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# Pricing and Reimbursement: Issues and Challenges

Panel Discussion

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# Pricing and Reimbursement: Issues and Challenges



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# Pricing and Reimbursement: Issues and Challenges



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# Pharmaceutical Pricing and Reimbursement in the MENA region

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ISPOR Regional Meeting – Dubai

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POLITICAL SCIENCE ■



# Acknowledgements



- Study: Pharmaceutical Pricing and Reimbursement in the Middle East and North Africa: A mapping of the current landscape and policy options for the future
- Research team: Victoria Tzouma, Bregtje Kamphuis, Anna-Maria Fontrier, Georgia Colville, Shadi Saleh, Panos Kanavos
- Primary data collection: Significant contribution from the broader stakeholder community - researchers/academia, government organisations, regulatory agencies, industry
- Financial support: Pharmaceutical & Research Manufacturers of America

# Outline

- Aims and objectives
- Analytical framework
- Methods
  - Systematic literature review
  - Primary data collection
  - Analysis
- Synthesis of Findings
  - Pricing policies
  - Reimbursement policies
  - Impact of policies on price levels, access and availability, and affordability, and international implications of policies
- Pricing Policy Strategy in MENA region

# Aims and Objectives

## Aim

- To analyse the current pricing and reimbursement policies, regulation and legislation in the Middle East and North Africa (MENA) region.

## Specific objectives

- Map, describe, analyse and critically appraise local pricing and reimbursement policies for pharmaceuticals in the MENA region
- Describe and analyse the current use of ERP systems
- Identify local best practices that can be shared effectively across the region
  - Recommend ways to improve current interventions
  - Outline a transition to a more robust value-based pricing system in the study countries

Analytical framework with associated endpoints, which were separated into 5 groups:

- a) Pharmaceutical Pricing Policies**
- b) (explicit focus on) External Reference Pricing (ERP) and its Salient Features**
- c) Pharmaceutical Coverage & Reimbursement Policies**
- d) Spillover Effects of Pricing Policies**
- e) Industrial Policies: Support for local and foreign manufacturers**



# Analytical Framework



Theme	Endpoints	Definition
<b>Pharmaceutical Pricing Policies</b>	<ul style="list-style-type: none"> <li>Pricing policies for in-patent pharmaceuticals</li> <li>Pricing policies for off-patent pharmaceuticals</li> <li>Pricing policies for generic pharmaceuticals</li> <li>Pricing policies for locally manufactured/imported pharmaceuticals</li> </ul>	Discusses current approaches to pricing and the extent to which they differ between different types of pharmaceutical products.
<b>External Reference Pricing (ERP): Salient features</b>	<ul style="list-style-type: none"> <li>Time ERP was introduced and responsible authority</li> <li>Role of ERP (used in pricing and/or reimbursement; does it have a supportive or main role in price setting?)</li> <li>Basket of countries (number of countries/type of country/selection criteria for basket countries)</li> <li>Price used to inform pricing decisions; price revisions; ref price calculation</li> <li>Information sources for identification and validation of ERP prices</li> </ul>	Reflects on the salient features of the prevailing ERP model, as the dominant method of pharmaceutical pricing, in order to identify similarities and differences across study countries in the way ERP is implemented across the region.
<b>Pharmaceutical Coverage &amp; Reimbursement Policies</b>	<ul style="list-style-type: none"> <li>Pharmaceutical financing (role of government, national health insurance, private health insurance, out-of-pocket (OOP) payments)</li> <li>Coverage and Procurement Policies</li> <li>Role of In-patent/off-patent/generic pharmaceuticals</li> <li>How ERP is used to shape coverage/reimbursement</li> <li>Incentives that ERP provides to improve efficient purchasing, incl. prescribing and procurement</li> <li>Generic prescribing and substitution</li> </ul>	Identifies the sources of finance for pharmaceutical products, the extent of OOPs and any supply- and demand-side policies relating to pharmaceutical coverage.
<b>Spillover Effects of Pricing Policies</b>	<p>Price levels</p> <p>Drug product shortages</p> <p>Access barriers</p> <p>Affordability issues</p> <p>International implications</p>	<p>Examines the impact of pricing and reimbursement policies on pharmaceutical price levels, and whether pricing policies lead to or can achieve acceptable prices for payers</p> <p>Explores whether there are product shortages as a result of pricing policies</p> <p>Assesses the extent to which pharmaceuticals are available on a timely basis, and with limited access barriers in the MENA countries.</p> <p>Examines whether pharmaceutical prices are aligned with the purchasing ability of patients and/or health care systems.</p> <p>It assesses the extent to which there are spill-over effects of ERP to third countries in terms of (a) launch delays, and (b) price convergence.</p>
<b>Industrial Policies &amp; manufacturer support</b>	<p>Support of local industry: Pricing incentives, tax breaks/exemptions, discounts, tendering/procurement, discounts, price caps</p> <p>Support of foreign/research-based industry: Pricing incentives, tax breaks/exemptions</p>	Analyses the degree to which the adopted pricing policies promote and/or are aligned to industrial policy objectives. Examines whether the support provided to local and multinational manufacturers (e.g. incentives for manufacturing and/or R&D investment), promotes industrial policy objectives or whether it acts as a barrier to achieving these.

