Course title	**Pharmaceutical Ethics, Legislation and Vigilance**				
Course Code	**PHRM205**				
Course Type	**Theoretical**				
Level	**Diploma**				
Year / Semester	**2nd Year / 4th Semester**				
Teacher's Name	**Charalambous Agis**				
ECTS	6	**Lectures / week**	3	**Laboratories / week**	0
Course Purpose and Objectives	The aim of the course is to provide students with basic knowledge of important legal regulations and ethical parameters related to medical and pharmaceutical practice. Students will be prepared to work as Medical Representatives in accordance with updated existing regulations. In addition, the course aims to introduce students to issues related to the structure, organisation and functioning of the legal and judicial authority of the Republic of Cyprus, as well as of the European Union and international organisations dealing with health-related issues. In addition, this course deals with the most important issues of Bioethics (ethical dilemmas on biomedical developments) as well as European regulations on the management of personal data (GDPR). Finally, the aim of this course is to introduce students to the safety of pharmaceuticals and pharmacovigilance, both before and after the marketing of products, especially as applied in Cyprus and Europe.				
Learning Outcomes	Upon completion of the course, students are expected to: **Knowledge** 1. **Be familiar** with the theory of state and European medical law and the legal regulations of pharmaceuticals. 2. **Understand** and **adapt** the relevant pharmaceutical regulations associated with Medical Representative profession. 3. **Be familiar** with the EU's competences and specialised committees. 4. **Understand** IFPMA, PhRMA and EFPIA codes of conduct. 5. **Understand** bioethics - ethical dilemmas in modern society. 6. **Understand** and **be aware** of personal data management issues. 7. **Be aware** of the key aspects of pharmacovigilance and its necessity in the pharmaceutical market and industry. 8. **Be aware** of pharmacovigilance from the regulatory point of view. **Skills** 9. **Perform** drug safety monitoring, reporting and closure activities. 10. **Evaluate** warnings, risk management and risk communication about adverse drug reactions. **Competences** 11. **Collate**, **organize** and **synthesize** information on the main bioethical principles and their legal framework. 12. **Reflect**, **infer** and **synthesize** data on the main bioethical concerns.				
Prerequisites	-	**Required:**	-		
Course Content	**<u>Pharmaceutical legislation</u>** • International organizations dealing with health issues. • The Cypriot Legislation.				

	• The Medicinal Products for Human Use (Quality, Supply and Pricing) Laws of 2001 to 2012. • The Narcotic Drugs and Psychotropic Substances Act. • The Medical Representatives Law 74 (I) of 2002 and the relevant amending Law 248(I) of 2004. • The Food Supplements Regulations 2004. • European Regulation on the Management of Personal Data (GDPR). • Code of Conduct for the International Federation of Pharmaceutical Industries (IFPMA), the Association of Pharmaceutical Researchers and Manufacturers (PhRMA) and the European Federation of Pharmaceutical Industries (EFPIA). **Bioethics** • Ethical Criteria for Promotion of Pharmaceutical Products • Introduction - Definitions and frameworks of Bioethics. International and National Bioethics Committees and related legislation. • Discussion, reflections and development of the following topics: Cloning (therapeutic and reproductive) - Assisted human reproduction (techniques, methods, moral dilemmas) - Euthanasia, Transplants - Brain Death, Abortion, etc. **Pharmacovigilance** • Regulatory framework for conducting clinical trials on humans within the European Union and Cyprus. • Basic concepts of pharmacovigilance and drug safety. • Regulatory requirements, adverse effects reporting, signalling and risk management. • Relationship between regulatory issues and delay in the authorisation of medicinal products. • Types of adverse effects. Key terminologies used in pharmacovigilance. Drug-related adverse effects terminologies. • Effective Communication in Pharmacovigilance: Communication in Drug Safety Crisis Management. Communicate with regulatory bodies, business partners, healthcare facilities and the media. • Creation of safety data: Pre-clinical, clinical and post-approval phase.
Teaching Methodology	The course content will be taught through: Power Point presentations, guided discussions with the active participation of students, individual and team work by students and the use of a variety of audiovisual media and other teaching tools as required for the delivery of each module.
Bibliography	***Greek Bibliography*** • KES College (2012), *Φαρμακευτική Νομοθεσία, Οι Περί Φαρμάκων Ανθρώπινης Χρήσης* (Έλεγχος Ποιότητας, Προμήθειας και Τιμών) Νόμοι του 2001 έως 2010 και οι διδασκόμενες συναφείς νομοθεσίες της Κυπριακής Δημοκρατίας. • Καπώνη Π. (2006). *Επίτομος Φαρμακευτική Νομοθεσία*, Εκδόσεις Φαρμακευτικός Κόσμος, Αθήνα , ISBN: 9608682924. • Παπαδάκη, Λ. (2017). *Ζητήματα ηθικής φιλοσοφίας και βιοηθικής: Καντιανές προσεγγίσεις*, Νήσος, ISBN 978-960-589-059-9. • Γκόλνα Χ. (2005). Φαρμακευτική πολιτική στην Ελλάδα και την Ευρώπη, Εκδόσεις Παπαζήση, Αθήνα, ISBN: 9600218404.

	• Συλλογικό έργο (2014). *Εισαγωγή στη βιοηθική: Ιστορικές και συστηματικές προσεγγίσεις*, Σύγχρονη Παιδεία, ISBN 978-960-357-119-3. • Montagne, M. and Waning, B. (2009). *Φαρμακοεπιδημιολογία Θεωρία και πράξη*. Εκδόσεις: Έλλην - ISBN-13: 978-960-697-032-0 ***English Bibliography*** • Plomer, A. (2005). *The law and ethics of medical research*, Cavendish, London, ISBN: 1-85941-687-X. • Mepham, Ben T. (2005), *Bioethics: an introduction for the biosciences, Oxford University Press*, Oxford, ISBN: 0-19-926715-4. • Singer, Peter A. (2008), *The Cambridge textbook of Bioethics, Cambridge University Press*, Cambridge, ISBN: 978-0-521-69443-8. • Valverde, J. L. (2005), *The challenges of the new EU pharmaceutical legislation, IOS Press*, ISBN: 1586035215. • Barton C. (2019). *Cobert's Manual Of Drug Safety And Pharmacovigilance*, 3rd World Scientific Publishing Co Pte Ltd,ISBN: 9789811215230. • The Safety of Medicines in Public Health Programs: Pharmacovigilance an essential tool. Who Publications, Geneva, 2006.
assessment	• Attendance and participation: 10% • Assignments / Essays: 40% • Final Written Examination: 50%
	Final written examination has two parts that are sat on the same day. The first part includes closed-ended questions, such as multiple choice questions, true or false, matching exercises, complete the gaps exercises, etc. The first part is usually worth 40% - 60% of the total marks of the exam paper. The second part includes open-ended questions that are meant to assess the students' abilities to analyse, reflect, explain, recall etc. The second part is usually worth 60% - 40%. The total marks of the exam paper are 100.
Language	Greek or English