

# Reflections on MEA Pharma Compliance & Code

## *from Corporate to Private*

**Joe Henein**

*President & CEO NewBridge Pharmaceuticals*

*Former Managing Director MENA - Wyeth 2004-2009*

*Chair Ethics Review Board – PhRMA MEA 2005-2009*

*Vice Chair PhRMA – MEA 2008 - 2009*



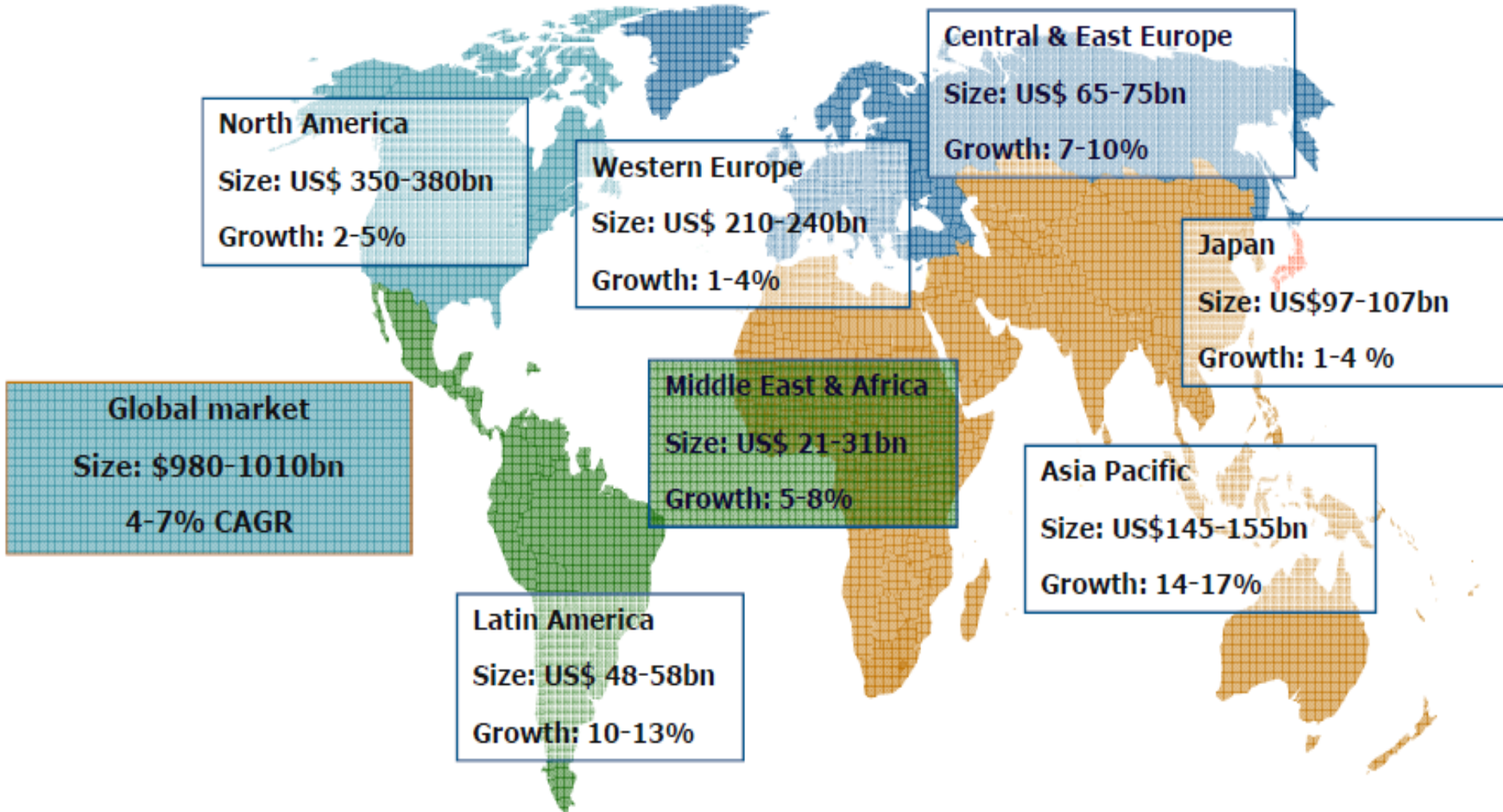
### Biography – Joe W. Henein

- ❑ Currently President & CEO NewBridge Pharmaceuticals - US/Kuwait privately backed company covering the AfMET Region – Africa Middle East & Turkey markets.
- ❑ 30 years experience in Pharma Industry covering ME, EU & Global
- ❑ Most recently Managing Director of Wyeth in MENA
- ❑ Prior responsibilities VP & Global Commercial Chair for numerous therapeutic areas Infectious, Metabolic Diseases & Women's Health Care, and various commercial roles in ECE & MEA
- ❑ Served in many global committees within the company; Development Council; Development Strategy Board; European Council
- ❑ Served as Vice Chair for Pharma MEA, and Chair of Ethics Review Board



