Ben-Gurion University of the Negev
Guilford-Glazer Faculty of Business and Management
Department of Health Systems Management

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:

Health Technology assessment and health policy making in Europe, Current status, challenges and potential: http://www.euro.who.int/__data/assets/pdf_file/0003/90426/E91922.pdf

EMA-HTA workshop Bringing together stakeholders for early dialogue in medicines development: EMA:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2014/05/WC500166228.pdf

Introduction to Health Technology Assessment:
https://www.nlm.nih.gov/nichsr/hta101/ta10103.html

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:
http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf

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

Jaroslawski S, Toumi M, Design of patient access schemes in the UK: influence of health technology assessment by the National Institute for Health and Clinical Excellence, Applied Health Economics and Health Policy, July 2011, Volume 9, Issue 4, pp 209-215

Jaroslawski S, Toumi M, Market access agreements for pharmaceuticals in Europe: diversity of approaches and underlying concepts, 2011, BMC Health Services, 10.1186/1472-6963-11-259

Toumi, M. & Jadot, G. (2014). Economic impact of new active substance status on EU payers' budgets: example of dimethyl fumarate (Tecfidera®) for multiple sclerosis. Journal of Market Access & Health Policy 2:23932

Remuzat, C., Toumi, M., & Falissard, B. (2013). New drug regulations in France: what are the impacts on market access? Part 2 – impacts on market access and impacts for the pharmaceutical industry. Journal of Market Access & Health Policy 1 :20892.

Michel, M. & Toumi, M. (2012). Access to orphan drugs in Europe: current and future issues. Expert. Rev. Pharmacoecon. Outcomes. Res. 12(1):23-29.

Maervoet, J. and Toumi, M. (1-11-2012). PHP132: Time to Market Access for Innovative Drugs in the UK, France, and Belgium. *Value Health* **15**[7], A312

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%).