



## CD 8.5.1 DISCIPLINE CURRICULUM

EDITION: 06

DATE: 20.09.2017

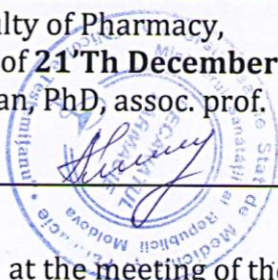
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**FACULTY OF PHARMACY**  
**STUDY PROGRAM 0916.1 PHARMACY**  
**CHAIR OF SOCIAL PHARMACY "VASILE PROCOPISIN"**

**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.

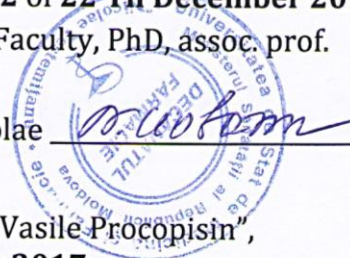
UNCU Livia



**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**  
(Internship)

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** internship is a continuity of the discipline mentioned study has a practical role in in the professional training of the future pharmacist. Internship based completely on the knowledge and skills obtained throughout the theoretical and practical study.

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

Management and pharmaceutical legislation internship aims to deepen the practical training of the future pharmacist by conducting its activity under the guardianship of teaching staff from the chair and staff of community pharmacies and medical institutions – bases of internship on the full range of activities related to pharmaceutical assistance of population in outpatient and inpatient, including pharmacies organizational issues.

With the objects of study medicine sick man – consumer of medicines, during the internship, the above-mentioned aim is achieved by extending the abilities of:

- ♦ managing workgroups within pharmaceutical companies;
- ♦ forming and analysis of the assortment of products for the pharmaceutical company;
- ♦ receiving, pricing and registration of prescription, receiving orders, organizing the preparation and dispensing of extemporaneous and industrial medicines;
- ♦ communication with coworkers and medicines consumers;
- ♦ organizing the activity of pharmaceutical companies and their subdivisions;
- ♦ ordering, receiving, storing and preserving the correct organization of pharmaceutical products;
- ♦ organization of internal pharmaceutical control in pharmaceutical companies;
- ♦ using methods in elaboration of economic indicators included in the business plan for pharmaceutical companies;
- ♦ applying methods of determining drug requirements for different levels of the health system;
- ♦ organization of procedures of making and finalizing the inventory of material values;
- ♦ applying of procedures and principles of evidence of material values, personnel, economic-financial activity, fixed assets, labor and wages etc.;
- ♦ applying of pricing mechanisms for medicines;
- ♦ determining the level of physical and economic accessibility of medicines for population;
- ♦ applying of computerized systems to solve various drug and pharmaceutical problems in the field of drug and pharmaceutical activity.

- **Language of training the discipline:** Romanian, English.
- **Beneficiaries:** students of the IV-th year, faculty of Pharmacy, specialty Pharmacy.





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### II. MANAGEMENT OF THE DISCIPLINE

Code of discipline		<b>S.08.O.085</b>	
Name of the discipline		<b>Management and pharmaceutical legislation</b> (Internship)	
Responsible for the discipline		<b>Mihail Brumărel</b> , PhD, associate professor	
Year	IV	Semester	<b>8</b>
Total number of hours, including:			<b>60</b>
Lectures	-	Practical/laboratory hours	-
Seminars	-	Self-training	<b>60</b>
Form of assessment	<b>C</b>	Number of credits	<b>2</b>

### III. TRENING AIMS WITHIN THE DISCIPLINE

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

*at the application level:*

- ✓ 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;
- ✓ 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 activities of pharmaceutical companies and pharmaceutical supplies;
- ✓ assure 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;
- ✓ 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;
- ✓ release pharmaceutical products with and without a prescription;





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- ✓ assure all conditions for compliance with the sanitary regime in pharmaceutical companies;
- ✓ assure compliance with the pharmaceutical regime in the preparation of medicines;
- ✓ to apply the types of internal pharmaceutical control and assess internal pharmaceutical drug quality;
- ✓ finalize (label) pharmaceutical formulations prepared in the pharmacy;
- ✓ determine the economic and financial results of pharmaceutical companies;
- ✓ ensure activity of pharmaceutical companies;
- ✓ 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 work of accounting and management 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;
- ✓ select and apply new processes and methods in pharmaceutical activity.

### IV. PROVIZIONAL TERMS AND CONDITIONS

Internship is allowed only to students who have studied and passed the Management and pharmaceutical legislation examination and according to the results of the medical examination are admitted for practical work in pharmaceutical companies and institutions.