# MEA Regional Code of Pharmaceutical Promotional Practices

## Global: IMS Regional Pharmaceutical Outlook in 2013 (US\$ Billions)

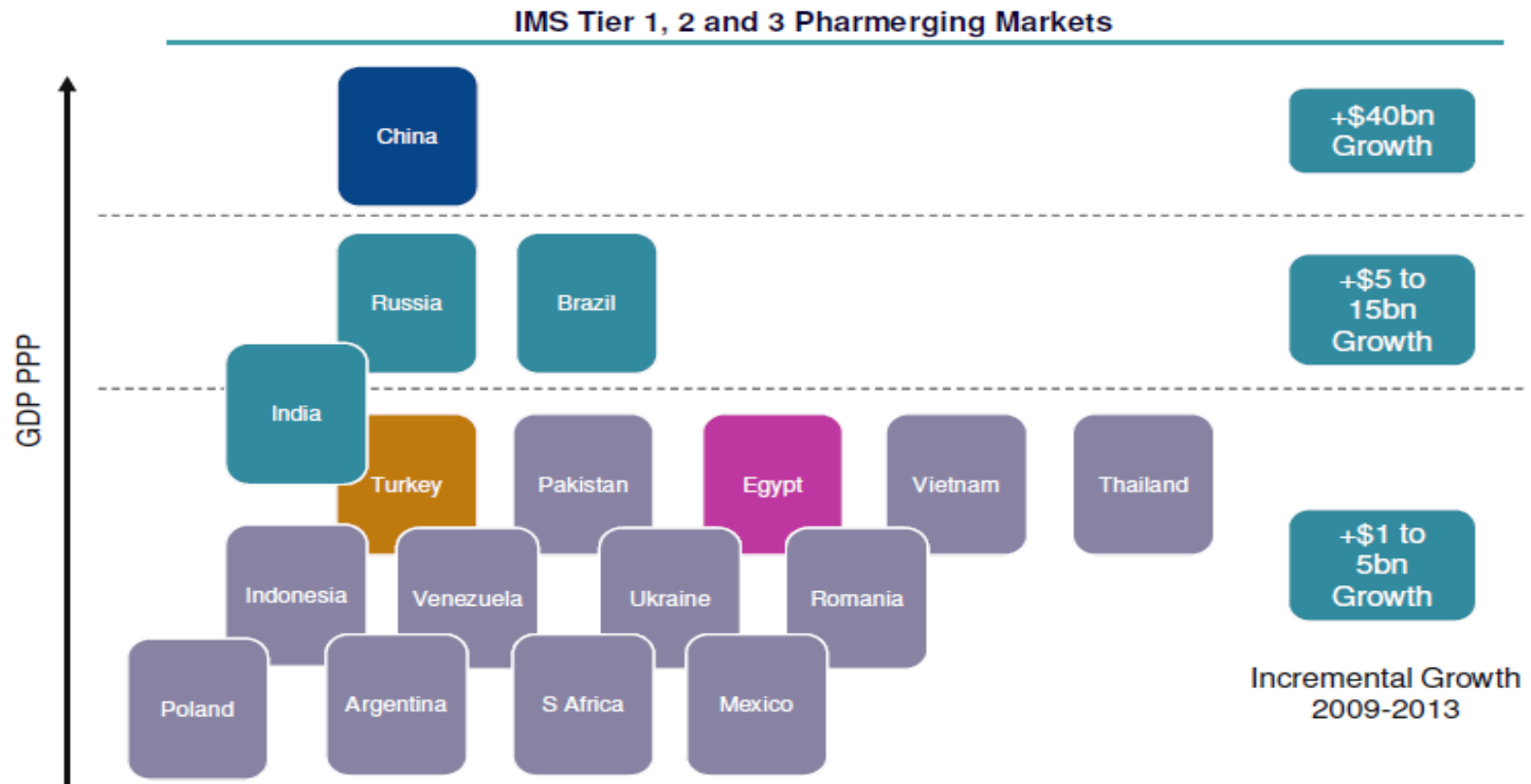


Source: IMS Health, Market Prognosis September 2009.



# MEA Regional Code of Pharmaceutical Promotional Practices

Changes in market dynamics drove IMS to a more hierarchical, nuanced definition of pharmerging markets



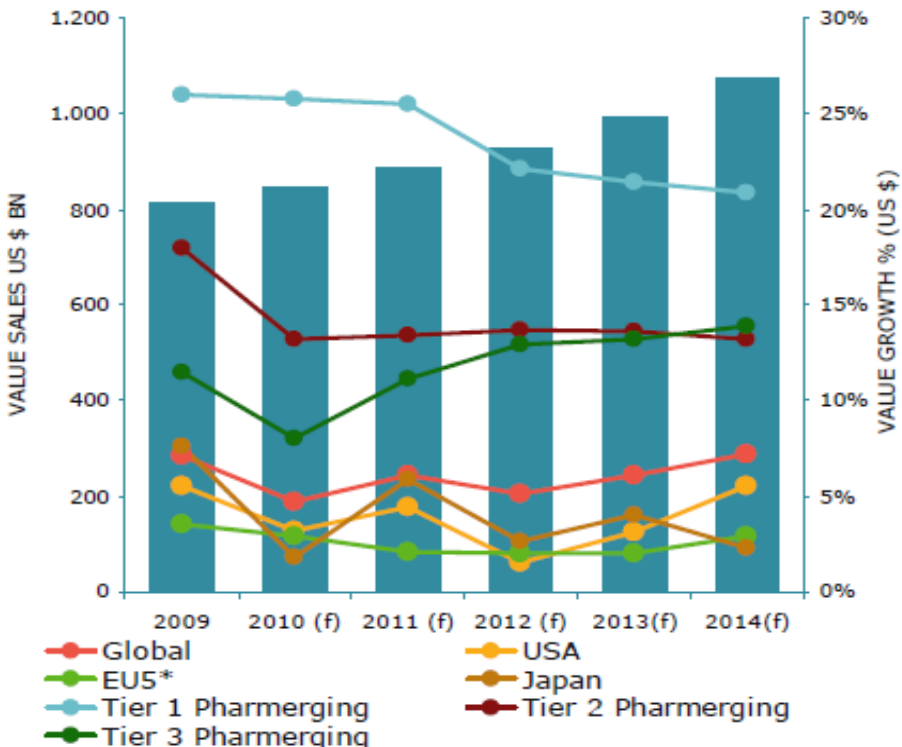


# MEA Regional Code of Pharmaceutical Promotional Practices

Global Pharma growth will start to recover in 2013  
Pharmerging markets will continue to see robust growth

## Global Pharma Historical Market Dynamics & Current Economic Environment

Global Sales and Market Growth



Mature Markets CAGR 2010-2014		Pharmerging Markets CAGR 2010-14	
US	2-5%	Tier 1	22-25%
Japan	2-5%	China	22-25%
Germany	1-4%	Tier 2	12-15%
France	0-3%	Brazil	12-15%
Italy	1-4%	Russia	10-13%
Canada	2-5%	India	15-18%
Spain	2-5%	Tier 3	10-13%
UK	1-4%	Pharmerging	14-17%
S. Korea	6-9%		
<b>Mature</b>	<b>2-5%</b>		

