Academy

Pharma Pricing - Reimbursement, Market Access and Regulatory Strategies

ONLINE TRAINING 26 - 29 February 2024 | 10 - 13 September 2024



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Course Information

LIVE ONLINE TRAINING	Part 1	26 February	Part 2	27 February	Part 3	28 February	Part 4	29 February	10am - 2pm AEDT
	Part 1	10 September	Part 2	11 September	Part 3	12 September	Part 4	13 September	11am - 3pm AEST

Key Learning Objectives

- Understand basic concepts related to access to essential medicines, transparency, and the pharmaceutical value chain
- Understand different pharmaceutical pricing and reimbursement policies
- understand the key components of Health technology assessment
- Explore methods of conducting an assessment
- identifying strategies to ensure timely market access
- Formulary Management

Who Will Benefit

- Pricing, Market Access Professionals who want to learn about regional markets
- Regulatory professionals who want to learn about commercial issues
- Strategic planners who want to know where they might go next
- Those who want insight into the way that markets influence each other
- Anyone who wants to understand global pricing issues



Dr. Salma Michor (PhD, MSc, MBA, CMgr, RAC-Treasurer), CEO, Michor Consulting

Meet Your Course Director

Salma has advised numerous global clients across Pharmaceutical, Medical and Food industries, including J&J, Novartis, Pfizer and Shire and many more. She had previously worked for Torrex-Chiesi (Chiesi Farmaceutici S.p.A); Wyeth Whitehall Export, and Croma Pharma GmbH and had been the Director of Global Supporting Operations – Medical Devices and Pharmaceuticals (Ophthalmology & Orthopedics) where she was in-charge of technical and leadership of four departments – including Regulatory Affairs and Compliance; Medical and Vigilance; Change Control and Life Cycle Management; as well as Packaging and Pharmaceutical editing. Her duties included overall leadership & personnel management, budgeting and strategic planning, liaison with external contractors, doctors and customers in 60 countries worldwide. Here she also gained first-hand experience with submission of clinical trials phases:I-III as well as turnaround management of post-Mergers and Acquisitions integration operations.

Her experiences include:

- Post-acquisition phase-out and closedown after M&As
- Managing DCP registrations
- Consolidation of Multi-language labelling texts for pharmaceutical products and medical devices
- Forming clinical and registration strategies for medicinal products (combination, generics)
- Labelling compliance for drugs & food supplement

- Authoring CMC sections for drug products or drug/ device combination products
- Preparing pharmaceutical and medical device companies for internal and FDA audits
- Managing large company-wide compliance projects (CAPA, GMP, ISO, etc)
- Preparing companies in 3rd countries for EMA, MHRA and AGES inspections and managing the whole biotech registration and clinical testing in the EU

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Course Information _

Course Outline

About the Course

Whilst significant opportunities exist in emerging markets, the heterogeneous nature of pricing & reimbursement environment causes enormous uncertainty to commercial success. This interactive programme has been built to enable attendees navigate through such complex policies, reimbursement systems and competition in pharmaceutical industry globally with spotlight in Asian countries. To help you develop successful market access strategies, this leading masterclass brings together practical case studies of numerous drug segments, including orphan drugs, oncology, biosimilars, generics, OTC among others.

DAY 1

PHARMA PRICING – REIMBURSEMENT

- · Introduction into reimbursement
- The pharmaceutical value chain
- Challenges for ensuring access to medicines
- Rationale for price regulations
- Pricing policies for new medicines and for generic and biosimilar medicines

Practical exercise

DAY 2

HEALTH TECHNOLOGY ASSESSMENT

- Introduction to HTA
- Core Concepts and Approaches to Early-Stage HTA
- Health Economics and Value Assessment Frameworks
- HTA High Versus Low-income Countries
- High-priced medicines, shortages, HTA
- Price regulation, and co-payment policies
- Projects and initiatives (e.g. WHO, Pharmaceutical Strategic for Europe, other regions

Practical exercise

DAY 3

MARKET ACCESS

- The patterns in pricing & reimbursement systems and processes in different countries
- · Market access challenges and opportunities
- Payers and the decision-making processes
- Who are the stakeholders across functions.
- Risk mitigation

Practical exercise

DAY 4

REGULATORY STRATEGIES

- HTA and Regulatory strategies
- Knowing the stakeholders
- Engaging with regulators
- · Avoiding market access pitfalls

FORMULARY MANAGEMENT

- ASEAN case study
- Rational selection of products methodology
- How drug selection works at national, regional and hospital level
- Procurement models and consortian
- Final negotiations international aspects
- Strategic Pharma Pricing Roadmap ASEAN's response to "Early Market Access"

Practical exercise

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Course Code	Location/ Format	Course Parts	Course Dates	Standard Price		Croat Savings
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