

POLI ESCOLA SUPERIOR SAÚDE TÉCNICO GUARDA	SUBJECT DESCRIPTION	<div style="text-align: right;"><i>Mário Rodrigues</i></div> MODELO PED.015.03
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Course	Pharmacy					
Subject	Medical devices and other health products					
Academic year	2021/2022	Curricular year	2nd	Study period	2nd semester	
Type of subject	Compulsory	Student workload (H)	Total: 67.5	Contact: 45	ECTS	2.5
Professor(s)	Mário José de Abreu Marques Rodrigues					
<input type="checkbox"/> Area/Group Coordinator <input checked="" type="checkbox"/> Head of Department		Mário José de Abreu Marques Rodrigues				

PLANNED SUBJECT DESCRIPTION

1. LEARNING OBJECTIVES

The learning objectives are for students to recognize the importance of different types of medical devices, taking into account the classification criteria and the determinants of risk. Besides these, it is also objective of this subject that students identify the most common used medical devices in the hospital and community pharmacies and to acquire the necessary knowledge and skills to use them correctly so that they can properly inform and advise the users on the correct use of medical devices.

2. PROGRAMME

- I. Definition of medical devices and definition of in vitro medical devices. Other types of medical devices: custom-made devices, active medical devices, implantable medical devices.*
- II. Classification of medical devices regarding the classes of risk. Criteria for classification and identification of medical devices in risk classes: Class I, Classes IIa and IIb and Class III.*
- III. Regulation on the use of medical devices. National and international legislation.*
- IV. The circuit of medical devices in Portugal.*
- V. The National System of Vigilance of Medical Devices (SNVDM).*
- VI. Examples of medical devices most commonly used in community and hospital pharmacies.*
- VII. Simulation of the use of some medical devices: determination of blood glucose, cholesterol and triglycerides, evaluation of blood pressure, use of devices to prevent sexually transmitted diseases. Counseling and information for the safe use of medical devices.*

3. COHERENCE BETWEEN PROGRAMME AND OBJECTIVES

To allow students to understand the importance of different medical devices, it has been essential that students recognize the different classes of medical devices according to the classification criteria, the determinants of risk and their use in clinical practice. Knowing the national and international legislation allowed students to understand the circuit of the medical devices, recognizing the actors in the processes of investigation and development of medical devices, in the processes of manufacture, distribution,

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surveillance and control of medical devices, as well as the importance of using the devices in different clinical situations, both in diagnosis and in therapy.

4. MAIN BIBLIOGRAPHY

Decreto-Lei n.º 145/2009 de 17 de junho – Regras de utilização, fabrico e utilização dos dispositivos médicos.

Deliberação n.º 514/2010, de 3 de março – Instrução do pedido à Comissão de Ética para a Saúde sobre investigação clínica com dispositivos médicos.

Deliberação n.º 939/2014, de 20 de março – Formulário de Notificação ao Infarmed.

Despacho n.º 7021/2013, de 24 de maio – Dispositivos Médicos de uso único reprocessados.

Jacobson B and Murray A. Medical devices: use and safety. Edinburgh, Elsevier, 2007.

Schreiner S. Bronzino J, Peterson D and Raton B. Medical instruments and devices: principles and practices. CRC Press, 2016.

Manual de Material de Penso com Ação Terapêutica. Conselho do Colégio de Especialidade de Farmácia Hospitalar, 2012

Regulamento (UE) 2017/745 do Parlamento Europeu e do Conselho de 5 de abril de 2017 relativo aos dispositivos médicos

Regulamento (UE) 2017/746 do Parlamento Europeu e do Conselho de 5 de abril de 2017 relativo aos dispositivos médicos para diagnóstico in vitro

Mário Rodrigues (2021/2022) – Lecture notes

5. TEACHING METHODOLOGIES (INCLUDING EVALUATION)

The teaching methodologies are adapted to the theoretical teaching with a masterful presentation of the contents and their systematization in an integrated way, to the theoretical-practical teaching and tutorial guidance, in which interactive discussion with students and the resolution of exercises were privileged.

The evaluation of the curricular unit result from the evaluation of the theoretical and theoretical-practical contents taught. Theoretical assessment results from two written tests (35%, each test) and the theoretical-practical assessment results from continuous assessment, where the participation and interaction of students in the discussion and analysis of topics in class and through the resolution of exercises is privileged (5%), the presentation and elaboration, in group, an information leaflet directed to inform health professionals about the clinical importance of the medical device and its instructions for use (25%).

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The approval by frequency in this subject is achieved with the positive evaluation and with the minimal final score of ten values, on a scale of zero to twenty values, obtained the sum of partial classifications. Regarding the continuous assessment of the course unit, in case the students have approved the theoretical-practical component, but not the theoretical one, the grade obtained in the information leaflets with a weighting of 25%, remained during the exam periods, it being only necessary that students take an examination of all theoretical and theoretical-practical syllabus taught with a weighting of 75%. Students covered by special statutes who did not attend a sufficient number of classes to allow continuous assessment of their performance were evaluated only by written tests and information leaflets, with a weighting of 75% and 25%, respectively.

The improvement in classification implies that all the theoretical and theoretical-practical syllabus contents will be examined during the periods foreseen for this purpose.

6. COHERENCE BETWEEN TEACHING METHODOLOGIES AND OBJECTIVES

The curricular unit are organized in theoretical, theoretical-practical and tutorial-tutorial classes. The theoretical classes are dedicated to the masterful exposition of the syllabus and in the theoretical-practical and tutorial-tutorial classes, interactive discussion with students is privileged, proceeding to the systematization of the most relevant and current aspects, using audiovisual media. As active learning activities, questions will be asked and exercises will be carried out to integrate the content presented, creating a space for debate and resolution of doubts. The use of some more common medical devices, in simulated clinical situations in the classroom, allows students to acquire the knowledge and practical skills for their correct use, as well as for the correct advice and information to be provided to users in the pharmacy.

The written evaluation, with direct and development questions, allows to evaluate the knowledge acquired and developed by the students, and the theoretical-practical evaluation allowed the integration of this knowledge allowing the students to develop critical reasoning and apply the acquired knowledge, through the debate.

7. ATTENDANCE

The contact hours for the theoretical-practical classes are of mandatory attendance and students are obligate to be in a minimum of 75% of the total hours allocated in the plan of study for this type of classes. Students who exceed the allowed absences and which were not covered by special statute are disapproved and cannot perform periodic assessment tests or final exam in the respective academic year.

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8. CONTACTS AND OFFICE HOURS

Márcio Rodrigues / marciorodrigues@ipg.pt / Office 4

Office hours – Monday: 14.00h-16.00h / Tuesday: 11.00h-13.00h

DATE

04 March 2022

SIGNATURE

Professor and Head of Department


 (Márcio José de Abreu Marques Rodrigues)