# Methods: Systematic Literature Review & Primary Data Collection



## Systematic Literature Review

### Aim

- to map available evidence on pricing and reimbursement policies in the study countries and identify the possible impact of these policies.

### Methods

- A detailed systematic search strategy
- Data extraction according to endpoints set in analytical framework

### Results

- 89 studies included for data extraction (23 peer-reviewed literature, 21 BMI reports, 41 grey literature sources, and 4 legislative documents)

## Primary Data Collection

### Aim:

- To complement our literature search, validate findings, and incorporate local insights to pinpoint regulatory challenges and derive recommendations, the clarification of gaps, barriers and bottlenecks identified throughout the mapping exercise.

### Methods:

- Development of Interview Discussion Guide, to ensure all interviews were semi-structured. The guide was designed according to the SLR endpoints and comprised 3 sections:
  - (a) Pricing policies and price setting;
  - (b) Reimbursement and coverage decisions; and
  - (c) Evidence of ERP impact within and across countries.

### Results

- Over 80 local experts and stakeholders were contacted; these included government officials, representatives from regulatory authorities, insurance organizations, pharmacy departments, and procurement agencies, among others, but also industry executives.

# Methods: Analysis

- Analysis was undertaken focusing on:
  - (a) Mapping, outlining and discussing current pricing and reimbursement policies in the study countries
  - (b) Outlining practical issues and challenges in the implementation of the widely used ERP in the study countries
  - (c) Studying whether national ERP systems adhered to best practice by using a validated methodological framework comprising 14 principles (Sullivan, Kanavos & Kalo, 2015) and endeavouring to showcase the performance of national ERP systems based on these principles
  - (d) Offering practical suggestions on how to improve operational procedures in the transition from price-focused to value-focused policies

No.	ERP best practice principle framework
1	The objectives of ERP systems should be clear and align with health system objectives
2	ERP systems should focus on in-patent products considered for the purposes of coverage, pricing and reimbursement decisions
3	Prices developed via ERP do not over-ride HTA conclusions or VBP approaches
4	The ERP system should have administrative simplicity and transparency
5	Stakeholders should participate in design and review of ERP system
6	Stakeholders are able to appeal regulator decisions
7	Reference countries should be selected based on similarities in economic status and health system objectives
8	International implications of ERP implementation should be considered
9	Publicly available ex-factory prices should form the basis of the ERP system
10	The mean of prices in reference countries should be used
11	ERP system respects patent status of products it covers based on provision of IP that prevail in reference country
12	ERP formula should avoid the impact of exchange rate volatility
13	Price revisions should be kept to a minimum and should be carried out consistently to avoid the perception of opportunistic behaviour
14	ERP-based prices should be aligned with other tools used when

## Results snapshot

# Pricing policies for in-patent pharmaceuticals

	Price in country of origin	Price of similar pharmaceuticals on the market – IRP	Prices found in official references or publications <sup>2</sup>	Therapeutic Significance	Pharmaco-economic studies/ Cost-Effectiveness Evidence	ERP	Price in Saudi Arabia	Proposed price by the manufacturer
<b>Algeria</b>						✓		
<b>Bahrain</b>	✓	✓	✓	✓	✓	✓		
<b>Egypt</b>						✓		
<b>Jordan</b>	✓	(✓) <sup>3</sup>			✓	✓	✓	✓
<b>Kuwait</b>						✓		
<b>Lebanon</b>	✓					✓		
<b>Morocco</b>						✓		
<b>Oman</b>	✓	✓	✓			✓		
<b>Qatar</b>						✓		
<b>Saudi Arabia</b>	✓	✓	✓	✓	✓	✓		✓
<b>UAE</b>	✓	✓	✓	✓	✓	✓		✓

