

**COURSE DATA****Data Subject**

<b>Code</b>	34093
<b>Name</b>	Legislation and Pharmaceutical Deontology
<b>Cycle</b>	Grade
<b>ECTS Credits</b>	4.5
<b>Academic year</b>	2018 - 2019

**Study (s)**

<b>Degree</b>	<b>Center</b>	<b>Acad. year</b>	<b>Period</b>
1201 - Degree in Pharmacy	Faculty of Pharmacy and Food Sciences	4	Second term
1211 - D.D. in Pharmacy-Human Nutrition and Dietetics	Faculty of Pharmacy and Food Sciences	5	Second term

**Subject-matter**

<b>Degree</b>	<b>Subject-matter</b>	<b>Character</b>
1201 - Degree in Pharmacy	26 - Pharmaceutical law and ethics	Obligatory
1211 - D.D. in Pharmacy-Human Nutrition and Dietetics	1 - Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética	Obligatory

**Coordination**

<b>Name</b>	<b>Department</b>
CANO CEBRIAN, MARIA JOSE	134 - Pharmacy and Pharmaceutical Technology

**SUMMARY**

The pharmacists are focused on promoting patient Health and, especially, on medicine as a very relevant tool in this process. In our rule of law, by constitutional mandate, the authorities have a responsibility to protect Health. Therefore the pharmaceutical professional activity is subject to intense regulation. It is very important that the future pharmacist has an in-depth knowledge of these rules and criteria that guide them, so that their performance falls within the law.

Moreover, professional practice for Health professionals is faced with ethical conflicts involving a personal reflection on values that should be conducted by a scientific methodology that ensures the result.



## 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.

## OUTCOMES

### 1201 - Degree in Pharmacy

- To possess and to understand the knowledge in the different areas of study included in the formation of the pharmacist.
- To apply this knowledge to the professional world, contributing to the development of Human Rights, democratic principles, principles of equality between women and men, solidarity, protection of the environment and promotion of a culture of peace with Gender perspective.
- Module: Law and Social Pharmacy -To know, understand and apply the legal, social and economic issues in the field of health and in particular with the medicine.
- Module: Law and Social Pharmacy -Basic knowledge of the National Health System, the health legislation in general and specifically related to the medications, medical devices and pharmaceutical industry.
- Know the ethical and deontological principles and act according to the laws, regulations and administrative provisions governing the exercise professional working with other health professionals and gaining skills to work in a team.
- Learn about the techniques of oral and written communication skills to inform users of the pharmaceutical establishments in terms intelligible and appropriate to the various levels of cultural and social environments.

## LEARNING OUTCOMES

At the end of the course the student should be able to:

- Understand the Spanish Health organization and the pharmaceutical organization.
- Locate international, state or regional regulations, necessary for the exercise of the pharmacy profession and the rational use of medicines.
- Know the legal guarantees that are articulated in the approval, manufacturing, distribution and rational use of medicines.



- Apply appropriate standards for pharmaceutical services.
- Address the ethical conflicts of pharmacy from the perspective of responsibility and on a scientific methodology.
- Know the basic legal aspects about clinical and animal research

## DESCRIPTION OF CONTENTS

### 1. National and Autonomic Health Organisation

1. Basic concepts in legislation and sources of law.
2. Fundamental health legislation. Organization of the National Health System. Cohesion and Quality Act. Agreement for pharmaceutical services in Valencia
3. Spanish organization and Valencian Community organization in the field of pharmacy and pharmaceuticals. Structure and functions of AEMPS and EMA. WHO.
4. Pharmaceutical representatives and associations.

### 2. Drug regulation

5. Medicines. Legal guarantees of medicines. Special medicines. Medical devices. Cosmetics. Personal hygiene products. Biocides. Products in the border of classification.
6. General notions of registration: application and approval procedures. Price of the drug. Financing. Changes in the authorization and obligations of the holder.
7. The packaging of medications. Concept. Legislation. Drug Information: labeling and package leaflet. Clinical container.
8. Veterinary medicines. Definition and types. Guarantees required of veterinary medicines. Spanish System of Pharmacovigilance of veterinary medicines.
9. Medical devices. Concepts and types of medical devices. Classification. Certification procedures.
10. Industrial manufacture of drugs. Definition and types of pharmaceutical laboratories, facilities and regulation. GMP.
11. Distribution of drugs and medical devices: regulations. Supply guarantees. Parallel distribution. Good distribution practices.
12. Promotion, information and advertising of medicines. Characteristics of the means used.



