



UNIVERSITY OF NICOSIA

ΠΑΝΕΠΙΣΤΗΜΙΟ ΛΕΥΚΩΣΙΑΣ

Course Code PHAR-380	Course Title Law, Ethics and Professionalism/Νομοθεσία, Επαγγελματισμός και Επαγγελματική Ηθική	Credits (ECTS) 4
Department Life & Health Sciences	Semester Fall	Prerequisites None
Type of Course Required	Field Pharmacy	Language of Instruction Greek/English
Level of Course 1 st Cycle	Year of Study 3 rd year	Lecturer George Antoniou

The aims of this module are to enable students to:

- provide students with a thorough knowledge and understanding of the law as it relates to the practice of pharmacy
- provide students with a thorough knowledge and understanding of the law as it relates to medicines regulation
- provide students with an understanding of the role of the professional bodies, in setting and maintaining standards of professional practice

The aims of this module are to enable students to:

- provide students with a thorough knowledge and understanding of the law as it relates to the practice of pharmacy
- enable student to recognise the duties and obligations that attend the roles and functions of pharmacists
- review the structure and the legislative framework for the National Health Service, the provision of pharmaceutical services, and complaints and disciplinary procedures
- provide students with an understanding of the role of the professional bodies, in setting and maintaining standards of professional practice
- provide students with an appreciation of professional codes and guidelines and of the principles and theories of ethics, and their application, to the healthcare professional
- provide an understanding and overview of selected legal and ethical issues arising in medical and health care law, including an analysis of relevant statutory material.
- help students to develop the process of applying critical thinking to decision-making, enhance reflective practice and engender professional development

Learning Outcomes:

After completion of the course students are expected to:

- know the theoretical background of the pharmaceutical legislation in force in the

European Union

- Understand the various issues related to legislation on medicinal products
- To provide basic information on issues related to the pharmaceutical legislation
- Understand and adapt to the provisions of the pharmaceutical legislation
- Understand the nature of bioethical issues involved in modern society
- Understand the ethical considerations in Pharmacy
- Be prepare for the licensing exams in Cyprus

After completion of the course students are expected to:

- demonstrate an ability to evaluate, comment critically on, and apply law relevant to pharmacy and medicines in a practice context
- demonstrate an ability to analyse duties, rights and obligations owed to patients by healthcare professionals
- demonstrate the ability to analyse in depth the implications of ethical and legal theories to issues such as consent, refusal of treatment, confidentiality, professional malpractice, competency, access to health care, resource allocation, medical research, product liability, and clinical negligence
- demonstrate an ability to evaluate critically professional self-regulation
- discuss the nature and role of law and describe the legal system, courts, sources of law, divisions of law and the nature of litigation
- describe the basic regulatory framework of medicines law and the application of this framework to particular aspects of pharmacy practice
- display knowledge and understanding of principle legislation and case law relating to pharmacy
- describe the duties and obligations arising from laws associated with the organisation, administration, and processes involved in the profession of pharmacy
- describe the provision of pharmaceutical services, and disciplinary procedures
- discuss the concepts of ethics and morality and their application to pharmacy and health care; describe basic ethical theories and principles; describe the special nature of moral judgment; and outline a frame-work for ethical decision-making
- describe some of the legal and ethical challenges posed by modern science and practice, and resulting from being a member of a multi-disciplinary health care team
- discuss professional responsibility and accountability; describe the legal standard of care and discuss the rationale for expanded pharmacist duties and liabilities; discuss the role of the pharmacist as a manager of risk and outline risk management strategies
- describe the mechanisms involved in the regulation of healthcare professionals

Course Contents:

The aims of this module are to provide students with a thorough knowledge and understanding of the law as it relates to the practice of pharmacy. It outlines the legislative framework for the provision of pharmaceutical services.

This course contains lectures on:

- Introduction to the structures and functions of the EU
- Laws and Regulations relating to the establishment, operation and organization of a

<p>Pharmacy</p> <ul style="list-style-type: none"> • Licensing, marketing, distribution of pharmaceutical products (GDP) • Legislation on generics • The role of importers and distributors <p>Pharmaceutical legislation, national and of the European union. Laws governing production, control, approval and dispensing drugs. European Union laws and directives for drug development, clinical trials, approval and pharmacovigilance</p> <ul style="list-style-type: none"> • Ethical principles in research (Helsinki Treaty , etc.) and in Pharmacy • Case studies (case studies)
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Learning Activities and Teaching Methods:

Lectures, class discussion, assignments

Assessment Methods:

Final Examination, Course work

Recommended Textbooks/Reading:

Κυπριακή Δημοκρατία	Περί Φαρμάκων Ανθρώπινης Χρήσης (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμος Αρ. 70(Ι) του 2001 και δευτερογενής νομοθεσία National legislation (summaries or abstracts): Medicinal products for human use laws No 70(I), 2001, The pharmacy and poison laws Cap 254, The Narcotics drugs and psychotropic substances law, The Cyprus association disciplinary rules and pension funds law.	Κυβ. Τυπογραφείο	2001-2014	-
Κυπριακή Δημοκρατία	Οι περί Φαρμάκων Ανθρώπινης Χρήσης (Ορθή Κλινική Πρακτική) Κανονισμοί	Κυβ. Τυπογραφείο	2003	-
Κυπριακή Δημοκρατία	Κεφ. 254 περί Φαρμακευτικής και Δηλητηρίων Νόμος και δευτερογενής νομοθεσία	Κυβ. Τυπογραφείο	1962-2014	-
Κυπριακή Δημοκρατία	Περί Ναρκωτικών	Κυβ.	1977-	-

	Φαρμάκων και Ψυχοτρόπων Ουσιών Νόμος και δευτερογενής νομοθεσία	Τυπογραφείο	2010	
Κυπριακή Δημοκρατία	Περί Φαρμακοποιών (Σύλλογοι, Πειθαρχία και Ταμείο Συντάξεων) Νόμος και δευτερογενής νομοθεσία	Κυβ. Τυπογραφείο	1972-2011	-
Ευρ. Κοινοβούλιο και Συμβούλιο	Οδηγία 2001/83/ΕΚ της 6ης/11/2001 περί κοινοτικού κώδικος για τα φάρμακα που προορίζονται για ανθρώπινη χρήση	Εφημερίδα των Ευρ. Κοινοτήτων	2001-2013	-

Recommended Textbooks/Reading:

Συγγραφείς	Τίτλος	Εκδότης	Έτος	ISBN
Dale and Appelbe	Pharmacy Law and Ethics	Pharmaceutical Press	2009	9780853698272
Robert M. Veatch Amy Haddad	Case Studies in Pharmacy Ethics	Oxford University Press	2008	9780195308129
Royal Pharmaceutical Society	Medicines Ethics and Practice-The Professional Guide for Pharmacists	Royal Pharm. Society	2013	9780857111265
Ευρ. Κοινοβούλιο και Συμβούλιο	Κανονισμός 726/2004 της 31 ^{ης} /3/2004 – φάρμακα και ευρ. οργ. φαρμάκων	Εφημερίδα των Ευρ. Κοινοτήτων	2004-2013	-