

<b>POLI</b> ESCOLA SUPERIOR SAÚDE <b>TÉCNICO</b> <b>GUARDA</b>	<b>SUBJECT DESCRIPTION</b>	<b>MODELO</b> PED.015.03
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Course	Pharmacy					
Subject	Medical Devices and Other Health Products					
Academic year	2023-2024	Curricular year	2nd	Study period	2nd semester	
Type of subject	Compulsory	Student workload (H)	Total: 81	Contact: 45	ECTS	3
Professor(s)	Cristiana Guimarães Martins Midões					
<input type="checkbox"/> Area/Group Coordinator <input checked="" type="checkbox"/> Head of Department		Cristiana Guimarães Martins Midões				

### PLANNED SUBJECT DESCRIPTION

#### 1. LEARNING OBJECTIVES

- O1 - Understand the concept of health products and of frontier products, and its framework in Portuguese legislation;
- O2 - Distinguishing health products from medicines;
- O3 - Distinguish medical devices from other health products;
- O4 - Distinguish the different medical devices from the risk of use;
- O5 - Know the most commonly used food supplements and adapted foods dispensed in pharmacies;
- O6 - Know the labeling rules of the different health product;
- O7 - Know how to advise and provide information on the most frequent health products in hospital and in community pharmacy;
- O8 - Recognize the importance of the evolution of knowledge in the area and the need to research current and scientific information on the development of new products.

#### 2. PROGRAMME

- 1) General Concepts: Health Products and Frontiers Products. Regulatory Authorities;
- 2) Medical Devices: Characterization of different medical devices. Classification of Medical Devices according to risk class. Regulation of Medical Devices. Most common medical devices in the community pharmacy and hospital;
- 3) Food supplements: Classification and frontier product. Regulation. Most Common Food Supplements in Pharmacy;
- 4) Foodstuffs Intended for Special Food;
- 5) Other products.

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### 3. COHERENCE BETWEEN PROGRAMME AND OBJECTIVES

*The program (points 1-5) is in accordance with the objectives of the CU (O1-O8) and allows a general integration of the concepts that distinguish the different health products from medicines and medical devices.*

*For better counselling it is important to realize the importance of the use and risk associated with health products by studying their classification, regulation, characteristics, and market surveillance.*

### 4. MAIN BIBLIOGRAPHY

*Legislação Portuguesa sobre dispositivos médicos ([www.Infarmed.pt](http://www.Infarmed.pt));*

*Legislação portuguesa sobre suplementos alimentares ([www.dgav.pt](http://www.dgav.pt));*

*Guidelines europeias ([www.ema.europa.eu](http://www.ema.europa.eu));*

*Documentos da FDA (<http://www.fda.gov>);*

*Artigos científicos específicos;*

*Ficha técnicas de dispositivos médicos, suplementos alimentares e produtos de nutrição.*

### 5. TEACHING METHODOLOGIES (INCLUDING EVALUATION)

*In the theoretical classes will be an exposition of syllabus contents, proceeding to the systematization of the most relevant and current aspects, encouraging students to interact and discuss the topics covered.*

*In theoretical-practical classes students will analyze scientific articles and official documents of the European Medicines Agency (EMA) and the National Authority for Medicines and Other Health Products (INFARMED), the Food and Drug Administration (FDA) and the Directorate General of Food and Veterinary (DGAV), related to the contents presented in the lectures, being privileged the interactive discussion with the students and the critical spirit in the interpretation and analysis of information. Practical exercises will be solved for resolution through search. In the tutorial classes students will be oriented for research and organization of information. The evaluation consists in the realization of two written tests (70%) (minimum 8 values) and in the carrying out of a group work (25%) and in the continuous assessment (5%).*

*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, it is necessary that students take an examination of all theoretical and theoretical-practical syllabus taught with a weighting of 100%.*

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*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 the group work carried out, 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 teaching methodologies are consistent with the objectives of the CU. The theoretical classes with exposition methodology, and which are always intended to be participatory, are the first approach to the contents in which students are encouraged to ask questions and make arguments based on the previous knowledge, being fundamental to achieve the objectives related to knowledge and memorization of concepts. On the other hand, the theoretical-practical classes, in which students developed continuous work in the classroom, related to knowledge acquired in theoretical classes allows the development of critical analysis and solving problems, being very important to achieve objectives related to attitudes and behaviors, which are fundamental for advising and providing information about products. The elaboration of the group work allows students to systematize information favoring acquisition of specific and general skills.*

## **7. ATTENDANCE**

*Attendance to 75% of theoretical-practical classes is mandatory. Students who do not comply with this frequency regime and who are not covered by a special statute fail and were not admitted to the final exam.*

## **8. CONTACTS AND OFFICE HOURS**

*Cristiana Midões | cmidoes@ipg.pt*

*Office hours – Wednesday: 10:00h-13:00h*

*Monday: 14:00h-15:00h*

## **DATE**

04 March 2024

<p>POLI</p> <p>ESCOLA SUPERIOR</p> <p>SAÚDE</p> <p>TÉCNICO</p> <p>GUARDA</p>	<p><b>SUBJECT DESCRIPTION</b></p>	<p><b>MODELO</b></p> <p>PED.015.03</p>
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**SIGNATURE**

Professor and Head of Department



(Cristiana Guimarães Martins Midões)