law for medicinal products in human medicine – structure and basic definitions. Connection with European medicines` legislation.
4. Requirements for activities with narcotic drugs and precursors. International and Bulgarian legislation in the field of narcotics.
5. Medicines placing on the market – procedures, institutions, documents and validity of marketing authorization.
6. Clinical trials, manufacturing and import of medicines – requirements, peculiarities and control.
7. Wholesale distribution and parallel trade of medicines – essence, requirements and control.
8. Retail distribution of medicines – community pharmacies and hospital pharmacies. Structure, order and organization of the work in the pharmacy. Pharmacy manager responsibilities.
9. Requirements for prescribing and dispensing of drugs. Rights of the pharmacists and requirements for different types of prescriptions.
10. Drug information, drug promotion and communication with the patients.
11. Pharmacoepidemiology and post-marketing surveillance. Methods for collecting and analyzing of post-authorization data about adverse drug reactions.
12. Managing drug supply process. Main steps and content.
13. Selection and procurement of medicines, paid with public resources. Regulatory requirements.
14. Good distribution practice. Effective stock control management.
15. Medicines utilization – essence, measurement of medicines utilization and factors affecting the medicines utilization.
16. Medicines prices and medicines pricing methodologies.

17. Marketing of pharmaceuticals and medical services, represented by pharmaceutical companies.
18. Pharmacoeconomics – essence, basic requirements and cost analysis.
19. Main pharmacoeconomical methods – Cost-utility analysis and cost-minimization analysis.
20. Main pharmacoeconomical methods – Cost-effectiveness analysis and cost-benefit analysis.
21. Application of pharmacoeconomics in the reimbursement, price formation and drug manufacturing.
22. Essence of pharmaceutical care – definitions, information sources, terminology and impact on the health system.
23. Pharmaceutical care – place in the modern pharmacy. Stages and steps of implementation of the Pharmaceutical care.
24. Formation of individual plan for pharmaceutical care. Priorities, therapeutical aims, mechanisms for monitoring.

#### LITERATURE:

Petrova et al., 2012, Social Pharmacy and pharmaceutical legislation, Medical University, Sofia

Petrova et al., 2013, Pharmacoeconomics, Infopharma, Sofia

Petkova et al., 2011, Pharmaceutical care, practical book, Sofia Sofia

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