

# COURSE OUTLINE

## 1 GENERAL

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| <b>SCHOOL</b>                                                                                                                                                                                                                                                          | School of Applied Biology and Biotechnology                                                                                                                                                      |                              |                |
| <b>ACADEMIC UNIT</b>                                                                                                                                                                                                                                                   | Department of Biotechnology                                                                                                                                                                      |                              |                |
| <b>LEVEL OF STUDIES</b>                                                                                                                                                                                                                                                | Postgraduate (Level 7)                                                                                                                                                                           |                              |                |
| <b>COURSE CODE</b>                                                                                                                                                                                                                                                     | (To be assigned)                                                                                                                                                                                 | <b>SEMESTER</b>              | 1st            |
| <b>COURSE TITLE</b>                                                                                                                                                                                                                                                    | Legislation of Phytotherapeutic Agents                                                                                                                                                           |                              |                |
| <b>INDEPENDENT TEACHING ACTIVITIES</b><br><i>if credits are awarded for separate components of the course, e.g. lectures, laboratory exercises, etc. If the credits are awarded for the whole of the course, state the weekly teaching hours and the total credits</i> |                                                                                                                                                                                                  | <b>WEEKLY TEACHING HOURS</b> | <b>CREDITS</b> |
| Lectures & Guided Study (Virtual & Pre-recorded)                                                                                                                                                                                                                       |                                                                                                                                                                                                  | 3                            |                |
| Case-study seminars / discussions / Group Projects                                                                                                                                                                                                                     |                                                                                                                                                                                                  | 1                            |                |
| <b>TOTAL</b>                                                                                                                                                                                                                                                           |                                                                                                                                                                                                  | 4                            | 6 ECTS         |
| <i>Add rows if necessary. The organisation of teaching and the teaching methods used are described in detail in section (4).</i>                                                                                                                                       |                                                                                                                                                                                                  |                              |                |
| <b>COURSE TYPE</b><br><i>general background, special background, specialization, general education, skills development</i>                                                                                                                                             | Specialization / Special Background                                                                                                                                                              |                              |                |
| <b>PREREQUISITE COURSES</b>                                                                                                                                                                                                                                            | Students are expected to have basic knowledge of medicinal product legislation (definitions, marketing authorization, renewal procedures) Introductory learning in plant science is recommended. |                              |                |
| <b>LANGUAGE OF INSTRUCTION AND OF ASSESSMENT</b>                                                                                                                                                                                                                       | English                                                                                                                                                                                          |                              |                |
| <b>MODE OF TEACHING</b><br><i>in-person (%)<br/>synchronous distance learning (%)<br/>asynchronous distance learning (%)<br/>(In the case of synchronous distance learning, the total weekly duration of teaching is recorded)</i>                                     | Synchronous distance learning (75%)<br><br>Asynchronous distance learning (25%)                                                                                                                  |                              |                |
| <b>AVAILABILITY TO ERASMUS STUDENTS</b>                                                                                                                                                                                                                                | No                                                                                                                                                                                               |                              |                |
| <b>COURSE WEBSITE (URL)</b>                                                                                                                                                                                                                                            | <a href="https://purdue.brightspace.com">https://purdue.brightspace.com</a>                                                                                                                      |                              |                |

## 2 LEARNING OUTCOMES

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| <b>Learning Outcomes</b><br><i>The course learning outcomes, specific knowledge, skills and competences of an appropriate level, which the students will acquire with the successful completion of the course are described.</i><br>Consult Appendix A <ul style="list-style-type: none"> <li>• Description of the level of learning outcomes for each qualifications cycle, according to the Qualifications Framework of the European Higher Education Area</li> <li>• Descriptors for Levels 6, 7 &amp; 8 of the European Qualifications Framework for Lifelong Learning and Appendix B</li> <li>• Brief Guide for drafting Learning Outcomes</li> </ul> |
| Upon successful completion of the course, students will be able to: <ul style="list-style-type: none"> <li>• Familiarize themselves with the specialized legislation governing medicinal</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