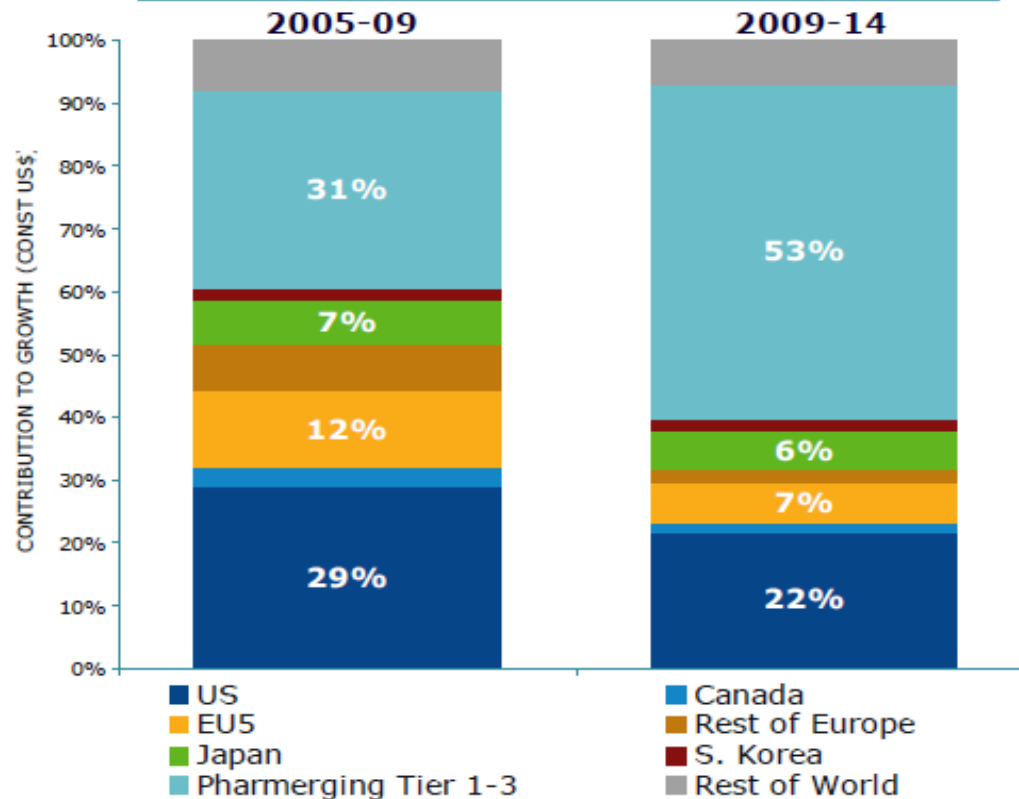
Source: IMS Health Market Prognosis September 2010; Tier 3 = Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, S. Africa, Thailand, Indonesia, Romania, Egypt, Pakistan, Ukraine



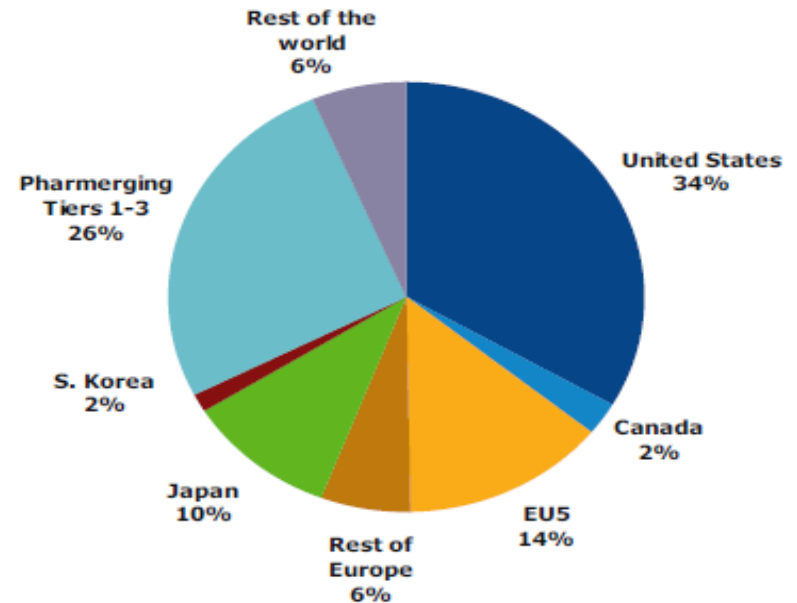
# MEA Regional Code of Pharmaceutical Promotional Practices

