

MEDICAL UNIVESRITY – PLOVDIV
FACULTY OF PHARMACY
DEPARTMENT OF ORGANISATION AND ECONOMICS
OF PHARMACY

PROGRAM

in

SOCIAL PHARMACY AND
PHARMACEUTICAL LEGISLATION
AND REGULATION

Approved by the Department Council - Protocol № 01/09.01.2023

Confirmed by the Faculty Council - Protocol № 01/25.01.2023

**MEDICAL UNIVERSITY – PLOVDIV
FACULTY OF PHARMACY**

Syllabus

| Discipline | Final exam/ semester | According to the Faculty of Pharmacy curriculum of MU-Plovdiv Academic hours | | | | ECTS | Academic hours in semester | | | |
|---|----------------------|--|----------|-----------|----------------|------|----------------------------|----|-------------|----|
| | | Auditorium | Lectures | Practices | Non-auditorium | | VIII semester | | IX semester | |
| | | | | | | | L | P | L | P |
| Social Pharmacy and Pharmaceutical Legislation and Regulation | IX | 150 | 60 | 90 | 184 | 12,3 | 30 | 45 | 30 | 45 |

DISCIPLINE:

Social Pharmacy and Pharmaceutical Legislation and Regulation

TYPE OF DISCIPLINE ACCORDING TO THE UNIFORM STATE REQUIREMENTS:

Mandatory

LEVEL OF QUALIFICATION:

Master (M)

FORMS OF TRAINING:

Lectures, practical classes, self-tuition

YEAR OF TRAINING:

IV and V course

DURATION OF TRAINING:

Two semesters

ACADEMIC HOURS:

60 teaching hours of lectures, 90 teaching hours of practical classes

TECHNICAL EQUIPMENT APPLIED IN THE TRAINING:

Multimedia presentations, discussions, solving practical problems, developing a thesis

FORMS OF EVALUATION:

Examination (written and oral), colloquia, development of theses

EVALUATION CRITERIA:

The grade is formed based on the examination – written and oral, and the colloquium results

ASPECTS OF EVALUATION CRITERIA:

Participation in discussions, colloquia, development of theses

SEMESTER EXAM:

Yes (written and oral examination)

STATE EXAM:

Yes

LECTURER:

Habilitated lecturer from Department of Organisation and Economics of Pharmacy

DEPARTMENT:

Department of Organisation and Economics of Pharmacy

ANNOTATION

The place and importance of the Social Pharmacy discipline and pharmaceutical legislation and regulation in the curriculum for preparation of medical specialists with professional orientation “Pharmacy” is determined by the character of the future professional activity to be performed by the Master of Pharmacy. It is one of the principal special disciplines in the education of the pharmacy students, which, based on the scientific methods and technologies, provides the regulatory framework for the practitioners of one of the professions regulated in the EU member-states and in Bulgaria. The overview of the medicine from research to the rational use and the various aspects (legal, economic, social, professional, ethical, etc.) of the pharmaceutical practice aims to prepare Master of Pharmacy as a key factor and to enhance their role within the health-care system.

The Curriculum includes some theoretical, methodological and practical issues of pharmaceutical management by reviewing current management approaches and methods of the social systems and public activities, the place of pharmaceutical subjects within the health-care system, management and control bodies at national, regional and local levels. Principal place is dedicated to the stages and activities in the medicine procurement process. Selection, determining the necessary quantities, supply, allotment, distribution and rational use requirements are reviewed in detail. The issues about the essence, tasks, structure, activities and organisation of the work in pharmacy stores, hospital pharmacies, pharmacy depots and other divisions of the pharmaceutical sector are covered to a sufficient level, which enables the implementation of contemporary control over the development, manufacturing and realization of medicines.

With a view to increasing the level of economic knowledge of the future Masters of Pharmacy, curriculum includes also some issues regarding the relations of the companies with the banks and budget, methods and systems for stock management, logistics, price formation, insurance rights and risks, etc. Topics associated with accountancy and record-keeping – essence, forms, methods and functions, are also foreseen.

The offered curriculum and structure of the education in Social Pharmacy and Pharmaceutical Legislation and Regulation covers the minimum government requirements for acquisition of Master of Pharmacy degree and complies with the new development trends in the pharmacist profession and practice in Bulgaria and the EU countries.

MAIN TASKS OF THE CURRICULUM

To acquaint the students with the main concepts, methods and legislative requirements related to pharmacy and health care in Bulgaria and the EU member states, as well as with the relations of the companies with the banks and budget, methods and systems for stock management, logistics, price formation, insurance rights and risks, etc. Topics associated with accountancy and record-keeping – essence, forms, methods and functions, are also foreseen. To familiarise the students with various pharmaceutical and international organisations.

The offered curriculum and structure of the education in Social Pharmacy and Pharmaceutical Legislation and Regulation covers the minimum government requirements for acquisition of Master of Pharmacy degree and complies with the new development trends in the pharmacist profession and practice in Bulgaria and the EU countries.