# Reimbursement & Procurement of in-patent pharmaceuticals

	IRP molecular	IRP therapeutic	IRP managed competition	ERP	HTA	RSA	Tendering	Formulary management	CCBA <sup>1</sup>	Negotiation	Budget Impact
<b>Algeria</b>	x	x	x	√-	x	√	x	√ <sup>2</sup>	√	√	√
<b>Bahrain</b>					x						
<b>Egypt</b>	x	x	x	x	x <sup>3</sup>	√	√	√ <sup>2</sup>	√	√	
<b>Jordan</b>					x		√				
<b>Kuwait</b>				x	x						
<b>Lebanon</b>	x	x	x	x	x	√	√	√	x	√	
<b>Morocco</b>	x	x	x	√-	x	x	√	x	√	√	
<b>Oman</b>					x						
<b>Qatar</b>	x	x	x	√	x	x	√	√	x	x	x
<b>Saudi Arabia</b>	x	x	x	x	x <sup>3</sup>	x	√	√	x	√	
<b>UAE</b>	x	x	x	x	x	x	x	√	x	√	

**Notes:** <sup>1</sup> Comparative clinical benefit assessment

<sup>2</sup> Only used in hospitals, not at national level

<sup>3</sup> Not currently using but HTA planned to be implemented in due course based on passed legislation or current government initiative

√- = Used as a reference price

# The role of demand-side: Generic prescribing and substitution

	Generic prescribing			Generic dispensing/substitution	
	Is there a generic prescribing policy in place?	Is generic prescribing mandatory or encouraged within existing policy? (n/a for countries with no relevant policies)	For generic mandatory prescribing policies, is there an IT system? (-' for non-mandatory systems)	Is there a generic substitution policy in place?	Is generic substitution mandatory or encouraged within existing policy? (n/a for countries with no relevant policies)
<b>Algeria</b>	✓	Encouraged	-	✓	Encouraged/mandatory
<b>Bahrain</b>	NA	Not mandatory	-	NA	NA
<b>Egypt</b>	* (not explicit)	N/A	-	✓	Encouraged
<b>Jordan</b>	✓	Mandatory	No	✓	Mandatory (public sector)
<b>Kuwait</b>	NA	Encouraged/Not mandatory	-	✓	Encouraged (public sector)
<b>Lebanon</b>	✓	Encouraged	-	✓	Encouraged
<b>Morocco</b>	NA	NA	NA	NA	NA
<b>Oman</b>	✓	Mandatory (public sector)	NA	✓	Encouraged (public sector)
<b>Qatar</b>	✓	Mandatory	NA	*	n/a
<b>Saudi Arabia</b>	NA	Not mandatory	-	✓	Encouraged
<b>UAE</b>	✓	Mandatory (public sector)	NA	✓	Encouraged

## Synthesis of key findings



# Synthesis of findings - Pricing policy

- **Dominance of ERP:** cost minimization tool in MENA by benchmarking against the lowest list prices in large baskets → prices converge downwards over time
- No account of **value of innovation** → need for local data and capacity building
- Large **ERP baskets** and repetitive referencing lead to complex ERP administration → delay in new product launching and reduced availability
- Absence of **formal value assessment** → need for a) transparent criteria and b) clear implementation mechanisms
- Use of discounted prices affects **transparency**
- Use of unrealistic and volatile **exchange rates** further lowering prices and availability → need for fixed exchange rates or moving averages
- **Patent Status** issues: using IRP + ERP coupled with differences in IP → price distortions
- Long **registration and pricing processes** → need for streamlined pricing process

# Synthesis of Findings – Pricing Policy

- Consequences of ERP Dominance
  - Availability issues
    - **Pricing policy:** low prices lead to delays in launching (even not launching) and withdrawal of products in/from the market
    - **Pricing system inflexibility:** highly regulated markets not accommodating external factors, or not considering inflation
    - **Protracted price negotiation and approval:** causes delay in market entry
  - Spillover effects, case of small markets and/or limited spending
  - International implications
  - Value of innovation
- Absence of Formal Value Assessment

# Synthesis - International implications of ERP

- Launch delays in other countries until reference countries set their prices
- Downward price conversion of innovative pharmaceuticals irrespective of economic status amplified by the GCC price harmonisation process
- Decision makers in the MENA region may be aware of these implications but very few attempt to mitigate them.