Prohibitions. Drugs that may be advertised. Features of the authorization. Regulatory criteria

### 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.

### 5. SEMINARS

List of proposed seminars:

- AEMPS
- Bioethics Cineforum.
- Bioethics in clinical assays. Helsinki Declaration.
- Labeling of medicines.
- Publicity of medicines.
- Quality control.
- Comparison between the mediterranean and the Middle/Northern Europe pharmaceutical models.
- Comparison of pharmaceutical models between different spanish authonomous communities.
- Prescription and compounding.
- Talk with specialist
- Debate

**WORKLOAD**

ACTIVITY	Hours	% To be attended
Theory classes	30,00	100
Seminars	10,00	100
Tutorials	2,00	100
Attendance at events and external activities	2,00	0
Development of group work	10,00	0
Development of individual work	1,00	0
Study and independent work	20,00	0
Readings supplementary material	10,00	0
Preparation of evaluation activities	15,00	0
Preparing lectures	5,00	0
Preparation of practical classes and problem	2,50	0
Resolution of case studies	1,50	0
<b>TOTAL</b>	<b>109,00</b>	

**TEACHING METHODOLOGY**

**Lectures** designed to the student to obtain basic knowledge.

**Practical classes** designed to compile and interpret recent legislation on current topics and the preparation of documentation on different procedures related to the professional activities. Discussions prepared and conducted by students will allow the development of a critical attitude on key matters.

AEMPs: Internet search.

Bioethics Cineforum: Visualization of a film of bioethic pharmaceutical interest. Solving practical questions based on bibliographic research and application of concepts.

Bioethics in clinical assays: Helsinki Declaration. Talk and solving practical questions based on bibliographic research and application of concepts.

Labeling of medicines: Symbol identification on commercial medicines packages.

Publicity of medicines: Visualization of old and current medicine spots in Spain to observe the evolution of the law on this topic. Comparison with international spots.





Quality control: Team work. Role playing.

Comparison between the mediterranean and the Middle-Northern European pharmaceutical models: Visualization of video recorded by the Valencian MICOF to defend the Mediterranean model at the European court. Bibliographic research and preparation of a compared text about the two models.

Comparison of pharmaceutical models between different spanish authonomous communities: Bibliographic research and preparation of comparative tables.

Prescription and compounding.

**Resolution** of questions and simulated problems, individually and in teams.

## EVALUATION

The evaluation will consist of grading the student activities and the acquisition of theoretical knowledge, separately, with a relative weight 30:70.

The seminars will emphasize the acquisition of specific competences in the matter and will be evaluated by attendance (minimum 80% to pass the evaluation) and submission of written tasks. Seminars will be the 25% of the final mark of the seminars. The tasks cannot be submitted if the student does not attend the seminar.

Theoretical aspects will be evaluated by a final written exam.

It is compulsory to have passed both, the seminars and the written exam to accomplish the subject.

5% of the grade will depend on the continuous evaluation by the professor and will take into account the participation in class, the ability to work in groups and the progressive acquisition of the specific language of the matter.

As stated by the CAT (May, 14<sup>th</sup>, 2012) in the first round of evaluation, any student that has not taken all of the evaluation activities will have a mark of "Not presented". In the second round, if a part of the evaluation activities is missing will appear as "Fail" in the final grade list.

## REFERENCES

### Basic

- Compendio de historia de la farmàcia y legislación farmacéutica. Francisco J. Puerto y Antonio González Bueno. Ed Síntesis, Madrid. 2010.
- Legislación del Medicamento. Biblioteca de textos legales. Ed Tecnos, Madrid 2008



- Función social de las oficinas de farmàcia. Dispensación y cuidado de la salud. J Esteva de Sagrera y Pilar Martín Barea. Ed Elsevier, Madrid 2006

#### **Additional**

- El consentimiento en la utilización de fármacos. Manuel Amarilla y Cecilio Álamo. AEDF editores. Madrid. 2000
- Atención farmacéutica y responsabilidad profesional. Javeir Sánchez-Caro y Fernando Abellán. Ed Comares, Granada. 2004
- Salud pública y Patentes farmacéuticas. Xavier Seuba Hernández. Bosch Mercantil. Barcelona 2008