EXPECTED RESULTS

The overall course of education is intended to enable the students to prepare individually and adequately all documents needed by a Master of Pharmacy to open a pharmacy store or wholesale depot and for work at various health institutions; to be familiar with the health-care legislation. At the end of the course of education each student must know how to organise the work in a community pharmacy, hospital pharmacy or pharmaceutical wholesale depot; to be familiar with the various premises in the pharmacy store and the order of medicines therein; to keep records; to control the stocks in the pharmacy store or wholesale depot; to organize individually marketing strategies.

LECTURE SCHEDULE
Course IV, Semester VIII

| № | TOPIC | HOURS |
|-----|---|-------|
| 1. | Pharmaceutical industry. Main participants in the pharmaceutical industry. Development of the pharmaceutical industry in Bulgaria. | 2 |
| 2. | Medicines policy-theoretical basis and components. Application of the Medicines policy and the National Health Strategy. | 2 |
| 3. | Legal framework for functioning of the pharmaceutical industry. Basis of healthcare and pharmaceutical legislation and regulation. Good practices as standards in pharmacy. | 2 |
| 4. | International Health Organizations. International Pharmaceutical Organizations. Bulgarian health and pharmaceutical organizations. | 2 |
| 5. | Bulgarian healthcare legislation and regulation. Health Act- purpose and scope. | 2 |
| 6. | Bulgarian healthcare legislation and regulation. Health establishments act- purpose and scope. Health insurance act- purpose and scope. | 2 |
| 7. | Bulgarian healthcare legislation and regulation. Medicinal products in Human Medicine Act- purpose and scope. | 2 |
| 8. | Bulgarian healthcare legislation and regulation. Narcotic substances and precursors control act- purpose and scope. | 2 |
| 9. | Harmonization of the pharmaceutical regulation. European pharmaceutical legislation. The role of WHO and ICH. | 2 |
| 10. | Medicinal products. Regulatory requirements on medicines development- safety, quality and efficacy requirements. Good Clinical Practice. | 2 |
| 11. | Marketing authorization of medicinal products in the European union. Legal requirements and main procedures. | 2 |
| 12. | Manufacturing of medicinal products. Legislative requirements to manufacturers. Good Manufacturing practice. | 2 |
| 13. | Pharmaceutical supply chain- fundamentals and main stages. Medicinal products selection. WHO's Essential medicines criteria. Quantification methods. | 2 |
| 14. | Contracting and delivery of MPs. Methods for selection of distributors. Distribution contracts-clauses. Public procurement act. Control of stocks by wholesale traders. | 2 |
| 15. | Medicines distribution. Wholesale trade with MPs. Wholesale trade with medical devices. Legal requirements to wholesale traders. Parallel trade with medicines. | 2 |

TOTAL: 30 hours

LECTURE SCHEDULE

Course V, Semester IX

| № | TOPIC | HOURS |
|------------|--|--------------|
| 1. | Retail trade with MP. Good Pharmacy Practice. Pharmacy-legal definition and social functions. Requirements for the premises and the organization of the work in pharmacies. Ordinance 28/2008. Community pharmacies and hospital pharmacies. | 2 |
| 2. | Particularities of the organization of work in hospital pharmacies. European standards for hospital pharmacy. | 2 |
| 3. | Medicines use. Factors affecting medicines use. Rational use of medicines. | 2 |
| 4. | Legal requirements to the prescribing and dispensing of medicinal products. Types of prescription blanks. | 2 |
| 5. | Medicines safety monitoring. Pharmacovigilance -aims. Side effects. Legal framework in EU and Bulgaria. | 2 |
| 6. | Pharmaceutical marketing. Historic background and definitions. Marketing tools. | 2 |
| 7. | Specifics of the pharmaceutical marketing. Ethical issues in pharmaceutical marketing. | 2 |
| 8. | Pharmaceutical information and advertising. Resources of medicinal information. Legal framework. Requirements to the summary of the product characteristics the package labeling and the product leaflets. | 2 |
| 9. | Distribution and dispensing of MPs containing narcotic substances, orphan medicines and non-prescription medicines. | 2 |
| 10. | Pricing and reimbursement of MPs. Main components of prices. Legal requirements to medicines pricing in Bulgaria. | 2 |
| 11. | Financing of the activities of pharmaceutical companies. Types of credits. Business and financial plan development. Financial flows. | 2 |
| 12. | Pharmaceutical accounting. Types of accounting documentation. Incomes and expenses categorization. Inventory-types and ways of performing. | 2 |
| 13. | Control of the pharmaceutical industry. Organization of audits. Regulatory bodies of the pharmaceutical objects - scope of work. | 2 |
| 14. | Professional organization of pharmacists. Undergraduate and postgraduate education of pharmacists. | 2 |
| 15. | Novel professional realization areas for pharmacists. Pharmacoepidemiology. Clinical pharmacy and evidence-based medicine. | 2 |

