



## CD 8.5.1 DISCIPLINE CURRICULUM

EDITION: 06

DATE: 20.09.2017

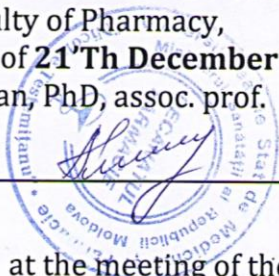
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**FACULTY OF PHARMACY**  
**STUDY PROGRAM 0916.1 PHARMACY**  
**CHAIR OF SOCIAL PHARMACY "VASILE PROCOPISIN"**

**APPROVED**

at the meeting of the Commission for Quality Assurance and Evaluation of the Curriculum,  
Faculty of Pharmacy,  
Minutes no. 2 of 21<sup>Th</sup> December 2017  
Chairman, PhD, assoc. prof.

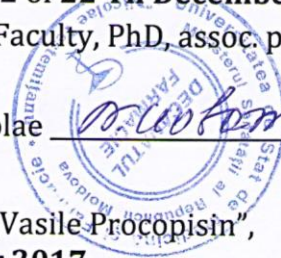
UNCU Livia



**APPROVED**

at meeting of the Council of the Faculty of Pharmacy,  
Minutes no. 2 of 22<sup>Th</sup> December 2017  
Dean of Faculty, PhD, assoc. prof.

CIOBANU Nicolae



**APPROVED**

at the meeting of the chair of social pharmacy „Vasile Procopisin”,  
Minutes no. 3 of 01<sup>Th</sup> November 2017  
Head of chair, PhD, assoc. prof.

BRUMAREL Mihail

## SYLLABUS

**DISCIPLINE: MANAGEMENT AND PHARMACEUTICAL LEGISLATION**

Integrated studies

Type of course: **Compulsory discipline**

Chisinau, 2017



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### I. INTRODUCTION

- **General presentation of the discipline: place and role of the discipline in the formation of specific competences of the professional/specialty training program**

**Management and pharmaceutical legislation** as an academic discipline establishes as the scientific basis of its management as a science of management and the right theoretical basis of law - essential components of the management process. The specificity of the discipline is conditioned by the continuous renewal of the legislative and normative acts which, to a great extent, constitute the applicative content of the theoretical-scientific postulates. By its content, the discipline has a scientific-practical approach to the elements and processes characteristic of the pharmaceutical system operating in market economy conditions, being also a basis for a better understanding of the special courses of pharmaceutical marketing, entrepreneurship, pharmaceutical care, etc.

- **Mission of the curriculum (aim) in professional training**

Being a pharmaceutical discipline, Pharmaceutical management and legislation aims to prepare the future pharmacist for the performance of his activity in pharmaceutical and health care institutions on issues related to the content and application of legislation on the conduct of pharmaceutical activity and the foundation and organization of the activity of pharmaceutical companies, organization of employment, relations in the work team, activities of local and state authorities and institutions for the coordination of pharmaceutical activity, exercise of economic activity, acquiring the methods of recording, analyzing and programming the economic and financial activity of the pharmaceutical enterprises and other fields of activity focused on satisfying the requirements of the population and medical-sanitary institutions in medicines, other pharmaceutical products and qualitative, effective and harmless pharmaceutical services.

Having as a study object drug and sick man - drug user - as the central elements of the managerial processes that take place in the pharmaceutical system and in order to achieve the above mentioned goal, the discipline has the following tasks:

**a) to provide specialists with knowledge in the field of:**

- ♦ in the field of scientific bases of management and lawmaking, knowledge management processes and laws and regulations in the field of drug and pharmaceutical activity;
- ♦ contemporary concepts of pharmaceutical assistance;
- ♦ principles regulating relations in the field of drug circulation;
- ♦ organization, coordination and operation of the quality assurance of pharmaceutical products;
- ♦ the organization of control over the pharmaceutical activity of drug production and distribution companies;
- ♦ licensing and accreditation of pharmaceutical companies, the authorization of drugs and their import;
- ♦ pricing principles for drugs;
- ♦ managerial and legislative-normative bases for the organization and functioning of the pharmaceutical enterprises;
- ♦ economic base, accounting and management applied in pharmaceutical companies.

**b) to assure the acquiring of practical skills on:**

- ♦ management of labor collectives in pharmaceutical companies;
- ♦ formation and analysis of product assortment for the pharmaceutical enterprise;
- ♦ receiving, examining and charging prescriptions, organizing the preparation and dispensing of extemporaneous and industrial medicines;
- ♦ communicating with coworkers and consumers of drugs;
- ♦ organizing the activity of pharmaceutical companies and their subdivisions;
- ♦ ordering, receiving, storing and preserving the correct organization of pharmaceutical products;



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- ♦ organization of internal pharmaceutical control in pharmaceutical companies;
  - ♦ using methods in elaboration of economic indicators included in the business plan for pharmaceutical companies;
  - ♦ methods of determining drug requirements for different levels of the health system;
  - ♦ procedures of making and finalizing the inventory of material values;
  - ♦ application of procedures and principles of evidence of material values, personnel, economic-financial activity, fixed assets, labor and wages etc.;
  - ♦ application of pricing mechanisms for medicines;
  - ♦ determining the level of physical and economic accessibility of medicines for population;
  - ♦ application of computerized systems to solve various drug and pharmaceutical problems in the field of drug and pharmaceutical activity.
- **Languages of training the discipline:** Romanian, English
  - **Beneficiaries:** students of the IV-th year, faculty of Pharmacy, specialty Pharmacy.

