

Course Unit	Option II - Law in Pharmacy and in medicines		Field of study	Pharmacy/Management and Administration in Health	
	Counseling and Information on Pharmacy		School	School of Health	
Academic Year	2014/2015	Year of study	1	Level	ECTS credits 4.0
Type	Semestral	Semester	2	Code	3238-493-1202-01-14
Workload (hours)	108	Contact hours	T 20 TP - PL - TC - S - E - OT - O -		

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s) Isabel Cristina Jornalo Freire Pinto

Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:

1. Recapitulate the evolution of the History of Pharmacy and Medicines
2. To perceive the economic evaluation of health; Understanding pharmacoeconomic evaluation, types of studies and the role of INFARMED; analyze national legislation on drug prices and reimbursement
3. Knowing the stages of pre-clinical and clinical trials and ethics; interpret the law applicable to clinical trials in Portugal; Understanding the laws of animal experimentation in Europe and Portugal
4. Identify and characterize the European and national institutions of drug regulation; analyze and understand the international and community laws of medicines
5. Study and understand the registration of biotechnology patents
6. Analyze and interpret the legislation on drugs advertising and Civil Liability of Pharmaceutical Industry
7. Examine laws applicable to the operation of pharmacies in Portugal; promote reflection on bioethics, ethics and the law in the practice of pharmacy

Prerequisites

Before the course unit the learner is expected to be able to:
Not applicable

Course contents

Medicines Law; Development of Medicines; Dynamics of Medicines, Pharmacy Law

Course contents (extended version)

1. Medicines Law
 - History of Pharmacy and Medicines
 - Pharmacoeconomics
2. Development of Medicines
 - Clinical Trials in Humans
 - Clinical Trials in Animals
3. Dynamics of Medicines
 - National Institutions and Community regulation of Medicine
 - International Law and Community Medicines
 - Biotechnology Patents
 - Medicines Advertising
 - Civil Liability of Pharmaceutical Industry
4. Pharmacy Law
 - Legal framework for Community Pharmacy
 - Pharmaceutical ethics

Recommended reading

1. Appelbe e Wingfield (2009). Dale and Appelbe's Pharmacy Law and Ethics, 9th edition. Pharmaceutical Press
2. Rascati KL. Introdução à Farmacoeconomia - Ed. Artmed, 2009. ISBN: 9788536320854
3. Legislação nacional aplicável aos EC com medicamentos de uso humano e proteção de dados: Lei nº46/2004, 19 de Agosto; DL n.º102/2007 - Diretiva n.º2005/28/CE; Lei n.º67/98 - Diretiva n.º95/46/CE
4. Legislação nacional aplicável ao preço dos medicamentos e comparticipações: Decreto-Lei n.º 112/2011, de 29 de Novembro; Decreto-Lei n.º 48-A/2010, de 13 de Maio
5. Legislação nacional sobre uso de animais para fins experimentais: Portaria nº 1005/92, Recomendação 2007/526/CE; Regulamento (CE) 1/2005; DL nº 265/2007

Teaching and learning methods

Expository, by promoting the critical spirit of students. Part of the class work on a system of distance education.

Assessment methods

1. The Normal season - (Regular, Student Worker) (Final)
 - Work Discussion - 25% (Oral presentation of group work - analysis of national legislation (minimum grade 8.25 values))
 - Final Written Exam - 75% (Realization of an individual written test on the Normal season exam day (minimum grade 8.25 values))
2. Resource / Improvement and Special seasons - (Regular, Student Worker) (Supplementary, Special)
 - Final Written Exam - 100% (Individual Written Test - realization of a written test on the Resource/Special season exam day)

Language of instruction

1. Portuguese
2. Portuguese, with additional English support for foreign students.

Electronic validation

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20-11-2014	21-11-2014	21-11-2014