

Name of discipline	Management and pharmaceutical legislation			
Type	Compulsory		Credits	5+5
Academic year	IV		Semester	VII-VIII
Number of hours	Course	15+15	Practice work	60+60
	Seminar	-	Self-training	75+75
Component	Specialized			
Course holder	Brumărel Mihail, PhD, associate professor Sîbii Lucia, university assistant Cheptanari-Bîrtă Nicoleta, university assistant			
Location	Chişinău, str. Nicolae Testemiţanu, 22, <i>Vasile Procopișin</i> University Pharmaceutical Center			
Conditionings and prerequisites of:	Program: 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.			
	Competences: working with computing technology and information systems, including the use of the Internet, document processing, the use of word processors, electronic tables and applications for presentations, communication skills and teamwork; statistical analysis; bibliographic analysis.			
Mission of the discipline	Being a pharmaceutical discipline Pharmaceutical management and legislation aims to prepare-re 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.			
Overview of the topics	General characteristic of management. Elements of management in the pharmaceutical activity. Management functions. Management research methods. Management of leadership. Decisions in the leadership process. Monitoring management of pharmaceutical activity. Organization management. General notions of law and legislation. Pharmaceutical legislation. Medicine manufacturing			

	<p>management. Quality assurance of medicines. Medication authorization management. Legal norms of medicines prescription. Pharmaceutical supply management and legislation. Pharmaceutical warehouse, tasks and functions. Pharmaceutical assistance system in outpatient population. Community pharmacy - organization and requirements. Management and legislation of pharmaceutical assistance in hospital. Accounting in pharmaceutical enterprises. Pricing of pharmaceutical products. Accounting of pharmaceuticals circulation. Turnover and its constituent. Stocks of pharmaceutical enterprises. Material assets turnover in pharmaceutical company. Cash flow in pharmaceutical companies. Work statement and emolument. Cost and expenditure of pharmaceutical company. Inventory of material assets in pharmaceutical companies.</p>
Outcomes	<ul style="list-style-type: none"> • to know the structure of the health system, internal components and external factors of influence on system activity; • to know the structure of pharmaceutical system, component subsystems, interaction and mutual influence of determinants external factors of system functioning; • to have skills to analyze the situation and stage of pharmaceutical assistance at different levels; • to know types of pharmaceutical companies, be able to organize the foundation of pharmaceutical companies and organization their activity; • to know and apply in pharmaceutical practice all legal norms established in pharmaceutical legislation and legislation related to the pharmaceutical activity; • to 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; • to know the performance of medicines and other pharmaceutical products submit documents characterizing authorization, licensing procedures, manufacturing, import and distribution;
Clinical skills	<ul style="list-style-type: none"> • to have skills in analyzing the situation and the level of pharmaceutical care at different levels; • to know and be able to apply in pharmaceutical practice the standards for ensuring the performance of medicines: the rules of good laboratory practice, clinical testing, manufacturing, transportation, storage, storage and distribution, pharmaceutical practice; • to know the basic rules of prescription and recommendation of medicines for outpatients and inpatients; • to evolve medical prescriptions in terms of compatibility, dosages, prices and other regulations in force; • be able to organize the pharmaceutical assistance of the population in outpatient and inpatient conditions;

	<ul style="list-style-type: none"> • to own and organize the monitoring of the process of rational use of medicines, including by performing the procedures established by pharmacovigilance; • to be able to plan the economic activity, ensure the realization of the plans and keep the primary record of the economic operations, draw up the management reports and determine the results of the economic activity of the enterprise; • to know and apply in practice the policies and procedures established by the legislation regarding the prices of medicines; • to be able to carry out the selection and all the procedures related to the circulation and the record of human resources in pharmaceutical practice; • to know and apply in practice the procedures for ensuring and controlling the integrity of material values.
Evaluation form	Exam