### II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		<b>S.07.O.069</b> <b>S.08.O.076</b>	
Name of the discipline		<b>Management and pharmaceutical legislation</b>	
Responsible for the discipline		<b>Mihail Brumărel</b> , PhD, associate professor	
Year	<b>IV</b>	Semesters	<b>7, 8</b>
Total number of hours, including:			<b>300</b>
Lectures	<b>34</b>	Practical/laboratory hours	<b>136</b>
Seminars	-	Self-training	<b>130</b>
Form of assessment	<b>C, E</b>	Number of credits	<b>10</b>

### III. TRAINING AIMS WITHIN THE DISCIPLINE

***At the end of the discipline study the student will be able to:***

***at the level of knowledge and understanding:***

- ✓ define basic notions: system, systemic approach, law, legislation, pharmaceutical activity, etc.;
- ✓ define the basic concepts of management, general concepts of management as a science and academic discipline;
- ✓ research of collective work processes to optimize them;
- ✓ know contemporary approaches, doctrines and modern schools of management;
- ✓ know the algorithms of decision making in the practice of pharmacy management;
- ✓ know the evolution and theories of management;
- ✓ know the functions of modern management and their role in leadership activity;
- ✓ know the methods of studying the work and determining the effectiveness of pharmacists working at different workplaces in pharmaceutical units;
- ✓ know the needs of equipment and ergonomic organization of workplaces in pharmaceutical units;



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- ✓ know the specifics of pharmaceutical management: structure, purposes and functions;
- ✓ know the types of organizations, the formal organization requirements and its characteristics;
- ✓ know the specifics of management functions in pharmaceutical companies;
- ✓ to know the structure of the health system in the Republic of Moldova, the organizational structure of the coordinating bodies in the assistance of the population with medicinal products;
- ✓ know the role and purpose of the pharmacy and the pharmacist in the health system;
- ✓ know legislation in the field of pharmaceutical and drug activity;
- ✓ know the principles and criteria for authorizing medicinal products;
- ✓ know the structure of the documentation accompanying at the registration of authorization for different drugs;
- ✓ know the conditions and documentation required for industrial production of drugs;
- ✓ know the assurance measures for pharmaceutical products quality;
- ✓ know the principles of expansion and location of pharmacies;
- ✓ learn the main control methods and particularities of their use in the pharmaceutical work-team;
- ✓ know the activities of managing pharmaceutical companies: planning, organization, motivation and control necessary to formulate and achieve the expected goal;
- ✓ know the nomenclature of essential pharmaceutical services;
- ✓ know rules of prescribing and drug delivery;
- ✓ know the types of internal pharmaceutical control;
- ✓ know the terms storage terms of medicinal products prepared in a pharmacy;
- ✓ know the basic requirements of sanitary regime in pharmaceutical enterprises;
- ✓ to know the particularities of verifying the integrity of material values;
- ✓ fully aware of legal provisions relating to the exercise of pharmaceutical activity;

### ***at the application level:***

- ✓ determine managerial skills, manager's leadership style;
- ✓ determine the specificities of pharmaceutical management functions;
- ✓ perform the functions of planning, organization, coordination, motivation and control of different pharmaceutical activities;
- ✓ identify internal and external environmental factors influence the activity of the pharmaceutical units and decision-making;
- ✓ perform the ergonomic endowment and organization of workplace in pharmaceutical units;
- ✓ assure safety of work, compliance with sanitary rules of personal and work hygiene;
- ✓ argue legal and organizational forms of activity in order to establish pharmaceutical companies;
- ✓ complete the documents for authorization of pharmaceutical activity;
- ✓ be able to identify the factors of the internal and external environment for the pharmaceutical activity of the units;
- ✓ organize the supply of pharmaceutical companies and pharmaceutical supplies;
- ✓ ensure the optimal range of pharmaceutical products for different levels of pharmaceutical assistance;
- ✓ determine the need for different groups of pharmaceutical products;
- ✓ draw up orders (requirements) for the supply of pharmaceutical products;
- ✓ create conditions for the organization of the preservation of pharmaceutical products;
- ✓ distribute pharmaceutical products in accordance with groups of organization keeping;
- ✓ argue the organizational structure of the community pharmacy depending on the conditions of its activity;
- ✓ arrange and equip workplaces in pharmaceutical companies;
- ✓ divide the service obligations between the employees of the pharmaceutical companies;



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- ✓ determine staffing needs for different divisions of pharmaceutical companies;
  - ✓ select frames for different pharmaceutical posts;
  - ✓ organize the working regime and activity of pharmaceutical companies;
  - ✓ determine the human resource needs for the pharmacy;
  - ✓ organize the activity of assistance with medicines, supply, drug preparation, accounting and management of the pharmacy;
  - ✓ organize the essential pharmaceutical service activities;
  - ✓ dispense pharmaceutical products with and without a prescription;
  - ✓ assure all conditions for compliance with the sanitary regime in pharmaceutical companies;
  - ✓ assure compliance with the pharmaceutical regime in the preparation of medicines;
  - ✓ prepare pharmaceutical forms according to prescriptions;
  - ✓ to apply the types of internal pharmaceutical control and assess internal pharmaceutical drug quality;
  - ✓ finalize (label) pharmaceutical formulations prepared in the pharmacy;
  - ✓ apply and use the principles of the Pharmacotherapeutical Formulary in the practice of health care institutions;
  - ✓ possess different methods of analysis and determine the necessary medicines included in Pharmacotherapeutical Formulary of health care institutions;
  - ✓ ensure the efficient functioning of the medical institution's pharmacy;
  - ✓ ensure the creation of the range of pharmaceutical products necessary for the medical institution;
  - ✓ organize the pharmaceutical supply of the medical institution by applying centralized procurement procedures;
  - ✓ organize the control of the keeping and rational use of medicines in hospital wards;
  - ✓ keep records of medicines and articles for medical use in the medical institution's pharmacy;
  - ✓ prepare and submit management reports on the circulation of material values in the medical institution's pharmacy;
  - ✓ determine the economic and financial results of pharmaceutical companies;
  - ✓ assure efficient activity of pharmaceutical companies;
  - ✓ provide planning, organization, coordination and control of pharmaceutical activity;
  - ✓ have skills in remuneration and work stimulation;
  - ✓ possess skills in managing the human, material, financial and informational resources of pharmaceutical companies;
  - ✓ keep records of household and financial operations;
  - ✓ draw up business plans for different activity indicators of the pharmaceutical companies;
  - ✓ possess skills to systematization and processing of data obtained as a result of economic activity;
  - ✓ organize the accounting and management work of pharmaceutical companies;
  - ✓ perform inventory of different types of material values;
  - ✓ legalize documents according to the inventory of material values;
  - ✓ be able to apply the rules of natural perishability depending on the results of inventory of material values;
  - ✓ carry out inspection of pharmacies, other pharmaceutical companies with the aim of assessing the quality of pharmaceutical care;
  - ✓ select and apply new processes and methods in pharmaceutical activity;
- at the integration level:**
- ✓ determine the specificity of using different decision-making methods in pharmaceutical activity to determine the specific use of different decision-making methods in pharmaceutical activity;