TOTAL: 30 hours

PRACTICAL CLASSES SCHEDULE

Course IV, Semester VIII

| № | TOPIC | HOURS |
|-----------|--|--------------|
| 1 | Medicines policy – concept and monitoring. Indicators for assessment of the medicines policy. | 3 |
| 2 | Generic medicines policy. Development and application of the medicines policy. | 3 |
| 3 | Health Act. Structure of the Act. Main definitions and terms. | 3 |
| 4 | Health Establishments Act. Structure of the Act. Main definitions and terms. Health Insurance Act. Structure of the Act. Major definitions and terms. | 3 |
| 5 | MPHMA. Structure of the Law. Major definitions and terms. | 3 |
| 6 | Control of Narcotic Substances and Precursors Act. Structure of the Law. Major definitions and terms. Institutions, controlling the application of narcotic substances for medical purposes. | 3 |
| 7 | Retail trade with medicines. Good Pharmaceutical practice. Pharmacy-legal definition and functions. Regulation of pharmacies throughout Europe. | 3 |
| 8 | Requirements to the arrangement, procedure and organization of work in community pharmacies. Ordinance №28/2008. Retail trade authorization requirements. | 3 |
| 9 | Organization of the work in hospital pharmacies. European standards for hospital pharmacy. | 3 |
| 10 | Medicines use. Factors affecting medicines use. Methods for quantification. Defined daily dose – calculation and application. | 3 |
| 11 | Regulations on prescribing and dispensing of MPs. Practical tasks with prescription blanks. E-prescriptions and pharmacy software. | 3 |
| 12 | Regulations on prescribing and dispensing of MPs. Dispensing MPs containing narcotic substances. Practical tasks with prescriptions for MPs reimbursed by the NHIF. | 3 |
| 13 | Pharmaceutical information and advertising. Resources of medicinal information. Legal framework. Requirements to the summary of the product characteristics the package labeling and the product leaflets. | 3 |
| 14 | Colloquium on topics 2-13. | 3 |
| 15 | Control of the pharmaceutical system. Institutions with control functions and activity scope. | 3 |

TOTAL: 45 hours

PRACTICAL CLASSES SCHEDULE

Course V, Semester IX

| № | TOPIC | HOURS |
|------------|--|--------------|
| 1. | Marketing authorization of medicinal products - procedures and legal requirements. Dossier for application for marketing authorization of the medicinal product. Practical tasks for medicines categorization (prescription and non-prescription medicines). | 3 |
| 2. | Medicines supply chain. Planning and organization of the medicines supply processes. | 3 |
| 3. | Medicines selection. Essential medicines list of the WHO. Positive drug list in Bulgaria. Medicines quantification-tasks, problems solving. | 3 |
| 4. | Contracting and delivery of MPs. Methods for selection of distributors. Distribution contracts-clauses. Public procurement act. | 3 |
| 5. | Medicines distribution. Wholesale trade with MPs. Legal requirements to wholesale traders. Organization of the activities performed in pharmaceutical warehouses. | 3 |
| 6. | Management of stocks. ABC method, VEN/VED method. Problems solving. | 3 |
| 7. | Pharmaceutical marketing- concept and development. Marketing tools. Marketing strategies for the products and services of community pharmacies. | 3 |
| 8. | Pricing and reimbursement of medicinal products. Maximum price of prescription-only MPs- problems solving. | 3 |
| 9. | Funding and crediting of pharmaceutical companies. Types of credits. | 3 |
| 10. | Types of economic accounting. Accounting records. Incomes and expenses in the pharmaceutical sector. Inventory-concept and types. Organization of inventory performing. | 3 |
| 11. | Pharmacoepidemiology. Medicines safety monitoring. Types of side effects. Safety reporting systems. | 3 |
| 12. | Professional organization of pharmacists. Undergraduate and postgraduate education of pharmacists. | 3 |
| 13. | Novel professional realization areas for pharmacists. Clinical pharmacy. Pharmacogenetics and pharmacogenomics. | 3 |
| 14. | Colloquium on topics 1-13. | 3 |
| 15. | Falsified medicines. Medicines verification. Bulgarian medicines verification organization. | 3 |

TOTAL: 45 hours

LECTURES – THESES

IV course, VIII semester

LECTURE No. 1 – 2 teaching hours

Pharmaceutical industry. Main participants in the pharmaceutical industry.

Development of the pharmaceutical industry in Bulgaria.

1. Introduction
2. Pharmaceutical industry management
3. Control bodies and participants in the pharmaceutical industry
4. National particularities and history of the pharmaceutical industry in Bulgaria

LECTURE No. 2 – 2 teaching hours

Medicines policy-theoretical basis and components.

Application of the Medicines policy and the National Health Strategy.

1. Medicines Policy
2. Main elements of the national medicines policy
3. National health strategy of MoH

LECTURE No. 3 – 2 teaching hours

Legal framework for functioning of the pharmaceutical industry. Basis of healthcare and pharmaceutical legislation and regulation. Good practices as standards in pharmacy.