Pharmerging markets will contribute more than half of the global growth between 2009-2014  
This \$160bn will take their global market share to 26%

Contribution to global growth, Const US\$



2014 Market share

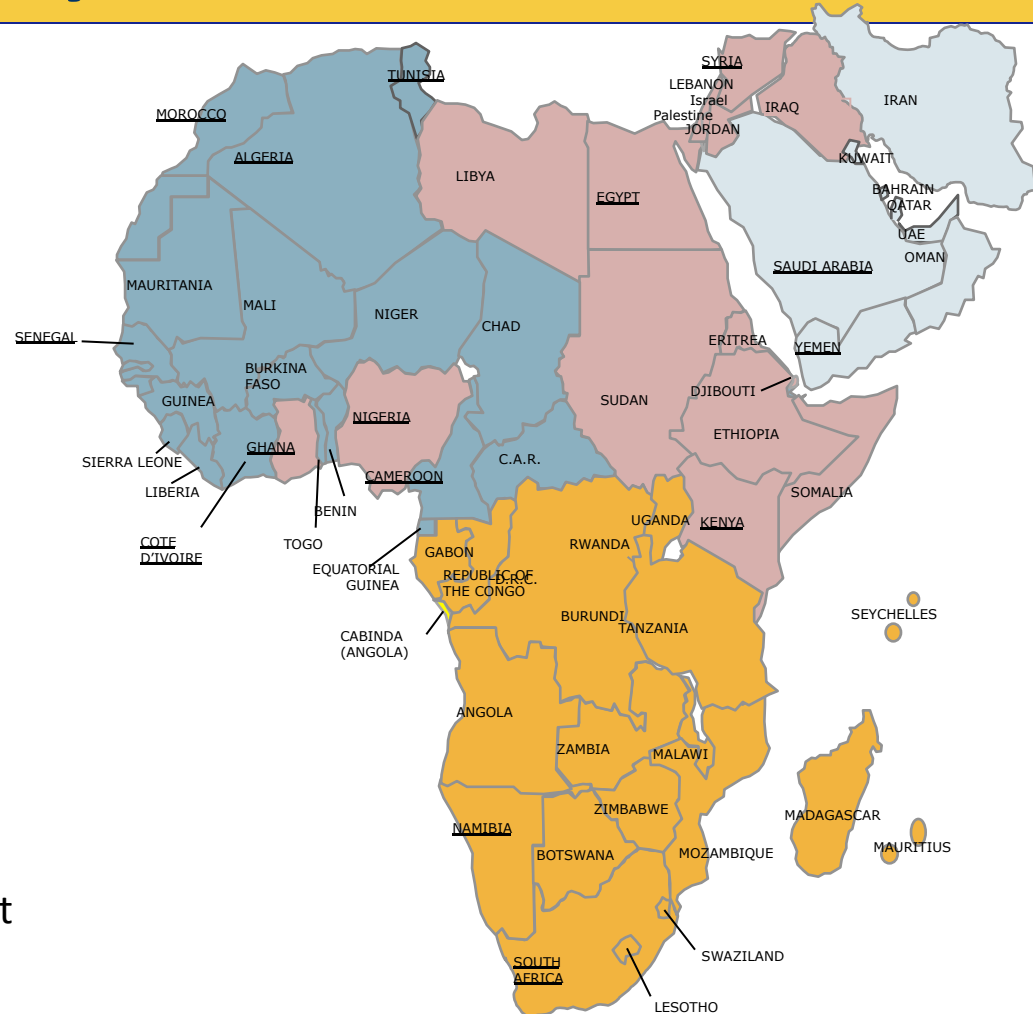


Source: IMS Health Market Prognosis, Sep 2010



# Middle East Africa – why we do business there.?

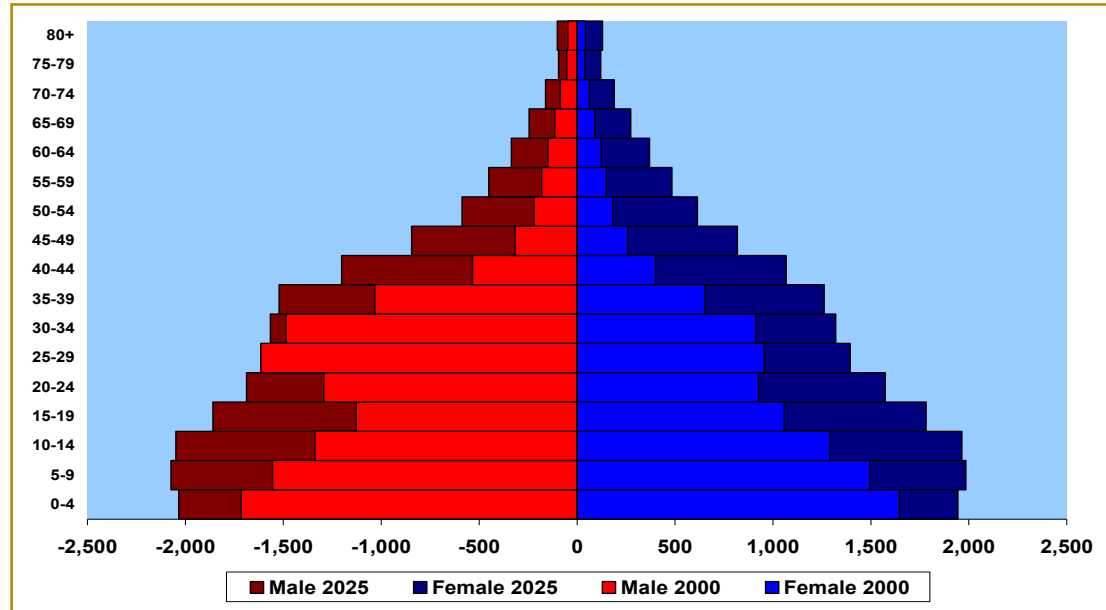
- Middle east & Africa will remain one of the fastest growing regions in the world over the next few years
  - Its growth resilience is supported by three drivers:
    - **Economic growth driving significant government spending on healthcare**
    - **A very young and fast-growing population**
    - **Increasing private investment flows as markets open up**
    - **Increased coverage and health insurance**
  
- The region has long-term growth potential since it includes some relatively wealthy but not-yet-saturated markets, fast-growing emerging, and undeveloped future ones





## MEA consists of 50+ countries & 600+ M inhabitants

Country	2010 Est. Pop. (M)	2009 GDP per Capita	2010 GDP per Capita
Qatar	1.352	68,871.71	81,962.96
UAE	5.055	46,856.80	49,995.31
Kuwait	3.606	31,482.03	37,451.21
Israel	7.43	26,796.71	26,843.07
Bahrain	1.06	19,455.29	21,096.69
Oman	3.062	18,013.00	20,331.55
Saudi Arabia	26.106	14,486.08	16,778.11
Lebanon	3.908	8,706.70	9,479.05
South Africa	49.863	5,823.58	6,609.01
Angola	17.831	3,971.59	4,793.32
Iran	75.35	4,459.68	4,777.33