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- ✓ apply the theoretical bases of management in solving the practical problems encountered in pharmaceutical activity;
- ✓ apply methods of managerial studies in pharmaceutical practice;
- ✓ appreciate the level of pharmaceutical assistants and to develop optimization strategies for them;
- ✓ assess the conformity of the conditions for the conduct of pharmaceutical activity for different undertakings;
- ✓ determine the content and directions for achieving the concept of pharmaceutical activity;
- ✓ define the general principles of organization and functioning of pharmaceutical companies with different legal forms of activity;
- ✓ to ensure the organization of the conformity of pharmaceutical products in the supply of pharmaceuticals and hospitals;
- ✓ analyze the situation regarding the level of pharmaceutical assistance for different administrative territories based on different criteria;
- ✓ to ensure the decision-making process of pharmaceutical activity;
- ✓ assure compliance with pharmaceutical ethics and deontology;
- ✓ propose measures to ensure the stable development of the pharmaceutical enterprise;
- ✓ assure the unity of the activity provided for quality services and the economic activity of pharmaceutical enterprise based on principle of obtaining the benefit for public health;
- ✓ assess performance/nonconformities pharmaceutical company, based on inspection results;
- ✓ to propose measures to help pharmaceutical companies to remove detected irregularities as a result of the inspection and prevention of breaches of the legal norms;

### IV. PROVIZIONAL TERMS AND CONDITION

**For proper assimilation of discipline is necessary to know:**

- ✓ sanitary-hygienic requirements of the location and expansion of pharmaceutical companies and their spaces;
- ✓ hygienic and anti-epidemic conditions assessment of pharmaceutical companies;
- ✓ occupational health and sanitary insurance regime in pharmaceutical companies;
- ✓ economic system of society and property relations;
- ✓ essence and fundamental features of a market economy, foundations of entrepreneurial activities of the enterprise (company) in the contemporary economy;
- ✓ basic notions of the financial and economic insurance of the health care and economy of medical institution;
- ✓ marketing concepts, and opportunities to practice them on health care.



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### V. THEMES AND ESTIMATE ALLOCATION OF HOURS

No.	THEME	Number of hours		
		Lec- tures	Practical hours	Self- training
1.	<b>Management elements in pharmaceutical activity.</b> Introduction to management. Basic concepts and characteristics of modern management. The evolution of management. Modern Management - as a specific type of management activity. Comparative Management. Pharmacy management specific features. The leadership processes. Functions of planning, organizing, coordinating, motivating entrainment, evaluation and control. Features on pharmaceutical management functions.	2	8	6
2.	<b>Management of leadership. Decision making process in management.</b> Methods and types of leadership. Leadership styles and types of leaders. Particularities of manager activities. Managerial hierarchy. Roles and responsibilities of management. Definition and classification of decisions. Factors influencing decision making process. Stages of decision making. Methods and models of decision making. Applying decision in pharmaceutical activity.	2	8	6
3.	<b>Management of organization.</b> Organization and management process. Environment of the pharmaceutical organization. The specificity of pharmacy as an organization. Effective organization. Ergonomics employment in pharmaceutical companies. <b>Human resources management.</b> Human resources management. Functions of human resource management. Stages of human resources management.	1	4	6
4.	<b>Public health. Health system.</b> General notions of public health. The Health system of the Republic of Moldova. Ministry of Health of the Republic of Moldova. Primary care. Inpatient health care (hospital). Urgent medical assistance. Maternal and child health care. Legal medicine. The Public Health (Preventive Medicine). Basic principles of compulsory health insurance. National health policy. <b>Pharmaceutical system. Coordination in pharmaceutical management.</b> General notions about system and coordination. Pharmaceutical system - health subsystem. Feature of pharmaceutical system of Moldova. Pharmaceutical system reform. Developments. Principles of pharmaceutical assistance. Pharmaceutical coordination models. Coordination of pharmaceutical system in Republic of Moldova. Strategic directions of pharmaceutical coordination. Tactical level. Medicines and Medical Devices Agency.	1	4	6
5.	<b>General concepts of law and legislation. Pharmaceutical legislation.</b> General notions of law, legislation, regulation. Classification of legal norms. The legal system. Development and systematization of normative act. <b>Pharmaceutical legislation - branch of health legislation.</b> State policy in the field of medicine (SPM). General purpose tasks and content of SPM. Law on pharmaceutical activity and its application in the pharmaceutical activities. Law on medicines and its application in the pharmaceutical activities. Legislation on drugs, psychotropic and toxic medicines. International conventions on narcotic drugs, psychotropic and toxic substances. Requirements and conditions established for the production, use, sale, warehousing, and storage of drugs, psychotropic and toxic medicines. Standardization activities in the field of narcotic drugs, psychotropic and toxic medicines in Republic of Moldova. Correlation of pharmaceutical legislation with other branches of law.	1	4	5
6.	<b>Activities in the pharmaceutical management system and authorization of pharmaceutical activity.</b> Pharmaceutical activity. Notion of "pharmaceutical activity" and their characteristic. Exercising pharmaceutical activity. Au-	2	4	4



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No.	THEME	Number of hours		
		Lec- tures	Practical hours	Self- training
	thorization of pharmaceutical activity through licensing.			
	<b>Intermediary assessment 1-6.</b>	-	4	4
7.	<b>Medicines and other pharmaceutical products as a subject of pharmaceutical assistance.</b> Definitions. Classification of products used in medicine. Overviews of medicines importance. Specific features of the medicine. The main stages of medicines development. Names types and classifications of medicines. Essential medicines. International, European and national standards of quality of medicines. Storage of medicines and other pharmaceutical products. <b>Marketing authorization of medicinal products.</b> General notions. Purpose and the order of authorization. Principles and criteria of medicines authorization. Authorization documentation. Medicines Commission. State Nomenclature of medicines. Registration certificate. Characteristics of medicines authorization in the European Union. Authorization of medical devices.	1	4	6
8.	<b>Quality assurance of medicines.</b> General notions of medicines quality assurance. General characteristics of the quality control system of medicines in the Republic of Moldova. Medicines quality control laboratory activities. Types of the state quality control of medicines and their characteristics. Supervision and pharmacovigilance. Monitoring adverse reactions. <b>Industrial production of medicines.</b> General requirements for the production of medicines. General characteristics of medicines production system in Republic of Moldova. Authorization of the medicine production. Technological documentation. Pharmaceutical factory. Laboratory of Pharmaceutical micro-production. Organization of work activity.	1	4	6
9.	<b>Pharmaceutical supply.</b> Characteristic of medicines supply system. Medicines supply cycle. Imports of medicines. The order (the process) for achieving the import of medicines in Republic of Moldova. Import authorization of medicines. Donations of medicines. <b>Pharmaceutical warehouse, tasks and functions.</b> Organizational structure. Organization of working in the pharmaceutical warehouse departments. Warehouse relationships with manufacturers of medicines and recipients. Calculating the required of medicines - principles and methods. Collaboration agreements. Reception and organization of storage for medicines and other pharmaceutical products. Evidence of movement of pharmaceutical products at the warehouse. Rules of good distribution practice of pharmaceutical products.	2	8	4
10.	<b>Pharmaceutical assistance system in outpatient population.</b> General characteristics of pharmaceutical assistance system. Principles of organization of pharmaceutical assistance. Extension and location of pharmacies. Rules for extending the network of pharmacies. Assessing the quality of pharmaceutical assistance system. <b>Community pharmacy. Tasks and functions of public access pharmacy.</b> Types of pharmacies. Requirements for rooms and pharmacy space. The floor plan of the premises. Insurance requirements for the sanitary regime in pharmacy. The sanitary requirements: room and equipment, cleaning rooms and pharmaceutical equipment, personal hygiene of employees in pharmaceutical companies. Sanitary rules to the production, transportation and storage of purified water and water for injection. The sanitary requirements for the spaces for medicines preparation in aseptic conditions. Organization of the activity of community pharmacy.	2	8	4



