

باوزير فارما للاستشارات Bawazir Pharma Consulting

Advance Regulatory SFDA Drug Pricing System Reimbursement and Market Access



Dates of The Training 14 April 2025 Saudi Arabia

www.bawazirpharma.com



2025 Saudi Arabia

OVERVIEW

The rise in costs of pharmaceutical products in general affects all sectors of the health care industry, including private insurers and patients. This workshop shall

give an overview on the pricing practices of

pharmaceutical products by SFDA .

In addition, a thorough discussion on reimbursement and market access will be discussed.

LEARNING OBJECTIVES

At the conclusion of this training, participants will be able to:

- Understand the history of pharmaceuticals pricing and the different types of pricing modalities.
- Understand the principals of SFDA pricing system.
- How to prepare your product pricing certificate. How to predict your product pricing
- How to petition pricing decision.
- Basics of reimbursement and market access.

KEY TOPICS

- History of Pharmaceuticals pricing
- Modalities of pricing
- Reference pricing and reimbursement
- Pharmacoeconomics
- Pharmaceutical Pricing Policies Regional Experience
- How to prepare your pricing certificate?
- How to predict your product price?

WHO WILL ATTEND

Professionals working in:

- Healthcare Executives
- Economists
- Pharmaceutical Industry
- Health Insurance Professionals
- Law professionals
- Pharma Regulatory Affairs
- Scientific Office Managers
- Regulatory Authorities.
- pharmaceutical manufacturers
- Pharmacist

Bawazir Pharma Approach

Bawazir Pharma approach is grounded in the belief that compliance and quality should be managed as any other critical business issue. Proper quality management and a state of regulatory compliance will result in a decrease in direct costs such as rejects, and indirect costs such as adverse events and recalls.

Bawazir Pharma offers professional services to complete all aspects of regulatory affairs. The depth of our experience and knowledge acquired from our work with the Regulatory authorities ,ICH, International Standards Organization is made available to our partners. Our team can guide your organization through compilation of an original submission, perform submission maintenance and step in to support your internal staff during workload peaks.



TRAINING PROGRAM

08:45 - 09:00 REGESTRATION and COFFEE

<u>09:00 - 10:00 SESSION 1</u>

Importance of the Pharmaceutical Pricing & its Impact on the Market

- History of Pharmaceuticals pricing
- Modalities of pricing
- Reference pricing and reimbursement.

10:00 - 11:00 SESSION 2

Pharmaceutical Pricing Policies – Regional Experience

- SFDA pricing rules
- What you should learn?

11:00 - 11:30 COFFEE BREAK

<u>11:30 – 12:30 SESSION 3:</u>

Pharmaceutical Pricing from Pharma Companies Perspective

- Position of the drug
- Pricing over the lifecycle of a drug
- Reimbursement and market access

12:30 -13:30 LUNCH

<u>13:30 – 15:30 SESSION 4</u>

Pricing Workshop

- How to prepare your pricing certificate?
- How to predict your product price?
- How to maximize your benefit from currency exchange rate?
- How to prepare your pricing petition?

16:00 END OO TRAINING

15:30 - 16:00: COFFEE BREAK



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REGESTRATION

REGISTRATION FEES

Registration fee including refreshment breaks and lunches and training course material

FEES	SAUDI RIYAL
ADMISSION FEES	SAR 2500.00
EARLY BIRDS REGISTRATION FEE	SAR 1500.00
PAY YOUR FEE BEFORE 12 April 2025	

Payment can be made by Card or Bank Transfer

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EXPERT TRAINER



Prof. Saleh A Bawazir CEO, Bawazir Pharma Consulting Center EX-Vice President for Drug Sector (SFDA)

Professor Bawazir worked for eight years as an advisor to the Minister of Health for pharmaceuticals. During his work, he chaired the committee that revised and updated the pharmacy law, updated drug registration procedures and established pharmaceuticals pricing guideline. He also represented the Ministry of health in the national committee that negotiate Saudi Arabia accession to the World Trade Organization (WTO) and the committee that establish the Saudi Food and Drug Authority (SFDA).

For the last nine years Professor Bawazir worked as vice president for drug affairs and advisor at the SFDA. During his work, he led the drug sector development through a strategic plan and managed to establish a state of the art drug regulatory system that ensure quality, safety and efficacy of the pharmaceutical products and contributed positively to overall public health. Under professor Bawazir supervision the SFDA built many electronic databases and regulatory framework that implement electronic Common Technical Document (eCTD) for drug submissions and established a strong regulatory framework for clinical trials and construct the Saudi Clinical Trial Registry (SCTR) Database. Under professor Bawazir leadership the drug sector at the SFDA is recognized as a leading drug authority in the region and worldwide. Furthermore, Professor Bawazir represented the GCC for the last eight years in the Global Cooperation Group under the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

