

Course Unit	Bioethics, pharmaceutical and food legislation	Field of study	Pharmaceutical Sciences
Master in	Natural Products and Bioprospecting	School	School of Agriculture
Academic Year	2023/2024	Year of study	1
Type	Semestral	Semester	2
Level	2-1	ECTS credits	6.0
Code	5012-740-1203-00-23		
Workload (hours)	162	Contact hours	T -    TP 60    PL -    TC -    S -    E -    OT 4    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, Maria da Conceição Constantino Fernandes

### Learning outcomes and competences

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

1. Understand ethical aspects associated with biotechnology and the principles of professional ethics
2. Knowing legal framework and stages of the research & development process for medicines, health products, pre-clinical and clinical trials, and their ethical principles.
3. Understand technical-scientific aspects of quality assurance, safety and efficacy of medicines and health products
4. Know the legislation and stages of monitoring the market for medicines and health products.
5. Know the quality and food safety policies in the European Union.
6. Know the HACCP methodology
7. Know the inspection, assessment and risk management processes in the food sector
8. Establish relationships between scientific knowledge and regulations that evaluate medicines, health products and foods

### Prerequisites

Before the course unit the learner is expected to be able to:

1. Basic knowledge of pharmacology
2. Basic knowledge of chemistry and microbiology

### Course contents

- 1 - Research and Development of new medicines and health products
- 2 - Medicines Legislation and Regulation
- 3 - Legislation and Regulation of Health Products
- 4 - Food quality control and food safety

### Course contents (extended version)

1. Research and Development of new medicines and health products
  - Preclinical trials. Ethic. Regulation; Clinical trials: Phases. Ethic. Regulation
  - Quality assurance and control, safety and effectiveness
2. Medicines Legislation and Regulation
  - Medicines regulatory organisms
  - Marketing-authorization (MA)
  - Disclosure and advertising of medicines
  - Pharmaceutical patents
  - Pharmacovigilance: National System. Monitoring and Notification
  - General rules: narcotics and psychotropics, generics, veterinary drugs
3. Legislation and Regulation of Health Products
  - Medical Devices: Classification, Compliance, Placing and Oversight on the Market
  - Cosmetics: Regulation. Classification, Import, Compliance, PIF, notification, market supervision
4. Food quality control and food safety
  - Food quality and safety
  - National and European legislation
  - Food hygiene - Codex Alimentarius; HACCP methodology
  - Functional foods
  - Risk assessment and control in food safety

### Recommended reading

1. Agência Europeia do Medicamento <http://www.ema.europa.eu/>
2. Autoridade Nacional do Medicamento e Produtos de Saúde <http://www.infarmed.pt>
3. Codexalimentarius <http://www.codexalimentarius>
4. European Commission. Directorate for public health and risk assessment <http://ec.europa.eu/health.index>
5. European Food Safety Authority <http://www.efsa.europa.eu>

### Teaching and learning methods

Theoretical lessons: Expositive methodology, providing study materials from the resources of e-learning. Practical lessons: Accomplishment of legislation analysis, discussion of practical cases and bibliographic research works. Evaluation: final examination of theoretical and practical issues with theoretical questions + group works developed during the practical lessons.

### Assessment methods

1. Alternative 1 - (Regular, Student Worker) (Final)
  - Final Written Exam - 75%
  - Work Discussion - 25% (oral presentation of group works (minimum score of 8 points))
2. Alternative 2 - (Regular, Student Worker) (Supplementary, Special)
  - Final Written Exam - 100%

### Language of instruction

Portuguese

Electronic validation			
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