### V. THEMES AND ESTIMATE ALLOCATION OF HOURS

No.	Name of work sectors, activities and skills	Number of hours
		Self-training
1.	<b>Familiarization with pharmacy.</b> Coordination of pharmaceutical system.	6
2.	<b>Activity in the manufacturing section</b> , including: 2.1. <i>Working at the place of pharmacist to accept prescriptions and deliver of medicines compounding.</i> 2.2. <i>Working at the place of pharmacist in the prescription department.</i> 2.3. <i>Working at the place of pharmacist preparing pharmaceutical feedstock.</i>	6
3.	<b>Familiarization with work of pharmacist manager.</b>	6
4.	<b>Activity in the section "Industrial Medicines".</b>	12
5.	<b>Working on "Records and pharmaceutical management."</b> 5.1. <i>Record of pharmaceuticals inputs.</i> 5.2. <i>Evidence of achievement of other types of outputs and losses of pharmaceuticals.</i> 5.3. <i>Evidence of funds.</i> 5.4. <i>Labor and wage records.</i> 5.5. <i>Records of fixed assets of small value and short term.</i> 5.6. <i>People management and pharmacy management.</i>	12





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No.	Name of work sectors, activities and skills	Number of hours
		Self-training
6.	<b>Organization of pharmacy branches.</b>	6
7.	<b>Inventory of material assets.</b>	6
8.	<b>The activity on the stocks department (the supply).</b>	6
<b>Total ore</b>		<b>60</b>

## VI. REFERENCE OBJECTIVES AND CONTENTS UNITS

Objectives	Content units
<b>Chapter 1. Organization of the activity of community pharmacy</b>	
<ul style="list-style-type: none"> <li>✓ perform the functions of planning, organization, coordination, motivation and control of different pharmaceutical activities;</li> <li>✓ identify internal and external environmental factors influence the activity of making;</li> <li>✓ perform the ergonomic endowment and organization of workplace in pharmaceutical units;</li> <li>✓ assure safety of work, compliance with sanitary rules of personal and work hygiene;</li> <li>✓ complete the documents for authorization of pharmaceutical activity;</li> <li>✓ be able to identify the factors of the internal and external environment for the pharmaceutical activity of the units;</li> <li>✓ argue the organizational structure of the community pharmacy depending on the conditions of its activity;</li> <li>✓ arrange and equip workplaces in pharmaceutical companies;</li> <li>✓ delegate work obligations between employees of pharmaceutical companies;</li> <li>✓ organize working arrangement of pharmaceutical companies;</li> <li>✓ determine staffing needs for different divisions of pharmaceutical companies;</li> </ul>	<p>Familiarizing with the pharmacy</p> <p>Familiarizing with head pharmacists work</p>
<b>Chapter 2. Assistance with medications the population</b>	
<ul style="list-style-type: none"> <li>✓ organize the activity of assistance with medicines, supply, drug preparation, accounting and management of the pharmacy;</li> <li>✓ organize the essential pharmaceutical service activities;</li> <li>✓ dispense pharmaceutical products with and without a prescription;</li> <li>✓ assure all conditions for compliance with the sanitary regime in pharmaceutical companies;</li> <li>✓ assure compliance with the pharmaceutical regime in the preparation of medicines;</li> <li>✓ to apply the types of internal pharmaceutical control and assess internal pharmaceutical drug quality;</li> <li>✓ finalize (label) pharmaceutical formulations prepared in the pharmacy;</li> <li>✓ select and apply new processes and methods in pharmaceutical activity;</li> </ul>	<p>Activity in the production department</p> <p>Activity in the "Industrial Medicines" department.</p> <p>Organizing the pharmacy subsidiaries activity.</p>





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Objectives	Content units
<b>Chapter 3. Supplying the pharmacy</b>	
<ul style="list-style-type: none"><li>✓ organize the supply of pharmaceutical companies and pharmaceutical supplies;</li><li>✓ ensure the optimal range of pharmaceutical products for different levels of pharmaceutical assistance;</li><li>✓ determine the need for different groups of pharmaceutical products;</li><li>✓ draw up orders (requirements) for the supply of pharmaceutical products;</li><li>✓ create conditions for the organization of the preservation of pharmaceutical products;</li><li>✓ distribute pharmaceutical products in accordance with groups of organization keeping;</li></ul>	Activity in the stock department.
<b>Chapter 4. Primary evidence in pharmacy</b>	
<ul style="list-style-type: none"><li>✓ determine the economic and financial results of pharmaceutical companies;</li><li>✓ assure efficient activity of pharmaceutical companies;</li><li>✓ possess skills in managing the human, material, financial and informational resources of pharmaceutical companies;</li><li>✓ keep records of household and financial operations;</li><li>✓ draw up business plans for different activity indicators of the pharmaceutical companies;</li><li>✓ possess skills to systematization and processing of data obtained as a result of economic activity;</li><li>✓ organize the accounting and management work of pharmaceutical companies;</li><li>✓ perform inventory of different types of material values;</li><li>✓ legalize documents according to the inventory of material values;</li><li>✓ be able to apply the rules of natural perishability depending on the results of inventory of material values;</li></ul>	Activity in the field of "Pharmaceutical Evidence and Management" Inventory of material values.

