ULISBOA
ESCOLA DE
PÓS-GRADUAÇÃO

International Market Access
PG Course -2nd Edition

LISBOA
UNIVERSIDADE DE LISBOA

FACULDADE DE FARMÁCIA
Universidade de Lisboa

Scientific Coordination

Maria Beatriz da Silva Lima, PharmD, PhD

Beatriz Silva Lima is PharmD and PhD in Pharmacology and is full professor of Regulatory Science and Pharmacology, Head of Regulatory Science, researcher at Research Institute of Medidicne (iMED.UL) and Dean of Faculty of Pharmacy of the Universidade de Lisboa.

Beatriz served more than 20 years of experience as an expert in nonclinical and regulatory science at the medicines agency in Portugal, INFARMED, and at the EMA, UK. She has been up to July 2012 member of the Committee of Human Medicines (CHMP), Committee of Advanced Therapies (CAT) and Scientific Advice Working Party (SAWP). She has been Chair of the Safety Working Party (SWP) and has been involved as Co-Deputy in ICH discussions on multiple guidelines on behalf of the European Commission. Since January 2014, for four years (maximum allowed two mandates) she Chaired the Scientific Committee of the Innovative Medicines Initiative (IMI), a PublicPrivate Partnership between EFPIA and the EC which funded through >5 billion euros >160 research projects developed by consortia of Academia, Industries, Regulators, Patients, the main stakeholders in medicines research and development. between 2019 and 2022 she served as a member of the Emerging Issues Committee of the ILSI-HESI, USA.

Current areas of research: Regulatory Science, Nonclinical Safety, Oncology, Pharmacology of metabolic diseases;

Furthermore, Beatriz is highly involved in national and international education in the area of regulatory science. I) She Coordinates a second cycle Master Course on Regulatory Science in the Faculty of Pharmacy of the Universidade de Lisboa (RAMPS), ii) she contributes to the EUDIPHARM master course (University of Lyon), the MIND Course (University of Copenhagen), ATRIUM Regulatory Course (University of Copenhagen and Atrium, Denmark).

Beatriz is Editor in Chief of the Regulatory Science Section of the Journal Frontiers and she Co-coordinated with Prof Per Spindler (University of Copenhagen) and Dr Kirstin Meyer (Bayer Healthcare) a Nonclinical Module on Regulatory Guidelines of the European Master Course (IMI sponsored) SafeSciMet, iii) and of a similar master also IMI sponsored ECMDC, led by the Semelweiss University, Hungary, iv) she integrates the PharmaTrain Course EUDIPHARM lead by the University of Lyon, and she contributes as faculty to the Medicademy Regulatory course on Regulatory as well as to the MIND course (University of Copenhagen). Beatriz Silva Lima has been one of the founders of EUPATI-Portugal, (European Patient Academy, IMI-funded project) Portugal/National Platform, where she served as member of the Steering Committee of the European National Platform, Co-Chairing the Executive Committee.

Helder Mota Filipe, PharmD PhD

Helder Mota Filipe is PharmD and PhD in Pharmacology and is associate professor of Regulatory Science and Pharmacology at the University of Lisbon (Faculty of Pharmacy), honorary senior lecturer at the Centre Translational Medicine & Therapeutics, Queen Mary University of London and principal investigator at ISBE – Institute for Evidence Based Health. He is vice-president (past presidente) of AFPLP – The Portuguese-Speaking Countries Pharmacists Association, member of the National Council of Ethics for the Life Sciences and specialist in Regulatory Affairs (OF).
In February 2022 was elected President of Ordem dos Farmacêuticos - Portuguese Pharmaceutical Society, the regulatory body of the pharmaceutical profession.

Helder Mota Filipe is serving, since 1994, as an expert in nonclinical and regulatory science at INFARMED, the national competent authority Portugal, and at the European Medicines Agency (EMA). For a decade he was vice-president and president of INFARMED, and member of the management board of EMA. He is currently member of the Medicines Evaluation Committee (CAM) and former member of the HTA Committee (CATS) at INFARMED. He was member of the executive board at the Ethics Commission for the Clinical Research (CEIC). In addition to teaching and research at the Faculty of Pharmacy of the University of Lisbon, he frequently collaborates with other higher education institutions.

