2023/ 2024



Become a market access specialist!

EMAUD's program integrates market access theory and practice throughout each step of a drug's life cycle and allows for real-world application. Students acquire the necessary skills to develop and implement strategic market access plans.



2023/2024 **EMAUD**

date

2023/2024

programme

5 modules, combining theory and practice:

Module 1:

Market Access Environment and Policy

Module 2:

Market Access Activities in Early Preparation Phase I/II

Module 3:

Market Access Activities in Phase III/Pre-Launch

Module 4:

Market Access Activities in Launch/Post Launch/LCM

Module 4bis:

Health Economics and Outcome Research (optional)

Module 5:

Market Access for Vaccines, Medical Devices and Diagnostics

time

5 x week + 3 days

Interactive Modules consist of:

- Pre-reading and preparation materials
 - Group workshops
 - Case studies

First rate contributors and lecturers:

Leading contributors join us from the academic world, pricing and HTA agencies, and industry organizations

Access to Annual Market Access Day:

Students are able to access and experience an international conference centered around the latest national regulations and future challenges with respect to economic constraints and/or payers' requirements.

Your own diploma

In order to successfully complete the degree program, a project is required: a research work (thesis).

The main objective of the thesis is to demonstrate your ability to ask and answer a relevant question and reflect upon the various stages of the process. Your thesis can cover one or several of the following topics:

- Literature review conducted according to state of art
- Review of HTA or pricing decisions
- · Landscape analysis
 - Case Study
 - Health economics project
 - Pharmaco-epidemiology project
 - Pricing research
 - Market Access Strategy
 - Market Access perspectives and drug development
 - Etc.

The thesis should be in English and should not exceed 50 pages or a maximum of 50 PowerPoint slides. It could be done jointly with up to 3 candidates maximum.

For sensitive case studies, we exert full confidentiality, ensuring that the thesis is not available to any third party and stored safely. A confidentiality agreement will be signed.

On successful completion of your course and positive evaluation of your research work, you will receive a diploma delivered by MAS. We do not deliver grade but positive or negative decision.



topic

Market Access Environment and Policy

date

16.10.2023/20.10.2023

programme of Module One:

Objective:

 Set the scene: health environment, health policies, market access regulations across a broad range of countries. Country-specific policies are presented by Public Agency Representatives.

Activities:

- Introduction to market access definition, concept, and principles
 - National stakeholders
 - Regional stakeholders
 - Local stakeholders
 - •Why has market access emerged? Decision-making
 - Market access strategies
 - *Adapting the strategy for each market access stakeholder
- Market access policies in Europe
- Market access policies outside Europe (USA, Canada, Japan, China, Middle East and North Africa)

Workshop & Case study

time

topic

Market Access Activities in Early Preparation Phase I/II

date

11.12.2023/15.12.2023

programme of Module Two:

Objective:

- · Readiness for Market Access activity in Early Stage
- Market Access landscape and strategy
- · Gap Analysis and activity prioritization
- · Market access planning, budgeting, and execution
- Support to development decision making
- Drivers and barriers of market access
- 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
 - Payer research
 - Price anchoring studies
 - Reimbursement evaluation
- Market Access Agreements
- Early HTA advice
- Value story development and Gap Analysis

Workshop & Case study

time

topic

Market Access Activities in Phase III/Pre-Launch

date

05.02.2024/09.02.2024

programme of Module Three:

Objective:

- · Readiness for Market Access activity in Pre-Launch
- 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

time

topic

Market Access Activities in Launch/Post-Launch/LCM

date

08.04.2024/12.04.2024

programme of Module Four:

Objective:

- Readiness for Market Access activity in Launch and Post-Launch
- Achieve P&R, HTA recommendations, and formulary inclusion at optimal prices/restrictions

Activities:

- Final Pricing Strategy
- Launch
 - Negotiation guide
 - Core Value Dossier
 - Adaptation Core Value Dossier to Local Needs
 - Strategic advice
- Negotiation Skills and Strategy
- 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; real life effectiveness
 - Scientific Lobbying

PROGRAMME

- Anticipate re-evaluation and update
- HTA dossier
- Monitor New entrants/Environment
- Interaction affiliates Region and corporate functions
- for successful market access

Workshop & Case study

time

MODULE 4bis

topic

Health Economics and Outcome Research

date

20.05.2024/23.05.2024 (optional)

programme of Module Four bis:

Objective:

- Understand the basis of Health Economics and Outcome Research
- Understand the concepts of HEOR and execute basic exercises including:
 - Develop specification of a model
 - Develop a model
 - Develop a utility instrument
 - Develop a protocol for micro-costing
 - Critical review of a model
- Morning lectures are centered around theory, while the afternoon session is dedicated to practical exercises

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

time

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Market Access for Vaccines, Medical Devices, and Diagnostics

date

17.06.2024/21.06.2024

programme of Module Five:

Objective:

- Market Access for non-drug interaction
- 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
- Innovation and future challenges
- Value-based pricing for diagnostics and devices

Workshop & Case study

time



Why a diploma in Market Access?

Market Access is a complex process. Today, it is the fourth hurdle in drug development and 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 EMAUD 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, Risk Management, and Decision Sciences.

What is the objective of the EMAUD diploma?

Gain an advanced understanding of the market access environment and principles
Focus on the latest regulations and guidelines in Europe and outside Europe
Draw a map of new actors: how they are becoming inescapable decision makers
Obtain techniques and tools to implement in students' real-world business
Develop knowledge in decision sciences
Facilitate collaboration and contacts with experts from different organizations, public or

Facilitate collaboration and contacts with experts from different organizations, public or private, who are main actors in the health industry and who confront these issues everyday Deliver the best practices of leading companies

Who should attend EMAUD?

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

Key Learnings:

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

Contributors:

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

REGULAR LECTURERS

ACADEMIC INSTITUTIONS

University of Aix-Marseille, France

Prof. Mondher Toumi

Corvinus University of Budapest, Hungary

David Danko, Associate Professor

University of Tokyo, Japan

Ataru Igarashi, Associate Professor

The Swedish Institute for Health Economics

(IHE), Sweden

Prof. Ulf Person

Tufts Medical Center Institute for Clinical Research and Health Policy Studies, Boston,

United States

Joshua Cohen, Associate Professor James Chambers, Associate Professor

University of Eastern Piedmont, Italy

Prof. Claudio Jommi

University of Bocconi, Italy

Prof. Monica Otto

Tsinghua University-Hospital Management

Institute

Prof. Vivian Chen

CONSULTANCY

Aurelie Miller, PhD

Emilie Clay, PhD

Samuel Aballea, PhD

Krzysztof Kloc

Beata Smela

Anna Kapuśniak

Piotr Wojciechowski

Michał Pochopień, PhD

Patrycja Jaros

Clement François, PhD

Cecile Remuzat, PhD

Elaine Julian

Oleg Borisenko, PhD

GOVERNMENTAL INSTITUTIONS

Catalan Health and Social Care Consortium, Spain

Prof. Antoni Gilabert

Instance Nationale de l'Évaluation et de l'accrédiation en Santé (INEAS)

Mouna Jameleddine

Scottish Medicines Consortium (SMC),

Scotland

Keith Tolley, PhD

European Organisation for Rare Diseases

(Eurodis)

François Houyez

The Federal Joint Committee (G-BA)

Meriem Bouslouk - Marx, PhD

Prof. Juergen Wasem

Fundació HITT - Health Innovation

Technology Transfer

Oriol Solà - Morales, PhD

REGULAR LECTURERS

PHARMACEUTICAL INDUSTRY

Kagan Atikeler, PhD
Phillippe Larame, PhD
Isaac Odeyemi, PhD
Zalmai Hakimi
Jean Baptiste Biere
Omar Dabbous
Sandrine Ruiz
Natasa Zibelnik
Gaël Le Rouzo
Tomas Matthews
Ekkehard Beck



A 5-module course completed in 1-3 years

The course is composed of 5 modules, each module runs for 5 consecutive days, with 1 HEOR optional module. Each module accounts for 28 hours, representing a total of 140 hours for the completion of the course. The 5 modules can be done separately and not necessarily in one year nor in any specific order (for example students may attend module 1 & 3 the first year, module 2 the second year, and module 4 & 5 during the third year).

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: administration@emaud.eu

Your application will be reviewed by a reading committee, and within 2 weeks you will receive a decision reached by the committee. If accepted, you will then receive your university registration

Contact

Chairman

Prof. Mondher Toumi, mondher.toumi@emaud.eu

Administrative Support

Magdalena Małek, administration@emaud.eu

Scientific Support

Emilia Strycharz-Angrecka, emilia.strycharz-angrecka@emaud.eu