	Launch delays	ERP leads to price (downward) convergence	GCC harmonisation leads to price convergence	Decision-makers attempt to mitigate international implications of ERP
<b>Algeria</b>	✓	-	-	✓
<b>Bahrain</b>	-	-	-	-
<b>Egypt</b>	✓	✓	✓	×
<b>Jordan</b>	✓	✓	✓	-
<b>Kuwait</b>	✓	✓	✓	-
<b>Lebanon</b>	✓	✓	×	-
<b>Morocco</b>	-	-	✓	×
<b>Oman</b>	-	-	-	-
<b>Qatar</b>	✓	✓	✓	-
<b>Saudi Arabia</b>	✓	✓	✓	-
<b>UAE</b>	?	✓	✓	×

- Fragmented Systems
- Dominance of Tendering in Public Procurement
- No explicit system of value assessment
- Increased *Interest* in HTA
- ERP as a Starting Point for Negotiations
- Move Towards more Active (Mandatory) Generic Prescribing

## Policy options for the future

# I. A Path to Medium- and Long-Term *Pricing Policy Strategy* in MENA countries

## MEDIUM-TERM: OPTIMISING CURRENT STATE AND CURRENT USE OF ERP

### Medium-term pricing policy state

- Administratively simple and transparent
- Possibility to appeal
- Appropriate country selection
- Consideration of international implications
- Use of ex-factory prices
- Use of mean prices
- Avoid impact of exchange rate fluctuations
- Price revisions to the minimum
- Gradual Adoption of HTA

### Long-term pricing policy state

- Clear objectives aligning with policy goals
- Focus on in-patent drugs
- ERP prices do not override HTA decisions
- Respect of patent status
- Alignment with negotiation tools

## LONG-TERM: MATURING TOWARDS A VALUE-BASED PRICING SYSTEM

## II. Transitioning from ERP to VBP (1)

### Current system limitations and way forward

- Cost minimisation through ERP can no longer be met: list prices in reference countries are artificial
- MENA countries can continue to implement ERP in the future as well as strive to adhere as much as possible to the best practice principles outlined in the previous section, but safeguard affordability not by resorting to the lowest price in extensive ERP baskets, but by implementing competent negotiation strategies and value assessment methods
- Establish a value assessment pathway where a negotiated approach is the preferred course of action

### Paving the way for a VBP system

- The transition to value assessments requires investment in two key areas: 1) institution-building, and 2) human capital and development of capabilities.
- MENA countries have many options concerning (a) the type of HTA system they can implement and (b) the type of model based on which value assessment will take place.
- Stages for the **type of HTA system**:
  1. *Stage 1*: HTA is not an explicit process to start with
  2. *Stage 2*: Capacity- and institution-building
  3. *Stage 3*: Establish an HTA mechanism based on “summary evaluation approach”.
  4. *Stage 4*: Establish an independent HTA agency or institute based on the principles of a “consultative approach”

## II. Transitioning from ERP to VBP (2)

### Model of value assessment options

Options for the **model of value assessment**:

1. *The clinical and cost-effectiveness model* uses economic evidence in addition to comparative clinical benefit
2. *The comparative clinical benefit assessment model* relies on ranking new interventions based on comparative efficacy/clinical benefit and making the pricing decision the subject of negotiation between government/insurance organisations and manufacturers
3. *The value-based pricing model* takes explicitly into consideration additional dimensions of value beyond effects and/or costs, such as disease severity, burden of disease, treatment innovativeness, equity considerations, etc.

