

6th Club

Friday 15 August 2025



Club Founder
Dr. Mahmoud Bahgat



Regulatory Affairs Club

Pharmacoeconomics relationship with
Regulatory Affairs & Pharma Industry
اقتصاديات الدواء وعلاقتها بالشئون التنظيمية والصناعات الدوائية

Online Zoom
7 pm Egypt - 7 pm KSA - 8 pm UAE



Dr. Zeyad Anany
RA Professional
Pharmacoeconomics Diploma



Co-Founder & Host:
Dr. Zeyad Anany





Pharmacoeconomics Relationship with Regulatory Affairs & Pharma Industry

Understanding the Interconnected Framework

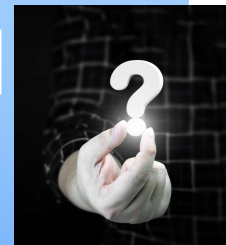
Zeyad Anany

My Background



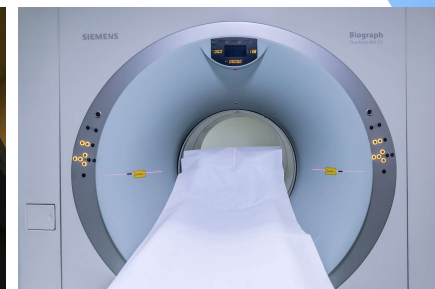
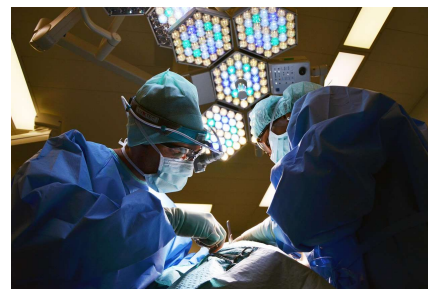
- Pharmacist
- Graduated in 2006 from Assiut University
- 19 years in Pharma industry spanning between quality control, regulatory affairs, pharmacovigilance, project management, and consultation
- Pharmacoeconomics Diploma from GUC 2025.

Can any healthcare system afford to supply all health interventions?



Health needs:

- Number of diseases increases
- Aging population
- Quality of life increases in developed countries
- Increased awareness about human rights even in developing countries



Resources are limited

- Hospitals
- Healthcare providers
- Rate of new pharmaceutical discoveries is slow
- Health care resources are not a priority in many countries
- Strict approval criteria

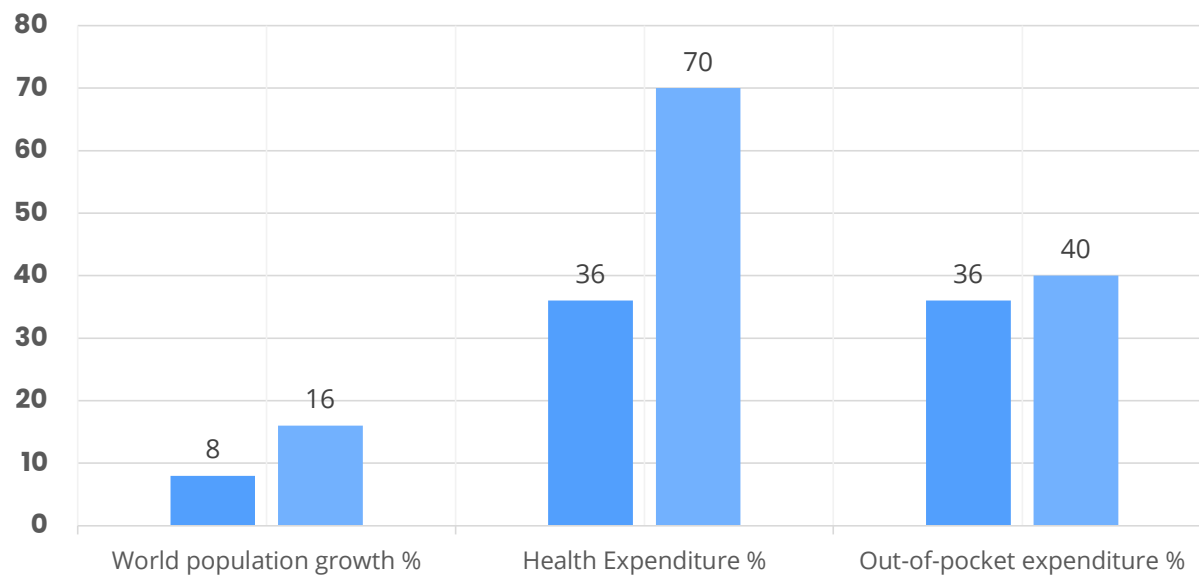


- Most efficient use of resources
- Evidence-based policy
- Pricing, reimbursement, and access decisions for new technologies



Healthcare & Market

MENA Health Data vs. World (2010-017)



Source: World Bank

What is Pharmacoeconomics?



