***SYLLABUS***

***for the State exam***

***in Social pharmacy and Pharmaceutical legislation***

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| 1. | Introduction – object, methods, tasks and goals. Basic concepts. Historical overview and stages in the development of pharmacy, pharmacy practice and profession. Relationship with other disciplines in the curriculum. |
| 2. | General concepts of jurisprudence. Legal rules and legal entities. Regulations - types, content, action, hierarchy. |
| 3. | Labor jurisprudence. Labour Code - origination of employment. Civil Servants Act. Law on State Administration. |
| 4. | Insurance law. Types of insurance risks. Health insurance rights and obligations. |
| 5. | National and European pharmaceutical legislation. National and European authorities and institutions in the field of medicinal products. International health and pharmaceutical organizations - species, areas of competence, role in aligning the requirements for medicinal products and activities with them. |
| 6. | Health legislation in Bulgaria – Law of Health, Law of Health Insurance, Low of Healthcare Establishments - general principles.  |
| 7. | Law on Medicinal Products in Human Medicine -General structure, scope, basic concepts. Harmonization with European directives. Regulations. |
| 8. | Narcotic Substances and Precursors - Act for the Control of Narcotic Drugs and Precursors. International Convention for the control of narcotic drugs and psychotropic substances. Convention on the suppression of illicit trafficking of narcotic drugs and psychotropic substances. Competent Authorities and policies to control and limit the spread of narcotic drugs. Responsibilities and duties of Master of pharmacy. |
| 9. | Regulated professions. Law on the Professional Association of Masters of Pharmacy. Professional rights and responsibilities. Recognition of qualifications within the EU and EEA.  |
| 10. | Drug regulation. Why we should regulate medicinal products? Disclaimer. Placing to the market of medicinal products – general provisions. Requirements for documentation for the Marketing Authorization of medicinal products. |
| 11. | Registration dossier of a medicinal product. Requirements, norms and standards. Modules. Format file. Specific requirements for different types of medicinal products. Assessment of authorization documentation. Assessment report. Public Assessment Report. |
| 12. | Procedures for the Marketing Authorization of medicinal products - types, scope, terms and responsibilities of the Marketing Authorization Holders and the Competent authorities (centralized procedure, mutual recognition and decentralized procedure, national procedure). |
| 13. | Placing to the market - Marketing Authorization of homeopathic and traditional herbal medicinal products. Specific requirements for homeopathic and traditional herbal medicinal products. Procedures for the Marketing Authorization and Registration of homeopathic and traditional herbal medicinal products.  |
| 14. | Renewal of the Marketing Authorization. Variations of Marketing Authorization. Classification, deadlines, procedures. Parallel imports of medicinal products. |
| 15. | Clinical trials – general provisions, clinical trials with vulnerable patients, Ethics committee, permission to conduct clinical trials, variations, suspensions of clinical trial, safety monitoring, non-interventional trials. Medical research projects. International law in the field of the clinical trials and medical research projects. |
| 16. | Manufacturing and Importation of medicinal products, active substances and medicinal products for clinical trials. Requirements, documentation, content and terms of procedures. Good Manufacturing Practice. Responsibilities of the Qualified person and the Quality control person. Person responsible for production.  |
| 17. | Wholesale of medicinal products - requirements, procedures, documentation and deadlines. Obligations and rights of the responsible Master of pharmacy. Good Distribution Practice.  |
| 18. | Retail sale of medicinal products. Types of pharmacies. Ownership and management, requirements and structure. Hospital Pharmacy - characteristics of status, activities and responsibilities. Features of modern pharmacy - trends and development directions. Features and characteristics of the pharmacies in the Member States. Good pharmacy practice. Procedures for issuing a permission for retail. Drug Stores. |
| 19. | Prescribing and dispensing of medicinal products. Ordinance for prescribing and dispensing of medicinal products. Types of recipes, recipes stages of work.Prescribing and dispensing of medicinal products partially paid and free recipes. |
| 20. | Prescribing and dispensing of medicinal products containing narcotics drugs to the pharmacy. Reporting of movement, accountability and control of narcotic drugs. |
| 21. | Labeling, Mock-ups and Product Information Leaflet of medicinal products.Classification of medicinal products.  |
| 22. | Pharmacovigilance.  |
| 23. | Pharmacoepidemiology. Basic concepts, objects, methods, goals and objectives. |