### Limitations to the establishment of a system of value assessment and overcoming these

- **Limitations** to HTA implementation:

1. Lack of expertise and critical mass
2. Lack of infrastructure in terms of established organisations and human resources
3. Broader infrastructure issues, such as the existence or not of a unified reimbursement system

- **Overcoming** current limitations

1. Decide on type of evidence requirements
2. Guidelines for submission
3. How assessments/appraisals are performed
4. What data informs assessments & local availability
5. What constitutes evidence
6. Whether stakeholders are consulted



### III. Re-thinking universal coverage and reimbursement



- Achieving universal health insurance coverage: needs to be the focus of policy attention over the next decade, at least in some of the MENA countries – there is significant space for improvements
  - Extend coverage and benefits where they do not exist
  - Extend the same coverage to all population groups/segments
  - Reduce OOP
- The transition to a unitary system with the same principles across all citizens is desirable on equity, efficiency and effectiveness grounds. It will require significant attention, investment as well as adherence to strict budgetary and efficiency principles.
- It will have implications for all components of the pharmaceutical value chain
  - *For new and innovative products:* (a) focus on value assessment of new and innovative treatments and (b) their timely incorporation into the benefits catalogue
  - For off-patent and generic products: focus on a more robust and consistent generics policy, both from a supply-side (pricing and price setting) and a demand-side (prescribing, dispensing, cost-sharing) perspective in order to capitalise on the financial benefits of genericisation.
- Beyond generating 'unitary' reimbursement systems, national pharmaceutical policies will need to address the issue of financing and its sustainability, a balanced industrial policy, the regulation of the distribution chain, and the assessment of policy interventions.

THANK YOU!

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# Pricing and Reimbursement: Issues and Challenges



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Ministry Of Health  
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# Pricing and Reimbursement Challenges

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Health Economics and Outcomes Research, University of Washington

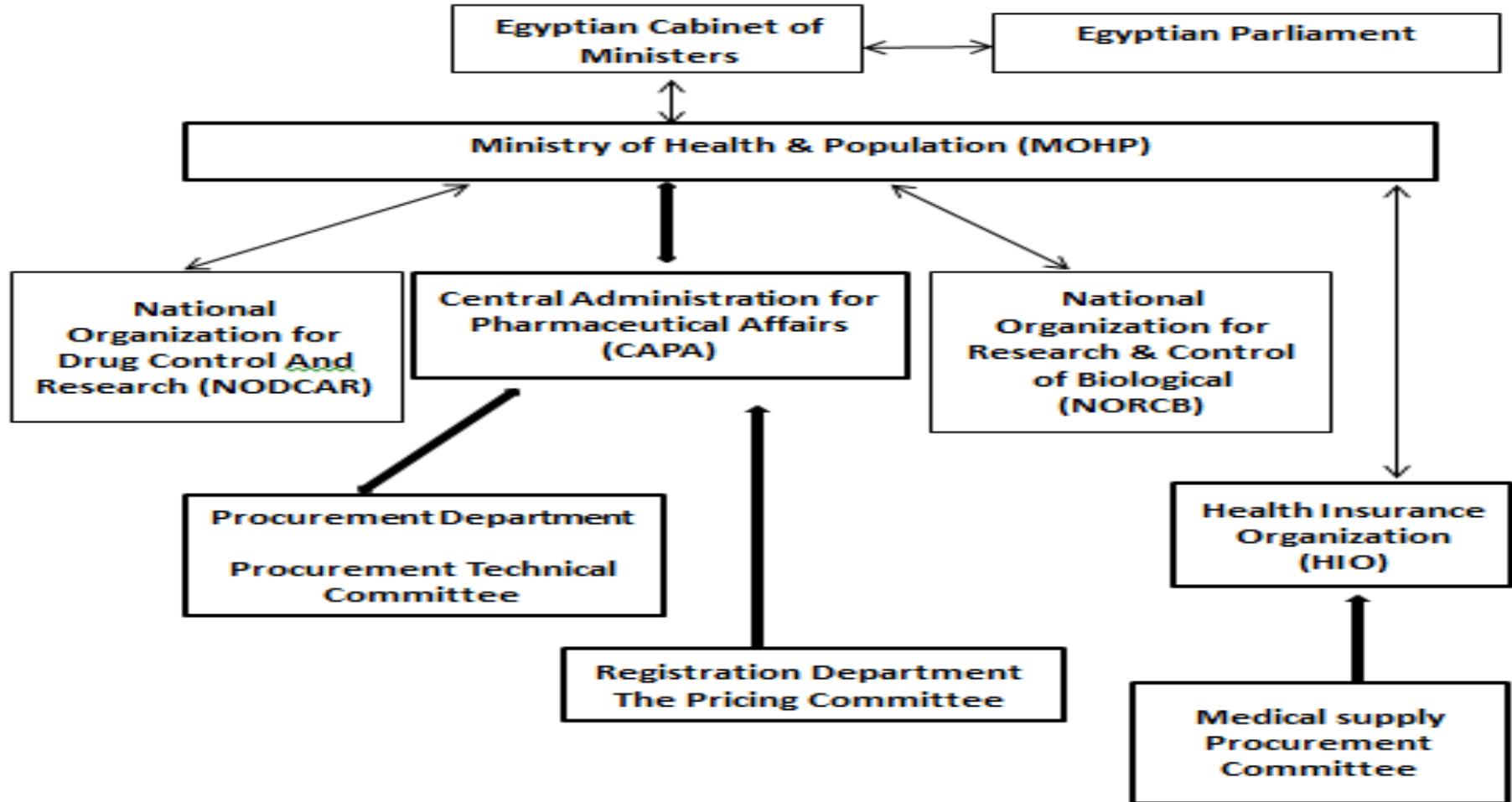
Principal member of Pharmacoeconomics committee, CAPA, Ministry of Health, Egypt

