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Minister of Health

CURRICULUM

for POST-GRADUATE SPECIALIZATON

ON

HOSPITAL PHARMACY

2016

1. Introduction

1.1. Postgraduate speciality name – "Hospital Pharmacy"

1.2. Duration of education and training – 3 (three) years

1.3. Required basic education – obtained Master's degree in "Pharmacy" and acquired professional qualification "Master of Pharmacy"

1.4. Definition of speciality: The postgraduate speciality Hospital Pharmacy for Masters of Pharmacy is a systematic, multidisciplinary and integrated process of theoretical and practical training and acquisition of competencies and skills to perform specific actions related to procurement, preparation, storage, production and distribution of medicines and medical devices in hospitals. The scope covers integral components such as counseling, consultation, management and monitoring related to the safe, effective and efficient use of material, financial and human resources to achieve optimal outcomes.

2. Objective

The objective of the Hospital Pharmacy specialization is to train staff working in the health system to perform specific activities and provide services related to the selection, supply storage, preparation and distribution of medicines and medical devices in hospital care settings. They should also provide advice to medical professionals and patients on the safe, efficient and effective use of medicinal products for optimal outcomes. This knowledge will allow more efficient performance of the professionals aspiring to become

hospital pharmacists in pharmacies of hospitals while optimizing the activities related to the selection, purchase, supply, prescribing, dispensing and preparation of medicines for maximum and informed results.

The aim is achieved by systematic acquisition of knowledge and practical skills in the field of social and administrative pharmacy, drug regulation, pharmacology, toxicology, pharmaceutical drug formulations, biopharmacy, health technology assessment, pharmacoepidemiology, medical devices, management, logistics and communication over a three-year course.

Modern theoretical background enables specializing professionals to participate actively and fully in activities promoting safety and quality of all processes related to medicinal products and medical devices concerning patients in hospitals.

3. Knowledge, skills and competencies residents are expected to acquire

Postgraduate training for acquiring specialty Hospital Pharmacy is oriented towards building knowledge and practical skills and competencies for management, logistics, standardization and organization processes related to drugs and medical devices in the hospital pharmacy. It provides additional knowledge to Masters of Pharmacy for pharmacological and toxicological aspects of drug therapy as well as pharmacoepidemiology and monitoring of product safety. There is a special focus in the training on furthering competencies for health technology assessment and the provision of hospital pharmacy services. Hospital Pharmacy specialization graduates will also acquire skills related to technological and biopharmaceutical aspects in the preparation and supervision of medicinal products in hospital pharmacies.

4. Education

4.1. Theoretical training – separate lecture modules in the course of 3 years.

4.2. Practical training – in the course of 3 years in Faculty of Pharmacy at a university, hospitals accredited for practical training for the specialty under the Healthcare Establishments Act.

4.3. Each module ends with a colloquium and/or individual assignment.

I. Curriculum by modules*

Year	Thematic modules	Form of education		Number of hours for theoretical education	Number of hours for practical education	Number of hours for self-study	Total number for the year
		regular	*distance*				
I	**I**	×	×	20	-	20	**130**
	II	×	×	30	20	20	
	III	×	-	10	-	10	
II	**IV**	×	×	30	10	20	**140**
	V	×	×	20	10	20	
	VI	×	-	20	10	-	
III	**VII**	×	×	20	15	10	**150**
	VIII	×	-	40	20	-	
	IX	-	×	-	-	45	
Total hours:				**190**	**85**	**145**	**420**

The theoretical education is held annually in the course of 15 working days on the premises of training facilities. The remainder of the time is intended for practical classes, distance learning, self-education, including time for independent work, papers and case studies, as well as preparation for and attendance of colloquia. The total number of academic hours required for completion of specialty is 420.

