

Name of discipline	International Pharmaceutical Legislation		
Type	Optional	Credits	2
Academic year	IV	Semester	VIII
Number of hours	Course	15	Practice work
	Seminar	30	Self-training
Component	Specialized		
Course holder	Adauji Stela, PhD, associate professor Șchiopu Tatiana, university assistant		
Location	Chisinau, str. Nicolae Testemițanu, 22, <i>Vasile Procopișin</i> University Pharmaceutical Center		
Conditionings and prerequisites of:	Program: knowledge and understanding of the general notions of law, legislation, legal norm, normative act, legislation related to the pharmaceutical activity.		
	Competențe: Respecting and application of legal norms from medicine and pharmaceutical activity' field. Application of knowledge from pharmaceutical activity' field with legal norms that ensure legality of pharmaceutical enterprise functioning.		
Mission of the discipline	<p>The mission of discipline is ensuring knowledge obtaining, which will allow for the future specialist-pharmacist the possibility to be employed in any type of pharmaceutical activity which provides international legal rules' interpretation an application in pharmacy' field.</p> <p>The aim of discipline is in-depth training and practical skills obtaining for interpretation and application of legal rules contained in international pharmaceutical legislation.</p>		
Overview of the topics	<p>International law: notions and basic principles. Pharmaceutical fields reglementated at international level. Regulation of drug elaboration research. Good drugs manufacturing practice. Good drugs manufacturing practice rules (GMP). Evolution of elaboration – implementation of GMP rules. Regulations and Directive UE on GMP rules. Good engineering practice (GEP). The role of International Society for pharmaceutical engineering (ISPE). Guidelines of BPFM: European, USA et al. Ensuring international legislation on quality, efficacy and drugs safety. Technical common document of International conference of Harmonization on drug authorization. Drugs authorization – basic principle of drugs' quality, efficacy and safety assurance placed on the pharmaceutical market.</p> <p>International conference of Harmonization (ICH). Good drug distribution practice (GDP) and good pharmacy practice (GPP). Good wholesale distribution practice (GDP). Regulation, Directives and Directions at EU level. Good pharmacy practice (GPP). Evolutionary aspects. Standards of International Pharmaceutical Federation. Pharmacist' role. Pharmaceutical services. Processes and results of pharmacy activity quality control. Good pharmacovigilance practice. Regulations and EU Directives that regulated pharmacovigilance. Parmaceutical inspection. Audit. Pharmaceutical Inspection Convention (PIC/S). Diference between PIC and PIC/S. Conditions for joining the PIC/S. Audit. Classification of non-compliance with GMP rules. PIC/S guideline on drugs manufacturing in medical</p>		

	<p>– sanitary institutions. Professional pharmaceutical organisations of international level. International Pharmaceutical Federation (IPF). IPF Councils and Foundation. International federation of pharmaceutical manufactures and associations (IFPMA). European Federation of Pharmaceutical Associations and Industries (EFPIA). Forums. Activities. Collaborations.</p>
Outcomes	<ul style="list-style-type: none"> • to know the norms included in the IPL; • to be able to interpret the norms included in the IPL; • in case of need, to ensure the activity organization of any pharmaceutical enterprise in accordance with the IPL provisions of the LFI; • to have knowledge that ensures the possibility of involvement in the harmonization process of national pharmaceutical legislation with international requirements.
Clinical skills	<ul style="list-style-type: none"> • to apply/respect the international pharmaceutical legislation provisions; • to analyze the compliance of national pharmaceutical legislation with IPL. • to argue the need of national norms harmonization to IPL norms; • to organize the activity of any pharmaceutical enterprise with respecting IPL provision.
Evaluation form	Exam