UNIVERSITY of NICOSIA

Course Syllabus

Course Code	Course Title	ECTS Credits
PHAR-624	Market Pricing and Reimbursement	10
Prerequisites	**Department**	**Semester**
None	Health Sciences	Fall
Type of Course	**Field**	**Language of Instruction**
Elective	Pharmacy	English
Level of Course	**Lecturer(s)**	**Year of Study**
2nd Cycle	Zampatis, Koulourou, Liaras	2nd
Mode of Delivery	**Work Placement**	**Corequisites**
e-learning	--	None

Course Objectives:

The success of a new innovative drug entering the market greatly relies on its price and whether it is reimbursed. While EMA can assess efficacy and safety reimbursement decisions are still a member state responsibility and respond to both clinical and economic criteria. Early consideration of reimbursement requirements is crucial in ensuring that the drug will be included in the reimbursement catalogue of national healthcare systems after marketing authorization has been granted.

Market pricing and reimbursement, in sum patient access to the new medicine or health care technologyis of strategic importance for every pharmaceutical company developing a new drug. While marketing authorization can be central, reimbursement is decided by each member state individually based on its laws, requirements, and demand. Due to the significance for its future success, pricing and reimbursement strategy may be devised as early as during planning of the pivotal clinical studies. Thus, following market authorization, national bodies evaluate the additional therapeutic benefit offered by innovative drugs relative to other new or existing treatments, and negotiate the price. The assessment aims at establishing whether a new drug is better than the established standard treatment with respect to efficacy and safety, information that is critical in deciding whether a drug can be reimbursable or not.

The objective of the course is to get a thorough understanding of the importance of pricing and reimbursement of drugs, the decision-making process and the stakeholders involved. The course aims to highlight the role of both regulatory affairs and patient access professional in this process.

Learning Outcomes:

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

- Critically evaluate the need and importance for pricing and reimbursement (patient or market access)
- Analyze the principles governing patient access in EU countries
- Apraise and value the pricing and reimbursement negotiations
- Evaluate and analyze the different methodologies utilized for demonstrating and communicating the value of a new medicinal product for the society, the health care system, the patient and the company.
- Compare and discuss different approaches in defining, measuring and appraising inputs and outcomes in the course of a health care technology evaluation

Course Content:

- Health care systems and archetypes of patient access pathways for access new medicines
- The role of the EU in shaping patient access to new medicines (regulatory and health care evaluation pathways
- Introduction to the concept, principles and use of health technology appraisal at EU and national levels both within and outside EU
- Overview of HTA methodologies
- Comparative approaches to value generation and value demonstration for new (medicines)
- Overview of data generation approaches for the establishment of new product value and health technology appraisal
- Comparative approaches for determining the prices of new drugs
- Comparative approaches in the reimbursement systems of new drugs
- Price and reimbursement of advanced therapeutic medicinal products / orphan medications in Europe
- European pharma legislation developments and their impact on patient access to new medicines

Learning Activities and Teaching Methods:

Teaching material including PowerPoint presentations with extended descriptions and explanations, asynchronous video presentations, additional readings (journal articles and ebooks), access to additional videos related to the course, synchronous meetings (WebEx), forums, chats, quizzes, case studies, wikis, and major assignments.

Assessment Methods:

Continuous Assessment (major assignments and weekly activities), Final Exam

Required Textbooks / Readings:

Title	Author(s)	Publisher	Year	ISBN
European Medicines Pricing and Reimbursement. Now and the	Martina Garau, Jorge Mestre-Ferrandiz, Michael Loh.	Taylor and Franscis	2016	9781315383064
Ensuring Access to medicines: how to redesign pricing, reimbursement and procurement. WHO Policy brief 30.	Sabine Vogler, Valeri Paris, Dimitra Panteli.	WHO	2018	ISSN 1997-8073
Exploring the consequences of greater price Transparency on the dynamics of pharmaceutical markets. OECD Health Working Papers No. 146, 2022	Eliana Barrenho, Ruth Lopert.	OECD	2022	