1. Law
 - 1.1. Legal rules
 - 1.2. Legal acts
 - 1.3. Legal subjects
2. Basis of healthcare and pharmaceutical legislation and regulation
3. Good practices as standards in pharmacy

LECTURE No. 4 – 2 teaching hours

International Health Organizations.

International Pharmaceutical Organizations. Bulgarian health and pharmaceutical organizations.

1. International Health Organizations
 - 1.1. International Red Cross (IRC)
 - 1.2. WHO
 - 1.3. UNESCO
 - 1.4. ILO
 - 1.5. UNICEF
2. Non-governmental organizations and unions
 - 2.1. Private foundations.
3. Role of WHO in internationalizing of the health legislation
4. International pharmaceutical organizations
 - 4.1. FIP
 - 4.2. PhRMA
 - 4.3. APhA
 - 4.4. EphEU
5. Bulgarian pharmaceutical organizations

LECTURE No. 5 – 2 teaching hours

Bulgarian healthcare legislation and regulation. Health Act- purpose and scope.

1. Brief historical review of health legislation in Bulgaria
2. Brief historical review of pharmaceutical legislation in Bulgaria
3. Health Act-purpose and scope
4. Health Act-implementation

LECTURE No. 6 – 2 teaching hours

Bulgarian healthcare legislation and regulation. Health establishments act-purpose and scope. Health insurance act-purpose and scope.

1. Health establishments act-purpose and scope
2. Health establishments-types and organization of activities
3. Health insurance act-purpose and scope
4. Insurance system –functions of the NHIF

LECTURE No. 7 – 2 teaching hours

Bulgarian healthcare legislation and regulation. Medicinal products in Human Medicine Act-purpose and scope.

1. MPHMA-aim
2. Purpose
3. Scope

LECTURE No. 8 – 2 teaching hours

Bulgarian healthcare legislation and regulation. Narcotic substances and precursors control act-purpose and scope.

1. UN convention on narcotic substances
2. Narcotic substances and precursors control act-purpose and scope

LECTURE No. 9 – 2 teaching hours

Harmonization of the pharmaceutical regulation. European pharmaceutical legislation. The role of WHO and ICH.

1. Brief historical review
2. European pharmaceutical legislation
3. EMA
4. ICH

LECTURE No. 10 – 2 teaching hours

Medicinal products. Regulatory requirements on medicines development-safety, quality and efficacy requirements. Good Clinical Practice.

1. Medicinal products-definition
2. Safety, quality and efficacy
3. Good Clinical Practice

LECTURE No. 11 – 2 teaching hours

Marketing authorization of medicinal products in the European union. Legal requirements and main procedures.

1. Medicines development
2. Marketing authorization of medicinal products in the European union
3. Centralized procedure
4. Mutual recognition procedure
5. National procedures

LECTURE No. 12 – 2 teaching hours

Manufacturing of medicinal products. Legislative requirements to manufacturers. Good Manufacturing practice.

1. Manufacturing of medicinal products
2. Legislative requirements to manufacturers
3. Good Manufacturing practice
4. Types of manufacturing processes

LECTURE No. 13 – 2 teaching hours

Pharmaceutical supply chain- fundamentals and main stages. Medicinal products selection. WHO's Essential medicines criteria. Quantification methods.

1. Pharmaceutical supply chain
2. PSC-planning and monitoring
3. Selection of medicines
4. Essential medicines
5. Quantification methods

LECTURE No. 14 – 2 teaching hours

Contracting and delivery of MPs. Methods for selection of distributors. Distribution contracts-clauses. Public procurement act. Control of stocks by wholesale traders.

1. Contracting and delivery of MPs
2. Methods for selection of distributors
3. Distribution contracts-clauses
4. Control of stocks by wholesale traders
5. Public procurement act

LECTURE No. 15 – 2 teaching hours

Medicines distribution. Wholesale trade with MPs. Wholesale trade with medical devices. Legal requirements to wholesale traders. Parallel trade with medicines.

1. Medicines distribution
2. Wholesale trade with MPs
3. Legal requirements to wholesale traders
4. Parallel trade with medicines

LECTURES – THESES

V course, IX semester

LECTURE No. 1 – 2 teaching hours

Retail trade with MPs. Good Pharmacy Practice. Pharmacy-legal definition and social functions. Requirements for the premises and the organization of the work in pharmacies. Ordinance 28/2008. Community pharmacies and hospital pharmacies.

1. Retail trade with MPs
2. Good Pharmacy Practice
3. Pharmacy-legal definition and social functions
4. Requirements for the premises and the organization of the work in pharmacies
5. Ordinance 28/2008
6. Community pharmacies and hospital pharmacies

LECTURE No. 2 – 2 teaching hours

Particularities of the organization of work in hospital pharmacies. European standards for hospital pharmacy.

1. Hospital pharmacy
2. Hospital pharmacist
3. EU standards for hospital pharmacy
4. Organization of the activities performed in hospital pharmacies

LECTURE No. 3 – 2 teaching hours

Medicines use. Factors affecting medicines use. Rational use of medicines.

