VNIVERSITAT DE VALÈNCIA

Course Guide
34093 Legislation and Pharmaceutical Deontology

COURSE DATA

Data Subject	
Code	34093
Name	Legislation and Pharmaceutical Deontology
Cycle	Grade
ECTS Credits	4.5
Academic year	2020 - 2021

Study (s)

Degree	Center	Acad. year	Period
1201 - Grado de Farmacia	Faculty of Pharmacy	4	Second term
1211 - PDG Farmacia-Nutrición Humana y Dietética	Faculty of Pharmacy	5	Second term

Subject-matter

Degree	Subject-matter	Character
1201 - Grado de Farmacia	26 - Pharmaceutical law and ethics	Obligatory
1211 - PDG Farmacia-Nutrición Humana y Dietética	1 - Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética	Obligatory

Coordination

Name	Department
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 - Grado de Farmacia

- 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 and Spanish organization.

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 pmedicines. 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.

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.

5. SEMINARS

List of proposed seminars:
Bioethics in basic research.
Bioethics in clinical assays. Helsinki Declaration.
Labeling of medicines.
Publicity of medicines.
Branches of Law (fundamental law)
Debate
Creation of infographics in the field of Pharmacy
Prescription and compounding.
Pharmacovigilancy

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
TOTAL	**109,00**	

TEACHING METHODOLOGY

Lectures designed to the student to obtain basic knowledge.

Practical classes (the so-called Seminars) designed to cpompile and interprete recent legislation on current topics and the preparation of documentation on diferent procedures related to the professional activities. Discussions prepared and conducted by students will allow the development of a critical attitude on key matters.

Bioethics. Debate after visualization of a documental video of bioethic pharmaceutical interest. Solving practical questions based on bibliographic research and application of concepts.

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.

Inverted or *flipped classroom* methodology, role-playing, case studies and collaborative learning in a block of pharmaceutical ethics and deontology

Prescription and economic assessment of compounding. Talk by pharmacovigilancy specialist. Games in classroom

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 realization of seminars will emphasize the acquisition of specific competences of the subject and will be evaluated by virtual clasroom quizzes(15%) and exam (10%). Therefore, the seminar block represents the 25% of the final grade. The remaining 5% will correspond to the attitude in class, delivery of tasks and attendance to all the seminars of the subject.

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.

As stated by the CAT (May, 14th, 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 professional. Javeir Sánchez-Caro y Fernando Abellán. Ed Comares, Granada. 2004
- Salud pública y Patentes farmacéuticas. Xavier Seuba Hernández. Bosch Mercantil. Barcelona 2008

ADDENDUM COVID-19

This addendum will only be activated if the health situation requires so and with the prior agreement of the Governing Council

1. Contents

The contents initially included in the teaching guide are maintained

2. Volume of work and temporal planning of teaching

The work for the student is maintained, derived from the number of credits, but the methodology of the activities changes with respect to the teaching guide, due to the current situation that makes it necessary to adopt a hybrid teaching model

3. Teaching methodology

- Theoretical classes: They will be developed in their classroom and in accordance with the course calendar, but with the appropriate modifications to comply with the safety regulations against CoVid19. Supposing that the capacity of the classroom does not allow the presence of the entire group of students, the students will be distributed by groups, so that 50% will be in the classroom while the other 50% will connect online (from home), alternating their attendance for weeks. The class will always be held following the schedule (date and time) approved by the Center.

- Tutorials and Seminars: They will be hold in their classroom according to the dates set by the course calendar.

Practical classes: Not applicable

If there were a worsening of the situation or a state of total confinement, all presential teaching would be carried out online with synchronous or asynchronous teaching, making all the necessary to have available to the student all material for the study of the subject.

4. Evaluation

If the evolution of the current pandemic allows it, it will be hold at classroom and in the terms indicated in the teaching guide. Only in case this is not possible, the evaluation will be carried out online, using multiple-choice questions in the virtual classroom that can be supplemented with short questions and/or on certain occasions, through an oral exam via videoconference.
The relative weight of theory, practices and seminars is maintained as indicated in the teaching guide