

**COURSE DATA****DATA SUBJECT**

**Code:** 34093  
**Name:** Legislation and Pharmaceutical Deontology  
**Cycle:** Undergraduate Studies  
**ECTS Credits:** 4.5  
**Academic year:** 2025-26

**STUDY (S)**

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Facultat de Farmàcia i Ciències de L'alimentació	4	Second quarter
1211 - Double Degree in Pharmacy and Human Nutrition and Dietetics	Facultat de Farmàcia i Ciències de L'alimentació	5	Second quarter

**SUBJECT-MATTER**

Degree	Subject-matter	Character
1201 - Degree in Pharmacy	Pharmaceutical law and ethics	COMPULSORY
1211 - Double Degree in Pharmacy and Human Nutrition and Dietetics	Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética	COMPULSORY

**COORDINATION**

CARCELLER ZAZO MARIA DEL CARMEN

**SUMMARY**

The pharmaceutical profession is focused on the promotion of the patient's health and, in particular, on the drug as an instrument. In our State of Law, through the constitutional mandate, the public authorities are responsible for protecting health, public authorities have the responsibility to protect health, so that the activity of the pharmaceutical professional is subject to intense regulation.

It is very important for the future pharmacist to have an in-depth knowledge of these regulations and the criteria that drive them, because their actions are framed within the framework of legality.

On the other hand, professional practice confronts health professionals with ethical conflicts that involve a personal reflection on values, but which must be developed according to a scientific methodology that guarantees its result.

All this will be carried out trying to promote the fulfillment of the Sustainable Development Goals (SDGs) of



the 2030 agenda.

## PREVIOUS KNOWLEDGE

### RELATIONSHIP TO OTHER SUBJECTS OF THE SAME DEGREE

There are no specified enrollment restrictions with other subjects of the curriculum.

### OTHER REQUIREMENTS

It is recommended that students have basic knowledge of pharmaceutical technology and pharmacology.

## COMPETENCES / LEARNING OUTCOMES

-

Acquire knowledge of epidemiology and prevention of communicable and non-communicable diseases.

Acquire knowledge of healthcare organisation: Healthcare systems. International public health.

Acquire knowledge of planning and prevention of occupational risks.

Acquire knowledge of the epidemiological and scientific methods, pharmacoepidemiology, pharmacovigilance, clinical trials and scientific evidence studies.

Act with autonomy in learning, making informed decisions in different contexts, issuing judgements based on experimentation and analysis, and transferring knowledge to new situations.

Collaborate effectively in work teams, assuming responsibilities and leadership roles and contributing to collective improvement and development.

Contribute to the design, development and implementation of solutions that respond to social demands, taking into account the Sustainable Development Goals as a reference.

Demonstrate critical and self-critical thinking in the field of the degree programme, considering aspects such as professional ethics, moral values and the social implications of the different activities carried out.

Have knowledge on healthcare planning.

Intervene in health promotion and disease prevention activities in the individual, family and community spheres, with a comprehensive and multiprofessional vision of the health-disease process.

Know and assess the determinants of health.

Know and understand, within the field of the degree programme, gender inequalities in society; integrate different needs and preferences based on sex and gender into the design of solutions and problem solving.

Know basic concepts of health and public health.



Know how to communicate effectively, both orally and in writing, adapting to the characteristics of the situation and the audience.

Know how to use strategies for promoting health and preventing disease.

Know methods and means of health education.

Know techniques and applications in the field of environmental health, sanitation and industrial hygiene, mainly in the pharmaceutical industry.

Know the most appropriate pharmacotherapy for each clinical situation, applying clinical guidelines with maximum scientific evidence.

Know the relationship between environment and health.

Module: Legislation and Social Pharmacy. Know the foundations of public health, intervene in activities of health promotion and disease prevention at individual and collective levels and contribute to health education, recognising the determinants of health.

Possess and understand knowledge in the different areas of study included in pharmacist training.

Propose creative and innovative solutions to complex situations or problems within the field of knowledge, to respond to diverse professional and social needs.