1. Medicines use. Factors affecting medicines use
2. Quantification and qualification methods to measure medicines use
3. Rational use of medicines-the role of the pharmacist

LECTURE No. 4 – 2 teaching hours

Legal requirements to the prescribing and dispensing of medicinal products.

Types of prescription blanks.

1. Prescribing of MPs
2. Dispensing of MPs
3. Prescription blanks-structure and types

LECTURE No. 5 – 2 teaching hours

Medicines safety monitoring. Pharmacovigilance-aims. Side effects. Legal framework in EU and Bulgaria.

1. Safety
2. Safety-monitoring
3. Pharmacovigilance-aims
4. Legal framework in EU and Bulgaria
5. Adverse drug reactions

LECTURE No. 6 – 2 teaching hours

Pharmaceutical marketing. Historic background and definitions. Marketing tools.

1. Marketing-concept and marketing strategies
2. Marketing tools
3. Pharmaceutical marketing
4. Demand

LECTURE No. 7 – 2 teaching hours

Specifics of the pharmaceutical marketing. Ethical issues in pharmaceutical marketing.

1. Pharmaceutical marketing
2. Marketing Mix
3. Ethical issues in pharmaceutical marketing

LECTURE No. 8 – 2 teaching hours

Pharmaceutical information and advertising. Resources of medicinal information.

Legal framework. Requirements to the summary of the product characteristics the package labeling and the product leaflets.

1. Organisation of medicine-related information
 - 1.1. Essence of medicine-related information
 - 1.2. Systems of medicine-related information
 - 1.3. Forms of medicine-related information
2. Legal framework. Requirements to the summary of the product characteristics the package labeling and the product leaflets

LECTURE No. 9 – 2 teaching hours

Distribution and dispensing of MPs containing narcotic substances, orphan medicines and non-prescription medicines.

1. Medicinal products containing narcotic substances
2. Green and yellow prescription blanks
3. Prescription and dispensing requirements
4. Orphan medicines
5. OTC medicines

LECTURE No. 10 – 2 teaching hours

Pricing and reimbursement of MPs. Main components of prices.

Legal requirements to medicines pricing in Bulgaria.

1. Price-definition
2. Pricing of medicinal products-international overview
3. Pricing and reimbursement in Bulgaria
4. National council on pricing and reimbursement- structure and functions

LECTURE No. 11 – 2 teaching hours

Financing of the activities of pharmaceutical companies. Types of credits. Business and financial plan development. Financial flows.

1. Financial institutions. Types of banks
2. Types of credits
3. Business and financial plan development
4. Financial flows

LECTURE No. 12 – 2 teaching hours

Pharmaceutical accounting. Types of accounting documentation. Incomes and expenses categorization. Inventory-types and ways of performing.

1. Accountancy
2. Accountancy Act
 - 2.1. Types of accounting systems
 - 2.2. Accounting documents
3. Inventory
 - 3.1 Types
 - 3.2 Organisation and order of inventory

LECTURE No. 13 – 2 teaching hours

Control of the pharmaceutical industry. Organization of audits.

Regulatory bodies of the pharmaceutical objects -scope of work.

1. Control of the pharmaceutical industry
2. Audits
3. Organization of audits
4. Regulatory bodies
5. Control function of BDA
6. Control function of NHIF

LECTURE No. 14 – 2 teaching hours

Professional organization of pharmacists. Undergraduate and postgraduate education of pharmacists

1. Professional organization of pharmacists- Bulgarian pharmaceutical union
2. Ethical code of BPHU
3. Undergraduate pharmacy education
4. Postgraduate education and specializations

LECTURE No. 15 – 2 teaching hours

Novel professional realization areas for pharmacists. Pharmacoepidemiology. Clinical pharmacy and evidence-based medicine.

1. Pharmacoepidemiology
 - 1.1. Origin
 - 1.2. International society for pharmacoepidemiology ISPE
 - 1.3. Pharmacoepidemiology studies
2. Clinical pharmacy and evidence- based medicine
3. The role of the clinical pharmacist
4. Clinical studies
4. Pharmaceutical care

PRACTICAL CLASSES – THESES

IV course, VIII semester

PRACTICAL CLASS No. 1 – 3 teaching hours

Medicines policy - concept and monitoring.

Indicators for assessment of the medicines policy.

1. Essence and main components
2. Monitoring of medicinal policy
3. Evaluation indicators

PRACTICAL CLASS No. 2 – 3 teaching hours

Generic medicines policy. Development and application of the medicines policy.

1. Generic medicines
2. Generic medicines policy
3. Development and application of the medicines policy

PRACTICAL CLASS No. 3 – 3 teaching hours

Health Act. Structure of the Act. Main definitions and terms

1. Health act-historic background
2. Structure of the act. Control bodies
3. Main definitions and terms
4. Patient rights and obligations
5. Non-conventional methods for improvement of the individual health

PRACTICAL CLASS No. 4 – 3 teaching hours

Health Establishments Act. Structure of the Act. Main definitions and terms. Health Insurance Act. Structure of the Act. Major definitions and terms.

