



Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-611	Regulation of Herbal Medicinal Products	7.5
Prerequisites	Department	Semester
None	Life and Health Sciences	3 rd
Type of Course	Field	Language of Instruction
Elective	Pharmacy	English
Level of Course	Lecturer(s)	Year of Study
2 nd Cycle	Eugenios Kokkalou	2 nd
Mode of Delivery	Work Placement	Co-requisites
Distance Learning	NA	NA

Course Objectives:

Herbal medicinal product is defined as any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.”

The purpose of the course is to provide knowledge on EU monographs covering the therapeutic uses and safe conditions of well-established and/or traditional use for herbal substances and preparations

To accomplish this the course will cover topics including:

- Information covering the use of herbal medicines in healthcare, their safety and efficacy and how they are registered.
- Awareness and knowledge of the scientific guidelines on herbal medicinal products for preparing marketing-authorization applications.
- The framework of issuing scientific opinions on herbal substances and preparations, along with information on recommended uses and safe conditions.

Ultimately, students will have a clear reference point for preparing or assessing an application for marketing authorization or registration of herbal medicinal products in European Union (EU) Member States.

Learning Outcomes:

After completion of the course students are expected to be able to:

1. Advise on issues on the EU framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition and provide answer on regulatory questions on herbal medicinal products
2. Present/Prepare an application for marketing authorization for a herbal medicinal product/traditional herbal medicinal product by accessing EU list entries adopted by the European Commission, referring to herbal medicinal products and extract/assess relevant information
3. Organize/perform a literature search on the herbal product, its constituents and any co-medication to get information on the specific product and evaluate databases for similar case reports for association with the same or similar herbal medicines or combination products.
4. Advise on the safety, quality and efficacy, in relation to human use, of herbal medicinal products which have a marketing authorization, product license or certificate of registration
5. Provide requirements in support of quality, safety and efficacy with respect of herbal medicines destined to enter the EU market

Course Content:

1. **Definitions**
2. **Legal framework**
3. **Herbal Medicine: An Introduction to Its History, Usage, Regulation, Current Trends, and Research Needs**
4. **Classification of Herbal Medicinal Products**
Scientific guidelines: guidelines that are specifically related to herbal medicinal products:
 - Quality
 - Non-clinical
 - Clinical
 - Safety of herbal substances/products
5. **Establishing EU standards/ European monographs**
6. **Integration of Herbal Medicine into Evidence-Based Clinical Practice: Current Status and Issues**
7. **Registration requirements for a traditional herbal remedy**
 - Traditional use
 - Well established use
 - Stand alone or mixed application

<p>8. The simplified registration procedure</p> <p>9. Product information</p> <ul style="list-style-type: none"> • requirements for product information on medicinal products (i.e. labels and package leaflets) including herbal medicines and traditional herbal medicines • Indications for the use, Key constituents, Pharmacokinetics, Duration of use, Clinical efficacy, Indications, Dosages, Undesirable effectsContraindications, Special warnings and precautions for use, Interactions with other medicinal products and other forms of interactionfor some of the most prominent and widely marketed pharmaceutical plants <p>10. WHO guidelines for quality control of herbal formulation and standardization of herbal medicinal products</p> <p>11. Advertising of Herbal Medicinal Products</p>
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Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and e-books), access to additional videos and commercials related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies and other formative and summative assessments.

Assessment Methods:

Continuous Assessment (assignments), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
Herbal Medicine: Biomolecular and Clinical Aspects, Second Edition (Oxidative Stress and Disease) 2nd Edition	Iris F. F. Benzie and Sissy WachtelGalor	CRC Press/Taylor & Francis;	2011	

Rational Phytotherapy: A physician's guide to herbal medicine b[Springer; 5th edition]	Volker Schulz, Rudolf Hänsel, Mark Blumenthal, V. E. Tyler			
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