European Market Access University Diploma (EMAUD) 2018-2019

*A **unique** and **innovative** course*

Emaud, is run by Academic Institute for Pharmaceutical Sciences (AIPS), The educational arm of Market Access Society (MAS)

The programme follows each step of the life cycle of a drug, integrating market access theory and practice for results that can be applied in the real world. Students will acquire the necessary skills to implement and develop a market access plan.

www.emaud.org

www.marketaccesssociety.org

Market Access Society

AT A GLANCE

Five modules mixing theory and practice

- Module 1: Market Access Environment
- Module 2: Market Access Activities in Early Preparation Phase I/II
- Module 3: Market Access Activities in Phase III/Pre Launch
- Module 3bis: Health Economics and Outcome Research (optional)
- Module 4: Market Access Activities in Launch/Post Launch/LCM
- Module 5: Market Access for Vaccines, Medical Devices and Diagnostics

Workshops

Case studies

Pre-reading material

First rate contributors

- Leading contributors coming from the academic world, pricing and HTA agencies, industry organisations.

Access to the Annual Market Access Day

- An international conference to get high level information on latest national regulations and future challenges with respect to economic constraints or payers requirements. A debate that cannot be missed.

Getting the EMAUD diploma

- 2 short professional theses to do:
  - A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study; and
  - A publication that should be submitted to pubmex indexed a scientific journal. If needed,

  support will be provided to students who have little experience in writing a publication.

Training Overview

Module 1 – 28h

Market Access Environment

Objective

- Set the scene: health environment, health policies, market access regulations in a broad range of countries. Countries specific policies will be presented by Public Agencies representatives.

Activities

- Introduction to the concept of market access
- Why has market access emerged? Decision-making chain
    - National stakeholders
    - Regional stakeholders
    - Local stakeholders
    - Market access strategies
        - Adapting the strategy for each market access stakeholder
- Market access policies in Europe
- Market access policies outside Europe (USA, Canada, Australia, Japan and New-Zealand) Market access perspectives and drug development
    - Key activities, outputs and benefits from Phase I to LCM: when to do what?

Workshop & Case study

Programme

Module 2 – 28h
Market Access Activities in Early Preparation Phase I/II

Objectives

- Market Acces Landscape, and strategy
- Gap Analysis and activity prioritization
- Market access planning, budgeting and execution
- Support to Development decision making
- Drivers and barriersfor acces
- Incorporate Market Access Issues in clinical development (P&R, HTA and Market Access Plan)

Activities

- Landscape analysis
    - Desk Research
        - Disease understanding
        - Mapping
        - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment, pricing)
- Pricing
    - Payer research
    - Price anchoring studies
    - Reimbursability evaluation

- Market Access Agreement
- Early HTA advices
- Value story development and gap analysis

Workshop & Case study

Programme

Module 3 – 28h
Market Access Activities in Phase III/Pre Launch

Objectives

- Monitor Changes
- Advocacy
- Managing uncertainty
- Pricing studies
- Market access focus on specific products

Activities

- Pricing
    - P&R environment
    - Price sensitivity
    - Payer research
    - External reference pricing
    - Pricing sequence
    - Price strategy
    - P&R risk evaluation
- Building an effective advocacy strategy to support market access
- Market access specificities in emerging countries
- Market access of specific products
    - Orphan drugs
    - Oncology products
    - Cell therapies
    - Mature products
    - Value added medicine
    - Combined products (fix combination and device drugs combination)
    - Biosimilars

Workshop & Case study

Programme

Module 3bis – 18h (optional)
Health economics and outcome research

Objectives

- Understand the concept of HEOR and realize basic exercise including:
  - Develop specification of a model
  - develop a model,
  - develop an utility instrument,
  - develop a protocol for micro-costing
  - Critical review of a model
- The morning lecture are theory and the afternoon is dedicated to practical exercise

Activities

- Health Economics and Outcome Research
  - Conceptual Model
  - PRO development
  - COI studies
  - Ballpark Modelling/Value Based Pricing
  - Early cost-effectiveness evaluation
  - Different types of models

Programme

Module 4 – 28h
Market Access Activities in Launch/Post Launch/LCM

Objectives

- Achieve P&R, HTA recommendation and Formulary inclusion at optimal prices/restrictions

Activities

- Pricing
- Launch
    - Negotiation guide
    - Core Value Dossier, and adaptation CVD to local needs
    - Strategic advice
- Life Cycle
    - Price database; Coordination sequence; Price Erosion
    - HEOR/Epidemiology
        - Launch
            - FDA/EMEA PRO submission dossier
            - Publication HEOR evidence (Cost-effectiveness, comparative effectiveness, clinical relevance, Phase III HEOR results)
            - Standard HTA dossier
            - Local Adaptation (Cost-effectiveness and local HTA Dossier)
            - HE studies
            - Post-hoc analyses
            - Publications
        - Life Cycle
            - IITs; Observational studies to demonstrate real life effectiveness (cohort, databases); Scientific Lobbying; Anticipate re-evaluation and update HTA dossier; Monitor New entrants/Environment
- Affiliates Responsibilities
    - Alert local issues/Policy management
    - Scientific stakeholder management & patient advocacy
    - Local studies
    - Adaptation, Submission and Negotiations
    - Communication/ Management of HTA decisions

Programme

Workshop & Case study

Module 5 – 28h

Market Access for Vaccines, Medical Devices and Diagnostics

Objectives

- Understand the specificities of Market Access for Vaccines, Medical Devices and Diagnostics.