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No.	THEME	Number of hours		
		Lec- tures	Practical hours	Self- training
	The organizational structure. Organizing workplaces. Specifics organization working in the pharmacy sections. Tasks and functions of inventories department. Branches of community pharmacies. Pharmacy staff. Material accountability and its application in pharmaceutical companies.			
11.	<b>Pharmacy manager. Managerial process. Human resources management in pharmaceutical system.</b> Pharmacy manager - the main authority of the company. Requirements of pharmacy manager. Organization of the work of pharmacist manager. Pharmacist manager relationship with subordinate. Managerial ethical issues. Specific features of pharmacist manager. Training, employment and certification of pharmaceutical cadres. Pharmacist's role in the public health system. Ethics and pharmaceutical deontology. Labor protection of pharmacist. Individual employment contract. The content and order of contract closeout.	2	4	4
	<b>Intermediary assessment 7-11. Colloquium.</b>	-	4	4
12.	<b>Legal norms of medicines prescription.</b> The general rules of medicines prescription. Prescription requisites and their particularities fulfill. Prescribing particularities for different groups of medicines (narcotics, toxic, psychotropic substances, etc.), categories of people and patients. Promoting rational prescribing of medicines.	2	8	5
13.	<b>Receiving, pricing and registration of prescription.</b> Reception of prescriptions. The basic principles of pricing of prescriptions. Methods of recording of prescriptions. Characteristics and primary evidence of receipt.	2	8	5
14.	<b>Technology of pharmaceutical compounding in pharmacy.</b> Task and functions of medicines preparation section. Reception area. Requirements. Equipment. Organizing workplaces of preparation for different dosage forms. General rules for the preparation of medicines. Measures to accelerate the preparation of medicines and insurance their quality. Preparation of pharmaceutical in the elaboration form. Evidence of in stock pharmaceuticals. <b>Quality control of extemporaneous preparation.</b> Factors which determine the quality of medicines. Organize of quality control of medicinal products prepared in pharmacies. Types and record of internal pharmaceutical control. Extemporaneous medicines quality assessment forms. <b>Pack labeling and dispensing medicines from pharmacy.</b> Types and content of labels for pharmaceutical compounding in pharmacy. Dispensing medicines from pharmacy. Special cases of medicines dispensing. Free and facilities dispensing of medicines. OTC medicines.	2	4	8
15.	<b>Management and legislation of pharmaceutical assistance in hospital.</b> General characteristic of the pharmaceutical supply system of hospitals. Hospital pharmacy. Organization of work activity. Organizing workplaces. The organizational structure. Rules of prescribing medicinal products for inpatients. Receiving orders, organizing the preparation and dispensing of medicines. Primary hospital pharmacy records. The formulary system. Determination of inpatient medications. Centralized procurement of medicines for public needs. Rules and recommendations for procurement of medicines. Tender organization. The concept of clinical pharmacy. General characteristics of clinical pharmacist activity. Inpatients organize working.	2	8	6



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No.	THEME	Number of hours		
		Lec- tures	Practical hours	Self- training
	<b>Intermediary assessment 12-15.</b>	-	4	4
16.	<p><b>Accounting in pharmaceutical company.</b> General concepts of accounting. The purpose and tasks of accounting. Requirements for accounting. Accounting types and standards. Accounting documents.</p> <p><b>Pricing of pharmaceutical products.</b> Notion of prices. Factors determining prices. Pricing policies. Systems for medicines price regulation. The basis for calculating the pricing of pharmaceutical products and pricing methodology for pharmaceuticals in Republic of Moldova.</p>	2	4	8
17.	<p><b>Pharmaceuticals turnover.</b> Record of pharmaceuticals input. Particularities of pharmaceuticals reception. Rules of reception. Additional sources of cumulatively increase the stock of pharmaceuticals.</p> <p><b>Turnover and its constituent.</b> Turnover – the importance, types and structure. The basic aim and tasks of directing the turnover in pharmaceutical companies. Determination of the volume and structure of turnover. Documenting turnover. Turnover record in cash and transfer. Evidence of gratuities.</p> <p><b>Stocks of pharmaceutical enterprises.</b> Classification and destination. Analysis and determination of normative products in pharmaceutical companies. Planning inputs of pharmaceuticals.</p> <p>Other types of pharmaceuticals consumption: to housekeeping necessities, first medical aid, quality control; natural losses; settlement; transfer to other groups out. Reassessment of pharmaceuticals products. Internal transfer of pharmaceuticals. Record documentation and accounting of people. Quantitative reporting of medicines turnover.</p>	2	8	4
18.	<p><b>Material assets turnover in pharmaceutical company.</b> Record of packaging, utensils, medicinal plant product and other material values. Long-term assets. Structure. Fixed assets. Recording of fixed assets. Depreciation and amortization of fixed assets. Determination of efficiency of the use of fixed assets. Evidence of little value and short articles.</p> <p><b>Cash flow in pharmaceutical companies.</b> Tasks of cash records. Evidence of cash. Operations of collecting and spending money and their documentation. Prepare cash register. The bank accounts of pharmaceutical companies. Evidence of operations changeover in account and settlement account. Cashless payment systems. Receivable and payable.</p>	2	4	6
19.	<p><b>Cost and expenditure of pharmaceutical company.</b> Notions of consumption and expenditures. Classification. Recording of expenditure.</p> <p>Tax Code. Taxes imposed in Republic of Moldova. Taxation of pharmaceutical companies.</p> <p><b>Work statement and emolument.</b> Employment and wage indices. Wage fund. Regular establishment. Labor productivity. The purpose of labor and wages records. Evidence of staff and time sheet. Salary systems and forms. Determination rate of wages of pharmaceutical personnel. Supplements to wages and bonuses. Charges from salary. Social assistance.</p> <p><b>Administration of pharmaceutical company.</b> Results of financial-economic activity of pharmaceutical companies. Added value and economic characteristics. Formation of added value. Factors affecting added value. Determination of realized and unrealized added value. Determination of results of financial and</p>	1	8	6



