Course Name: Market Access for Technologies in Healthcare
Instructor: Prof. Mondher Toumi, Aix-Marseille University (France)
Credits: 3 (39 academic hours)
Level: Graduate level

Summary and Objective:
The market access workshop aims at providing the student with the background knowledge to:

- Get an overview of the history, specific vocabulary, concept and definition commonly used in market access for technologies in healthcare.
- Understand the market access policies in different countries.
- Apply the various concepts to develop a market access strategy.
- Be able to have a critical assessment of a market access strategy.

Topics to be covered:

1. Market Access: concept, definitions
   - Where does market access come from?
   - Tariff and non-tariff measures
   - Market access definition
   - Value definition
   - Value based pricing
   - Market access international comparison:
     - Market access strategies
     - National stakeholders
     - Regional stakeholders
     - Local stakeholders
2. Market Access policy in selected countries

- Australia
- Canada
- France
- Germany
- Italy
- Japan
- Poland
- Spain
- Sweden
- UK
- US

3. HTA and Payers risk management vs Regulators

- Difference between payers and regulators
- Uncertainty
- How to address payers’ uncertainties?
- Managed entry agreement MEA
  - Terminology
  - Why doing MEA?
  - Case studies

4. Early entry

- Early access tools
- Adaptive pathways
- Conditional marketing authorisation
- Accelerated assessment
- Compassionate use
- Breakthrough therapy designation
- Fast track

5. External reference pricing

- Definition
- Which countries apply ERP?
6. **HTA scientific advice**
   - Market Access Activities in Early Preparation Phase I/II
   - Advantages of Early definition of product value
   - Possibility of early scientific advice in many countries
   - Questions to be addressed

7. **Market Access Landscaping**
   - Disease Environment/Management
   - Desk Research
   - Mapping
   - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment)
   - Observational Studies (cohort, database)

8. **Pricing research studies**
   - Type of studies
   - Price database; Coordination sequence; Price Erosion
   - Strategic advice
   - Life Cycle

9. **Payers value proposition**
   - Steps from approval to success
   - What is value?
   - Dimensions of improvement vs comparator
   - Clinical trial value assessment
   - Core Value Dossier, and adaptation CVD to local needs
   - Adaptation, Submission and Negotiations
   - FDA/EMEA PRO submission dossier

10. **Real world evidence (RWE) for payers**
    - Definition
    - Importance of RWE
    - Transferability and generalizability
    - Case studies of RWE in different countries
3 workshops & case studies
- Building a Market access strategy for a new product
- Preparation for Early dialogues
- Alzheimer case study

Pre-reading materials:

EMA-HTA workshop Bringing together stakeholders for early dialogue in medicines development:

Introduction to Health Technology Assessment:

Pharmaceutical pricing: the use of external reference pricing:
http://www.rand.org/content/dam/rand/pubs/research_reports/RR200/RR240/RAND_RR240.pdf

Access to new medicines in Europe:

A comparison of HAS & NICE guidelines for the economic evaluation of health technologies in the context of their respective national health care systems and cultural environments


HTA-EMA scientific advice, TOPRA presentation

**Workshop Evaluation:**

Active participation in class discussions (10%). Class participation is required in all workshop’s days.

At the end of the workshop, students will have to answer a short quiz aiming at appreciating the market access concept understanding and ability to navigate the complexity of market access field (10%).

Workshop evaluation will be based on a project delivered by the students which is based on class materials and the three workshops (80%).