# MANAGED ENTRY AGREEMENTS (MEA) IN EGYPT, LEBANON, SAUDI ARABIA, AND UNITED ARAB EMIRATES

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## AGENDA

- **Innovation & Access To Medicines**
- **Regulatory Perspective**
- **Managed Entry Agreements: Key Issues**
- **The UAE: Facts, Figures & Healthcare System**
- **Summary**

## Introduction: Innovation & Market Access

- Spend on prescription medicines is one of the fastest growing cost components of modern health care systems.
- Promoting rational access to innovative medicines the key driver for quality Healthcare service and lead to utilize HC resources efficiently.
- Using economic evaluation methods as a decision making tools will promote value based spending and facilitate rational patient access to medicines.



## Innovation & Market Access

- **10-15** years required to make a medicine
- **$1,300,000,000** = Average cost to develop one medicine.
- **Pre-Registration:**
  - Pre-clinical testing: Lab or Animal (Phase 0)
  - Clinical testing in Human: (3 Phases): 1: volunteers, 2 patients, 3 multi-centre
- **Registration/ Market Authorization**
  - Safety, Quality , Efficacy & cGMP
  - Cost: Affordability, Efficiency, Reimbursement
- **Post registration:**
  - Post Marketing Surveillance, Outcomes research
  - Monitoring : Good PV Practice

## Access to Medicines: Regulator Responsibilities

- Protect patients welfare
- Promote & Support drug innovation and research to serve patients and the community.
- Develop frameworks& standards that assure patient safety, the quality, availability, affordability and rational use of medicines**.**



## Access To Medicines: Traditional Methods

- External Reference Pricing: price from other countries
- Internal reference-based pricing: similar entity, class, indication
- Volume-price agreement/Tendering
- Other methods: negotiation, ceiling price, floor price
- Profit control
  - Wholesaler margins/ Mark up
  - Pharmacy margin/ Mark up

## Access To Medicines : Modern Methods

- ***Value based pricing (VBP)***

  A system of evaluating new pharmaceuticals and establishing a maximum price based on clinical effectiveness and other factors. Increasingly common in health care systems worldwide. Where payers and pharma companies agree to link payment for a medicine to value achieved, rather than volume. Agreements dictate price (and/or coverage) relative to actual (i.e., observed in real world)



## Accelerate Market Access for Innovated Medicines: Pay For Performance

*Managed Entry Agreement* (MEAs)

*Performance-Based Risk-Sharing Arrangements* (PBRSAs)/

Involve a plan by which the performance of the product is tracked in a defined patient population over a specified period of time and the level or continuation of reimbursement is based on the health and economic outcomes achieved

ISPOR TASK FORCE REPORTS Performance-Based Risk-Sharing Arrangements Guideline, 2013
https://www.ispor.org/risk-sharing-health-program-guideline.pdf

## MANAGED ENTRY AGREEMENTS

Deferent names

- Coverage with Evidence Development (CED)
- Pay-for-Performance Agreements
- Risk-Sharing Agreements
- Performance-Based Risk-Sharing Arrangements
- Access with Evidence Development
- Practiced in many countries i.e.: UK, USA, France, Italy & Netherland



## When Is a PBRSA Worthwhile or Desirable?

The payer has four major options

- 1. Adopt (or partially adopt) despite the uncertainties, with the option to revisit the decision if more information becomes available.
- 2. Refuse to adopt until the manufacturer supplies better evidence to address the uncertainties.
- 3. Demand or mandate a lower price such that the uncertainty about value for the payer is reduced.
- 4. Enter into a Performance-Based Risk-Sharing Arrangements PBRSA that
  - a) manages utilization/outcome at the patient level or
  - b) is a form of CED in which evidence is collected across patients for a review, potentially leading to pre-specified adjustments or later ad hoc adjustments in price or utilization.

ISPOR TASK FORCE REPORTS Performance-Based Risk-Sharing Arrangements Guideline, 2013

## MEAs/PBRSAs: Key Issues

- The risk shared between payers & manufacturers
- Good for innovated drugs has:
  - No enough/ underdeveloped evidence about its cost effectiveness
  - High budget impact
  - Clear clinical outcome
  - Clear methods for measuring its effects
- The coverage linked to
  - Outcome: health and cost
  - Prospective/retrospective



## MEAs/PBRSAs: Key Requirement

- Implementation Plan & cost.
- Tracking performance system.
- Key Performance Indicators
- Outcome measure ( Health/Economic)
- Trust between payer and Pharma
- Active communication

## AGENDA

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- Regulatory Perspective
- Managed Entry Agreements: Key Issues
- **The UAE: Facts, Figures & Healthcare System**
- Summary



## The United Arab Emirates: Facts and Figures

- Population: 9.3 million (est 2014) [1, 2]
- Total life expectancy at birth ≈ 77 years
- Total GDP 2013 ≈ 384 $ bn [3] 2nd in GCC 3rd in MENA region
- One of most organized & fastest growing health care markets in the GCC
- Has highest per capita drug expenditure in ME
- Has strong HC infrastructure
- UAE has the most attractive Investment environment[4]
- UAE is a medical tourism hub in the GCC and the Middle East