He has supervised 10 doctoral theses and more than two dozen master's theses in the areas of pharmacology, experimental medicine, regulatory science and medicines policy. He is the Author of more than 130 publications in international peer-reviewed scientific journals and more than 300 communications to scientific meetings in those scientific areas.

Ana Filipa Alexandre

Market Access Strategist - Freelancer
Former VP Pricing and Market Access EMEA at Santen

With over 15 years of experience, Ana is a seasoned market access professional with a proven track record of building and leading high-performing international teams and launching products.
Throughout her career, Ana has successfully spearheaded market access strategies for numerous products across diverse therapeutic areas and throughout the product lifecycle. Ana holds a PharmD from the Faculty of Pharmacy of the University of Lisbon, a Master's degree in Public Health (Health Economic Outcomes Research stream) from the London School of Hygiene and Tropical Medicine and a European Market Access University Diploma. Recently she obtained an INSEAD certificate in "Leadership Communication with Impact.
Ana has a strategic and positive mindset, which enabled her to effectively launch multiple products, ensuring optimal pricing that benefited the Company, the payer, and the patient, who will have access to the treatment/intervention. She excels in designing early access strategies and evaluating potential new assets, as she understands the payer's needs and knows how to integrate them into the strategy.
In addition to her professional achievements, Ana is a dedicated people leader, known for her strong influencing skills and efficient communication. Widely recognized as a leader and valued team player, Ana adapts quickly to new environments and cultures, leveraging a proactive, problem-solving approach and an innovative mindset essential for achieving successful outcomes

Passionate about personal growth and development, she is committed to continuous learning and thrive on new challenges.

Alexandre Baptista

Freelancer in the fields of HEOR, Market Access and Epidemiology/RWE.

Alexandre has worked in the Data Generation team in Oncology and IBD for the European and Canada Regions at Takeda until January 2019. There, he had functions of Head of the Department and as Manager.

Prior to joining Takeda, he worked as a freelancer and external consultant in the fields of health economics, market access and epidemiology. Also, Alexandre worked as a Value Consultant in Adelphi Values where identified solutions and defined projects to inform the development of value propositions and communications to optimize pricing, reimbursement, and market access. Furthermore, Alexandre worked as a global health economist, at the pharma headquarters of Solvay Pharmaceuticals in Germany and Switzerland.

Alexande has been the Scientific coordinator of training workshops in Health Economics and Market Access for the Portuguese Pharmacists Society. These workshops had the presence of international and national KOLs from Academia, Pharmaceutical companies, INFARMED, and from the National Association of Pharmacies from 2014 until 2022. During these years more than 300 healthcare professionals received education in these workshops.

Completed the Foundation and Advanced Modelling courses from York University and holds a Degree in Pharmacy from the Faculty of Pharmacy of the University of Lisbon, a MSc in

Epidemiology from the Faculty of Medicine of the University of Lisbon and a MSc in Health Economics from the University of York. Always available and learning.

Recently has achieved an INSEAD certificate in the "Emerging Leaders in the Digital Age" course and a certificate at Oxford University in Health Economics Evidence in Clinical Trials.

Program

An important detail to note is that, to enhance the learning experience, there will be 10-minute breaks after every 50 minutes of classes

1st week – 9:00h- 13:00h (total: 4h)- 14th September

- Introduction to the course and participants – 50 min **Prof. Beatriz Lima, Prof. Helder Mota Filipe, Ana Filipa e Alexandre Baptista**
- Introduction to Market Access- 45min **Ana Filipa Alexandre e Alexandre Baptista**
    - Market Access, its importance and history
    - Basic concepts and principles
- Market Access and what it encompasses **–** 60 min **Sofia Borges -Value, Access and Policy Manager at Amgen**
- **What is Governmental Affairs, definitions, basic concepts and principles-** 30 min **Sofia Borges - Value, Access and Policy Manager at Amgen**
- Presentation of the Case studies – 20 min **Ana Filipa Alexandre e Alexandre Baptista**