Lecturer-Health Economics, Faculty of Pharmacy, Arab Academy & Cairo University

Treasurer of International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Egypt Chapter

Any statement used on my slides are  
reflecting my personal views on the  
Egyptian pricing and reimbursement  
system

# Decision Makers & Influencers in Egypt

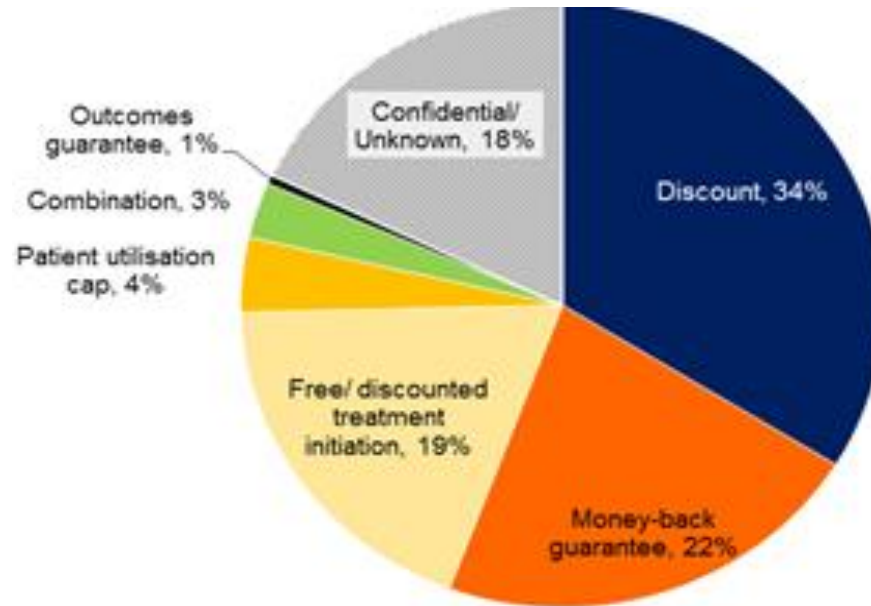


# Important issues

The main issues with pricing policies include the need to create equitable access, sustainable supply and procurement policies.

Some prices of patented medicines are confidential, though policymakers are becoming more aware of the impacts and consequences of policies they did previously.

# Types of MEA applied for cancer medicines in European countries



Source: Pauwels K, Huys I, Vogler S, Casteels M, Simoens S. Managed entry agreements for oncology drugs: Lessons from the European experience to inform the future. *Front Pharmacol.* 2017;8(APR):1–8.



# Challenges in Egypt

Lack of consistent price regulation.

Patients with lower income had lower access to innovative medicines, with availability often subject to higher out-of-pocket payments by patients.