1.UAE Statistics www.uaestatistics.gov.ae
2. World Bank Reports www.worldbank.org
3. MOE 2013
4. The Global Competitiveness Index Report 2014

# UAE VISION

We want to be among the best countries in the world by 2021

"With our Citizens at the heart of development, we strive to become one of the most competitive countries in the world"

**His Highness Sheikh Mohammed Bin Rashid Al Maktoom**

"نسعى في دولة الامارات الى ان نكون من اكثر دول العالم تنافسية
مع وضع مواطنينا في صميم عملية التنمية"

صاحب السمو الشيخ محمد بن راشد آل مكتوم



## World Economic Forum
## The Global Competitiveness Report 2014–2015

| | Economy | Score[1] | Prev.[2] | Trend[3] |
|---|---|---|---|---|
| 1 | Switzerland | 5.70 | 1 | |
| 2 | Singapore | 5.65 | 2 | |
| 3 | United States | 5.54 | 5 | |
| 4 | Finland | 5.50 | 3 | |
| 5 | Germany | 5.49 | 4 | |
| 6 | Japan | 5.47 | 9 | |
| 7 | Hong Kong SAR | 5.46 | 7 | |
| 8 | Netherlands | 5.45 | 8 | |
| 9 | United Kingdom | 5.41 | 10 | |
| 10 | Sweden | 5.41 | 6 | |
| 11 | Norway | 5.35 | 11 | |
| 12 | United Arab Emirates | 5.33 | 19 | |
| 13 | Denmark | 5.29 | 15 | |

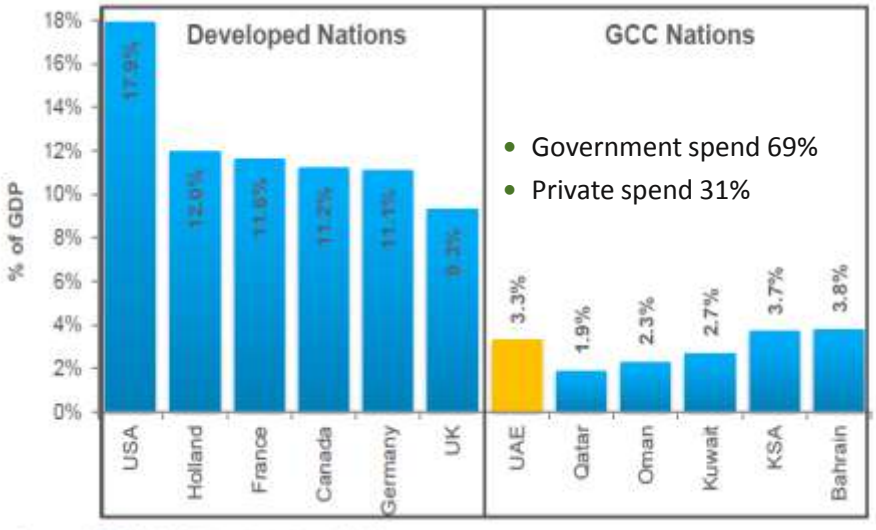
## Healthcare System in the UAE

- Industry is fuelled with latest technology
- Private sector participation has increased over last few years
- Health Insurance models becoming the dominant way of health funding

| | |
|---|---|
| **Regulator** | • Federal laws<br>• International obligations<br>• Ministry of Health & Local health Authorities |
| **Provider** | • Governmental & Semi Gov.<br>• Private sector<br>• *Free Medical Zones* |
| **Payer** | • Governments<br>• Health Insurance ( Gov. Employers & Individuals)<br>• Individuals & Non profit organization |



## Healthcare Spending as % of GDP




- Government spend 69%
- Private spend 31%

*Source: UNDP 2012, Calibers International 2013*

## Pharmaceuticals: Regulatory Culture

- > 84% of registered pharmaceuticals are imported
- Strong Intellectual Property Protection
- MoH regulates
  - Conventional & Complementary Medicines, Medical Devices and Veterinary Medicines
  - Drug Price, profit margin for pharmacy &distributer
  - Medical &health related advertisements
- Fast Track: Accelerated approval and access to life saving and innovative drugs i.e. Bydureon (exenatide); Gilenya (fingolimod), Trulicity (dulaglutide)
- PV/ Risk management plan for each registered medicine mandatory within registration process



## Pricing Medicines in the UAE

- Drug prices regulated by MoH Pharmacy Law 4/ 1983
- Pricing criteria
  - CIF Price for Imported medications
  - Ex-Factory price for local manufacturing
  - International/ External Price Referencing (EPR)
  - Internal reference/comparative pricing
  - Profit Control:
    - Local Agent margin
    - Pharmacy margins

## Access to Medicines in the UAE Mile Stones

| Initiatives | Year |
|---|---|
| ***Price comparison study ( local study)*** | ***2010*** |
| Price reduction initiative, waves (1&2) | 2011 |
| Price reduction initiative, wave (3) | 2013 |
| ***New Pricing Criteria ( June 2013)*** | ***2013*** |
| ***GCC Price Harmonization: Dollarization & CIF Unification*** | ***2013*** |
| ***MENA External Price Referencing (EPR) Survey*** | ***2014*** |
| Price reduction initiative, wave 4 | 2014 |
| Price reduction initiative, wave 5 | 2015 |



