

Course Unit	Pharmaceutical Legislation and Bioethics		Field of study	-	
Bachelor in	Pharmacy		School	School of Health	
Academic Year	2023/2024	Year of study	1	Level	1-1
Type	Semestral	Semester	1	ECTS credits	5.0
Code	9549-803-1104-00-23				
Workload (hours)	135	Contact hours	T -	TP 60	PL -
			TC -	S -	E -
			OT 7,5	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, Natalia Cordeiro Vara

### Learning outcomes and competences

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

1. To know and identify the different phases of research and development of new medicines and their ethical and legal implications, nationally and internationally;
2. Identify and know national and community legislation and entities of medicines regulation;
3. To know and understand the Medicines Statute and general rules for the legal use of medicines and health products;
4. Understand the Market Introduction Authorization (MIA) process through the understanding of drug evaluation, licensing and monitoring procedures;
5. Studying the Pharmaceutical Patents Register; Analyze and interpret the legal framework for medicines advertising;
6. Identify and analyze the legislation applicable to the operation of community pharmacies and hospitals;
7. Understand the importance of Bioethics in health, as well as identify principles of bioethics, its conceptions and its impact on the pharmacy activity;
8. Analyze the Professional Ethics Code; Promote reflection and critical thinking on the basis of bioethics, deontology and law in the practice of pharmacy professionals

### Prerequisites

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

### Course contents

1. Drug Development
2. Drug Dynamics
3. Pharmacy Law
4. Bioethics and Deontology

### Course contents (extended version)

1. Medicines Development
  - Development Steps of new medicines
  - Clinical Trials in Human Beings - Regulation and Ethical Issues
  - Animal experimentation - Regulation and ethical issues
2. Medicines Dynamics
  - Medicines Regulation - Entities and National, Community and International Legal Framework
  - Medicines Statute in Portugal
  - General rules for the legal use of medicines and health products
  - Market Introduction Authorization
  - Pharmaceutical Patents
  - Medicines Advertising
3. Pharmacy Law
  - Legal Regime of community pharmacy
  - Regulation of hospital pharmacy
4. Bioethics and Deontology
  - Health and Ethics - Ethics, Morals, Deontology and Bioethics: origin, history and assumptions
  - Moral Development, Ethical Dilemma, Decision Making, Appearance and Role of Ethics Committees
  - Deontological Code - Pharmaceutical Deontology: assumptions contained in the ethics code
  - Ethics and applied research: analysis of scientific articles on bioethics issues.

### Recommended reading

1. Appelbe e Wingfield (2009). Dale and Appelbe's Pharmacy Law and Ethics, 9th ed. Pharmaceutical Press | Archer, L. , Biscaia, J & Osswald, W (2001). Novos Desafios à Bioética. Porto: Porto Editora, Lda
2. Pita JR (2010). A farmácia e o medicamento em Portugal nos últimos 25 anos. Periódico do CIEDA e do CIEJD. Nº2/3 Jan/Dez. ISSN 1647-6336
3. Lei 46/2004 (Lei 21/2014); DL 102/2007-Dir2005/28/CE; Lei 67/98-Dir95/46/CE; Port 1005/92, Rec. 2007/526/CE; Reg(CE)1/2005; DL 265/2007; DL 176/2006 (DL 5/2017); Port 224/2015; DL 307/2007 (DL 75/2016)
4. INFARMED (<http://www.infarmed.pt>); DGAV (<http://www.dgv.min-agricultura.pt/portal/page/portal/DGV>); DGS ([www.dgs.pt](http://www.dgs.pt))
5. EMA (<http://www.ema.europa.eu/>); UMC-WHO (<http://www.who-umc.org/>); FDA (<http://www.fda.gov/>); CEIC (<http://www.ceic.pt>)

### Teaching and learning methods

Interactive lectures between teacher and student, with debate and active student participation in the learning process. The scientific methodology reflection / action will be used as a future tool in the profession of Pharmacy Technician. The student will be guided in order to promote the research in order to develop works on themes related to the curricular content

### Assessment methods

1. Alternative 1 - (Regular, Student Worker) (Final)
  - Final Written Exam - 70% (minimum score of 8 points)
  - Work Discussion - 30% (Oral presentation/discussion of group works (minimum score of 8 points))
2. Alternative 2 - (Regular) (Supplementary, Special)
  - Final Written Exam - 100%
3. Alternative 3 - (Student Worker) (Final, Supplementary, Special)
  - Final Written Exam - 100%
4. Erasmus students - (Regular, Student Worker) (Final, Supplementary)
  - Development Topics - 100% (Review or other work on pharmaceutical and bioethics legislation)

Language of instruction

Portuguese, with additional English support for foreign students.

Electronic validation			
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