Implementation of value based pricing on very limited cases

Shortage in supply of medicines

# Opportunities in Egypt

The effectiveness of pricing policies would be enhanced by having robust competition policies and good governance

The selection and procurement process of new innovative medicines should be build on evidence based data

Re-assessment of prices

New social health insurance system

Thank you

# Pricing and Reimbursement: Issues and Challenges



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# Pricing & Reimbursement in Saudi Arabia: Challenges & Opportunities

Abdulaziz H. Al-Saggabi, B.Sc., M.Sc., Pharm.D.  
Director, Drug Policy & Economics Center  
Ministry of National Guard Health Affairs

# Saudi Pharmaceutical & Health Spending

	2018 *	2021*
Pharmaceutical Sales (USDbn)	7.9	9.2
Pharmaceutical Sales (SARbn)	29.6	34.7
Pharmaceutical Sales as % of GDP	1.08	1.04
Pharmaceutical Sales as % of Health Expenditures	21.2	21.5
Health Spending (USDbn)	37.19	43.21
Health Spending (SARbn)	139.48	162.03

\*BMI Forecast

# Introduction

- Competent Authorities in KSA
  - Market Authorization & Pricing
    - Saudi Food & Drug Authority (SFDA)
  - Reimbursement
    - Government Health Care Sectors
    - Private Hospitals/ Insurers
- Actions for Pricing & Reimbursement
  - During Marketing Authorization
    - Pricing
  - After Market Authorization
    - Reimbursement and Procurement.

# Challenges

- Increased prices, number and complexity of high cost pharmaceuticals
- Independent Reimbursement Decision-Making
- Lack of National Reimbursement system that optimize the use of cost-effectiveness in reimbursement decision-making in a national level.
- Limited Risk Sharing/ Managed Entry Agreements including outcome-based agreements.



# Opportunities

- KSA 2030 Vision
  - 2020 National Transformational Program (NTP)
    - Increase the efficient utilization of available resources
    - Achieve efficiency of government spending
- Newly formed National Committee for High Cost Medication
  - Unified Reimbursement Decision-Making
  - National HTA Program
- Unified Procurement through NUPCO

Thank You

# Pricing and Reimbursement: Issues and Challenges



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# Pricing and Reimbursement: Issues and Challenges

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Senior Director and Head, Public Affairs MENA

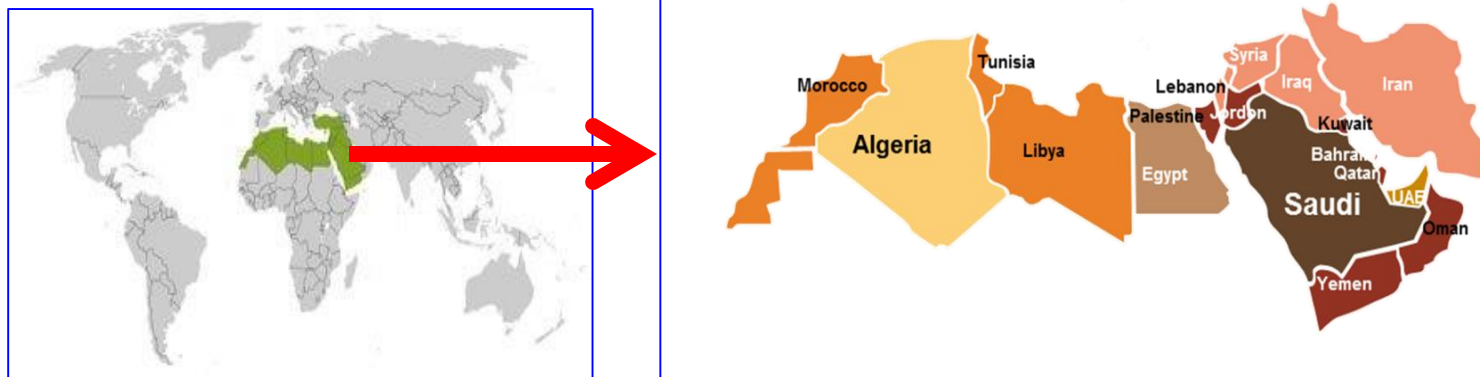
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ISPOR Regional Meeting – Dubai

