COURSE DATA

Data Subject	
Code	34093
Name	Legislation and Pharmaceutical Deontology
Cycle	Grade
ECTS Credits	4.5
Academic year	2019 - 2020

Study (s)

Degree	Center	Acad. year	Period
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

Degree	Subject-matter	Character
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

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 - 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:
Bioethics in basic research.
Bioethics in clinical assays. Helsinki Declaration.
Labeling of medicines.
Publicity of medicines.
Quality control.
Comparison between the mediterranian and the Middle/Northern Europe pharmaceutical models.
Comparison of pharmaceutical models between different spanish authonomous communities.
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.

Quality control. Team work. Role playing.

Comparison between the mediterranian 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 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 exam, with a value of 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. Contenidos

Se mantienen todos los contenidos inicialmente programados en la guía docente para las sesiones teóricas y los seminarios.

2. Volumen de trabajo y planificación temporal de la docencia

La guía docente preveía 30 horas de clases de teoría y 10 horas de seminarios. Tanto seminarios como teoría se impartirán en su totalidad. Se mantienen las 10 horas de seminarios sustituyendo los seminarios presenciales tras el confinamiento por tareas en el aula virtual previo envío delos materiales necesarios para su correcto desarrollo. Mantenimiento de la planificación temporal docente tanto en días como en horario.

3. Metodología docente

Subida al aula virtual de los materiales para estas sesiones (diapositivas). Mismos materiales previstos en la guía original para la docencia presencial, con la incorporación de notas y material complementario para suplir las clases teóricas. Además, se ha subido al aula virtual enlaces a videos alojados en el servidor MMedia que tienen como finalidad explicar los conceptos más difíciles del bloque de bioética y deontología farmacéutica. Los seminarios que quedaban por impartir, se han adaptado para realizarlos telemáticamente por medio de tareas.

4. Evaluación

Prueba de evaluación final: Se basará en un examen con 30 preguntas entre las que pueden aparecer tipo test, Verdadero falso, y otras posibilidades que brinda el aula virtual. El examen se subirá al aula virtual como cuestionario a la hora prevista para el inicio del examen según el calendario oficial.

La duración del examen será de 60 minutos. Será la hora que figure en la actividad Tarea del aula virtual como hora de entrega la que se tenga en cuenta para entender que se ha entregado en plazo. Después se realizará la prueba para evaluar los seminarios de la asignatura, excepto el seminario de bioética que será evaluable, y tendrá una duración de 20 minutos.

Si una persona no dispone de los medios para establecer esta conexión y acceder al aula virtual, deberá contactar con el profesorado por correo electrónico en el momento de publicación de este anexo a la guía docente.

5. Bibliografía

No hay modificaciones