## New Pricing (6 June 2013):Key Changes

1. **Dollarization: CIF Prices in USD***
2. **Medicines are categorized in 3 categories** as per CIF price in AED

| A | B | C |
|---|---|---|
| CIF ≤ 250 AED | CIF >250 to 500 AED | CIF >500 AED |
| Ph Margin: 24% | Ph Margin: 20% | Ph Margin: 17% |

3. **New Profit Margins: Total Margin = 35-43% from CIF to RP/PP**
   - **Wholesaler margin: 15% of CIF** (11% of WSP)
   - **Pharmacy margins** : **17-24% of WSP** (20-28% from CIF)

* The Ex-Factory price in AED for local companies will substitute for the CIF import price AED

## GCC CIF Unification & Dollarization

**Background:**

- Decision been approved by the GCC Supreme Council (27th session December 2006) to:
  - Unify the CIF export price of medicines to the GCC countries (as per the lowest in the GCC )
  - All CIF in U.S. dollars/ Dollarization
  - Total Mark-up (wholesaler& pharmacy) not more than 45% of CIF price.
- Pricing unit at GCC Central registration
- New GCC Pricing criteria

www.sgh.org.sa



## Implications of External Price Referencing of Pharmaceuticals in Middle East Countries

- Zoltán Kaló[1,2], Ibrahim Alabbadi[3], Ola Ghaleb Al Ahdab[4], Daoud Al-Badriyeh[5], Maryam Alowayesh[6],
- Abdulaziz H Al-Saggabi[7], Mahmoud Elmahdawy[8],
- Vito Luigi Tanzi[9], Faleh Mohamed Hussain Ali[10],
- Hamad S Alsultan[11], Kasem S Akhras[12], Zoltán Vokó[1,2], Panos Kanavos[13]

1) Eötvös Loránd University, Budapest, Hungary,
2) Syreon Research Institute, Budapest, Hungary
3) University of Jordan, Amman, Jordan
4) Ministry of Health, Abu Dhabi, United Arab Emirates
5) College of Pharmacy, Qatar University, Doha, Qatar
6) Kuwait University, Yarmook, Kuwait
7) Ministry of National Guard Health Affairs, Riyadh, Saudi Arabia
8) Ministry of Health, Cairo, Egypt
9) American University of Beirut, Beirut, Lebanon
10) Supreme Council of Health, Doha, Qatar
11) Dasman Diabetes Institute, Dasman, Kuwait
12) Novartis, Dubai, United Arab Emirates
13) London School of Economics and Political Science, London, United Kingdom

## Pharmacoeconomics Landscape

***Current Status***

- The interest in Pharmacoeconomics & HTA increased among regulator, health care providers and payers
- Managed Entry Agreement/ Risk- sharing arrangements not implemented yet
- There is high need for PE and Health Economic education, training & related research in the UAE and GCC countries
- ***ISPOR UAE chapter promoting in line with ISPOR mission the followings:***
  - Promoting awareness about Pharmacoeconomics and outcomes research
  - Capacity Building: via collaboration with Academia to Include PE in the curricula in Pharmacy colleges at both Undergrad and Postgraduates studies. And currently there are dedicated PG course (MSc Clinical Pharmacy) in two universities in the UAE
  - Highlighting the need to use PE methods formally in policy decision making
  - And Organize conference, educational and training activities



## Pharmacoeconomics Landscape

***Future Plans***

- Complete & publish the UAE PE Guideline
- Promote access to innovated drugs via MEA/ Risk-sharing arrangements
- Update related policies and treatment guidelines
- Promote research and conduct drug use studies and outcomes research

## Executive Summary

- Risk sharing agreement, value based pricing and Budget impact analysis, are an example for methodologies that promote patient access to innovated medicine
- Barriers to the use of such economic evaluation formally are exciting
- Independent research are needed in the UAE and MENA to assess and evaluate key attributes and barriers in drug use, prescribing trends, pricing& reimbursement system and using economic evaluation as decision making tools.
- Appropriate education for decision makers, healthcare professionals and the public are required
- Academia & regional ISPOR Chapters has an important role in Capacity Building, Training & Education and in Developing and implementing PE & HTA in MENA



## Executive Summary

- Quality healthcare services, Quality Education and capacity building are at the top of UAE government agenda
- Favourable regulatory environment in the UAE help in accelerating the access to innovative medicines.
- GCC Price Harmonization (Dollarization and CIF Unification) will help in promoting the access to innovative drugs in the GCC.
- Joint efforts & collaboration among stakeholders to develop & implement related policies, strategies and action plan are the key driver to promote rational access to medicines and for creating a sustainable quality and value-driven health care system in the UAE and MENA region in order to :
  - Enhance related regulations and policies
  - Using economic evaluation formally
  - Implement and promote the use of MEA/ PB risk-sharing arrangements
  - Capacity building

# Thank You

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