** Duration of each module – 5 (five) study days; each module ends with a colloquium and/or individual assignment.*

II. Theoretical syllabus

First year

Module I. Administrative pharmacy and regulation

Theoretical education – topics (total 20 study hours)

1. Basic principles of pharmaceutical regulation. Good practices for medicines.

2. European regulatory framework for medicines and activities related to them.

3. National regulatory framework for medicines and activities related to them.

4. Legal regulation of operations of healthcare establishments.

5. Regulatory framework for hospital pharmacies in the EU and Bulgaria.

6. Challenges and basic principles of eHealth/ mHealth and verification of authenticity of medicines.

7. Good pharmaceutical practice with a focus on hospital pharmacy.

8. Regulation of clinical trials for medicinal products - the place of the hospital pharmacy, rights and obligations of hospital pharmacists.

9. Accreditation - requirements, procedures and indicators for assessing the activities in the hospital pharmacy.

10. Documentation, control and reporting of activities in the hospital pharmacy.

Distance education – topics *(self-study)*

11. Historical development of hospital pharmacy.

12. Reading, writing and critical analysis of pharmaceutical scientific publications.

13. Operation and use of electronic documents and potential of their application.

14. International and European organizations related to the development of hospital pharmacy.

15. Case study - participation of Masters of Pharmacy in hospital councils, boards, and committees.

Module II. Hospital pharmacy organization and medical devices

Theoretical education – topics (total 30 study hours)

1. Theoretical principles of management. Basic rules and principles of pharmaceutical management.

2. Management of human resources. Continuing training, specialization, and courses.

3. Documentation and standard operating procedures in hospital pharmacies.

4. Information systems, electronic documents and software.

5. Routine monitoring and conducting of audits. Inspections and self-evaluation.

6. Drug donation. Regulatory requirements and procedures. Good Donation Practice of the World Health Organization.

7. Furnishing and equipment of hospital pharmacies. Contemporary concepts, requirements, standards, and recommendations. Principles and practice of ergonomics.

8. Automated systems for arrangement, selection, and packaging of medicinal products in hospital pharmacies.

9. Organization of operational handling of and work equipment for cytotoxic drugs.

10. Standards and requirements for centralized preparation of drugs in hospital pharmacies.

11. Requirements and rules for management of pharmaceutical waste. Classification of waste and methods of waste treatment.

12. Legal regulation of medical devices. Classification. Material requirements. CE marking. Symbols related to labeling of products. Blocking, withdrawal, and destruction of medical devices.

13. Nomenclature systems in medical devices. Implantable medical devices.

14. Pricing of medical devices. Payment by the National Health Insurance Fund for medical devices for hospital use.

15. Safety of medical devices. Systems for supervision, reporting, and evaluation of incidents related to medical devices. Corrective actions.

Practical education – total of 20 study hours

1. Preparation of organizational chart of duties and processes in hospital pharmacies.

2. Implementation of tasks related to audits and inspections.

3. Solving of cases related to hospital pharmacies management.

4. Preparation of documentation for drug donation.

5. Solving of situational tasks related to disposal and destruction of medicinal products and medical devices.

6. Reporting incidents with medical devices with a focus on safety issues.

7. Tasks for classifying and labeling of medical devices.

Distance education – topics (*self-study***)**

1. Origination and development of the science of management.

2. Systemic approach to management. Development and application of the ‘sustainable development’ concept. Management at hospital pharmacy level.

3. Knowledge, skills, and qualities hospital pharmacists are required to possess in order to be efficient managers.

4. Manufacturing of medical devices. Innovative medical devices. Custom-made medical devices.

5. Case study – description of a medical device for a procurement procedure.

Module III. Ethics and communication in the practice of hospital pharmacists

Theoretical education – topics (total 10 study hours)

1. Ethics and deontology – fundamentals and major theoretical principles.
2. Principles of effective communication. Staff recruitment and management – essence principles, stages, and significance.
3. Contemporary pharmaceutical and drug information systems. Information flows management.
4. Science, education, and research activities in hospital pharmacies. Practices and programs for training of students, PhD students, and residents.
5. Patient rights and guaranteeing patient safety – essence and practical implications for health care establishments.