2nd week – 9:00h- 13:00h (total: 8h) – 21rd September

- Evidence Synthesis- 1h 45min **Osvaldo Santos - Coordenador do EnviHeB Lab, ISAMB; Professor Assistente da Faculdade de Medicina, Universidade de Lisboa, Portugal**
- Clinical Outcomes Assessment – 1h 45min **Zalmai Hakimi - Director Health Economics Outcomes Research at Sobi, Swedish Orphan Biovitrum AB**
- Q&A (10 min)

3rd week – 9:00h- 13:00h (total: 12h) – 28th September

- HEOR
    - Fundamental concepts, principles, and their applicability – 3h 20 min **Klara Dimitrovová – Senior Health Economics Researcher at CEFAR**

- Q&A (10 min)

4th week – 9:00h- 13:00h (total: 16h) – 5th October

- HEOR
  - Interpretation and analyses of articles -1h 45 min **Alexandre Baptista**
  - Economic models and their differences – 1h 45 min **Bruno Macedo HTA Consultant**

- Q&A- 10 min

5th week – 9:00h- 13:00h (total: 20h) –12 th October

- Key Market Access activities throughout the development of a product until Ph3- 3h 20 min **Sara Lopes – VP, Global pricing & Market Access Operations at Shionogi**
  - Understanding the epidemiology of the disease
  - Competitors
  - Strategy
  - Planning, execution, and implementation of activities (Early HTA advice, TPP, Value Dossier, Models, etc)
  - Cross functional activities - liaison with internal stakeholders (Development, Medical, Comercial, etc)
  - Drivers and barriers for access

- Q&A (10 min)

6th week – 9:00h- 13:00h (total: 24h) –19th October

- Market access activities during Ph3 of clinical development and pre-launch – 3h 20 min **João Carrasco - Director Global Market Access Lead Ophthalmology at Bayer & Ana Filipa**
  - The Global, Regional and affiliate matrix for a successful Access plan
  - Value Messages and Value Proposition
  - Gap analysis and prioritization
  - Pricing activities (pricing sequence, external reference pricing, payer research, price strategy, P&R environment)
    - Practical examples

- Q&A (10 min)

7th week – 9:00h- 13:00h (total: 28h) – 26th October

- Market access Life Cycle Management activities, Portuguese example – 3h 20 min **Bárbara Aranda da Silva - New Products & RWE Manager at Novartis Portugal**

- Q&A (10 min)

8th week – 9:00h- 13:00h (total: 32h) – 2nd November

- The role of Governmental Affairs and Public Affairs in Market Access Strategy -1h 45 min **Francisca Charrua Market Access & Public Affairs Manager at LEO Pharma**
- The role of the Pharmacy Industry Associations regarding the Access of Medicines at country level **–** 45min **Inês Teixeira -Economics Affairs Director APIFARMA**
- The role of the Pharmacy Industry Associations regarding the Access of Medicines at an European level- 1h **Tina Taube - Director Market Access & Orphan Drug Policy Lead EFPIA**
- Q&A (10 min)

9th week – 9:00h- 13:00h (total: 36h) – 9th November

- Regulation (EU) 2021/2283 on health technology assessment (HTAR)- 2h **Prof. Rui Ivo – Chair of the Heads of the HTA Agencies Group and President of INFARMED**
    - History – how it started
    - How this new legislation will contribute to improving the availability of innovative technologies, in the area of health.
    - What does this new framework look like and what are the main advantages.