Pharmacoeconomics is the field of study that evaluates the behavior or welfare of individuals, firms, and markets relevant to the use of pharmaceutical products, services, and programs.

The focus is frequently on the cost (inputs) and consequences (outcomes) of that use.

William F. McGhan and Renée J.G. Arnold; Pharmacoeconomics From Theory to Practice

"Pharmacoeconomic analysis" is the set of analysis methodologies aimed at identifying, measuring and evaluating the costs and related consequences (benefits/outcomes) of two or more therapeutic alternatives.

WHO definition

Pharmacoeconomic methods document the **costs** and **benefits** of therapies and pharmaceutical services and establish priorities for those options to help in appropriately allocating resources in ever-changing healthcare landscapes and reimbursement environments/schema.



...HOW to maximize the health of population given constrained health producing resources.

What is Pharmacoeconomics?



Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

Health economics is a sub-discipline of economics, which applies the theories and methods of economics to all aspects of health and health care.

Economics is the study of scarcity and the means by which we deal with this problem.

History of Health Economics

Early Foundations (Pre-1940s)

1931: Bureau of Medical Economics established by the American Medical Association (AMA) – one of the earliest institutional efforts linking economics and medicine.

Post-WWII Expansion and Conceptual Development

1958: *Selma Mushkin* publishes “Towards the Definition of Health Economics” – often considered the formal “birth” of health economics as a distinct discipline.

1960s: Conceptual understanding of health care as both a social service and an economic good solidifies.

Institutional Growth and Global Spread

1980s–1990s: Rapid spread of health economics to Europe and Japan, including establishment of academic centers and university programs.

1990s: Governments like Australia and Canada require cost-effectiveness and budget impact analysis for medical technology reimbursement..

Globalization and Emerging Markets

Rise in industry-affiliated health economists and roles within pharmaceutical and medical device industries.

Pre-1940s

1940s–1960s

1980s–1990s

2000s–2010s

2010s–Present



History of Health Economics

THE AMERICAN ECONOMIC REVIEW

VOLUME LIII

DECEMBER 1963

NUMBER 5

UNCERTAINTY AND THE WELFARE ECONOMICS OF MEDICAL CARE

By KENNETH J. ARROW*

I. *Introduction: Scope and Method*

This paper is an exploratory and tentative study of the specific differentia of medical care as the object of normative economics. It is contended here, on the basis of comparison of obvious characteristics of the medical-care industry with the norms of welfare economics, that the special economic problems of medical care can be explained as adaptations to the existence of uncertainty in the incidence of disease and in the efficacy of treatment.

1963



Pharmacoeconomics Aspects



Economic

direct, indirect, and intangible costs compared with the consequences of medical treatment alternatives.

Clinical

medical events that occur as a result of disease or treatment.

Humanistic

consequences of disease or treatment on patient functional status, or quality of life, measured along several dimensions, e.g., physical functioning, social functioning, general health perceptions and well-being.

ECHO Model

Pharmacoeconomics Study Types



Cost of Illness (COI)

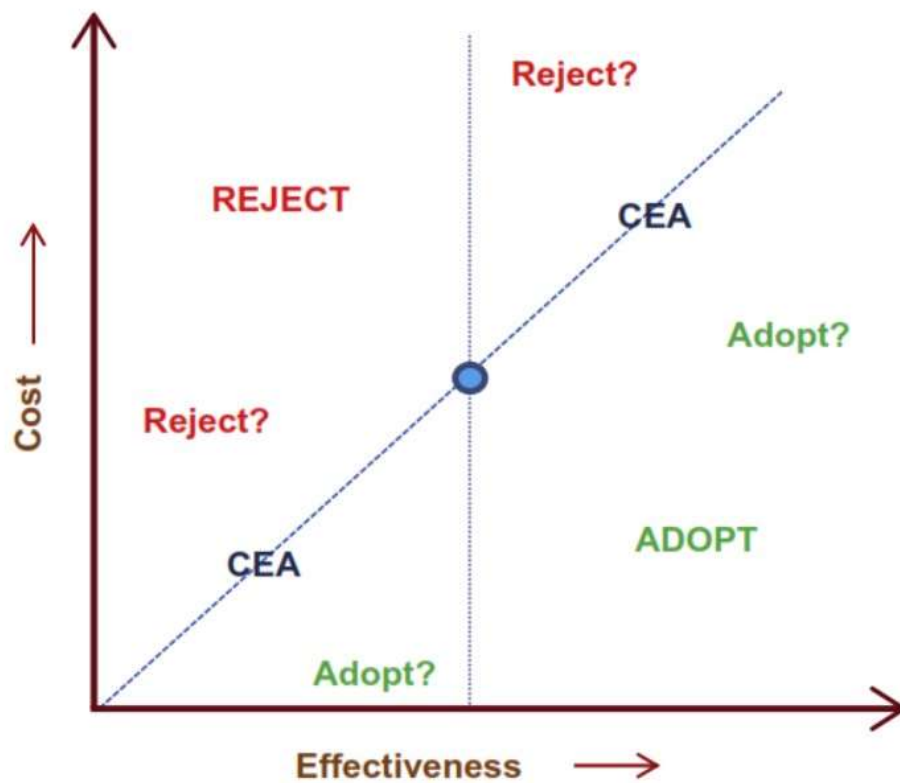
Burden of Disease (BOD)