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No.	THEME	Number of hours		
		Lec- tures	Practical hours	Self- training
	economic activity (income, benefit and profitability) in pharmaceutical company.			
20.	<p><b>Monitoring management of pharmaceutical activity.</b> General terms of pharmaceutical control function. Characteristic of the state control system over pharmaceutical activity. State bodies control of pharmaceutical activity and their functions. Pharmaceutical Inspection. Tasks and functions. Organization of pharmaceutical inspection. Types of inspection. Duties of pharmacists - inspectors.</p> <p>Contravention Code and the Penal Code and their application in the pharmaceutical activity. Evaluation and accreditation of pharmaceutical companies.</p> <p><b>Inventory of material assets in pharmaceutical companies.</b> General notions. Commission of inventory. The inventory overview mode. Inventory particularities of different types of material values. Determination of inventory results. Notes on forms used in the inventory.</p>	2	4	5
	<b>Intermediary assessment topic 16-20.</b>	-	4	4
	<b>Practical skills testing</b>	-	4	4
<b>Total</b>		<b>34</b>	<b>136</b>	<b>130</b>
		<b>300</b>		

## VI. REFERENCE OBJECTIVES AND CONTENTS UNITS

Objectives	Contents units
<b>Chapter 1. Management and application of its elements (components) in the pharmaceutical field.</b>	
<ul style="list-style-type: none"> <li>✓ define the basic concepts of management, the general notions of management as a science and academic discipline;</li> <li>✓ research collective work processes to optimize them;</li> <li>✓ know contemporary approaches, doctrines and modern managerial schools;</li> <li>✓ know decision-making algorithms in practice of pharmaceutical management;</li> <li>✓ know evolution and theories of management;</li> <li>✓ know modern management functions and their role in leadership;</li> <li>✓ know methods of work studying and determining effectiveness of pharmacists work on different jobs in pharmaceutical units;</li> <li>✓ know needs for ergonomic endowment and organization of workplace in pharmaceutical units;</li> <li>✓ know specifics of pharmaceutical management: structure, goals and functions;</li> <li>✓ know types of organizations, formal requirements of the organization and its characteristics;</li> <li>✓ know specifics of management functions in pharmaceutical companies;</li> <li>✓ determine managerial skills, leadership style of leader;</li> <li>✓ determine specificities of pharmaceutical management functions;</li> <li>✓ perform the functions of planning, organization, coordination, motivation and control of various pharmaceutical activities;</li> <li>✓ identify the factors of the internal and external environment influencing the activity of pharmaceutical units and decision-making;</li> </ul>	The general feature of management.
	Management elements in pharmaceutical activity.
	Management of leadership. Decision making process in management.
	Management of organization.
	Human resources management in pharmaceutical system.



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- ✓ perform the ergonomic endowment and organization activities in the pharmaceutical units;
- ✓ to assure safety of work, compliance with sanitary rules of personal and work hygiene;
- ✓ perform functions of planning, organization, coordination, motivation and control for different types of pharmaceutical activities;
- ✓ be able to identify the factors of the internal and external environment of the pharmaceutical units;
- ✓ determine specificity of using different decision-making methods in pharmaceutical activity;
- ✓ apply theoretical bases of management in solving of practical problems encountered in pharmaceutical activity;
- ✓ apply managerial study methods to pharmaceutical practice.

### Chapter 2. Pharmaceutical system - part of the health system.

- ✓ define basic notions of: system, system approach, law, legislation, pharmaceutical activity, etc.;
- ✓ know the structure of the health system in the Republic of Moldova, organizational structure of coordinating bodies in assistance of the population with medicines;
- ✓ know role and purpose of the pharmacy and the pharmacist in health system;
- ✓ know legislation in the field of pharmaceutical and drug activity;
- ✓ argue legal and organizational forms of activity in order to found pharmaceutical companies;
- ✓ complete documents for authorization of pharmaceutical activity;
- ✓ determine particularities of pharmaceutical activity conduct;
- ✓ appreciate the pharmaceutical assistants level and develop optimization strategies for them;
- ✓ assess the compliance of conditions for pharmaceutical activity conduct with different of different pharmaceutical companies;
- ✓ determine the content and directions for achieving the concept of pharmaceutical activity;
- ✓ define general principles of organization and functioning of pharmaceutical companies with different legal forms of activity;

Public health.  
Health system.  
Pharmaceutical system.  
Coordination in pharmaceutical management.

General notions of law and legislation. Pharmaceutical legislation – branch of health legislation.

Activities in the pharmaceutical management system and authorization of pharmaceutical activity.

### Chapter 3. Medicines and pharmaceutical market supply activities.

- ✓ know definitions to the concept of medicine (original, generic, essential, vital, allopathic, homeopathic, etc.), sick person, drug user;
- ✓ know principles of medicines classification;
- ✓ know principles and criteria for medicines authorization;
- ✓ know the structure of supporting documentation in requesting of authorization for different medicines;
- ✓ be familiar with the conditions and documentation necessary for industrial production of medicines;
- ✓ know measures of pharmaceutical products quality assurance;
- ✓ know the principles and conditions of medicines storage;
- ✓ to organize pharmaceutical purveyance activities of pharmaceutical companies and pharmaceutical supplies;
- ✓ assure the optimal range of pharmaceutical products for different levels of pharmaceutical assistance;
- ✓ determine necessity for different groups of pharmaceutical products;
- ✓ prepare orders (requirements) for supply of pharmaceutical products;

Medicines and other pharmaceutical products as a subject of pharmaceutical assistance.  
Marketing authorization of medicinal products.