Algeria	35.502	4,026.89	4,417.98
Jordan	6.126	3,828.61	4,061.69
Morocco	31.972	2,864.54	2,941.14
Syria	20.867	2,578.82	2,877.65
Egypt	78.238	2,450.39	2,758.83
Iraq	32.046	2,107.91	2,505.35
Nigeria	156.051	1,141.91	1,371.31
Ghana	23.699	671.33	754.709



- GDP/Capita ranges from \$ 670 to \$ 82,000
- Region Population Growth Rate of 3%
- More than 40% of the population under 25 years of age
- Published report by McKinsey projects treatment demand in the Arabian Gulf Countries will increase by 240% by 2025, led by oncology, cardiovascular, and diabetes





# Great News for the Industry....But

- Changing landscape...
  - Region growing in importance, while not ready for the changing environment
  - Increased scrutiny of industry promotional practices in US/EU
  - New codes launched by industry associations
  - Companies responding with heightened compliance environment and commitments launching new stricter codes



# MEA Regional Code of Pharmaceutical Promotional Practices

## FirstWord<sup>SM</sup>

Where people who know first, go first

October 31, 2007

### Report claims drugmakers giving expensive gifts to doctors in developing countries

by Daniel Beaulieu

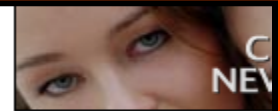


## Report claims drug companies influencing doctors

Posted Wed Oct 31, 2007 4:24pm AEDT

Consumer advocates say patients may be at risk because of the influence d have over the medication doctors choose to prescribe.