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| <p>products, with a specific focus on Phytotherapeutic agents in the EU and Greece.</p> <ul style="list-style-type: none"> <li>Identify and differentiate the main groups of active phytochemical constituents (e.g., alkaloids, flavonoids, polyphenols, essential oils) and their respective biological activities.</li> <li>Navigate and search for legislative information regarding medicinal products using primary digital platforms, committee sections, and official information pages.</li> <li>Analyze the legislation of cosmetics and the specific requirements for natural ingredients used in their formulations across Europe, Greece, and the USA.</li> <li>Evaluate the risks and benefits of popular herbal remedies provided to patients.</li> <li>Apply the legislative frameworks for Herbal Medicinal Products (HMP) and medicinal cannabis in Greece and Europe, including authorized products and safety profiles.</li> <li>Understand and implement the principles of Good Manufacturing Practice (GMP) and Good Agricultural and Collection Practice (GACP) in the context of phytotherapy.</li> <li>Master the procedural requirements for labeling, packaging, and marketing authorization processes.</li> <li>Synthesize the principles of efficacy and safety for HMPs, with a specialized emphasis on the concept of synergism.</li> </ul> |                                                                                                 |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <p><b>General Competences</b></p> <p><i>Taking into consideration the general competences that the degree-holder must acquire (as these appear in the Diploma Supplement and are stated below), at which of the following does the course aim?</i></p> <table> <tr> <td><i>Search, analysis and synthesis of data and information, with the use of the necessary technology</i></td><td><i>Project planning and management</i></td></tr> <tr> <td><i>Adaptability to new situations</i></td><td><i>Respect for difference and multiculturalism</i></td></tr> <tr> <td><i>Decision-making</i></td><td><i>Respect for the natural environment</i></td></tr> <tr> <td><i>Working independently</i></td><td><i>Showing social, professional and ethical responsibility and sensitivity to gender issues</i></td></tr> <tr> <td><i>Team work</i></td><td><i>Criticism and self-criticism</i></td></tr> <tr> <td><i>Working in an international environment</i></td><td><i>Production of free, creative and inductive thinking</i></td></tr> <tr> <td><i>Working in an interdisciplinary environment</i></td><td><i>.....</i></td></tr> <tr> <td><i>Production of new research ideas</i></td><td><i>Other...</i></td></tr> <tr> <td></td><td><i>.....</i></td></tr> </table>                                                                                                     |                                                                                                 | <i>Search, analysis and synthesis of data and information, with the use of the necessary technology</i> | <i>Project planning and management</i> | <i>Adaptability to new situations</i> | <i>Respect for difference and multiculturalism</i> | <i>Decision-making</i> | <i>Respect for the natural environment</i> | <i>Working independently</i> | <i>Showing social, professional and ethical responsibility and sensitivity to gender issues</i> | <i>Team work</i> | <i>Criticism and self-criticism</i> | <i>Working in an international environment</i> | <i>Production of free, creative and inductive thinking</i> | <i>Working in an interdisciplinary environment</i> | <i>.....</i> | <i>Production of new research ideas</i> | <i>Other...</i> |  | <i>.....</i> |
| <i>Search, analysis and synthesis of data and information, with the use of the necessary technology</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <i>Project planning and management</i>                                                          |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Adaptability to new situations</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <i>Respect for difference and multiculturalism</i>                                              |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Decision-making</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <i>Respect for the natural environment</i>                                                      |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Working independently</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <i>Showing social, professional and ethical responsibility and sensitivity to gender issues</i> |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Team work</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <i>Criticism and self-criticism</i>                                                             |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Working in an international environment</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <i>Production of free, creative and inductive thinking</i>                                      |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Working in an interdisciplinary environment</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <i>.....</i>                                                                                    |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
| <i>Production of new research ideas</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <i>Other...</i>                                                                                 |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |
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| <ul style="list-style-type: none"> <li>Search for, analysis, and synthesis of data and information through the use of primary legislative databases and academic literature.</li> <li>Working independently via the preparation of the final manuscript report and weekly assessments.</li> <li>Team work through the development and delivery of collaborative group presentations.</li> <li>Working in an international environment by studying and comparing EU, Greek, and US regulatory frameworks.</li> <li>Criticism and self-criticism through the critical evaluation of case studies during presentations.</li> <li>Respect for the natural environment and sustainability by fostering awareness of ethical principles in the use of natural resources.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                 |                                                                                                         |                                        |                                       |                                                    |                        |                                            |                              |                                                                                                 |                  |                                     |                                                |                                                            |                                                    |              |                                         |                 |  |              |

### 3 COURSE SYLLABUS

This course provides a detailed exploration of the legal and regulatory landscape for phytotherapeutic and herbal medicinal products, comparing frameworks in the European Union, Greece, and the United States. The curriculum is structured into the following thematic pillars:

- **Regulatory Foundations of Medicinal Products:** Introduction to the legal frameworks in Europe and Greece, focusing on the roles of the European Medicines Agency (EMA) and the National Organization for Medicines (EOF).
- **Lifecycle Management of Authorizations:** Detailed analysis of initial marketing authorizations, variation procedures, and renewal processes.
- **Pharmacovigilance & Safety:** Legislative requirements for monitoring the safety of human medicinal products and the specific documentation required for pharmacovigilance procedures.
- **Phytotherapeutic & Herbal Medicinal Products (HMP):** \* Classification and authorization of natural medicinal products.
  - Principles of efficacy and safety, with a focus on the concept of chemical synergism in plant extracts.
  - Application procedures and technical requirements for submitting an HMP dossier.
- **Cosmetics & Natural Ingredients:** \* Comparative legislation between the EU (Regulation 1223/2009), Greece, and the USA (MoCRA 2022).
  - The use of natural ingredients in cosmetic formulations and navigation of the CosIng (EU Cosmetic Ingredient) database.
- **Medicinal Cannabis Frameworks:** Specialized focus on the legislation in the Greek territory, comparative analysis with other EU and non-EU countries, and the safety profiles of authorized cannabis-based active substances.
- **Quality & Production Standards:** Implementation of Good Manufacturing Practice (GMP) and Good Agricultural and Collection Practice (GACP) specifically for phytotherapy.
- **Technical Requirements:** Detailed study of legal mandates for labeling and packaging of phytotherapeutic agents.
- **Emerging Technologies:** The evolving role and regulatory implications of Artificial Intelligence (AI) in the development and monitoring of medicinal products and cosmetics

### 4 TEACHING AND LEARNING METHODS - ASSESSMENT

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| <b>MODE OF TEACHING</b><br><i>Face-to-face, distance learning, etc.</i> | <b>Distance Learning</b> <ul style="list-style-type: none"><li>• Synchronous distance learning: 75% (39 hours)</li><li>• Asynchronous distance learning: 25% (13 hours)</li></ul> |
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| <p><b>MODE AND FREQUENCY OF COMMUNICATION WITH THE STUDENTS</b></p>                                                                                                                                      | <ul style="list-style-type: none"> <li>• Weekly Synchronous Sessions: A 3-hour live lecture and a 1-hour workshop are held weekly. These sessions focus on the real-world application of legislation and student-led case studies.</li> <li>• Student Consultation: Instructors hold "Virtual Office Hours" or by appointment, providing academic guidance via teleconference.</li> <li>• LMS Communication: Updates and reminders are posted at least twice weekly via the Brightspace "Announcements" tool.</li> <li>• Asynchronous Interaction: Discussion forums are monitored daily, with a guaranteed response time of 24–48 hours for academic queries.</li> <li>• Feedback Mechanism: Detailed individualized feedback on group presentations and manuscript reports is provided electronically within two weeks of submission.</li> <li>• Email Support: Direct contact with the instructional team via university email, with a response time of 24–48 hours.</li> </ul> |
| <p><b>ENSURING THE MODE OF COMMUNICATION AMONG STUDENTS</b></p> <p><i>Team assignments and discussions, collaborative learning platforms with the use of AI, video conference, QA sessions, κ.α.</i></p> | <p>The course is designed to foster a collaborative learning environment, ensuring that students can interact effectively despite the distance-learning format:</p> <ul style="list-style-type: none"> <li>• Collaborative Case Study Analysis: During the synchronous weekly workshops, students are placed in virtual breakout rooms to solve complex regulatory problems, such as identifying the correct authorization pathway for a specific herbal product or navigating the CosIng database.</li> <li>• Group Project Development: Students work in teams of 2–3 to develop their Oral Presentations and the Final Manuscript Report. This requires frequent peer-to-peer coordination, resource sharing, and collective decision-making.</li> </ul>                                                                                                                                                                                                                        |

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|                                                                                                                                                      | <ul style="list-style-type: none"> <li>• <b>Structured Discussion Forums:</b> Dedicated threads in Brightspace allow students to share insights on current legislative updates (e.g., changes in medicinal cannabis laws) and provide feedback on each other's ideas.</li> <li>• <b>Collaborative Learning Tools:</b> Students utilize cloud-based suites (e.g., Google Workspace, Microsoft 365) to co-author regulatory dossiers and presentation slides, simulating the professional collaborative workflows of regulatory affairs departments.</li> <li>• <b>AI-Enhanced Collaboration:</b> Students are permitted to use AI tools for brainstorming and structuring group assignments, provided they follow the mandatory disclosure and instructor approval guidelines.</li> </ul>                                                                                                                                                                                                                                                                                                           |
| <b>USE OF INFORMATION AND COMMUNICATIONS TECHNOLOGY</b><br><i>Use of ICT in teaching, in laboratory training, in the communication with students</i> | <p>The course extensively utilizes modern Information and Communication Technologies (ICT) to facilitate high-quality distance learning and training and communication with Students:</p> <ul style="list-style-type: none"> <li>• <b>Learning Management System (LMS):</b> Brightspace hosts all instructional modules, legislative texts, and video resources.</li> <li>• <b>Virtual Classroom:</b> Synchronous Video Conferencing is used for synchronous lectures and real-time analysis of regulatory case studies.</li> <li>• <b>Interactive Modules:</b> Use of digital assets and structured online quizzes to reinforce understanding of EU and Greek legislation.</li> <li>• <b>Regulatory Databases:</b> Training in the use of official portals such as the EMA (European Medicines Agency) website, the EOF (National Organization for Medicines) portal, and the CosIng (Cosmetic Ingredient) database.</li> <li>• <b>Digital Documentation:</b> Use of professional software for drafting and organizing marketing authorization dossiers and pharmacovigilance reports.</li> </ul> |