## DESCRIPTION OF CONTENTS

### 1. National and Autonomic Health Organisation

1. Basic concepts in legislation and sources of law.
2. Fundamental health legislation and Spanish organization.

Unit 3. Medicines. Legal guarantees of medicines. Special medicines. Medical devices. Cosmetics. Personal hygiene products. Biocides. Products in the border of classification.

Unit 4. General notions of registration: application and approval procedures. Price of the drug. Financing. Changes in the authorization and obligations of the holder.

Unit 5. Veterinary medicines. Definition and types. Guarantees for medicines for veterinary use. Spanish Pharmacovigilance System for Veterinary Drugs.

Unit 6. Medical devices. Concepts and types of medical devices. Classification. Certification procedures.

Unit 7. Industrial manufacture of drugs. Definition and types of pharmaceutical laboratories, facilities and regulation. GMP.



## 2. Drug regulation

Unit 3. Medicines. Legal guarantees of medicines. Special medicines. Medical devices. Cosmetics. Personal hygiene products. Biocides. Products in the border of classification.

Unit 4. General notions of registration: application and approval procedures. Price of the drug. Financing. Changes in the authorization and obligations of the holder.

Unit 5-. Veterinary medicines. Definition and types. Guarantees for medicines for veterinary use. Spanish Pharmacovigilance System for Veterinary Drugs.

Unit 6. Medical devices. Concepts and types of medical devices. Classification. Certification procedures. Unit 8. Distribution of drugs and medical devices: regulations. Supply guarantees. Parallel distribution. Good distribution practices.

## 3. Pharmaceutical services

13. Community Pharmacies. Pharmaceutical regulation: national and Valencian Community. Authorization to operate a pharmacy (requirements and procedure) and modifications. Drug deposits. Standards in relation to performance.

14. Community Pharmacies. Principles of good design and quality control in pharmacies. Actions related to drug safety. Prescriptions. General rules of medicine supply and prescribing of narcotics and psychotropic drugs. Drug use in special situations

15. Hospital pharmacy services. Pharmaceutical services in socio-health nursing. Pharmaceutical Services in Health Departments. Deposits of drugs: Autonomic Regulations.

## 4. Pharmaceutical deontology and bioethics

16. Introduction to Ethics. Concept of ethics and pharmaceutical deontology.

17. Code of ethics in Pharmaceutical fields. Concept. General and particular characteristics of the professional activity.

18. The pharmaceutical and basic biomedical research. Ethics principles and current laws.

19. Drugs in clinical research and clinical trials. Declaration of Helsinki. Bioethics committees and clinical research. Use of drugs in special situations.

List of proposed seminars:

Branches of law (fundamental legislation)

Creation of infographics in the field of Pharmacy

Pharmacovigilance

Drug labeling.

Drug advertising.

Medical prescription and compounding.

Electronic dispensing (2h)



## 5. SEMINARS

List of proposed seminars:

Branches of law (fundamental legislation)

Creation of infographics in the field of Pharmacy

Pharmacovigilance

SDG in the field of Pharmacy

Bioethics of clinical trials.

Pharmaceutical control at the border

## WORKLOAD

### PRESENCIAL ACTIVITIES

Activity	Hours
Tutorials	2,00
Theory	33,00
Seminar	10,00
<b>Total hours</b>	<b>45,00</b>

### NON PRESENCIAL ACTIVITIES

Activity	Hours
Attendance at other activities	2,00
Individual or group project	11,00
Independent study and work	30,00
Preparation of lessons	7,50
Preparation for assessment activities	15,00
Resolution of case studies	1,50
<b>Total hours</b>	<b>67,00</b>

## TEACHING METHODOLOGY

The teaching methodology will consist in:

- 1) **Lecture (theoretical class)** designed for the student to obtain basic knowledge.
- 2) **Seminars** designed to promote the collection and interpretation of recent legislation on current issues and with the application of regulations for the preparation of documentation for activities related to the profession. Some of the methodologies that will be used will be:
  - **Bioethics debate:** Declaration of Helsinki. Lecture and resolution of questions involving bibliographic research and application of theoretical concepts.
  - **Visualization and analysis of audiovisual material** about placebo use in clinic research.
  - **Drug labeling.** Identification of symbols on commercial drugs. Drug advertising. Viewing of



current and old Spanish drug advertising videos to observe the evolution of legislation in this field. Comparison with international advertisements.