1. Health establishments-definition and classification
2. Structure and managing bodies in the health establishments
3. Control of the activities performed in health establishments
4. The place of the pharmacist in the health establishment
5. Types of insurance systems. Insurance in Bulgaria
6. National health insurance fund (NHIF)

PRACTICAL CLASS No. 5 – 3 teaching hours

MPHMA. Structure of the Law. Major definitions and terms.

1. Main definitions and concepts
2. Structure of the act (MPHMA)
3. Medical product-definition
4. Regulations on manufacturing, wholesale trade and retail trade with MPs
5. Bulgarian drug agency-functions

PRACTICAL CLASS No. 6 – 3 teaching hours

CONTROL ON NARCOTIC SUBSTANCES AND PRECURSORS ACT (CNSPA)

1. Structure of the act
2. Main definitions and concepts
3. Instructions controlling the use of narcotic substances for medical purposes
 - 3.1. Solving of practical cases to determine the compliance between Bulgarian and international legislation for control on narcotic substances
 - 3.2. Conditions and documents for issue of license for work with narcotic substances
 - 3.3. Conditions and documents for issue of license for work with narcotic substances to pharmaceutical wholesale companies

PRACTICAL CLASS No. 7 – 3 teaching hours

RETAIL TRADE

1. Types of pharmacies
2. Organisation of work in pharmacy for out-patient service
 - 2.1. Ordinance № 28 of 9.12.2008 for the arrangement, order and organization of work at pharmacy stores and nomenclature of medical products

PRACTICAL CLASS No. 8 – 3 teaching hours

Requirements to the arrangement, procedure and organization of work in community pharmacies. Ordinance №28/2008. Retail trade authorization requirements.

1. Ordinance № 28 of 2008
2. Types of pharmacies
3. Pharmacy – premises
4. Pharmacy manager – legal requirements
5. Requirements on the storage and dispensing of MPs
6. Documentation requirements

PRACTICAL CLASS No. 9 – 3 teaching hours

PARTICULARITIES OF THE ORGANIZATION OF WORK AT A HOSPITAL PHARMACY

1. Organisation of work at a hospital pharmacy
 - 1.1. Main specifics and characteristics – financing, organisation of supply, control
 - 1.2. Work with medicine chart – prescribing and dispensing medicines to hospital patients
 - 1.3. Ordinances. List of medicines available in hospital pharmacies

PRACTICAL CLASS No. 10 – 3 teaching hours

Medicines use.

1. Factors affecting medicines use
2. Defined daily dose-definition and calculation
3. Practical tasks and problem solving
4. Discussing examples for irrational medicines use

PRACTICAL CLASS No. 11 – 3 teaching hours

LEGAL REQUIREMENTS TO PRESCRIBING AND DISPENSING OF MEDICINES.

1. Prescriptions
 - 1.1. Types of prescription blanks
 - 1.2. Practical work with prescriptions
 - 1.3. Pharmacy software
 - 1.4. E-prescriptions and digital healthcare

PRACTICAL CLASS No. 12 – 3 teaching hours

PRESCRIBING AND DISPENSING DRUGS. Regulations on prescribing and dispensing of MPs. Dispensing MPs containing narcotic substances. Practical tasks with prescriptions for MPs reimbursed by the NHIF.

1. Prescribing and dispensing medicines containing narcotics
2. Yellow and green prescription blanks
3. Practical tasks with prescriptions for MPs reimbursed by the NHIF

PRACTICAL CLASS No. 13 – 3 teaching hours

Pharmaceutical information and advertising.

1. Resources of medicinal information
2. Legal framework
3. Requirements to the summary of the product characteristics
4. Package labeling and product leaflet
5. Types of pharmaceutical advertising

PRACTICAL CLASS No. 14 – 3 teaching hours

COLLOQUIUM

PRACTICAL CLASS No. 15 – 3 teaching hours

Control of the pharmaceutical system.

1. Institutions with control functions and activity scope
2. Taking samples of MPs for quality control assessments-rules
3. Comparison between inspections performed by the BDA and the RHI inspectors
4. Questions and tasks
5. Blocking and marketing withdrawal of medicinal products that showed quality or safety discrepancies

PRACTICAL CLASSES – THESES

V course, IX semester

PRACTICAL CLASS No. 1 – 3 teaching hours

Marketing authorization of medicinal products- procedures and legal requirements.

1. Dossier for application for marketing authorization of the medicinal product
2. Practical tasks
3. Practical tasks for medicines categorization (prescription and non-prescription medicines)

PRACTICAL CLASS No. 2 – 3 teaching hours

Medicines supply chain. Planning and organization of the medicines supply processes.