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|                                                          | <ul style="list-style-type: none"> <li>• Administrative Hub: Brightspace Announcements for weekly task updates and technical instructions.</li> <li>• Asynchronous Forums: Moderated Discussion Boards for debating the ethics and implementation of phytotherapeutic legislation.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>TECHNOLOGICAL EQUIPMENT REQUIREMENTS</b>              | <p>To ensure full participation and access to the instructional materials, students must have the following:</p> <ul style="list-style-type: none"> <li>• Personal Computer / Laptop: A modern system capable of supporting document processing and high-definition video conferencing.</li> <li>• High-Speed Internet Connection: Broadband access is essential for attending live sessions and navigating complex international regulatory databases without latency.</li> <li>• Peripherals: A functional webcam and high-quality microphone/headset for active participation in workshops and group presentations.</li> </ul> <p>Software &amp; Tools:</p> <ul style="list-style-type: none"> <li>• LMS Access: Standard web browser for the Brightspace platform.</li> <li>• Installation of the Zoom client or other approved teleconference platform for synchronous sessions.</li> <li>• Productivity Suite: Microsoft Office or equivalent for drafting manuscripts and dossiers.</li> <li>• Institutional Infrastructure: Students are provided with institutional access to digital library resources and specialized scientific/legal databases required for their research.</li> </ul> |
| <b>PLAGIARISM POLICY/<br/>PLAGIARISM DETECTION TOOLS</b> | <p>The program maintains a zero-tolerance policy towards academic dishonesty and plagiarism, ensuring that all submitted work reflects the student's original research and critical thinking.</p> <ul style="list-style-type: none"> <li>• Plagiarism Policy: Plagiarism is defined as using the words, ideas, results, or images of others without proper attribution, as well as self-plagiarism (resubmitting prior work).</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

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|                                                                                                                                                                                                                                                                                                                                                                                                          | <ul style="list-style-type: none"> <li>Students are required to follow the Purdue Honor Pledge ("As a Boilermaker pursuing academic excellence, I pledge to be honest and true in all that I do. I will neither give nor receive aid unless the instructor authorizes it").</li> <li>In alignment with the Agricultural University of Athens (AUA) regulations, all postgraduate assignments and the final thesis must comply with the institutional standards for originality.</li> </ul> <p>Plagiarism Detection Tools:</p> <ul style="list-style-type: none"> <li>Turnitin: All written assignments (Manuscript Reports, Discussion Board posts, and the final Thesis) are systematically screened through the Turnitin plagiarism detection software.</li> <li>Originality Reports: Instructors review detailed similarity reports generated by Turnitin to identify improperly cited content or excessive overlap with existing literature.</li> <li>AI Writing Detection: The program utilizes Turnitin's AI writing detection feature to identify instances where generative AI tools may have been used outside the permitted guidelines.</li> <li>Consequences: Instances of academic dishonesty are handled according to the procedures of the Office of Student Rights and Responsibilities (OSRR) at Purdue and the Assembly of the Department of Biotechnology at AUA. Sanctions may range from failure of the assignment to dismissal from the dual-degree program.</li> </ul> |
| <p><b>ARTIFICIAL INTELLIGENCE POLICY</b></p> <p>(1) The use of Artificial Intelligence is prohibited in all circumstances</p> <p>(2) The use of Artificial Intelligence is allowed only with the permission of the instructor</p> <p>(3) The use of Artificial Intelligence is allowed only with an explicit reference to the literature</p> <p>(4) Students are free to use Artificial Intelligence</p> | <p>(2) The use of Artificial Intelligence is allowed only with the permission of the instructor</p> <p>(3) The use of Artificial Intelligence is allowed only with an explicit reference to the literature</p> <p>Description &amp; Implementation: In this course, a constructive but regulated approach to Generative AI (e.g., ChatGPT, Gemini) is adopted:</p> <ul style="list-style-type: none"> <li>Permitted Use: Students are allowed to use AI tools primarily as "collaborative partners" for brainstorming, structuring outlines, or</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

