MSc programs in Health Technology Assessment and Pharmacoeconomics

FIRST SEMESTER

Subject: Introduction to Medicine

Thematic units for lectures and exercises

General medical knowledge & terminology

Oncology

Metabolic and endocrine diseases

Cardiovascular diseases

Gastrointestinal and respiratory diseases

Infections and vaccines

Psychiatric and neurological disorders

Respiratory diseases

Diseases of the excretory system

Diseases of the sense organs

Diseases of the musculoskeletal system

Basics of health promotion and preventive medicine

Methods for conducting clinical trials

Methods for conducting clinical trials

International Public Health Policy in the 21st Century.

Subject: Introduction to Social Sciences

Thematic units for lectures and exercises

What are social sciences?

Social Science Theory: Sociology, Psychology and Anthropology, Scientific Techniques and Fields

The intersection of health and social sciences

What is management as a social science?

What is health management?

Societies and associations related to social health sciences and public health

Reports of WHO, ISPOR etc. related to social sciences

Public health and social sciences

Research in the social sciences? An interdisciplinary research process

Research Methods (Appendix and Discussion)

Ethics, Bioethics and Research Ethics (Theory and Concept)

Documenting the social health sciences (discussion)

Future of social and interdisciplinary sciences

Application (Visit to a social equal association)

Written task

Subject: Introduction to health economics and pharmacoeconomics

Thematic units for lectures and exercises

General concepts in HE

Concepts used in HE and PhEcon.

Market and healthcare

Health care financing

Health equality

Demand driven by supply.

Streamlining and setting priorities in healthcare

Age as a factor in health care prioritization

Theoretical foundations of PhEcon

Types of PhEcon studies

Measuring quality of life in health care

Role and nature of HTA

Subject: Pharmaceutical system and market access

Thematic units for lectures and exercises

Structure of the pharmaceutical system, national and international organizations. National drug policy - concept and development. Evidence from real practice to include in the manuals.

Research policy and development of new drugs, GCP requirements

Legislative requirements for pharmaceutical production, GMP requirements

Legislative requirements for TE with drugs, GDP requirements

Legislative requirements to the retail trade of medicines, GDP and GPP requirements

Marketing of medicines in Europe and worldwide. Classification of drugs. Market access routes in Europe.

Medication use, measurement and evaluation

Pharmaceutical market and market access. Market structure and main players.

Patients and their medications, consent and adherence to therapy. Patient-reported outcomes of therapy.

Pharmaceutical information and promotion. Value Dossiers.

Development of a strategy for the access of a new drug to the market. Strategic drug pricing. Price referencing, pricing strategies.

Pharmacovigilance and safety.

Measurement, monitoring and evaluation of drug policy outcomes in the pharmaceutical sector. Access agreements: main objectives and essential elements.

Simulation of MEAs: based on health systems; financial based on therapeutic outcome.

Essay presentation and semester exam

Discipline: Quantitative analysis in PharmEcon

Thematic units for lectures and exercises

Introduction to translational medicine, clinical trials, and product development in the pharma, biotech, and medical device industries.

An introduction to the ethical, legislative and regulatory aspects of clinical requirements, product development and the evaluation of new technologies.

Scientific research, hypothesis testing; types of error and concept of statistical power.

Descriptive and analytical - epidemiological studies and measures for their evaluation (frequency, morbidity and morbidity).

The design of clinical trials - protocol.

Epidemiology and biostatistics in health studies (1) – descriptive methods; MCQ/Q&A 4

Epidemiology and biostatistics in health research ((2) – inferential methods; MCQ/Q&A 5

Health Technology Development: Translational Medicine, Clinical Trials, Legislation, OST in Reimbursement

Review of primary and secondary evidence used in legislation, health policy and OH&S. Overview of the OST process.

An overview of the process in EMEA, NICE, clinical trial ethics panels, NICE committees and public utility assessment.

Epidemiology/Biostat design of primary evidence 1 – descriptive: characteristics, application, strengths and limitations. MCQs/Q&As

Epidemiology/Biostat design of primary evidence 2 - impact: characteristics, application, strengths and limitations.