1. Medicines supply chain
2. Stages of MSC. Types of MSC-advantages and disadvantages
3. Planning and organization of the medicines supply processes
4. MSC in Bulgaria

PRACTICAL CLASS No. 3 – 3 teaching hours

Medicines selection.

1. Essential medicines list of the WHO
2. Positive drug list in Bulgaria
3. Medicines quantification – tasks, problems solving

PRACTICAL CLASS No. 4 – 3 teaching hours

Contracting and delivery of MPs.

1. Methods for selection of distributors
2. Distribution contracts-clauses
3. Public procurement act

PRACTICAL CLASS No. 5 – 3 teaching hours

Medicines distribution.

1. Wholesale trade with MPs
2. Legal requirements to wholesale traders
3. Organization of the activities performed in pharmaceutical warehouses

PRACTICAL CLASS No. 6 – 3 teaching hours

Management of stocks.

1. ABC method
2. VEN/VED method
3. Problems solving

PRACTICAL CLASS No. 7 – 3 teaching hours

Pharmaceutical marketing

1. Concept and development
2. Marketing tools
3. Marketing strategies for the products and services of community pharmacies

PRACTICAL CLASS No. 8 – 3 teaching hours

Pricing and reimbursement of medicinal products.

1. Pricing
2. Reimbursement in Bulgaria
3. Maximum price of prescription-only MPs
4. Problems solving

PRACTICAL CLASS No. 9 – 3 teaching hours

Funding and crediting of pharmaceutical companies.

1. Funding and crediting of pharmaceutical companies
2. Types of banks
3. Types of credits
4. Development of financial and business plan

PRACTICAL CLASS No. 10 – 3 teaching hours

Accounting.

1. Types of economic accounting
2. Accounting records
3. Incomes and expenses in the pharmaceutical sector
4. Inventory-concept and types
5. Organization of inventory performing

PRACTICAL CLASS No. 11 – 3 teaching hours

Pharmacoepidemiology.

1. Pharmacoepidemiology
2. Medicines safety monitoring
3. Types of side effects
4. Safety reporting systems
5. Practical tasks

PRACTICAL CLASS No. 12 – 3 teaching hours

Professional organization of pharmacists.

1. Bulgarian pharmaceutical union
2. Undergraduate and postgraduate education of pharmacists
3. Ethics in pharmacy

PRACTICAL CLASS No. 13 – 3 teaching hours

Novel professional realization areas for pharmacists.

1. Clinical pharmacy
2. Pharmacogenetics
3. Pharmagenomics

PRACTICAL CLASS No. 14 – 3 teaching hours

Colloquium on topics 1-13.

PRACTICAL CLASS No. 15– 3 teaching hours

Falsified medicines.

1. Falsified medicines
2. Medicines verification
3. Bulgarian medicines verification organization

BIBLIOGRAPHY

1. Генка Петрова, В. Петкова И. Гетов, А. Стоименова, Ал. Савова, М. Манова, Х. Лебанова, Е. Григоров, Св. Георгиева, Ст. Георгиев, М. Димитрова, М. Камушева, З. Миткова, К. Андреевска, Д. Грекова, В. Маджаров, *Социална фармация и фармацевтично законодателство*: София : Инфофарма ЕООД, 2017, ISBN 978-954-92652-6-2
2. Наредба № 28 от 9.12.2008 за устройството, реда и организацията на работата в аптеките и номенклатурата на лекарствените продукти Наредба №7/2000 на МЗ за задължителните данни върху опаковките и в листовките на лекарствените продукти и към указанията за употреба на медицинските изделия
3. Наредба № 1 от 25 Януари 2012 г. за изискванията към рекламата на лекарствени продукти
4. ЗАКОН ЗА ЗДРАВЕТО, Държавен вестник, брой 40 от 29 май 2012 г.
5. ЗАКОН ЗА ЛЕЧЕБНИТЕ ЗАВЕДЕНИЯ, ДВ, бр. 45 от 14 юни 2011 г.
6. ЗАКОН ЗА МЕДИЦИНСКИТЕ ИЗДЕЛИЯ , Изм. ДВ. бр. 39 от 20 май 2011 г.
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8. ЗАКОН ЗА ХРАНИТЕ, Изм. ДВ. бр. 8 от 25 януари 2011 г.
9. [ЗАКОН ЗА ЛЕКАРСТВЕНИТЕ ПРОДУКТИ В ХУМАННАТА МЕДИЦИНА](#), В сила от 13.04.2007 г., изм. ДВ. бр. 60 от 5 август 2011 г.
10. [ЗАКОН ЗА ТРАНСПЛАНТАЦИЯ НА ОРГАНИ, ТЪКАНИ И КЛЕТКИ](#), Изм. ДВ. бр. 9 от 28 януари 2011 г.
11. [ЗАКОН ЗА КОНТРОЛ ВЪРХУ НАРКОТИЧНИТЕ ВЕЩЕСТВА И ПРЕКУРСОРИТЕ](#), Изм. ДВ. бр. 12 от 8 февруари 2011 г.
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13. [Наредба № 1 от 25 януари 2012 г. за изискванията към рекламата на лекарствените продукти](#), Издадена от Министерството на здравеопазването, обнародвана в Държавен вестник, брой 10 от 3 февруари 2012 г.
14. [Наредба № 29 от 9 декември 2008 г. за условията и реда за организация на работата в дрогерията](#), Издадена от Министерството на здравеопазването, изм. в Държавен вестник, брой 2 от 6 януари 2012 г.
15. [Наредба за регулиране и регистриране на цените на лекарствените продукти, условията, правилата и критериите за включване, промени и/или изключване на лекарствени продукти от ПЛС и условията и реда за работа на Комисията по цени и реимбурсиране](#), Приета с ПМС № 340 от 14.12.2011 г., обнародвана в Държавен вестник, брой 100 от 20 декември 2011 г.
16. Начева Р., *Обща теория на счетоводството*, Тракия-М, София, 2001
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CONSPECTUS

