UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
IMPH-450	Pharmacy Law & Ethics and Drug Regulation/ Φαρμακευτική Νομοθεσία, Επαγγελματική Ηθική και Φαρμακορρύθμιση	6
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall/Spring
Type of Course	**Field**	**Language of Instruction**
Compulsory	Pharmacy	Greek/English
Level of Course	**Lecturer(s)**	**Year of Study**
1st Cycle	Dr Christos Petrou/ Dr Panagiotis Petrou/Invited experts	4th
Mode of Delivery	**Work Placement**	**Corequisites**
Face-to-Face	N/A	N/A

Course Objectives:

The main objectives of the course are 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 be able 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
- understand and adapt to the provisions of the pharmaceutical legislation
- 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
- describe the basic regulatory framework of medicines law and the application of this framework to 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
- describe the mechanisms involved in the regulation of healthcare professionals

Course Content:

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 Pharmacy
- Licensing, marketing, distribution of pharmaceutical products
- Legislation on generics
- The role of importers and distributors
- 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
- Ethical principles in research (Helsinki Treaty, etc.) and in Pharmacy
- Case studies

Learning Activities and Teaching Methods:

Lectures, class discussion, assignments

Assessment Methods:

Final exam, Midterm exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
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	Κεφ. 254 περί Φαρμακευτικής και Δηλητηρίων Νόμος και δευτερογενής νομοθεσία	Κυβ. Τυπογραφείο	1962-2014	-
Κυπριακή Δημοκρατία	Περί Ναρκωτικών Φαρμάκων και Ψυχοτρόπων Ουσιών Νόμος και δευτερογενής νομοθεσία	Κυβ. Τυπογραφείο	1977-2010	-
Κυπριακή Δημοκρατία	Περί Φαρμακοποιών (Σύλλογοι, Πειθαρχία και Ταμείο Συντάξεων) Νόμος και δευτερογενής νομοθεσία	Κυβ. Τυπογραφείο	1972-2011	-
Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use	European Parliament, Council of the European Union		-	
Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications	European Parliament, Council of the European Union			
Regulation (EC) No 726/2004 of the	European Parliament,			

European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency	Council of the European Union			
Directive 2013/55/EU of the European Parliament and of the Council of 20 November 2013 amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation')	European Parliament, Council of the European Union			

Recommended Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Pharmacy Law and Ethics	Dale and Appelbe	Pharmaceutical Press	2009	9780853698272
Case Studies in Pharmacy Ethics	Robert M. Veatch Amy Haddad	Oxford University Press	2008	9780195308129

Medicines Ethics and Practice-The Professional Guide for Pharmacists	Royal Pharmaceutical Society	Royal Pharm. Society	2013	9780857111265
Κανονισμός 726/2004 της 31ης/3/2004 – φάρμακα και ευρ. οργ. φαρμάκων	Ευρ. Κοινοβούλιο και Συμβούλιο	Εφημερίδα των Ευρ. Κοινοτήτων	2004-2013	-