Budget Impact Analysis (BIA)

Pharmacoeconomics Study Types

<i>Type of Analysis</i>	<i>Costs</i>	<i>Consequences</i>	<i>Result</i>
Cost Minimisation	Money	Identical in all respects.	Least cost alternative.
Cost Effectiveness	Money	Different magnitude of a common measure eg., LY's gained, blood pressure reduction.	Cost per unit of consequence eg. cost per LY gained.
Cost Utility	Money	Single or multiple effects not necessarily common. Valued as "utility" eg. QALY	Cost per unit of consequence eg. cost per QALY.
Cost Benefit	Money	As for CUA but valued in money.	Net £ cost: benefit ratio.

Pharmacoeconomics Study Result





Relationship

Regulatory Affairs

International Reference pricing (IRP)

- All (except two) countries in MENA takes the lowest price.
- Mostly, prices are fixed for 5 years (except some cases in Egypt, KSA, Jordan).
- Internal reference pricing for generics and biosimilars.



01 Egypt

02 Kingdom Of Saudi Arabia



Relationship

Regulatory Affairs

01 Egypt

Decree 499

- The lowest price in reference countries.
- If price available in less than 5 reference countries, Comparative study (Pharmacoeconomics) with alternatives.
- Pharmacoeconomics Unit in EDA.





Relationship Regulatory Affairs

02 Kingdom Of Saudi Arabia

- Pharmacoeconomics / Economic Evaluation Studies are part of the pricing file in KSA.
- Studies such as BIA, CEA, CUA, and CMA are now mandatory for registration process (July 2025).
- Re-evaluation for products requiring prove of the health outcomes.



Study options for all types of submissions

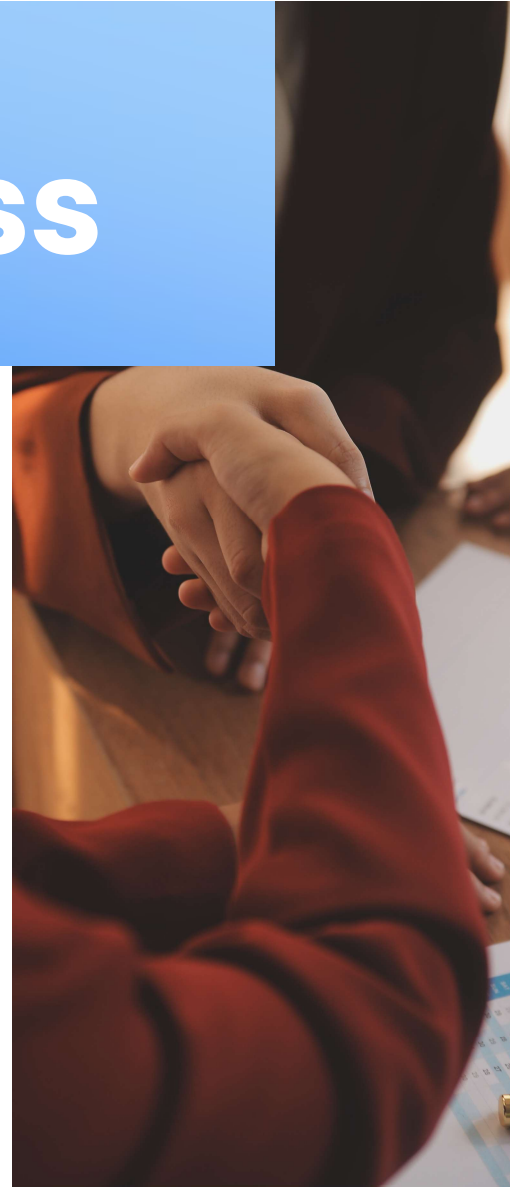
Product type	BIA	CMA	CEA	CUA
New Chemical	✓	x	✓	✓
Biological	✓	x	✓	✓
Generic Chemical	✓	✓	x	x
Biosimilar	✓	✓	x	x



Relationship Market Access

The set of strategies, activities, and processes that pharmaceutical (pharma) and medical technology (MedTech) companies develop to ensure that their products (drugs, devices, other technologies) are made available and adequately priced in a specific health system.