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|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>refining the linguistic clarity of their written reports (e.g., the final manuscript report).</p> <ul style="list-style-type: none"> <li>• Instructor Approval: Use of AI for specific assignments must be discussed with and approved by the instructor during the initial stages of the project.</li> <li>• Mandatory Disclosure: If AI tools are used, students must include a dedicated "AI Disclosure Statement" in their work, explicitly describing which tool was used and for which part of the assignment.</li> <li>• Academic Integrity: Students remain 100% responsible for the accuracy and scientific validity of the final output. AI-generated text must be critically verified against primary peer-reviewed literature.</li> <li>• Prohibited Use: Using AI to generate entire assignments, perform primary data analysis without disclosure, or bypass critical thinking components of the course is strictly prohibited and constitutes academic dishonesty.</li> </ul> |                          |
| <p><b>ORGANISATION OF TEACHING</b></p> <p><i>The mode and methods of teaching are described in detail.</i></p> <p><i>Lectures, seminars, laboratory practice, fieldwork, study and analysis of bibliography, tutorials, work placements, clinical practice, art workshop, interactive teaching, educational visits, project, essay writing, artworks, etc.</i></p> <p><i>The student's study hours for each learning activity are stated, as well as the hours of independent study, according to the principles of the ECTS.</i></p> | <b>Activity</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Semester workload</b> |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Lectures (Synchronous distance learning - 3h/week)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 39                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Case-study seminars / workshops (Synchronous - 1h/week)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | 13                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Independent study of asynchronous modules & digital content                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | 30                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Study and analysis of bibliography                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 30                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Preparation for Weekly Multiple-choice questions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 15                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Preparation of Group Oral Presentation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 10                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Preparation of Final Manuscript Report                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 13                       |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Course total</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>150</b>               |
| <p><b>STUDENT ASSESSMENT</b></p> <p><i>Description of the assessment method</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                   | Language of assessment: English                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                          |



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| <p><i>Language of assessment, methods of assessment, formative or summative assessment, multiple choice questions test, short answer questions, essay questions, problem solving, written work, essay/report, oral examination, public presentation, laboratory assignment, clinical examination of patient, art interpretation, other</i></p> <p><i>Specifically-defined evaluation criteria are given, and if and where they are accessible to students.</i></p> | <p><b>Methods of assessment:</b><br/>The assessment is summative and is designed to measure the achievement of learning outcomes throughout the semester. It consists of the following components:</p> <ul style="list-style-type: none"> <li>• <b>Weekly Multiple-Choice Questions (30%):</b> These weekly assessments evaluate the comprehension of the specific content covered in each course module.</li> <li>• <b>Group Presentation (30%):</b> An oral presentation that emphasizes the critical evaluation of regulatory case studies.</li> <li>• <b>Final Report - Manuscript Style (30%):</b> Students are required to write a detailed report on the submission process for a medicinal product application, formatted as a scientific manuscript.</li> <li>• <b>Class Participation &amp; Discussion (10%):</b> Ongoing evaluation of student engagement during synchronous sessions and asynchronous discussions.</li> </ul> <p><b>Evaluation Criteria:</b></p> <ul style="list-style-type: none"> <li>• <b>Specifically defined criteria:</b> Each assignment is graded according to a specific rubric.</li> <li>• <b>Accessibility:</b> All grading rubrics, percentages, and scales are available in the syllabus and on the Brightspace LMS.</li> <li>• <b>Feedback:</b> Students receive graded feedback at least twice during the term (once before the withdrawal deadline and once before finals).</li> </ul> |
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## 5 RECOMMENDED BIBLIOGRAPHY

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| <p><b>Required Readings:</b></p> <ol style="list-style-type: none"> <li>1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency</li> <li>2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use</li> <li>3. Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use</li> <li>4. Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for</li> </ol> |
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human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

5. Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

6. Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council Text with EEA relevance

7. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

8. FDA, Modernization of Cosmetics Regulation Act of 2022 (MoCRA), <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra>

9. Cannabis policy: status and recent developments, [https://www.euda.europa.eu/publications/topic-overviews/cannabis-policy/html\\_en](https://www.euda.europa.eu/publications/topic-overviews/cannabis-policy/html_en)

10.EOF, Legislation of medicinal cannabis, <https://www.eof.gr/farmaka-farmakeftiki-kanavi/>