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

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

**PC1:** 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:** 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;





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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; active engagement of specialist in process of accomplishing the mission of pharmaceutical entity.

**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.

**PC6:** Receiving messages on various socio-cultural environments, including communication in multiple languages; using of problem-solving capacity in pharmaceutical work collaboratively with 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 pharmacists 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 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;
- Be able to organize the foundation of pharmacy and organize its activities;
- 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 pharmaceutical performance standards and be able to apply Good Pharmaceutical Practice to pharmaceutical practice;
- Know and assure internal pharmaceutical control at all stages of their circulation on in pharmacy;
- 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





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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 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

Nr.	Expected product	Strategies for achieving	Evaluation criteria	Deadline
1	Internship Agenda	Performing assigned tasks for each sector of activity within the community pharmacy.	The fullness and accuracy of the individual assignments performance, stipulated in the methodological recommendations regarding the internship	During the first and second semesters
2	Set of primary evidence of the economic-financial operations in the pharmacy documents	Preparation of documents for authorization of types of activity performed by pharmacy Preparation of primary evidence documents for all economic and financial operations in pharmacy.	The number of operations illustrated in the documents. The accuracy of the documents preparation.	During the first and second semesters
3	Study on level assessment of the pharmaceutical assistance to the population	Prepare a questionnaire on the level of the population's pharmaceutical assistance. Questioning pharmacy visitors. Processing of questionnaire data.	Formulating the questions in the questionnaire. Number of people surveyed. Analysis and interpretation of results.	During the first and second semesters

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

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

During the internship, the individual work of the student prevails. In order to facilitate the realization of the program of internship and individual work, students have access to the entire teaching material used for teaching the subject during the semester.

Students are encouraged to make extensive use of learning methods such as observation, benchmarking, classification, development schemes, modeling situations, interviewing, questioning, etc.

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

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, materials available on the results of practice-base pharmacy activity.





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

**Current:** Currents checks during the internship.

**Final:** Final mark of internship is the annual average mark, that consists of oral interview on program acquiring and student individual work during the internship.

Annual average mark will be expressed in numbers according to the grading scale indicated in table.

Marks 5 and more are equivalent with mark "attested", which will be transferred to the student record book.

### Method of marks rounding at the assessment stages

Grille of average 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	
8,51-9,00	9	B
9,01-9,50	9,5	
9,51-10,0	10	

**Remark:** Absence at colloquy without acceptable reason is registered as "absent" and is equivalent with mark "not attested". Student has the right to 2 repeated supports of unprompted colloquy.

## 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.





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### *B. Additional:*

1. Voitcu M., Căraușu Elena-Mihaela - Marketingul medicamentelor, Editura Gr. T. Popa, Iași, 2004.
2. Ghid farmacoterapeutic=фармакотерапевтический справочник /C. Matcovschi, V. Procopișin, B. Parii. - Ch.: Î.S. F.E.-P. „Tipografia Centrală”. 2006. 1424 p.
3. Ețco C. - Management în sistemul de sănătate. Chișinău, Ed. Epigraf, 2006.
4. 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.
5. Voitcu M., Căraușu Elena-Mihaela - Management sanitar și farmaceutic.; Iași, Ed. „Gr. T. Popa”, UMF, 2003.
6. Tootelian, D. H., Wertheimer, A. I., Mikhailitchenko, A. Essentials of Pharmacy Management, Pharmaceutical Press, 2012, 446 p. ISBN 978-085-711-018-3.
7. Herist, K. N., Rollins, B., Perri, M. Financial Analysis in Pharmacy Practice, Pharmaceutical Press, 2011, 225 p. ISBN 978-085-369-897-5.
8. Chisholm-Burns, M. A., Vaillancourt, M. A., Shepherd, M. Pharmacy Management, Leadership, Marketing, and Finance, Jones & Bartlett Publishers, second edition, 2012, 600 p. ISBN 978-144-965-725-3.
9. Aparasu, R. R. Research Methods for Pharmaceutical Practice and Policy, Pharmaceutical Press, 2011, 310 p. ISBN 978-085-369-880-7.
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.