Epidemiology/Biostat Design of Primary Evidence 1 – Statistical Testing and Confidence Interval: Characteristics, Application in OST, Strengths and Limitations

Biostat – analysis of primary evidence 2 – statistical power and its calculation; superiority, equivalence and non-superiority studies; selecting outcome details, KEY outcomes and minimal important difference (MID) for patients

Introduction to Clinical Trial Data Collection

An introduction to the key biostatistical components of the statistical analysis of clinical trials (SAP); Clinical Study Report (CSR); registration of the study; statistical reporting (SAMPL) review by reviewers and published

Seminar - modern issues of HTA

Biostat Primary Analysis of Evidence 3 – Effect Size Measurement: Characteristics, Application in OST, Positives and Limitations

Biostat primary evidence analysis 4 – regression characteristics, application in OST, strengths and limitations

Epidemiology/Biostatistics Primary Evidence Analysis 5 – Regression: Linear; logistic methods

Epidemiology/Biostatistical primary analysis of evidence 6 – survival/time to event: Kaplan-Meier analysis; survival patterns

Multidisciplinary team in HTA – role of statistics and evidence synthesis methodology

Introduction to the Role of the Scientific Advisory Board for Regulatory Approval and Reimbursement

New methods in biostatistics

Biostat 'clinic' (appropriate support) - practice/training

Characteristics of the quality of evidence in HTA

Introduction to reporting standards: CONSORT (RCT), PRISMA (Reviews), STROBE (Observational in epidemiology); AGREE (Guidelines)

Selection, use and reporting of quality assessment tools

Biostat 1-way evidence analysis 7 – long-term survival/time-to-event analysis: characteristics, application of OST, strengths and limitations

Biostat - 2-armed evidence analysis - meta analysis: characteristics, application in HTA, positive sides and limitations

Introduction to practical assignment/formative exercise

Practice/formative assessment – 'developing evidence for HTA agency'

Practice/formative assessment – presentation of a file to the HTA assessment committee

An introduction to evidence-based biostatistics

Subject: Health technologies and principles of OT

Thematic units for lectures and exercises

Definitions, types and classification of health technologies

Components of HTA

HTA cycle

Critical appraisal of studies

Application of HTA according to the specific context

A systematic review and meta-analysis

Economic evaluation

Making a decision

HTA for medicines.

HTA and non-pharmaceutical technologies.

Legislative, social and ethical aspects of HTA.

Dissemination and presentation of HTA results.

MCDA, barriers to HTA, quality of care and HTA.

Underutilized technologies and HTA,

Agreements on access and HTA, innovation and HTA.

Subject: Evidence synthesis in health care

Thematic units for lectures and exercises

Lecture-introduction to the module, list of literature and library materials, IT systems

Lecture-introduction to the implementation of a systematic review of the literature; presentation of the main guide: 'Doing a systematic review: a student's guide'

Introductory lecture on quality assessment Chapter 4 of 'Doing a systematic review: a student's guide', (online reviews presented by the authors)

Questions and answers about conducting a systematic literature review.

Lecture-introduction to data extraction chapter 5 of 'Doing a systematic review: a student's guide',

(online reviews provided by the authors)

Lecture-introduction to understanding and synthesizing data chapter 6 'Doing a systematic review: a student's guide', (online reviews presented by the authors)

Q&A (for quality assessment and data extraction)

An introductory lecture to frame the discussion and conclusions sections Chapter 7 of 'Doing a systematic review: a student's guide', (online reviews presented by the authors)

Application of the synthesis of evidence (example with the experience of the teaching institution) General presentation of the systematic review process;

Presenting and updating systematic reviews;

Questions and answers (about the systematic review application and reporting)

Errors in analysis of clinical trial data; Data abstraction; Assessing the quality of systematic reviews

Abstract/Questions and answers - formative assessment

Meta-analysis – review, application, results

Structure and Methods ('Anatomy and Physiology') of the Cochrane Review

Structure and methods of evidence submitted for NICE technology assessment

Seminar - review of conditions in LDCs and the humanitarian sector (EvidenceAid)

Systems review: RevMan/Coevidence/EPPI-Reviewer/Microsoft Access - practical exercise

Feedback and discussion of the practical session (week 4)

Seminar - modern problems in OST (invited national experts)

MA Models - Fixed Effect Analysis; Random effect analysis;

Heterogeneity; Planned subgroup analysis; review/statistical systems/ 'clinical' software - practical exercise

Research results – regression, variance, subgroup analysis; meta regression – a practical exercise.