Distance education – case study project (*independent work***)**

Second year

Module IV. Pharmacological and toxicological aspects of drug therapy

Theoretical education – topics (total 30 study hours)

1. Clinical trials. Good Clinical Practice (GCP). Drug safety in pre-clinical and clinical trials.
2. Pharmacokinetics and drug metabolism.
3. Therapeutic drug monitoring.
4. Pharmacokinetics and pharmacogenomics.
5. Drug interactions – levels and monitoring.
6. Drug therapy in patients at risk – pediatric, geriatric patients, pregnancy and lactation.
7. Management of hospital-acquired infections. Antibiotics treatment and resistance.
8. Treatment of disorders of the central nervous system. Genetic aspects of neurodegenerative conditions and pharmacotherapy. Monitoring of treatment of disorders of the central nervous system.
9. Pain management – pathophysiology, pharmacology, and clinical and pharmaceutical aspects of pain. Adjunctive therapy in oncology.
10. Treatment of cardiovascular disorders – acute myocardial infarction, heart rhythm disorders, heart failure. Pathophysiology and pharmacotherapy. Monitoring of treatment of cardiovascular disorders.
11. Coagulation disorders. Monitoring of anticoagulation therapy.
12. Cancer treatment – antitumor chemotherapy and monitoring. Target and adjunctive cancer treatment.
13. Therapy in transplantology. Immunosuppressors - monitoring.
14. Diabetes mellitus – pathophysiology and pharmacotherapeutical approaches.
15. Rear diseases treatment.
16. Parenteral nutrition – indications, route of administration, and main components. Stability and compatibility of drugs with parenteral nutrition systems.
17. Radiopharmaceuticals – application in nuclear medicine. Adverse reactions in radiopharmaceuticals use.
18. Iatrogenic disorders and drug-induced damages.
19. Drug toxicity. Acute intoxications and toxidromes. Antidote treatment.
20. Medication errors and polypragmasy.

Practical education – topics (total 10 study hours)

1. Dosage regimen for drugs with problematic kinetics (e.g. gentamicin, digoxin, sodium valproate, theophylline, etc.).
2. Impact of comorbidity (renal and/or liver failure) on drug kinetics.
3. Interpretation of clinical laboratory indicators and implications for pharmacotherapy.
4. Pharmacotherapy guidelines.
5. Discussion of pharmacotherapy case studies.

Distance education – topics *(self-study)*

1. Drug interactions at pharmaceutical, pharmacokinetic, and pharmacodynamic level – clinical significance/relevance.
2. Drug interactions - approaches and evaluation methods.
3. Adverse drug reactions – mechanisms. Case studies.

Module V. Health technology assessment and hospital pharmacy services

Theoretical education – topics (total 20 study hours)

1. The concepts of evidence-based medicine and pharmacy.
2. Health economics, pharmacoeconomics, and health technology assessment – basic concepts, principles, interconnections, objectives and tasks.
3. Main methods of cost-effectiveness analysis of drug therapies. Identification of costs and benefits.

Measuring the balance between resources inputs and treatment outcomes.

4. Principles of good practice for analytical solution modeling in evaluating health technology assessment.

5. Role of pharmacists in improving response to treatment and quality of life of patients. Tools for evaluation of quality of life.

6. Recording and tracking of data related to intake of medicinal products.

7. Techniques for improving quality of life of patients.

8. Rules, principles, and recommendations for special pharmaceutical care for patients in home settings. Motivation of patients for active involvement in their own treatment.

9. Counseling and recommendations by pharmacists on the regimen of nutrition and taking of medicinal products in home settings. Enteral nutrition.

