

1. COURSE DESCRIPTION – GENERAL INFORMATION			
1.1. Course teacher	Assistant Professor Ivan Pepić, PhD	1.6. Year of study	5 th
1.2. Name of the course	Health Legislation	1.7. Credit value (ECTS)	1,5
1.3. Associate teachers	-	1.8. Type of instruction (number of hours L+E+S+e-learning)	15+0+0+0
1.4. Study programme (undergraduate, graduate, integrated)	Integrated study of Pharmacy	1.9. Expected enrolment in the course	130
1.5. Status of the course	Compulsory	1.10. Level of use of e-learning (1, 2, 3 level), percentage of instruction in the course on line (20% maximum)	2 nd
2. COURSE DESCRIPTION			
2.1. Course objectives	<p>Students will gain the awareness of the basic regulations in the Republic of Croatia that regulate: (i) the pharmaceutical and medical biochemical activity; (ii) testing, production, trade, (pharmaco)vigilance, quality control and supervision of medicinal products and medical devices; (iii) the rights, duties, tasks and objectives in the field of health care; (iv) the rights and obligations of the compulsory health insurance; (v) the rights and obligations of voluntary (additional, supplementary and private) health insurance.</p> <p>The student will understand the legal framework of the health care system in the Republic of Croatia.</p>		
2.2. Enrolment requirements and required entry competences for the course	Enrolled 9 th semester.		
2.3. Learning outcomes at the level of the study programme to which the course contributes	<ul style="list-style-type: none"> • Application of professional knowledge and skills in pharmacotherapy interventions and implementation of pharmaceutical patient care while respecting the legislation of the current health policy and guidelines/principles of pharmaceutical ethics and deontology. • Monitoring and participation in drug distribution. • Use of information technology and databases in order to improve professional knowledge, skills and self-education. • Application of the legal and ethical principles of the profession in independent and team work. • Application of the professional knowledge in procedures of laboratory diagnostics, evaluation of the clinical significance of the biochemical and molecular markers, detection of sources of error and variability of laboratory analysis, interpretation of the laboratory analysis results considering their analytical and clinical aspects while 		

	respecting the current legislation, health policy and guidelines/principles of medical biochemistry profession.				
2.4. Expected learning outcomes at the level of the course (4-10 learning outcomes)	<p>After passing the exam, the student will be able to:</p> <ol style="list-style-type: none"> 1. Explain the basic characteristics of the entire health care system in the Republic of Croatia; 2. Name and explain the regulations governing the pharmacy profession in the Republic of Croatia; 3. Name and explain the regulations governing the medical biochemistry profession in the Republic of Croatia; 4. Name and explain the rules of drug prescribing that can be used in the therapy within the health care system through the compulsory or supplementary health insurance; 5. Name and explain the health services and health institutions at the primary, secondary and tertiary level of health protection and health activities at the (Croatian) health institutes, as well as the structure, basic tasks and authorities of the Croatian Chamber of Pharmacists and Croatian Chamber of Medical Biochemists; 6. Analyse the public health service network; 7. Explain the principles and measures in order to ensure and reduce the risk to health and life of patients; 8. Name basic testing procedures, authority approval, production, labelling, classification, transport, (pharmaco) vigilance, advertising, quality control and supervision of medicinal products and medical devices; 9. List the types of diagnostic tests carried out in general, specialist, subspecialist and clinical medical-biochemical laboratories. 				
2.5. Course content broken down in detail by weekly class schedule (syllabus)	<p>LECTURES:</p> <ul style="list-style-type: none"> • Health care; Patients' Rights Protection. • Health insurance: compulsory, supplementary, additional and private. • Legal regulations concerning medicinal products. • Legal regulations concerning medical devices. • Legal regulations concerning pharmaceutical activities. • Legal regulations concerning medical-biochemical activities. 				
2.6. Type of instruction	lectures seminars and workshops exercises online in entirety mixed e-learning field work	independent study multimedia and the internet laboratory work with the mentor (other)	2.7. Comments:		
2.8. Student responsibilities					
2.9. Screening of student's work	Class attendance	0.5	Research	1	Practical training

(specify the proportion of ECTS credits for each activity so that the total number of CTS credits is equal to the credit value of the course)	Experimental work		Report		
	Essay		Seminar essay		(Other--describe)
	Tests		Oral exam		(Other—describe)
	Written exam		Project		(Other—describe)
2.10. Grading and evaluation of student work over the course of instruction and at a final exam	The course is the theoretical part of the professional training.				
2.11. Required literature (available at the library and via other media)	Title				
	Health Care Act ("Official Gazette" No. 150/08, 71/10, 139/10, 22/11, 84/11, 154/11, 12/12, 35/12, 70/12, 144/12)				
	Health Care Quality and Social Welfare Act ("Official Gazette" No. 124/11)				
	Patients' Rights Protection Act ("Official Gazette" No. 169/04)				
	Compulsory Health Insurance Act ("Official Gazette" No.150/08, 94/09, 153/09, 71/10, 139/10, 49/11, 22/12, 57/12, 90/12, 123/12, i 144/12)				
	Voluntary Health Insurance Act ("Official Gazette" No.85/06, 150/08, 71/10)				
	Medicinal Products Act ("Official Gazette" No.76/13)				
	Medical Devices Act ("Official Gazette" No.76/13)				
	Law on Pharmacy ("Official Gazette" No.121/03, 35/08, 117/08)				
Law on Medical-Biochemical Activities ("Official Gazette" No.121/03, 117/08)					
2.12. Optional literature	Drug Abuse Prevention Act ("Official Gazette" No.7/01, 87/02, 163/03, 141/04, 40/07, 149/09, 84/11, 80/13) Ordinance on Food Supplements ("Official Gazette" No.46/11 i 41/13) Ordinance on nutrition and health claims ("Official Gazette" No.84/10, 113/11, 42/13) Ordinance on prescribing and dispensing of prescription medicinal products ("Official Gazette" No.17/09, 46/09, 4/10, 110/10, 131/10, 1/11, 16/11, 52/11, 129/13, 146/13, 45/14, 81/14) Regulations on the categorisation of medical-biochemical tests of the Croatian Chamber of Medical Biochemists Law on nutrition and health claims, and foods enriched with nutrients ("Official Gazette" No. 39/13)				
2.13. Methods of monitoring quality that ensure acquisition of exit competences	Evaluation of learning outcomes is an integral part of the final exam.				