



Study program: Integrated Academic Studies in Pharmacy			
Course title: Pharmaceutical Legislation and Ethics			
Teacher: Aleksandra D. Nikolić			
Course status: compulsory			
ECTS Credits: 3			
Condition: History of pharmacy			
Course aim The aim of this course is to introduce the historical aspects of the development of pharmacy as a science, and understanding the importance and role of pharmacists in the healthcare system and its relationship to other segments of the healthcare organisation. Introduction to basic ethical principles of the medical and pharmaceutical industry. Knowledge of national, European and international legislation in the field of pharmacy. Introducing model and organization of the Health Care System in Republic of Serbia..			
Expected outcome of the course: Students know the historical and cultural foundations of the development of pharmaceutical profession and the pharmaceutical sciences; understand the role and necessity of personal continuing professional development. The student acquires knowledge of legislation and ethical standards in the profession and develop pharmaceutical ability and ethical analysis in pharmaceutical health care. Pharmacy students will acquire the skill to produce pharmaceutical-technological formulation for indoor and outdoor use, the type of solution, extractive preparations, suspensions and emulsions, according to the applicable regulations and based on the recipe prescribed by a doctor. The student knows and applies a variety of communication skills in pharmacy and society; know the difference between legal and ethical problems that the pharmacist is facing in their professional work; knows and is able to apply the laws, by-laws and trade laws that govern all aspects of the pharmaceutical industry.			
Course description <i>Theoretical education</i> <ol style="list-style-type: none"> 1. Basic ethical principles among pharmacists (history, oath, ethical standards and moral values) 2. Ethics between clinical and preclinical research. Biomedical research. 3. Pharmaceutical deontology. European regulation and International basic guidelines 4. National policy in Healthcare and Pharmacy (Pharmaceutical Chamber, License) 5. Legislation in healthcare system in Serbia – introducing and analysis of Laws in healthcare system 6. Registration of drugs and medical devices. Importance and role of Medicines and Medical Devices Agency of Serbia (ALIMS) 7. Organisation of Health Care System in Republic of Serbia. Network of health institutions 8. Importance and role of the pharmacist in Health Care System <i>Practical education</i> Analysis and discussion about practical cases.			
Literature <i>Compulsory</i> <ol style="list-style-type: none"> 1. Anderson S. Making Medicines - a brief history of pharmacy and pharmaceuticals, 1st ed. Pharmaceutical Press, 2005. 2. Actual Laws and other Acts of Republic of Serbia in the medical and pharmaceutical area 			
Number of active classes		Theoretical classes: 30	Practical classes: 15
Teaching methods Lectures. Interactive classes, practical classes.			
Student activity assessment (maximally 100 points)			
Pre-exam activities	points	Final exam	points
Lectures-activity	10	Written	70
Practices-activity		Oral	-
Colloquium	20	
Essay			