10. Providing services with value added in hospital pharmacies. Point-of-care testing (POCT).

11. Role of hospital pharmacists in activities promoting health and preventive screening.

Practical education – total 10 study hours

1. Financial models for controlling drug costs and budgeting. Problems involving discounting.

2. Analysis of data on use of medicinal products and designing of models for forecasting purposes.

3. Collecting data required for health technology assessment.

4. Discussion of case studies in cytostatic treatment and problems related to its application.

5. Discussion of case studies in transplantation and problems related to its application.

Distance education – topics *(self-study)*

1. Dispensing of drugs containing narcotic substances. Legal requirements, protocols and organization of processes.

2. Sequential therapy.

3. Quality standard of services in oncological pharmacy.

4. Translational medicine.

5. Advanced therapy medicinal products.

Module VI. Quality assurance, standardization, and logistics

Theoretical education – topics (total 20 study hours)

1. Quality, quality management approaches, international quality standards applicable in hospital pharmacy.

2. Role of pharmacists in assuring quality and safety in hospital pharmacies.

3. Risk management in hospital pharmacies.

4. Protocol of actions in case of patient medication errors.

5. Terms and conditions for treatment with medicinal products without market authorization for Bulgaria. Inclusion, modifications, and procurement of medicinal products in the list under Art. 266a, para 2 of the Medicinal Products for Human Use Act.

6. Designing, issuance, introduction, and monitoring of standards and operating guidelines for hospital pharmacies.

7. Logistics and stock management – concepts, principles, objectives, methodology, and models. Logistics process and activities.

8. Types of hospital pharmacies stock. Batches and shelf life. Computer-based inventory management system. Barcodes.

9. Integrated supply chain management. Stock planning for shortages and emergency contingencies.

10. Logistics instruments and analyses.

Practical education – total 10 study hours

1. Designing of hospital pharmacy risk management guidelines.

2. Solving of tasks related to logistics processes in hospital pharmacies.

3. Solving of tasks related to stock.

Third year

Module VII. Epidemiology and pharmacoepidemiology

Theoretical education – topics (total 20 study hours)

1. Epidemiology and pharmacoepidemiology – definition, scope, application.

2. Main concepts in epidemiology and pharmacoepidemiology. Measuring health and disease. Diseases incidence rates comparison.

3. Non-interventional studies – PASS and PAES.

4. Descriptive epidemiological studies. Analytical studies.

5. Introduction to statistics.

6. Hypothesis verification and connection and correlation analysis. Potential errors and confounding.

7. Algorithms for assessment of causal relationships and of risk.

8. Use of ADR databases for the purposes of post-authorization and pharmacoepidemiological studies.

9. Comparative studies of effectiveness. Non-inferiority studies.

10. Pharmacoepidemiology in practice – application of causal relationships methods, incidence rate, acuteness and severity and outcome. Benefit/risk ratio.

Seminar trainings – topics (total 15 study hours)

1. Post-authorization drug monitoring – essence and characteristics.

2. Requirements towards and obligations of the EMA, PRAC, national regulatory authorities and market authorization holders.

3. Approaches promoting reporting of ADR by health professionals and patients.

4. National system for monitoring and registration of adverse drug reactions. Generation of signals/reports.

5. Adverse drug reactions and drug-related problems. Application of data on drug use in pharmacoepidemiology.

6. Specifics in selection and construction of samples for pharmacoepidemiological studies.

7. Meta-analysis in pharmacoepidemiology as a risk assessment tool.

Distance education – topic *(self-study)*

1. Risk management plan for a specific medicinal product – content, activities, protocol of actions and identification of potential risks.

Module VIII. Technological and biopharmaceutical aspects of drug preparation and control in hospital pharmacy settings

Theoretical education – topics (total 40 study hours)

1. European Good Manufacturing Practices (GMP) guidelines. Pharmaceutical quality system. Staff, premises, equipment, documentation, production, and quality management. Place and role of GMP for pharmaceutical practice in hospital pharmacy settings.

2. Reformulation and formulation of classic magisterial and pharmacopoeial formulations in hospital pharmacy settings – problems and solutions. Requirements towards the quality of starting materials, excipients, and preservatives. Stability/instability and incompatibility. Types of stability and shelf life.