Quality assurance of medicines. Industrial production of medicines.

Pharmaceutical supply.  
Pharmaceutical



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- ✓ create conditions for organization of pharmaceutical products preservation;
- ✓ distribute pharmaceutical products in accordance with organizational groups of preservation;
- ✓ assure the organization preservation conformity of pharmaceutical products in supply of pharmaceutical companies and hospitals.

warehouse, tasks and functions.

### Chapter 4. Pharmaceutical assistance system in outpatient population. Community pharmacy.

- ✓ know the principles of expansion and location of pharmacies;
- ✓ to acquire the main methods of handling, and the peculiarities of their use in pharmaceutical collective;
- ✓ be aware of the activities of leading pharmaceutical companies: planning, organization, motivation and control needed to formulate and achieve the desired goal;
- ✓ argue the organizational structure of the public pharmacy according to conditions of its activity;
- ✓ arrange and equip workplaces in pharmaceutical companies;
- ✓ divide service obligations between employees of pharmaceutical companies;
- ✓ determine the staffing needs for different subdivisions of pharmaceutical companies;
- ✓ to select personnel for different pharmaceutical posts;
- ✓ organize working regime and activity of pharmaceutical companies;
- ✓ determine the human resources required for the pharmacy;
- ✓ organize assistance with medicines, supply, preparation of medicines, pharmacy records and management;
- ✓ analyze the situation regarding the level of pharmaceutical assistance for different administrative territories based on different criteria;
- ✓ assure the decision-making process of pharmaceutical activity;
- ✓ assure compliance with pharmaceutical ethics and deontology.

Pharmaceutical assistance system in outpatient population.  
Community pharmacy. Tasks and functions of public access pharmacy.

Pharmacy manager. Managerial process of pharmaceutical company.

### Chapter 5. Management of Essential Pharmaceutical Services.

- ✓ be familiar with the nomenclature of essential pharmaceutical services;
- ✓ know the prescribing and delivery medicines rules;
- ✓ possess the types of internal pharmaceutical control;
- ✓ be familiar with terms of storage of medicines prepared in the pharmacy;
- ✓ know the basic requirements of sanitary regime in pharmaceutical companies ;
- ✓ organize the essential pharmaceutical service activities;
- ✓ release pharmaceutical products with and without a prescription;
- ✓ organize preparation of medicines;
- ✓ assure all compliance conditions with sanitary regime in pharmaceutical companies;
- ✓ assure compliance with the pharmaceutical regime in the preparation of medicines;
- ✓ prepare pharmaceutical forms according to medical prescriptions;
- ✓ apply all types of internal pharmaceutical control and assess the quality of the medicines;
- ✓ definitive (label) pharmaceutical forms prepared in the pharmacy.

Legal norms of medicines prescription.

Receiving, pricing and registration of prescription.

Technology of pharmaceutical compounding in pharmacy.  
Quality control of extemporaneous preparation.  
Pack labeling and dispensing medicines from pharmacy.

### Chapter 6. Management and legislation of pharmaceutical assistance in hospital

- ✓ know the structure and particularities of inpatient assistance system with medication;

Management and legislation of



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- ✓ know and apply in practice general principles of organization and functioning of pharmacies in medical institutions, their attributions, space, endowment and management;
- ✓ know clinician pharmacist fields of activity, his rights and obligations;
- ✓ know and possess prescription medicines rules in inpatient patients;
- ✓ apply and use in practice of health care institutions the principles of Drug Formulary ;
- ✓ to know different methods of analysis and to determine the necessity for the medicines included in Drug Formulary of medical institution;
- ✓ assure efficient functioning of hospital pharmacy;
- ✓ assure optimal assortment of pharmaceutical products for medical institution;
- ✓ organize the pharmaceutical supply the health care institution by applying the centralized procurement procedures;
- ✓ organize the control of the preservation and rational use of medicines in hospital wards;
- ✓ keep evidence of medicines and articles for medical use in hospital pharmacy;
- ✓ prepare and submit management reports on the circulation of material values in hospital pharmacy.

pharmaceutical assistance in hospital.

### Chapter 7. Records and pharmaceutical management in pharmaceutical companies.

- ✓ determine the results of the economic – financial activities in pharmaceutical companies;
- ✓ assure efficient activity of the pharmaceutical companies;
- ✓ assure planning, organization, coordination and control of pharmaceutical activity;
- ✓ possess abilities for stimulation and remuneration of labor;
- ✓ possess skills on managing human, material, financial and informational resources in pharmaceutical companies;
- ✓ keep accounting of housekeeping and financial operations in pharmaceutical company
- ✓ draw up business plans for different activity indicators of the pharmaceutical companies;
- ✓ possess skills to systematization and processing of obtained data;
- ✓ organize the activity of registering and managing pharmaceutical companies;
- ✓ propose measures to ensure the stable development of pharmaceutical companies;
- ✓ assure the unity of activity of providing the quality services and economic activity of the pharmaceutical companies based on principle of obtaining benefit for population health.

Accounting in pharmaceutical company.  
Pricing of pharmaceutical products.

Pharmaceuticals turnover.  
Turnover and its constituent. Stocks of pharmaceutical enterprises.

Material assets turnover in pharmaceutical company.  
Cash flow in pharmaceutical companies.

Cost and expenditure of pharmaceutical company.  
Work statement and emolument.  
Financial statements.

### Chapter 8. Pharmaceutical activity exercise and resource entirety control

- ✓ know the verifying integrity particularities of material values;
- ✓ fully aware of legal provisions relating to the exercise of pharmaceutical activity;
- ✓ perform inventory of different types of material values;
- ✓ legalize documents according to the inventory of material values;

Monitoring management of pharmaceutical activity.



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- ✓ be able to apply the rules of natural perishability depending on results of inventory of material values;
- ✓ carry out inspection of pharmacies, other pharmaceutical companies with the aim of assessing the quality of pharmaceutical assistance;
- ✓ to select and apply new processes and methods in pharmaceutical activity;
- ✓ assess the performance/non-compliance of the pharmaceutical companies based on the results of the inspection;
- ✓ propose methodical aid to pharmaceutical companies for removing non-compliances detected as a result of inspection and prevention of breaches of the legal norms.

Inventory of material assets in pharmaceutical companies.