## THE INDEPENDENT



Home > News > Health

14 November 2007 16:34

### Drug companies attacked over gifts for Third World doctors

By Jeremy Laurance, Health  
Published: 31 October 2007

Multinational drug companies with gifts and inducements value, an investigation has

## The Washington Post

### EX-PFIZER MANAGER FOUND GUILTY OF OBSTRUCTION

Tues March 17, 2009

Department of Justice Press Release April 15 2009, Eastern District NY  
Quest Diagnostics to Pay U.S. \$302 Million to Resolve Allegations That a Subsidiary Sold

## theguardian International

### Drug firms try to bribe doctors with cars

AstraZeneca announces \$52 million to settle off-label allegations



WEB RADIO

Nov 14, 2007

Midday Update

Oct 31, 2007

## Call for ban on drug company gifts to doctors

SYDNEY - DRUG companies should be banned from giving doctors gifts, a global consumer group said on Wednesday as it released a report detailing medics lavished with fancy dinners, laptops and airconditioning.

THE STRAITS TIMES  
Latest News



continued emphasis on effective monitoring and auditing with an explicit requirement for a risk assessment & mitigation process



## .... A Prevailing Image



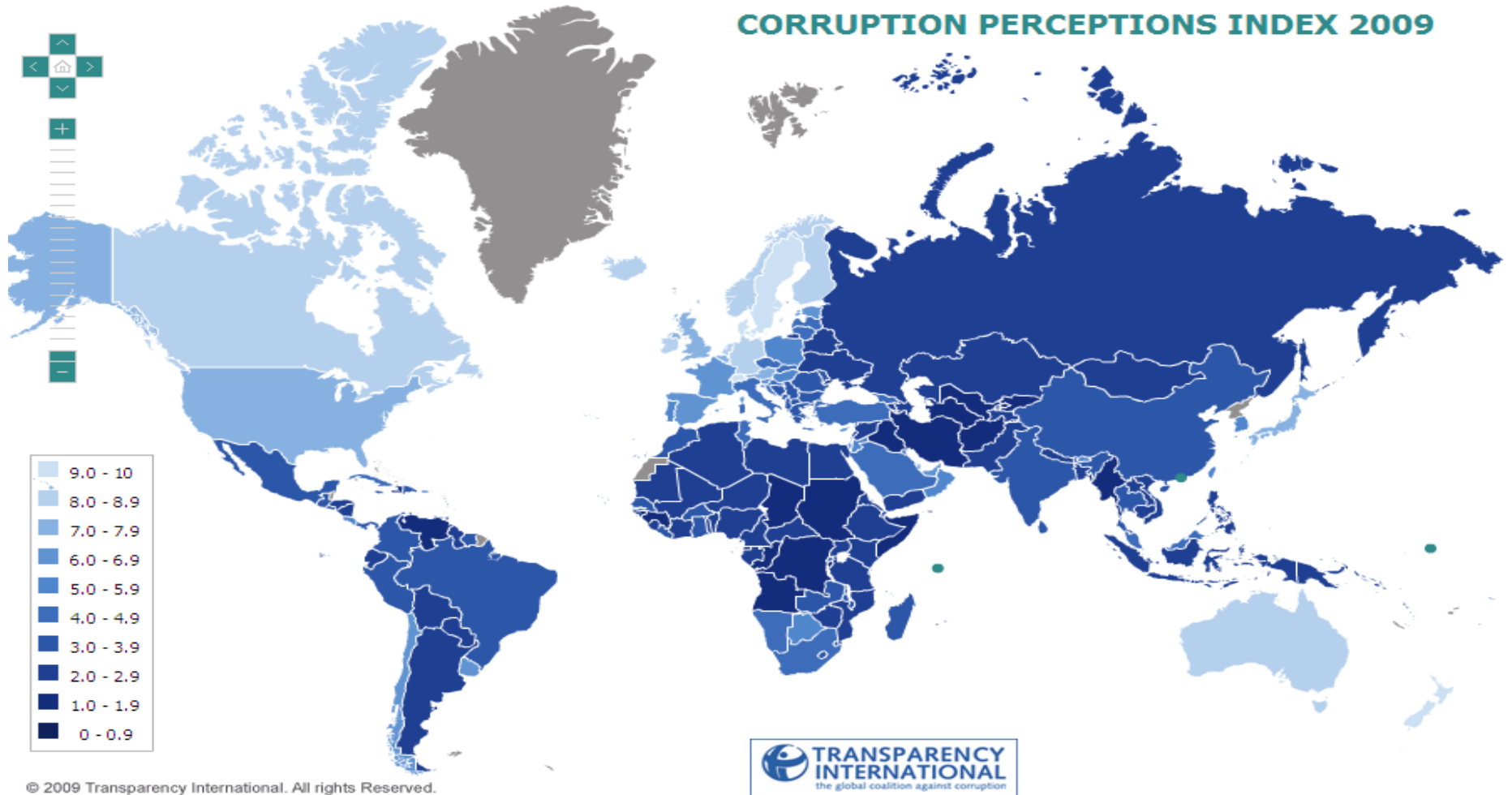
# Drugs, Doctors and Dinners

How drug companies influence health in the developing world





## ....and Prevailing Perception & Facts





# Middle East Pharma Prevailing Compliance Challenges

- Wide geographical region with different regulations
- No applicable laws or codes to regulate the pharmaceutical products promotion and practices
- No mechanisms to approve promotional materials to control messages and off label use
- Most Physicians are somehow affiliated with government