- **"Flipped classroom"**: role-playing, case studies and collaborative learning in block of ethics and pharmaceutical deontology.
- **Talks by a specialist** in different topics of interest related with the subject.

**3) Tutorials** in reduced groups of students or individualized (personalized) according to the established calendar.

## EVALUATION

All the activities carried out by the student and the acquisition of theoretical knowledge will be evaluated through the delivery of assignments (seminar) and final exam.

Seminar activities will have a value of 25% of the final grade. The theoretical exam will be worth 70% of the final grade. Additionally, the remaining 5% of the final grade will come from the continuous and direct evaluation by the teaching staff of the theoretical lessons, seminars and tutorials.

The completion of seminars will highlight the acquisition of specific competences of the subject and will be evaluated through the delivery of assignments and questions included in the exam.

The theoretical knowledge of the lectures (theory classes) will be scored on the basis of a final written exam.

**In order to pass the course, it is a prerequisite to have taken and passed (50% of the grade; 5/10) both the seminars and the final exam, separately and independently. In the event that the seminars are not passed, the student will have to recover them by means of a specific written exam (on all the seminars seen during the academic year in question) in the second call of the final exam.**

**Copying or plagiarism of any assignment of the evaluation will make it impossible to pass the course**, and the student will be subjected to the appropriate disciplinary procedures. It must be taken into account that, according to article 13. d) of the University Student Statute (RD 1791/2010, December 30), it is the duty of a student to refrain from using or cooperating in fraudulent procedures in the evaluation tests, in the work performed or in official university documents.

In the face of fraudulent practices will proceed as determined by the "Protocol of action against fraudulent practices at the University of Valencia" (ACGUV 123/2020): <https://www.uv.es/sgeneral/protocols/c83.pdf>.

In accordance with the provisions of article 6.5 of the UV Evaluation and Grading Regulations for Bachelor's and Master's degrees, the continuous evaluation activities, which in this subject are the seminars, may be considered mandatory attendance and, therefore, not recoverable. **The professor will highlight the specific seminars that are mandatory in a public document available in the Virtual Classroom.** In the event that, for justified reasons (medical or official procedure), the student cannot attend any of these activities, he/she



will have to inform the professor well in advance. In this way, the person in charge of the course will be able to assign the student a session in another subgroup within the same group or any other measure that the professor considers convenient. Changes between different groups of seminars will not be allowed. **The duration established for the delivery of the seminar assignments will be one week. The date for the delivery of the assignments for each seminar will be specified at the beginning of the course in a public document available in the Virtual Classroom. On the other hand, seminar grades from previous academic years will not be kept.**

According to the guidelines of the CAT of Pharmacy (May 14, 2012), **those students who do not take the theory exam, but have participated and have a grade in some of the teaching activities (seminars, tutorials) will be graded as "Not Presented" in the first call, but if they still do not take the theory exam, the final grade that will appear in the second call will take into account the grades obtained in the different activities and, consequently, may appear as "Failed".**

## REFERENCES

- Compendio de historia de la farmàcia y legislaci3n farmac3utica. Francisco J. Puerto y Antonio Gonz1lez Bueno. Ed Sntesis, Madrid. 2010.
- Legislaci3n del Medicamento. Biblioteca de textos legales. Ed Tecnos, Madrid 2008
- Funci3n social de las oficinas de farmàcia. Dispensaci3n y cuidado de la salud. J Esteva de Sagrera y Pilar Mart3n Barea. Ed Elsevier, Madrid 2006
- El consentimiento en la utilizaci3n de f1rmacos. Manuel Amarilla y Cecilio 1lamo. AEDF editores. Madrid. 2000
- Atenci3n farmac3utica y responsabilidad profesional. Javeir S1nchez-Caro y Fernando Abell1n. Ed Comares, Granada. 2004
- Salud p1blica y Patentes farmac3uticas. Xavier Seuba Hern1ndez. Bosch Mercantil. Barcelona 2008