COURSE DATA

Data Subject	
Code	43025
Name	Law and bioethics
Cycle	Master's degree
ECTS Credits	3.0
Academic year	2021 - 2022

Study (s)

Degree	Center	Acad. year	Period
2138 - M.D. in Research in and Rational Use of Medicines	Faculty of Pharmacy and Food Sciences	1	First term

Subject-matter

Degree	Subject-matter	Character
2138 - M.D. in Research in and Rational Use of Medicines	3 - Law and bioethics	Obligatory

Coordination

Name	Department
MELERO ZAERA, ANA	134 - Pharmacy and Pharmaceutical Technology

SUMMARY

Subject basically theoretical that attempts to explore the rules concerning the performance of the health professionals and the guarantees established by law for drugs and medical devices. It is relevant to this Master as both constitute a large part of the tools available to the professional practice. It also discusses the major ethical dilemmas involved in health care practice. The practices are directed to discuss on current case law.

PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

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

Other requirements

There is no registration restriction

OUTCOMES

2138 - M.D. in Research in and Rational Use of Medicines

- Students should apply acquired knowledge to solve problems in unfamiliar contexts within their field of study, including multidisciplinary scenarios.
- Students should be able to integrate knowledge and address the complexity of making informed judgments based on incomplete or limited information, including reflections on the social and ethical responsibilities associated with the application of their knowledge and judgments.
- Students should demonstrate self-directed learning skills for continued academic growth.
- Be able to make quick and effective decisions in professional or research practice.
- Be able to access the information required (databases, scientific articles, etc.) and to interpret and use it sensibly.
- Be able to integrate new technologies in their professional and/or research work.
- Be able to access to information tools in other areas of knowledge and use them properly.
- To be able to assess the need to complete the scientific, historical, language, informatics, literature, ethics, social and human background in general, attending conferences, courses or doing complementary activities, self-assessing the contribution of these activities towards a comprehensive development.
- Dominar los aspectos éticos y legales del medicamento tanto a nivel asistencial como los relacionados con los ensayos preclínicos y clínicos.
- Resolver de dilemas éticos derivados del empleo de medicamentos.

LEARNING OUTCOMES

At the end of the teaching-learning process the student should be able to:

1. Search the applicable regulations in the elementary sources of law and critical analysis of the legislation and case law on issues of interest

2. Understand the fundamentals of legal professional responsibility

3. Be aware of the legal guarantees of medicine and health products

4. be aware of the ethical principles and ethics of Health practice

5. be able to analyze the case law on medicine and the NHS and to solve ethical dilemmas arising from the use of drugs

DESCRIPTION OF CONTENTS

1. Rules

Unit 1: Sources of information in legislation
Unit 2: Civil and criminal liability of health professionals. The principle of confidentiality in clinical practice: professional secrecy. Conscientious objection.
Unit 3: Rights and duties of users of the health system. Impact of the European Data Protection Regulation. Consumer law and derivative liability.
Unit 4. The autonomy of the patient. The right to information and informed consent. Refusal to treatment and required treatments.

2. Ethics

Unit 5: Principles of bioethics in the development and use of medications.
Unit 6: Access to medicines and SDGs. The fair distribution of health resources.
Unit 7: Ethical and legal aspects of animal research.
Unit 8: Ethical and legal aspects of research in humans.

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	22,00	100
Seminars	6,00	100
Computer classroom practice	2,00	100
Development of group work	20,00	0
Study and independent work	15,00	0
Readings supplementary material	10,00	0
TOTAL	**75,00**	

TEACHING METHODOLOGY

During the activities, both theoretical and practical, the applications of the subject contents in relation to the Sustainable Development Goals (SDG) will be indicated. This is intended to provide knowledge, skills and motivation to understand and address these SDGs, while promoting reflection and criticism.

The first activity is dedicated to donating the necessary items to support the autonomous work and is structured in a reminder of the normative hierarchy and the description of the structure of the available databases, which is to reinforce both specific tasks in the classroom virtual. From that moment on, the theoretical modules are developed, with documentary support to the virtual classroom and active d'aprenentatge methodologies. It will use the inverted class for the most recent continguts for the students and direct training (practical cases, reviews, comments) for others. The seminars consist of the exposition by part of a group of students of the applicable regulations in a current question related to the topic and the implications for the health system or the serious users. Both the preparation of the seminar and the corresponding documentation were supervised by one of the professors.

EVALUATION

At the end of the presentation of the didactic material there will be a brief questionnaire to assess the learning of the fundamental concepts (30%).

In the evaluation of the presentation in the seminars, the documentation of the matter will be taken into account as well as the ability to exhibit the subject in the Seminar and the defense of it in the time of debate (50%). The written work will evaluate both the formal aspect and its content, and especially the validity of the arguments used in the discussion of the subject (20%).
To successfully complete the subject, you must attend at least 80% of the scheduled seminars.

REFERENCES

Basic

- Ley 44/2003, de 21 noviembre de Ordenación de las profesiones sanitarias. Dirección del Estado. BOE 22 noviembre 2003, núm. 280.
  Ley 38/2003, de 17 de noviembre. General de Subvenciones. Dirección del Estado. BOE 18 noviembre 2003, núm. 276.
  Ley 16/2003, de 28 mayo, de cohesión y calidad del Sistema Nacional de Salud. Dirección del Estado. BOE 29 mayo 2003, núm. 128.
  Ley 53/2002, de 30 diciembre. Medidas Fiscales, Administrativas y de la Orden Social. Dirección del Estado. BOE 31 diciembre 2002, núm. 313.
  Ley 41/2002, de 14 noviembre. Ley básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica. Dirección del Estado. BOE 15 noviembre 2002, núm. 274.
  Ley 24/2001, de 27 diciembre. Medidas fiscales, administrativas y de la orden social. Jefatura del Estado. BOE 31 diciembre 2001, núm. 313; rect. BOE 24 mayo 2002, núm. 124. BOE 2 julio 2002, núm. 157.

Real decreto-ley 5/2000, de 23 junio. Medidas urgentes de contención del gasto farmacéutico público y de racionalización del uso de los medicamentos. Jefatura del Estado. BOE 24 junio 2000, núm. 151; rect. BOE 28 junio 2000, núm. 154
Ley orgánica 15/1999, de 13 diciembre. Normas reguladoras de la protección de datos de carácter personal Jefatura del Estado. BOE 14 diciembre 1999, núm. 298.
Ley 4/1999, de 13 enero. Modifica la Ley 30/1992, de 26-11-1992, de Régimen jurídico de las administraciones públicas y del procedimiento administrativo común.

Additional

- Comentarios y Concordancias a la Ley de Garantías y Uso Racional Medicamentos
  Olivera Massó, Pablo, Editorial Aranzadi, S.A., 2007

La ordenación sanitaria en España (Libro electrónico). Macarena Hernández Bejarano. Editorial Aranzadi S.A., 2004

Consentimiento informado, El. José Guerrero Zaplana. Editorial Lex Nova, 2004

Responsabilidad Médico Sanitaria y del Medicamento. Álvaro Luna Yerga, Sonia Ramos González Editorial Civitas (2004)

ADDENDUM COVID-19

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

3. Teaching methodology

Although in principle teaching has been scheduled face-to-face, in the event that sanitary conditions impose it, the theoretical sessions and seminars planned to take place in person will go on to video conferences by * Blackboard * Collaborate or similar, and the corresponding questionnaires will be carried out using virtual classroom tools.

4. Evaluation

The use of virtual tools will make the questionnaires have a weight of 40%, the preparation and defense of the seminars 40% and the written work, 20%.