

Course Title	Pharmaceutical Legislation, Law and Ethics				
Course Code	PHA502				
Course Type	Compulsory				
Level	BSc (Level 1)/ MPharm (Level 2)				
Year / Semester	4 th (8 th Semester)				
Teacher's Name	Ms Stavroulla Theophanous Kitiri, Dr Georgios Papagiouvannis				
ECTS	6	Lectures / week	2	Laboratories/week	-
Course Purpose	<p>Aim of this course is to acquaint the students to: the pharmaceutical legislation of Cyprus and of the European Union; the pharmaceutical laws governing production and control of drugs and medicines; the approval and dispensing of drugs; the European Union laws and directives for drug development; approval of clinical trials; Pharmacovigilance; objectives and organisation of EMEA offices and branches. Further aims are the presentation of general principles of ethics in drug development; principles of ethics for experiments using drugs, experimentation in experimental animals, clinical trials, on dispensing drugs and in pharmacotherapy; drugs and medicines patenting and ethical principles. The politics and ethics in national drug prices, orphan drugs, problems in the developing world and morality. Role of the World Health Organisation against diseases and high drug prices; attempts for low-cost, safe and efficient drugs and medicines. Handling and disposing expired and partly used medicines.</p>				
Learning Outcomes	<p>By the end of this course, the students should be able to:</p> <ul style="list-style-type: none"> • Identify the laws governing the production and control of drugs and medicines in pharmaceutical industry; the establishment of a community pharmacy; pharmaceutical education; the whole trade of drugs and medicines; • Identify the European Union legislation on actions concerning drugs and medicines; EU offices on drugs, i.e. EMEA, organisation and function; • Recognise legislation of drug illegal production and trafficking, particularly of narcotics; ethics and moral rules, in any position a pharmacist practices his/her profession; • Describe the role of the pharmacy in a city and in a hospital; the role of the pharmacist in society; • Recognise WHO role and function; • State the laws governing clinical trials of medicines and pharmacovigilance; • Analyse the organisation and function of the State Drug Control Offices, the Cyprus "Pharmakeftikes Ypiresies"; • Apply ways of disposal of expired or partly used drugs. 				
Prerequisites	None		Corequisites	None	
Course Content	Pharmaceutical legislation, national and of the European union. Laws				

	<p>governing production, control, approval and dispensing drugs. European Union laws and directives for drug development, clinical trials, approval and pharmacovigilance. The EMEA offices and branches.</p> <p>General principles of ethics. Ethics in drug development, experimentation, clinical trials, drug dispensing and pharmacotherapy.</p>
Teaching Methodology	<p>The teaching methodology includes lectures offering the theoretical background for a better perception and consolidation of the provisions of the four basic laws of national law and of several European directives and regulations.</p> <p>Methods such as discussion, questions/answers, pros/cons, debates, role playing and case studies are used to enhance student's participation. Detailed presentations using PowerPoint are included in the lesson. Access to European directives is demonstrated.</p>
Bibliography	<p>(a) <u>Textbooks</u>:</p> <ul style="list-style-type: none"> • Collection of the relevant Cyprus Legislation (four basic laws of national law) • Collection of the relevant European Union Legislation (several European directives and regulations). <p>(b) <u>References</u>:</p> <ul style="list-style-type: none"> • "Medicines, Ethics and Practice: A Guide for Pharmacists", Royal Pharmaceutical Society of Great Britain, Pharmaceutical Press; 43rd edition, 2019.
Assessment	<p>Course work 50%. Final Examinations 50%;</p> <p>The evaluation of the course is performed by (a) a written mid-term exam during the semester, which examines specific modules of the course and it accounts for 50% of the overall grade, and (b) a written final exam, which examines all modules of the course, and it accounts for 50% of the overall grade.</p> <p>All written exams conclude open questions and multiple choice questions. Students are prepared for the above written exams by discussion, questions/answers, pros/cons, debates, role playing and case studies</p> <p>The final assessment of the students is formative and summative and is assured to comply with the subject's expected learning outcomes and the quality of the course.</p>
Language	Greek, English