### VII. PROFESSIONAL (SPECIFIC) (SC) AND TRANSVERSALS (TC) COMPETENCES AND STUDY OUTCOMES

#### Professional (specific) (SC) competences:

**PC1:** Knowledge of the theoretical bases of Pharmaceutical Management and Legislation; general principles in design, analysis and registration of pharmaceutical para-pharmaceutical products; knowledge of general principles of organization and operation of pharmaceutical companies with different legal forms of business; knowledge of the legislative framework in the field of pharmaceutical activity; awareness of rights and obligations pharmacist.

**PC2:** Forecasting basic economic indices of pharmacy achievements, pharmaceutical stocks; circulation costs; benefit; assessing trends in the development of population assistance with medicines; practical implementation of patient counseling and pharmaceutical assistance, assessment of medical prescriptions.

**PC3:** Designing of practical work in the pharmaceutical system according to the diversity of professional roles; using and adaptation of theoretical knowledge in the field of pharmacy to practical work situations; streamlining professional activity by introducing innovative pharmaceutical elements; application of the pharmaceutical legislation requirements in the pharmacist's practical work; computer knowledge as a working tool in the theoretical and practical pharmaceutical activity; establishing correlation between components of pharmaceutical activity process and health care system of the population; continuously streamlining of pharmaceutical activity by introducing innovations and implementation of invention in the field.

**PC4:** Diagnosing the particularities and organizational culture of enterprises and institutions of pharmaceutical system, where the pharmacist works; design and coordination of pharmaceutical activity in different enterprises and institutions: community pharmacies; hospital pharmacy; pharmaceutical warehouse; medicine factory, laboratories for quality control and certification of medicines, etc.; active engagement of specialist in process of accomplishing the mission of pharmaceutical entity; demonstrate ability to make decisions aimed at pharmaceutical system improving.

**PC5:** Determining the criteria for assessing efficacy of pharmaceutical and personal activity system according to actual conditions in specific social context; determining leadership methods based on pharmaceutical activity assessment results; identify research problems pharmacy field; knowing the methodology of scientific research in the practical work of a pharmacist or a head of the pharmaceutical unit.

**PC6:** Receiving messages on various socio-cultural environments, including communication in multiple languages; using of problem-solving capacity in pharmaceutical work collaboratively with



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physicians; promoting the principles of tolerance and compassion for patients; using of information technologies (and computer) in pharmaceutical activity.

### Transversal competences (TC):

**TC1:** Promoting of logical reasoning, practical applicability, evaluation and self-assessment in decision-making process; compliance with pharmaceutical ethics and deontology rules in the production, analysis, transport and delivery of medicinal products to the population and medical institutions.

**TC2:** Identification of training needs according to evolution of pharmaceutical system; determining the priorities in continuing of pharmacist's professional training; assessing the changes in the pharmaceutical system as a condition of its functionality.

**TC3:** Performing activities and exercising the specific team works roles to. Promoting initiative, dialogue, cooperation, positive attitude and respect for other people, empathy, altruism and continuous self-improvement.

### Study outcomes:

#### At the end of the course the student will be able to:

- Know the structure of the health system, internal components and external factors of influence on system activity;
- Know the structure of pharmaceutical system, component subsystems, interaction and mutual influence of determinants external factors of system functioning;
- Have skills to analyze the situation and stage of pharmaceutical assistance at different levels;
- Know types of pharmaceutical companies, be able to organize the foundation of pharmaceutical companies and organization their activity;
- Know and apply in pharmaceutical practice all legal norms established in pharmaceutical legislation and legislation related to the pharmaceutical activity;
- Know the conditions for exercising of pharmaceutical activity and be able to finalize and present the documents set to the regulatory authorities for authorization of pharmaceutical activity;
- Know the performance of medicines and other pharmaceutical products submit documents characterizing authorization, licensing procedures, manufacturing, import and distribution;
- Know and be able to apply pharmaceutical performance standards to pharmaceutical practice: Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice Good Distribution Practice, Good Storage Practice and Good Pharmacy Practice;
- Know and assure internal pharmaceutical control and state control of medicines quality at all stages of their circulation on the pharmaceutical market;
- Possess rules of medicines prescription and recommendation medicines for outpatient and inpatient patients;
- Evolve medical prescriptions in terms of compatibility, doses, prices and other regulations;
- Be able to organize outpatient and inpatient pharmaceutical assistance to the population;
- Possess and organize the rational use of medicines monitoring, including by carrying out the procedures established by pharmacovigilance;
- Be able to plan the economic activity, ensure the realization of the plans and keep the primary records of the economic operations, prepare the management reports and determine the results of the economic activity of the enterprise;
- Possess and apply its policies and procedures established by legislation regarding medicine



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prices;

- Be able to perform selection and all procedures related to the movement and human resource records in pharmaceutical practice;
- Know and apply in practice the procedures for assuring and controlling the entirety of material values.

### VIII. THE STUDENT'S SELF-TRAINING

No.	Expected product	Strategies for achieving	Evaluation criteria	Deadline
1	Working with the manual and legislative and normative acts.	Working systematically library and media library. Using existing electronic sources on the topic under discussion.	1. Quality of formed suggestions, logical thinking, flexibility. 2. Quality of informational material systematization obtained by own activity.	During the first and second semesters
2	Preparing a report (the topics are proposed) and its presentation.	Analysis of relevant sources on the topic of report. Analysis, systematization and synthesis of information on the proposed topic. Compilation of report in accordance with requirements and its presentation.	1. Quality of systematization of selected information material 2. Concordance of the information with the proposed topic. 3. The argumentation level of conclusions. 4. Ingeniousness and creativity in presentation preparing. 5. Use of bibliographic sources.	During the first and second semesters
3.1	Essay writing (the topics are proposed)	Analysis of materials in which this topic is discussed. Material analysis, comparing different points of view on this issue. Exposure in the thesis form: theory, evidence and experts opinions. Formulation exposure of own position on this topic.	1. Quality of systematization of selected information material. 2. The ability of understanding and analyzing the subject. 3. Capacity of formulating exposure of own position on this topic. 4. Ability to use creativity and gained knowledge. 5. Presentation of bibliographic sources	During the first and second semesters
3.2	Case study on a topical issue	Selection and description of the case study. Analysis of the causes of the issues raised in the case study. Deduction expected outcome of the case.	1. Ability to identify topical issues. 2. Analysis, synthesis, generalization of data obtained through own investigation. 3. Capacity of formulating exposure of own position on this topic. 4. Formation of an algorithm of knowledge based on obtained conclusions. 5. Use of bibliographic sources.	During the first and second semesters
3.3	Analyzes in the field of pharmaceutical policies	Analysis and synthesis of recognized policy experiences. Selecting needs of the population, the research itself, use / research result; confirmation or refutation of the hypothesis contemplated.	1. The ability to think and approach systemic and situational issues. 2. Presentation of research results in the form of a cause-effect-result diagram. 3. Ability to understand the available methods for analyzing the effects of policy interventions.	During the first and second semesters



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No.	Expected product	Strategies for achieving	Evaluation criteria	Deadline
			4. Integrating personal perspectives into pharmaceutical policy development. 5. Use of bibliographic sources.	