Complex methods in ES (1): Introduction to survival analysis (Time-to-event (survival) analysis); individual patient data; indirect treatment comparison and network meta-analysis; practical task/ongoing assessment

Complex methods in ES (2): practical exercises for analysis of survival (Time-to-event (survival) analysis); individual patient data; indirect treatment comparison and network meta-analysis; practical task/ ongoing assessment

Practical exercise/ ongoing assessment - 'from literature to practice - planning and implementing data abstraction and analysis; Summary of available evidence (evidence statements)

Experience with systematic reviews and international/national reimbursement systems; complex methods IPD, NMA and complex methods in public health care; Introductory summative assessment; Introduction to course evaluation

Seminar/Instructions for preparation of individual tasks

Completion of the individual assignment

Submission of the prepared assignments (a. Meta-analysis based on reports of studies submitted as a RevMan file, b. Report of the results of an analysis of the evidence using evidence statements); c. Assessing the quality of a systematic review that includes a meta-analysis)

SECOND SEMESTER

Subject: HTA and Pharmacoeconomics in practice for different health systems

Thematic units for lectures and exercises

An introduction to HTA and pharmacoeconomics using the UK as a prime example for national and regional decision-making

An introduction to HTA and Pharmacoeconomics in Germany and France

An introduction to HTA and pharmacoeconomics in the Scandinavian countries (Norway and Sweden)

An introduction to HTA and pharmacoeconomics in other countries with public health systems, e.g. Canada, Australia and New Zealand

An introduction to HTA and Pharmacoeconomics in the United States

An introduction to HTA and pharmacoeconomics in various countries of Central and Eastern Europe

EUnetHTA project. EUnetHTA model, cooperation activities in Europe.

Comparative analysis of the OST and pharmacoeconomics systems in the countries of Central and Eastern Europe and other countries

Application of OST and pharmacoeconomics in the process of pricing and reimbursement of new drugs in Central and Eastern Europe

Solving real-world cases in pricing and reimbursement: a review of different examples

Input agreements as an approach to implementing OST analysis.

Development of new models based on OST to optimize agreements for access to new medicines, including the application of the so-called adaptive pathways for new drugs

Supporting the reimbursement process of new orphan drugs and oncology drugs through OST, including the implementation of a potential multi-criteria approach (MCDA) in the countries of Central and Eastern Europe

Overcoming inequality in access to biological and other medicines between Central and Eastern European countries and Western European countries through different OH&S approaches. Generic and biosimilar drugs

Homework the cold ones.

Seminar on coated material and its application

A highly interactive week where students will participate in discussions where they will advocate for the future implementation of OST in their own countries using ISPOR good practices for research and evaluation.

Subject: Health economics and Pharmacoeconomics

Thematic units for lectures and exercises

Introduction, analytical framework and methodologies

Health economic and financial analysis

Cost-Minimum Analysis (CMA)

Cost-Effectiveness Analysis (CEA)

Cost-utility analysis (CUA)

Cost-Benefit Analysis (CBA)

Budget Impact Analysis (BIA)

Methodologies for measuring quality of life and preference-based assessments

DALY methodologies and measurement of the burden of diseases

Discrete event simulation

Patient compliance, persistence and consent to therapy

Measurement of NNT indicators; NND; NNH

Measurement of survival

Presentations on the topic of critical evaluation of literary data

Presentations on the topic of critical evaluation of literary data

Subject: Modeling – economic and pharmacoepidemiological models

Thematic units for lectures and exercises

Introduction, a framework for modeling in healthcare

Models of decision making

Markov models 1

Transition probabilities and decision making

Markov models 2

Models of budget impact

Development of the models

Model validation

Cost-benefit analysis and investments in health care

Model of investment in dental care

Strategic pricing in healthcare

Decision support models for the pharmaceutical industry, application in pricing decisions

Making a decision to develop a new product

Stochastic sensitivity analysis

PSA concept, PSA parameters

Value of information analysis

Surrogate outcomes in economic models

Modeling colorectal cancer screening

Modeling individual patient decisions (Simul8)

The interpretation of the simulation result

Development of a conceptual model

Disease modeling

Modeling the long-term outcomes of diabetes

Introduction to Diabetes Modeling Issues

Syreon Diabetes Model

Presentation, summary, closing remarks

Subject: Statistics and eHealth

Thematic units for lectures and exercises

An introduction to health informatics as a dynamic equilibrium

Methods 1 – Lightweight System Methods (SSM)

Methods 2 – change management

Method 3 MULTIVIEW

Information technology 1

Information technology 2

Information Management 1

Information management 2

Formative Presentations

Legislative management of information 1

Legislative control of information 2 GDPR: The future of data protection in EUROPE

Synthesis 1 – The English National IT Program as a case study

Synthesis 2 – Balancing the information equilibrium

Synthesis 3 - Scanning the Horizon - Future of Health Informatics

Synthesis 4 - feedback and discussion

THIRD SEMESTER

Subject: Health Management (Elective)

Thematic units for lectures and exercises

Health Needs Assessment - An Introduction to Financial, Information, Administrative and Human Resource Management

Leadership - students learn about how healthcare leaders and managers gather data for the purposes of improving strategies and implementing corrective actions to improve outcomes and delivery of healthcare services

Organizational Behavior - Students are introduced to the fundamentals of organizational behavior through motivational theory, reward systems, dynamic teamwork, and group problem solving.