Activities

- Overview of the market and strategy
- Mapping of the access process in Europe and outside Europe
- Definition, regulation, classification, certification
- HTA and NITAG
- Vaccines in emerging countries: a worldwide paradigm
- Specificities for health economics assessment and value demonstration
- Dealing with innovation and future challenges
- Toward a value based pricing for diagnostics and medical devices

Workshop & Case study

Programme

Why a course of Market Access?

Market Access is a complex process. It is the fourth hurdle in drug development and is today an inescapable reality. It has become the driver of the global income of a new product/drug. No company providing drugs or devices can expect to succeed without designing a pricing and reimbursement strategy early in the development process. The concept of Market Access requires as much knowledge as professional capabilities. It is situated at a crossroads of multiple disciplines that all form an integral part of a valid comprehensive course. The course, exclusively taught in English, is a pioneer degree in the field of Market Access. Speakers and contributors come from institutional organizations, the academic world and the healthcare industry. Their presentations will cover Market Access Policies, Pricing in Europe and outside Europe, Health Economics, Health Technology Assessment (HTA) and Risk Management and Decision Sciences.

What is the objective of the course?

- Get an advanced understanding of the Market Access environment and principles
- Focus on the latest regulations and guidelines in Europe and outside Europe
- Draw a mapping of new actors : how they become inescapable decision makers
- Give techniques and tools to implement in their business
- Develop knowledge in decision sciences
- Allow contacts with experts from different organizations, public or private, who are main actors in the health industry and who deal with the issues everyday
- Deliver the best practices of leading companies

Key Learning

- Set up a successful pricing and market strategy
- Develop, validate and execute a market access plan
- Build value story to optimize market access
- Understand strengths and pitfalls of available evidence
- Design a pricing research
- Define a pricing strategy
- Anticipate the future paradigm changes in market access

Who should attend?

EMAUD is intended for students and professionals in the fields of life science and healthcare industries including policy decision makers.

Contributors

European HTA and pricing agencies, non-governmental agencies, industry representatives and academics.

ACADEMIC INSTITUTIONS

University of Aix-Marseille, France
Prof. Mondher TOUMI
Prof. Pascal AUQUIER
University of Lyon 1, France
Prof. Michel LAMURE
Tufts Center for the Study of Drug Development, USA
Prof. Joshua COHEN
Health Economics Institute, Sweden
Prof. Ulf PERSSON
University of Bocconi, Italy
Prof. Claudio JOMMI
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University of Aberdeen, Scotland
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Catholic University of Sacred Heart Rome
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University of Tokyo, Japan
Dr. Ataru IGARASHI

GOVERNMENTAL INSTITUTIONS

HAS, France
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Tech2Market, France
Mr. Mathieu CYNOBER
European MS Platform, Belgium
Mr. Christoph THALHEIM
Medicines Development and Training service, France

Regular lecturers

PHARMACEUTICAL INDUSTRY

Lundbeck
Dr. Susana MURTEIRA (Japan)
Mr. Clément FRANCOIS (USA)
Dr. Patrice VERPILLAT (France)
Mrs. Dominique MILEA (Singapore)
Amgen, France
Dr. Chantal GUILHAUME
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Mrs. Sibilia QUILICI
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Novartis, Switzerland
Mr. Patrick MOLLON
Astellas Pharma, UK
Dr. Isaac ODEYEMI
Synovate, UK
Mr. Chris KING
Ipsen, France
Mrs. Gabrielle NAYROLES
Dr. Simon SHOHET
Eucomed, Belgium
Mr. Merlin RIETSCHEL
Abbott, Switzerland
Mrs. Kelly WONG
TEVA, The Netherlands
Mr. Adam PLICH
Air Liquide, France
Mrs. Patricia ALEGRE

Regular lecturers

A 5-module-course to be taken in 1 to 3 years – in Paris, France

The course is composed of 5 modules of 5 consecutive days and 1 HEOR optional module scheduled during the year. Each module counts for 28 hours, which represents a total of 140 hours for the complete course. The 5 modules can be done separately not necessarily in only one year and not in any specific order (for example module 1 & 3 the first year, module 2 the second year, and module 4 & 5 the third year). The course is validated after the submission of two professional theses:

- A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study; and
- A publication that should be submitted* to a scientific journal. If needed, support will be provided to students who have little experience in writing a publication.
  **The submission will be sufficient to qualify for the diploma.*

A course exclusively given in English

Speakers and contributors come from **institutional organizations**, the **academic world** and the **healthcare industry** of Europe and outside Europe.

To apply

Please send CV and a cover letter to: application@emaud.eu
Your application will be reviewed by a reading committee, and within two weeks we will give you the committee's decision. If accepted, you will then receive your university registration file.

Contact

- **Chairman**
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