3. Parenteral formulations and aseptic preparation – specific features and requirements. Requirements of GMP. Production principles and general requirements. Prevention of cross-contamination. Risk assessment and demonstration of suitability.

4. Parenteral formulations and aseptic preparation. Process validation. Starting materials, technological processes, and intermediary controls, packaging materials and packaging, final controls and batch/product release. Purification and purification validation.

5. Preparation of parenteral nutrition solutions and infusion solutions; mixing solutions for intravenous infusion – requirements, compatibility, stability, choice of packaging, controls.

6. Preparation of formulations containing cytostatic agents. Specific features, risk assessment, and control methods. Requirements towards preparation of solutions of cytostatic drugs.

7. Radiopharmaceuticals and nuclear medicine. Requirements and considerations vis-à-vis their preparation in hospital pharmacy settings.

8. Technological and biopharmaceutical considerations in selecting pharmaceutical formulation and route of administration – from product-oriented pharmacy to patient-oriented pharmacy. Preparation of individual prescriptions – private technologies, labeling, and packaging.

9. Specific features and requirements vis-à-vis drug formulations for pediatric patients. Major problems hospital pharmacists face in preparation of drug formulations for pediatric use – selecting rational, efficient, and safe drug formulation. Critical assessment of types of pharmaceutical formulations with relevant advantages and disadvantages in pediatric use.

10. Specifics and requirements vis-à-vis drug formulations for geriatric patients. Physiological specifics. Considerations in selecting rational technological formulation.

11. Chronopharmacy and chronopharmacology. Specific requirements and technological solutions related to preparation. Potential advantages of chronopharmaceutical formulations.

12. Biological and biosimilar medicinal products – essence, main concepts, specific features. Biotechnology-based manufacturing process and manufacturing of biological molecules. Methods for assessment of quality, efficacy, and safety of biosimilars.

Practical education – total 20 study hours

1. Solving of cases – reformulation and formulation of magisterial and pharmacopoeial formulations. Considerations and approaches related to preparation of rational, efficient, and safe pharmaceutical formulations.

2. Preparation of classic magisterial and pharmacopoeial formulations – liquid, semisolid, for rectal, vaginal use – problems and solutions.

3. Preparation of multi-particulate solid dosage drug forms – pellets and spheroids with non-modified and modified release and filling in gelatin capsules. Evaluation of potential and advantages of multi-particulate solid dosage forms in pharmaceutical practice.

4. Preparation of solid dosage forms with modified release based on the principles of chronopharmacy.

5. Preparation of age-specific drug formulations for pediatric use. Evaluation of application-related potential and limitations of various pharmaceutical forms and technological approaches to preparation.

Module IX. Providing therapy and preparation of care plan for specific patient groups

Distance education – preparation of an individually chosen case study (self-study)

I. Colloquia topics by year

First year

1. Pharmaceutical and drug regulation and Good Pharmaceutical Practice in hospital pharmacies.

2. Hospital pharmacy organization and management and medical devices.

Second year

3. Pharmacological and toxicological aspects of drug therapy.

4. Health technologies and hospital pharmaceutical services evaluation.

5. Quality assurance, standardization, and logistics.

Third year

6. Pharmacoepidemiology and pharmacovigilance.

7. Technological and biopharmaceutical aspects in preparation of magisterial and pharmacopoeial formulations in hospital pharmacy settings.

5. Synopsis for state examination

1. Regulation of pharmaceutical activities in health care establishments.

2. Pharmaceutical management in hospital pharmacies. Management of human resources.

3. Standards for drugs and pharmaceutical services – good practices.

4. Furnishing and equipment of hospital pharmacies. Contemporary concepts, requirements, standards, and recommendations. Principles and practice of ergonomics.