Marketing of healthcare organizations - introducing students to marketing concepts in healthcare. Participants learn to understand the healthcare market and consumer behavior

Quality management and patient safety - students learn to apply quality indicators to improve the health care system.

Intermediate exam (colloquium)

Health Financing - Provides participants with the necessary knowledge about the various models of financing in health care, incl. state funding, mandatory and voluntary health insurance.

Principles of Leadership and Ethical Boundaries in Health Care - Studying the foundations of effective leadership in the complex settings of the health care system. Topics covered are skills and qualities of a successful leader, strategic planning, and ethics.

Management of public health units - students learn the essential skills of managing an organization, as in public health the roles of manager and decision-maker and policy-maker are performed by the same individuals.

Health Professional Leadership - learning the practical skills required to develop an effective leader in the face of challenges facing any health care system. Students gain insight into the impact of leadership on others and gain a deeper understanding of how leadership impacts health care performance.

Teamwork - students learn how to create better working relationships and how to improve communication between team members.

Healthcare consulting organizations - training future healthcare consultants and training in how to create and implement policies and procedures to achieve organizational goals and maximize results.

Change and Innovation in the Healthcare Sector - students learn how to evaluate and create business models based on entrepreneurial activities in healthcare and the factors that shape ventures in the healthcare sector.

Presentation of an individual assignment and shaping of the final grade

Subject: Health Technology Regulation (Elective)

Thematic units for lectures and exercises

The key differences between legislation in the health sector; European legislation in the pharmaceutical sector - basic provisions; European legislation versus national legislation in the field of health technology; ethical considerations in the pharmaceutical sector

The conditions for conducting clinical trials with medicinal products

Conditions and procedures for the authorization of medicinal products in Europe; Responsible institutions; obligations of the Marketing Authorization Holder (MAH); life cycle of medicinal products; monitoring of drug safety; counterfeit medicines

Generic drugs, patent law; drug distribution (wholesale, pharmacists, parallel trade, direct delivery, online pharmacies); product information; drug advertising

European health legislation and its impact on local rules and requirements for pricing and reimbursement in the respective countries; principles of HTA and relevant market strategies of PRU; Reference pricing of medicinal products; risk sharing schemes

The role of OST in the process of implementing the transparency directive; relevant experience of the countries of Central and Eastern Europe; international comparison of HTA implementation at national level

The role of the new European regulations in the field of medical devices and its impact on the market of medical devices; HTA of medical devices

Impact of EU legislation on public procurement procedures for the purchase of consumables in hospitals; administration of HTA in hospital settings

Innovative strategies in HTA; specific features of medicines for rare diseases – access to the market, reimbursement; European Medicines Agency (EMA); adaptive pathways to improve the access of medicines to the market (Adaptive pathways); EMA support for the development of new medicines to meet unmet medical needs (PRIME: priority medicines).

European post-registration requirements for pharmaceutical technologies and medical devices

WHO and essential medicines; US Food and Drug Administration (FDA) health technology regulations

Sources of information on health systems regulations; literature review of differences in differences in health care regulations; examples of health technology delivery in health care systems

Examples of drug and HTA pricing and reimbursement decisions, decisions on hospital tendering, specific HTA issues

Completion of the course; summary of student projects

Subject: Health and Pharmaceutical Diplomacy (Elective)

Thematic units for lectures and exercises

Global Health Diplomacy, Development and History

Introduces students to healthcare marketing concepts. Getting to know the market features and consumer behavior in the health services market.

Participants and stakeholders

How the different participants in the global health services market interact and cooperate, how dialogue and negotiation is established between the individual participants and stakeholders.

Health care development negotiations - complex multilateral bargaining

Participants learn how to analyze case studies and negotiate processes at national, regional and global levels.

Health security from a global perspective

Provides awareness of global health security threats and ongoing initiatives such as the Global Health Security Agenda. Participants learn how trends in other sectors can affect health security and gain skills for dealing with a health crisis.

Global Epidemiology

Participants are prepared to understand the application of epidemiological methods to determine risk factors and disease prevalence.

Complex negotiation

Students learn how to deal with critical situations in order to achieve satisfactory results by using the mechanisms of negotiation, mediation and dispute resolution