September 20<sup>th</sup>, 2018

# The MENA Region

*Dynamic, rapidly growing region with great potential*



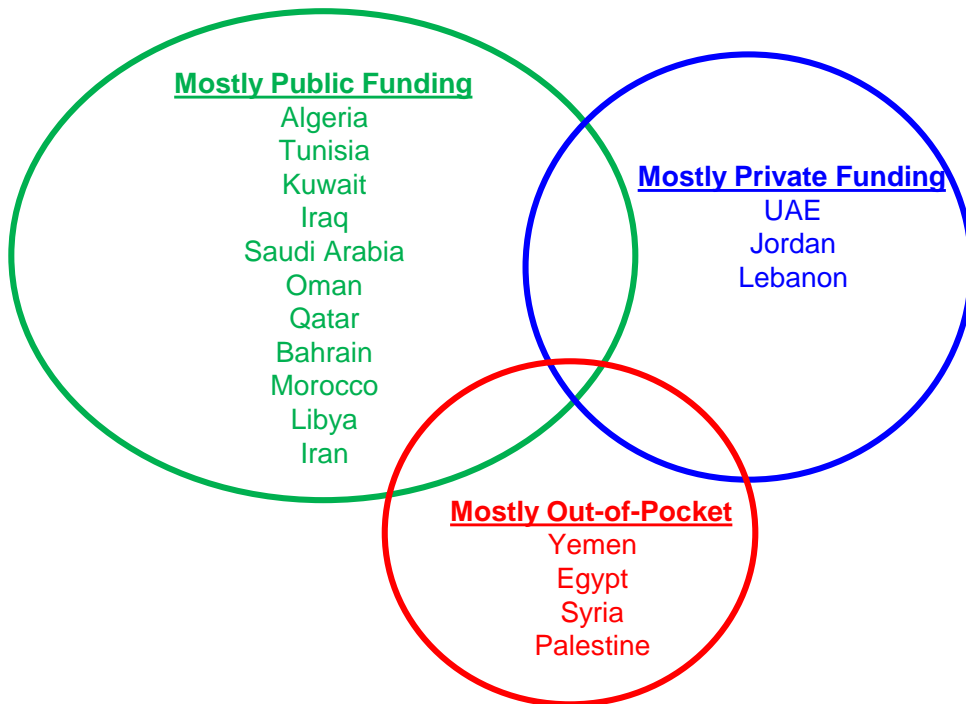
**Pharma Market Size (\$b) (BMI)**

Market	2016	2017	2022	2017-22 CAGR
Saudi Arabia	7.4	7.5	9.8	5.5%
Algeria	3.6	3.7	4.8	5.2%
UAE	2.6	2.8	4.1	7.7%
Iran	2.0	2.2	3.5	9.5%
Egypt *	1.9	2.0	2.3	2.7%
Others	10.3	10.6	13.6	5.1%
<b>Total</b>	<b>27.9</b>	<b>28.9</b>	<b>38.2</b>	<b>5.7%</b>

Indicator	World	MENA	MENA %	Source
Land (Sq. km)	134,325,130	11,370,611	8%	WB (2016)
Population (millions)	7,442,000,000	436,720,722	6%	WB (2016)
Life expectancy (years)	71.889	73.32	.	WB (2016)
Birth rate (per 1,000)	19.08	23.32	.	WB (2016)
Death rate (per 1,000)	7.65	5.02	.	WB (2016)
GDP (Trillion, US \$)	75.54	3.1	4%	WB (2016)
Oil Production (Barrels, Bil)	1,492.16	857.28	57%	OECD (2016)

# Payer Landscape in MENA

## *A Mix of Public, Private and Self-Pay Markets*



# Ideal Pharmaceutical Pricing System

- Places great emphasis on **value** of innovation
- **Transparent, predictable and sustainable**
- **Separates** MA approval from Reimbursement
- Reasonable **reimbursement** timelines

# Pricing Challenges in MENA Region

- Predictability, transparency
- Cost, not value-driven
- Application of the existing ERP system
- Harmonization process (operational aspects)
- Localization policies
- Procurement policies
- Currency stability



# The Opportunities

- National Health Coverage
- Gradual implementation of value-base system
  - Embrace new Patient Access models
- Optimization of ERP
  - Price convergence (vs harmonization)
  - Differential pricing system
- Transparent reimbursement system
- Stakeholder engagement and dialogue

**Thank you**

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# Pricing and Reimbursement: Issues and Challenges



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