| 24. | Borderline products. Determining the origin of products.Medical devices. Food and food supplements. Biocides. Cosmetic products. |
| 25. | Medicinal products used in pediatrics. |
| 26. | Orphan drugs. Advance therapy.  |
| 27. | State control of medicinal products. Competent Authorities responsible for state control. Type of inspection. Sanctions.  |
| 28. | Terms and conditions for sampling and testing on medicinal products for state control. Blocking and withdrawn of medicinal products from the market. |
| 29. | National Drug Policy. Elements of the national drug policy. Essential medicines, pricing and reimbursement of medicinal products. Selection of medicinal products. Criteria and recommendations of WHO. Standards and practices in the EU. |
| 30. | Drug utilization and rational drug use. Availability and affordability of medicines. Independent sources of drug information. Best practices for drug administration. The role of clinical pharmacy. |
| 31. | Relationships between companies and the budget. Tax system. Types of taxes, items of tax, collection.  |
| 32. | Accounting - definition, goals, reporting systems, documents, and terms of safekeeping. Methods of accounting. Inventory. |
| 33. | Banking. System of organization of the banking system. Role and functions of money. Monetary and fiscal policy. Relationships between companies and banks. Finance and investment analysis. Financing and lending to the pharmaceutical companies. Funding sources and types of loans. |
| 34. | Pharmaceutical management and operations management. Basic functions of the manager. Operational and strategic management.  |
| 35. | Pharmaceutical marketing. Basic concepts in marketing. Types of consumer demand. Types of marketing and basic functions. |
| 36. | Marketing concepts - nature and development. Marketing strategies - methods and techniques. Management of the marketing mix. Specific features of the pharmaceutical marketing. |
| 37. | Prices and pricing of medicines. Control and regulation of prices. Systems for reimbursement of medicinal products. Positive list of medicines. Provision of medicines under the Law of Health. |
| 38. | Measuring and Estimating Costs. Costing terms. Cost categorization. Alternative methods of categorization. Perspective. Timing adjustments for cost. Average versus marginal or incremental costs. Resources for cost estimations. |
| 39. | Cost-Minimization Analysis |
| 40. | Cost-Effectiveness Analysis Presentation of cost and effectiveness. Cost-effectiveness grid. Cost-Effectiveness plane. Incremental net-benefit analysis. Intermediate outcomes versus primary outcomes. Efficacy versus effectiveness.  |
| 41. | Cost-Utility Analysis. Steps in calculating QALYS. |
| 42. | Cost-Benefit Analysis. Advantages and disadvantages of Cost-benefit analysis. Conducting of Cost-benefit analysis. Difference between costs versus benefits. Measuring indirect and intangible benefits. Calculating of results of costs and benefits. Calculating of cost/benefit ratio. Evaluations of Cost-benefit analyses in literature. |
| 43. | Health-Related Quality of Life: Health Status Measures-HRQoL: Utility measures versus health status measures. General or generic measures. Disease specific measures. Domains of health status. General health perception. Pharmacoeconomics and health status measures.  |
| 44. | Decision Analysis: Steps in decision analysis.  |
| 45. | Markov Modeling: Steps in Markov Modeling. Disadvantages of Markov. Modeling. Advanced issues. Calculation methods. Half-cycle corrections.  |
| 46. | Pharmacoeconomics of Pharmacy Services. History of pharmacy services. Review of research. Summaries of specific multipharmacy projects.  |
| 47. | Health Technology Assessment. Stakeholders in health technology assessment. Essence of health technology assessment. Clinical effectiveness assessment. Economic analysis (assessment) of the health technology. Assessment (analysis) of the budget impact of the health technology. Assessment of social, ethical and organizational aspects of the health technology.  |
| 48. | The concept of "Pharmaceutical care". The pharmacist and the process of drug use. Safety and effectiveness of drug use. Main objectives, functions and phases of pharmaceutical care. Pharmaceutical care in the practice of pharmacy - monitoring of therapeutic results. |
| 49. | Strategies to improve the compliance of the patient. The relationship of doctor-patient-pharmacist - a major factor in the level of compliance. Ways to improve the level of compliance by improving communication.Ethical, psychological and deontological issues of pharmaceutical care to patients. |
| 50. | Pharmaceutical care in real practice. Assessment of therapeutics results. |
| 51. | Pharmaceutical care of patients with cardiovascular diseases.  |
| 52. | Pharmaceutical care of patients with diabetes.  |
| 53. | Pharmaceutical care of patients with asthma.  |
| 54. | Pharmaceutical care of children.  |
| 55. | Pharmaceutical care of elderly patients - patients with hypertension, musculo-skeletal disorders, insomnia, nervous system disorders.  |