### IX. METHODOLOGICAL SUGGESTIONS FOR TEACHING-LEARNING-ASSESSMENT

#### • *Teaching and learning methods used*

Lectures, practical classes, individual work, internship. Lectures are given by the course responsible. Practical classes are individualized. Each student solves individually problems in workbook or template documents. At the end of the practical classes, each theme in the workbook is verified and signed by the teacher. For the knowledge assessment and practical skills different interactive teaching procedures observation, analysis, comparison, modeling, etc. are used

#### • *Applied teaching strategies /technologies applied (specific to the discipline)*

During the studies, some specific methods are used: "Brainstorming", "Group Interviews", "Case Studies", etc. Individual work in teaching includes study of supplementary materials for every topic from mandatory and supplementary bibliographical sources, from available databases via communication networks of legislative and normative acts regulating pharmaceutical activity.

Individual work in the learning process includes the study of additional material for each subject from basic and additional bibliographic sources from the available databases through the communications networks of legislative and normative acts regulating pharmaceutical activity. Each student by the end of the discipline study must submit and present a report as a course paper with the topic of the teacher's indication, which fall within the studied topics.

#### • *Methods of assessment (including the method of final mark calculation)*

**Current:** frontal and/or individual control of the preparation level for laboratory by testing, control papers, group discussions, case study analysis. During the laboratory work - solving problems and exercises, performing role-playing games to completed topics, checking the results of the laboratory work performance.

During the study year it is organized 4 control assessments (2 in each semester) in written/oral form and test-control. Mark on written/oral test is calculated including the current assessment results.

**Intermediate.** Semester VII is finalized with a colloquium. The mark for the colloquium is calculated based on first two control assessments and student individual work. The marks 5 and more it is equivalent with mark "attested", which will be transferred in student record book.

At the end of study year, average annual mark will be calculated based on positive marks for all control assessments and student individual work.

**Final:** Complex exam after semester VIII in 3 stages: practical skills, test-control and oral answer.

Final mark (weighted) is based on positive marks ( $\geq 5$ ) of all constituent parts: average annual mark – 30%, practical skills – 20%, test-control – 20% and oral answer – 30%.

The average annual mark and all the final examination stages marks (practical skills, test-control, oral answer) will be expressed in numbers according to the grading scale indicated in the table.

Final mark obtained will be expressed in number with two decimal that will be transferred to the student record book.



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### Method of marks rounding at the assessment stages

Grille of intermediate marks (annual average mark, examination stages marks)	National grading system	Equivalent ECTS
1,00-3,00	2	F
3,01-4,99	4	FX
5,00	5	E
5,01-5,50	5,5	
5,51-6,00	6	
6,01-6,50	6,5	D
6,51-7,00	7	
7,01-7,50	7,5	C
7,51-8,00	8	
8,01-8,50	8,5	B
8,51-9,00	9	
9,01-9,50	9,5	A
9,51-10,0	10	

**Remark:** Unreasonable absence at exam is registered as "absent" and is equivalent with 0 (zero). Student has the right for 2 repeated sustaining of not passed exam.

## X. RECOMMENDED LITERATURE:

### A. Compulsory:

1. Safta V., Brumărel M., Ciobanu N., Adauji S. - Management și legislație farmaceutică, - F.E.P. „Tipografia Centrală”, - Chișinău, 2012.
2. Procopișin V., Safta V., Brumărel M. - Bazele activității farmaceutice, - F.E.P. “Tipografia Centrală”, - Chișinău, 2002, versiunea în limba rusă: Кишинэу, 2003.
3. Reglementarea activității farmaceutice. (Culegere de acte legislative și normative) / Colectiv de autori: redactor responsabil – VASILE PROCOPIȘIN, Editura „Vector”, 2007, – F.E.P. “Tipografia Centrală”, – Chișinău, 2007.

### B. Additional:

1. Voitcu M., Căraușu Elena-Mihaela - Marketingul medicamentelor, Editura Gr. T. Popa, Iași, 2004.
2. Ețco C. - Management în sistemul de sănătate. Chișinău, Ed. Epigraf, 2006.
3. Carată A. - Management, marketing și legislație farmaceutică. Management în domeniul farmaceutic. - Vol. I. Ed. a 2-a, rev., Ed. didactică și pedagogică, R.A., - București, 2008.
4. Voitcu M., Căraușu Elena-Mihaela - Management sanitar și farmaceutic.; Iași, Ed. „Gr. T. Popa”, UMF, 2003.
5. Tootelian, D. H., Wertheimer, A. I., Mikhailitchenko, A. Essentials of Pharmacy Management, Pharmaceutical Press, 2012, 446 p. ISBN 978-085-711-018-3.



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8. Aparasu, R. R. Research Methods for Pharmaceutical Practice and Policy, Pharmaceutical Press, 2011, 310 p. ISBN 978-085-369-880-7.
9. Ghid farmacoterapeutic=фармакотерапевтический справочник /C. Matcovschi, V. Procopișin, B. Parii. - Ch.: Î.S. F.E.-P. „Tipografia Centrală”. 2006. 1424 p.
10. Tăerel Adriana-Elena Resursele sistemului farmaceutic – componente ale politicii medicamentului. Editura Tehnoplast, - București, 2009.
11. Standardele Naționale de Contabilitate, vol. 1 și 2 // Moldpres, Chișinău, 1998.
12. Crișan O. Profesii de farmacist. Probleme de legislație, Cluj-Napoca, Ed. Medicală Universitară „Iuliu Hațieganu”, 2001.
13. Managementul afacerilor mici și mijlocii (coordonator C. RUSU); Chișinău, Ed. LOGOS, 1993.
14. Лозовая Г., Лопатин П., Глембоцкая Г.; Менеджмент фармацевтической организации. Москва, МЦФЭР, 2000.