Посветени на хуманността
МЕДИЦИНСКИ УНИВЕРСИТЕТ – ПЛОВДИВ
4002 Пловдив, бул. Васил Априлов № 15А

www.mu-plovdiv.bg

Dedicated to humanity
MEDICAL UNIVERSITY – PLOVDIV
15A, Vasil Aprilov Blvd., 4002 Plovdiv, Bulgaria

Катедра по фармацевтични науки
4002 Пловдив, ул. Братя Бъкстон № 120
email: pharm.sciences@ff.mu-plovdiv.bg

Department of Pharmaceutical Sciences
120, Bratya Bakston St., 4002 Plovdiv, Bulgaria
email: pharm.sciences@ff.mu-plovdiv.bg

SYLLABUS FOR THE SEMESTER EXAM
in SOCIAL PHARMACY AND PHARMACEUTICAL LEGISLATION
for students in V course for the academic year 2023/2024

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.

11. Pharmaceutical legislation of the European Union. Role of WHO and ICH.

12. Medicinal products. Process of developing new medicines. Legislative requirements for the development of new medicines – safety, quality and efficacy.

13. Marketing Authorization for medicinal products in the EU – legislative requirements and basic procedures.

14. Medicinal dossier – structure and main sections. Determining the regimen of prescribing and dispensing of MPs.

15. Manufacturing of medicinal products – structure of the pharmaceutical industry, legislative requirements, and types of production procedures.

16. Medicines supply chain. Concept and main stages. Management of MSC.

17. Selection of drugs as an element of MSC. WHO’s list of essential medicines – criteria and recommendations.

18. Quantification methods of medicinal products.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. Community 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. 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 inventory.

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.

Prepared by:

/Assoc. prof. St. Gueorguiev, PhD/