5. Approaches and instruments for risk management in hospital pharmacies.

6. Requirements and rules related to pharmaceutical waste management. Classification of waste and methods of waste treatment.

7. Legal regulation of medical devices Classification. Material requirements. CE marking. Safety of medical devices.

8. Standards for efficient communication, drug information, and sources of data.

9. Pharmacoepidemiology – essence, concepts, content of science-based approach.

10. Steps of medical products study. Clinical, interventional, non-interventional studies.

11. Traceability of drug safety - requirements towards and obligations of health professionals, regulatory authorities and market authorization holders.

12. Instruments for risk assessment in pharmacoepidemiology.

13. Place and role of GMP in pharmaceutical practice in hospital pharmacy settings. Pharmaceutical quality system.

14. Health economics, pharmacoeconomics, and health technologies evaluation – basic concepts, principles, interconnections, objectives and tasks.

15. Main methods of cost-effectiveness analysis of drug therapies. Identification of costs and benefits.

16. Role of pharmacists in improving response to treatment and quality of life of patients. Tools for quality of life evaluation.

17. Rules, principles, and recommendations for special pharmaceutical care for patients in home settings. Motivation of patients for active involvement in their own treatment.

18. Clinical trials. Good Clinical Practice (GCP).

19. Pharmacokinetics and drug metabolism.

20. Drug interactions – extents and monitoring.

21. Mechanisms of antibiotic resistance and monitoring of antibiotic therapy.

22. Target and adjunctive therapy in oncology.

23. Therapeutic drug monitoring. Monitoring of the therapy of some disorders of the central nervous system.

24. Therapeutic drug monitoring. Monitoring of the therapy of some disorders of the cardiovascular system.

25. Pharmacotherapy of pain. Treatment strategies.

26. Coagulation disorders. Anticoagulation therapy monitoring.

27. Parenteral nutrition – indications and main components.

28. Drug toxicity. Acute intoxications and toxidromes. Antidote treatment.

29. Reformulation and formulation of classic magisterial and pharmacopoeial formulations in hospital pharmacy settings – problems and solutions.

30. Technological and biopharmaceutical considerations in selecting pharmaceutical formulation and route of administration - from product-oriented pharmacy to patient-oriented pharmacy.

31. Parenteral formulations and aseptic preparation – specific features and requirements.

32. Preparation of formulations containing cytostatic agents. Specific features, risk assessment, and control methods. Requirements towards preparation of solutions of cytostatic drugs.

33. Specific features and requirements vis-à-vis drug formulations for pediatric patients in hospital pharmacy settings. Critical assessment of types of pharmaceutical formulations with relevant advantages and disadvantages in pediatric use.

34. Solutions for parenteral nutrition and infusion – requirements, compatibility, stability, controls.

35. Radiopharmaceuticals and nuclear medicine. Requirements and considerations vis-à-vis their preparation in hospital pharmacy settings.

36. Biological and biosimilar medicinal products – essence, main concepts, identity, similarity.

37. Logistics and inventory (stock) management – concepts, principles, methodology, and models. Logistics process and activities.

38. Types of inventory in the hospital pharmacy. Batches and shelf life. Computer-based inventory management system. Barcodes.

39. Integrated supply chain management. Stock planning for shortages and emergency contingencies.

40. Role of the hospital pharmacist in promoting health, in awareness-raising campaigns and prevention and screening actives.

List of Recommended Reading and Study Materials

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11. Ръководство за практически занятия по фармакотерапия (Под редакцията на С. Константинов), ИК «Софттрейд», София, 2011.
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13. Токсикология за студенти по фармация (под редакцията на М. Мичева и А. Аструг), «Полиграфюг» АД, София, 2015.
14. Фармакотерапия (под редакцията на С. Константинов и Г. Момеков). Софттрейд 2015.
15. Al-Sabbagh, A. , E. Olech, J.E. McClellan, C.F. Kirchhoff. Development of Biosimilars Seminars in Arthritis and Rheumatism, 2015.
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