- MA is a multidisciplinary, strategic function for product adoption.
- Pricing must balance access, affordability, and innovation sustainability.
- Comprehensive cost assessment = direct + indirect + intangible costs.
- Accurate costing supports evidence-based, value-driven healthcare decisions.



HEOR

Health Economics

Focuses on the costs associated with healthcare. It addresses questions like:

- How much does a new drug or treatment **cost** compared to existing options?
- Is it **cost-effective** (does it provide good value for money)?
- What is the **budget impact** if a health system adopts a new intervention?



Outcomes Research

Evaluates the results of healthcare interventions in real-world settings. Outcomes research focuses on:

- **Clinical outcomes** (e.g., survival rates, disease progression).
- **Patient-reported outcomes** (e.g., quality of life, pain levels).
- **Economic outcomes** (e.g., healthcare resources utilization, hospital readmission rates, productivity).



Relationship Pharma Science



Quality, Safety & Efficacy

How well a drug works under **strictly controlled** clinical conditions



Effectiveness

How well a drug works in normal clinical practice (**real-life conditions**)



Efficiency

How **cost-effective** a drug is in normal clinical practice ("**do not waste resources**")

Health Technology Assessment HTA



Health Technology Assessment HTA

Health technology assessment (HTA) is a systematic and **multidisciplinary** evaluation of the properties of health technologies and interventions covering both their direct and indirect **consequences**. It is a multidisciplinary process that aims to determine the **value of a health technology** and to inform guidance on how these technologies can be used in health systems around the world.

World Health Organization

1. Independency
2. Transparency
3. Timeliness
4. Consultation
5. Scientific firmness
6. Contestability

NICE National Institute for
Health and Care Excellence

HAS
HAUTE AUTORITÉ DE SANTÉ

CADTH

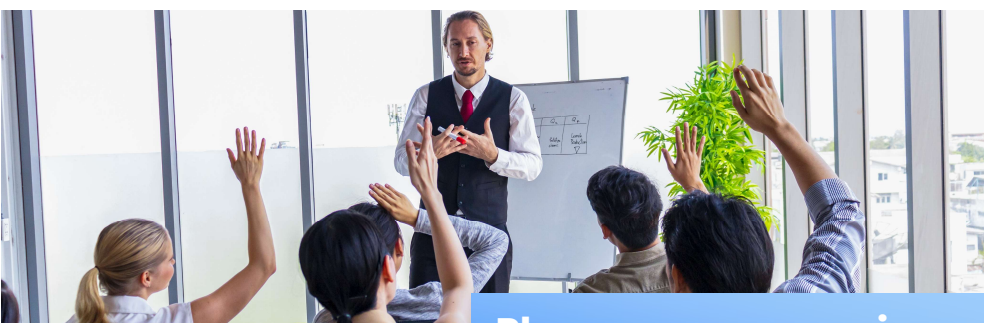
DI^{VI}DI
medicalknowledge
German Institute of Medical
Documentation and Information

AIFA

INAHTA

Month	EMI	Principal	Interest	Principal Bal	Total Principal Payment	Total Interest payment	Total EMI payment
1	1,708.58	1,242.49	466.08	68,757.51			
2	1,708.58	1,250.77	457.81	67,506.74			
3	1,708.58	1,259.09	449.48	66,247.65			
4	1,708.58	1,267.48	441.10	64,980.17			
		1,275.92	432.66	63,704.25			
		1,284.41	424.16	62,419.84			
			415.61	61,126.88			
			407.00	59,825.31			
				58,515.07			
				57,200.00			
				55,880.00			
				54,560.00			
				53,240.00			
				51,920.00			
				50,600.00			
				49,280.00			
				47,960.00			
				46,640.00			
				45,320.00			
				44,000.00			
				42,680.00			
				41,360.00			
				40,040.00			
				38,720.00			
				37,400.00			
				36,080.00			
				34,760.00			
				33,440.00			
				32,120.00			
				30,800.00			
				29,480.00			
				28,160.00			
				26,840.00			
				25,520.00			
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				16,280.00			
				14,960.00			
				13,640.00			
				12,320.00			
				11,000.00			
				9,680.00			
				8,360.00			
				7,040.00			
				5,720.00			
				4,400.00			
				3,080.00			
				1,760.00			
				40.00			

Economic Evaluations



Pharmacoeconomics Training



Strategy & Teams Development

How I can Help?

01. Regulatory Economic Evaluation files

Cost-effectiveness studies, Budget Impact Analysis

02. Pharmacoeconomics & Regulatory Trainings

Concept, related skills, hands-on, and Advanced

03. Strategy & Team Development

Regulatory Affairs, Pricing, Market access teams

Thank You



Zeyad Anany



Phone Number

+201010934670



LinkedIn

<https://www.linkedin.com/in/zeyadananyofficial/>