- The role of a HTA agency and its importance in the reimbursement of medicines/Medical devices (INFARMED – Portuguese Agency)**–** (1h 20 min) **Susana Duarte**
- Q&A (10 min)

10th week – 9:00h- 13:00h (total: 40h) – 16th November

- Payer perspective – 50 min **Prof. Hélder Mota Filipe - Associate Professor at Faculty of Pharmacy, University of Lisbon, and President of the Portuguese Pharmaceutical Society**

- EU HTA regulation implementation - current situation and remaining concerns for EU countries. – **Prof. Mira Pavlovic** (50 min) **Associate Professor, Pharmacological and Regulatory Science, Lisbon University, Portugal**
- Market Access in Portugal- 1h 40min **Sergio Vilão - Managing Partner & Market Access Manager na Formifarma**
- Q&A- 10 min

11th week – 9:00h- 13:00h (total: 44h) –23 th November

- Market Access in Spain – 1h 45 min **Gloria Tapias- Founder and Executive Director Get Access Consulting**
- Market Access in UK, NICE and SMC- 1h 45min **Rodrigo Almeida – Global HEOR and HTA Expert**
- Q&A (10 min)

12nd week – 9:00h- 13:00h (total: 48h) – 30th November

- Market Access in France- 1h 45min **Marta Contente Global HEOR and HTA Expert**
- Market Access in Italy – 1h 45min **Paolo Di Rienzo - Associate Director Health Economics Outcomes Research Astellas Italy**
- Q&A (10 min)

13th week – 9:00h- 13:00h (total: 52h) – 7th December

- Market Access in Germany – 1h 45min **Joern Hanusch - Market Access & Health Economics Consultancy / Interim Management**
- Market Access in the Nordic Countries **–** 1h 45min **Diogo Belbute- Global Associate Director, Value Strategy and Payer Engagement at Novo Nordisk**
- Coaching of Case Studies - **(15 min)** – groups of 4 people

14th week -20:00h- 22:00h (total: 54h) - 13 December

- Market Access in Brazil- 1h 45 min -**Rodrigo Antonini Ribeiro Health Economics and Health Technology Assessment Consultant at HEMAP Consulting**
- **Q&A** -10 min

15th week – 9:00h- 13:00h (total: 58h) – 14th December

- Market Access in China **–** 1h 45min **Marta Contente - Global HEOR and HTA expert**
- Market Access in Japan **–** 1h 45min **Emiko Yoshida- Founder and consultant at Healthcare to All co. ltd**
- Q&A-10 min

15th week – 20:00h- 22:00h (total: 60 h) – 10th January

- Market Access in USA – 1h 45min **Trevey Davis Health Insurance Specialist - Division of Alternative Payment Model Infrastructure at CMS-CMMI, and Mauricio Ferri - Executive Director - US HEOR - Cardiovascular Lead at Bristol Myers Squibb**
- Coaching of Case Studies - **(10 min)** – groups of 4 people

16th week – 9:00h- 13:00h (total: 64h) – 11th January

- Overview of RWD vs. RWE in Access – 50 min **Alexandre Baptista**
- Different types of observational studies and its importance for the Access of medicines/medical devices **–** 1h 20 min **Ana Sofia Afonso – Director Pharmacoepidemiology at Lilly International**
- The role of a CRO in the RWE field **–** 1h 20 min **Patricia Medina - Head of Medical Intelligence, RWD & Analytics - Oracle Life Sciences**
- Q&A (10 min)

17th week – 9:00h- 13:00h (total: 68h) – 18th January

- RWE and Guidelines - Darwin EU – 1h 45min **Luis Pinheiro - Senior Epidemiology Expert at EMA**
- RWE and its impact in the Access strategy – 50 min **Marta Contente**

- The Portuguese experience in Digital Health in the Pharmacy area -50 min - **Ema Paulino - President at Grupo ANF**
- Q&A (10 min)

18th week – 14:00h- 18:00h (total: 72 h) – 25th January

- Case Study Presentations- (4 groups 20min each) – **Ana Filipa Alexandre, Alexandre Baptista, Marta Contente & João Carrasco (2h 30 min)**
- Q&As about what was discussed during the course - **20min - all**
- Feedback - **10 min**

- End of the Course