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.
3. Concept of good practices in pharmacy.
4. Medicines policy. Components of medicines policy. Generic drug policy.
5. Follow-up of medicines policy.
6. Health Act – purpose, scope and structure.
7. Health Insurance Act – purpose, scope and structure.
8. Medical Establishments Act – purpose, scope and structure.
9. Medicinal Products in Human Medicine Act – purpose, scope and structure.
10. Control of Narcotic Substances and Precursors Act – purpose, scope and structure.
11. International health and pharmaceutical organizations and their role in the field of healthcare.
12. Harmonization of pharmaceutical legislation.
13. Pharmaceutical legislation of the European Union. Role of WHO and ICH.
14. Medicinal products. Process of developing new medicines. Legislative requirements for the development of new medicines - safety, quality and efficacy.
15. Marketing Authorization for medicinal products in the EU – legislative requirements and basic procedures.
16. Medicinal dossier – structure and main sections. Determining the regimen of prescribing and dispensing of MPs.
17. Manufacturing of medicinal products - structure of the pharmaceutical industry, legislative requirements, types of production procedures.
18. Medicines supply chain. Concept and main stages. Management of MSC.
19. Selection of drugs as an element of MSC. WHO's list of essential medicines – criteria and recommendations.
20. Quantification methods of medicinal products.
21. Delivery of medicines – stages. Methods for selection of suppliers. Contract clauses. Public procurement act.
22. Stocks – concept, meaning, types. Stock management.
23. Distribution of medicines as an element of the medicines supply process. Wholesale trade of medicines. Main functions of wholesale traders.
24. Legislative requirements for wholesale trade with medicines. Organization of work in wholesale warehouses. Good distribution practice. Parallel trade with medicines.
25. Marketing – development and definitions. Marketing strategies. Marketing tools.
26. Specific features of pharmaceutical marketing. Ethical issues in pharmaceutical marketing.
27. Retail trade of medicinal products. Structure and legal requirements for the medicines retail system. Good pharmacy practice.
28. The pharmacy – legislative status and public functions. Requirements for the structure, order and organization of work in pharmacies. Types of pharmacies.

29. Hospital pharmacy – features in the organization of work. Management of the hospital pharmacy and its place in the structure of the hospital.
30. Medicines use. Factors affecting medicines use. Rational medicines use.
31. Legislative requirements for the prescription and dispensing of medicines. Types of prescription blanks. Electronic prescription. Pharmacy software.
32. Prescribing and dispensing of medicinal products containing narcotic substances. Prescribing and dispensing of medicinal products, reimbursed by the National Health Insurance Fund (NHIF).
33. Monitoring of drug safety. Pharmacovigilance objectives. Side effects. Legal framework in the EU and Bulgaria.
34. Medicinal information and advertising – definitions, sources, types. Legal framework.
35. Requirements for the summary of product characteristics, data on the packaging and leaflets of the medicinal products.
36. Distribution of specific groups of drugs – MPs containing narcotic substances, orphan medicines, self-medication and over-the-counter medicines.
37. Prices and pricing of medicines. Basic elements of the price of medicines. Legislative framework of pricing in the EU and Bulgaria.
38. Legislative environment of the professional organization of pharmacists. Ethical aspects of professional organizations.
39. Undergraduate and postgraduate education of pharmacists – pharmacy specialties. Pharmaceutical personnel management.
40. 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.
41. Accounting. Types of accounting documents. Incomes and expenses in pharmaceutical companies.
42. Inventory – organization and procedure. Types of inventories.
43. Control of the pharmaceutical system. General concepts. Legislative regulation of control. Institutions with control functions and scope of their activity.
44. 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.
45. New areas of regulation of the pharmaceutical system and the pharmaceutical profession – pharmacoepidemiology, clinical pharmacy, pharmacogenetics and pharmacogenomics.

STATE EXAM CONSPECTUS

1. Medicines policy. Components of medicines policy. Generic medicines policy. Follow-up of medicines policy.
2. Legal environment of functioning of the pharmaceutical companies. 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.