- Companies have to operate through third parties in most of the countries, like distributors
- Pharma company image was not bright;
  - Excessive Samples
  - Excessive bonus goods
  - Excessive entertainment and gifts
- No control on dispensing – Role of Pharmacist





## Meeting in Lebanon

### السنيورة رأس اجتماعاً لمواد تصنيع الادوية بمشاركة فيلتمان وإيميه ورينو وخليفة

في اتجاه رئيس مجلس الوزراء تهدف إلى حماية المصالح الصناعية وحماية المواطنين اللبنانيين في الوقت نفسه. وبالفعل، فإن بعض الأدوية مصنعة ومباعة في السوق العالمية بدون الضمانة التي يؤمنها المختبر الذي اخترع وصنع هذا المنتج. وبالتالي، فإن المريض الذي يتناول هذه الادوية لا يستطيع أن يتأكد من أن هذه التركيبة هي المناسبة له أو أن الكميات المركب منها هذا الدواء هي صحيحة. وعليه، فإن السفراء طالبوا لبنان باحترام عدد من القواعد العالمية الأساسية سواء في الاستيراد أو في تجارة هذه الأدوية.

واضاف: الامر يتعلق بتحديد نقاط عدة، هي:  
أولاً: تفعيل المتطلبات المتعلقة بحماية المعطيات الموجودة في ملفات الاعتماد بهدف تفادي المنافسة غير الشرعية.

ثانياً: تفعيل نظام حماية لشهادات الأدوية المناسبة للمستثمرين بهدف السماح للمختبرات بتأمين الحماية المنظمة للتركيبات الجديدة.

– التتمة في الصفحة ١٢ –



• الرئيس السنيورة مترئساً الاجتماع الدوائي

وسياسة الدولة بالنسبة الى الأصول المتبعة في منظمة التجارة العالمية تنفيذا للكثير من القرارات والاتفاقات المعقودة بين لبنان والدول الأوروبية. بعد الاجتماع الذي استمر ساعة ونصف ساعة، أدلى السفير الفرنسي ببيان، في حضور السفير الأميركي وسفير الاتحاد الأوروبي، جاء فيه: إن سفراء الولايات المتحدة وفرنسا ورئيس بعثة الاتحاد الأوروبي، ومعهم ممثلون لمصانع الأدوية، اتخذوا خطوة مشتركة

ترأس رئيس مجلس الوزراء فؤاد السنيورة في السرايا الحكومية امس، اجتماعاً حضره وزير الصحة العامة والاقتصاد والتجارة الدكتور محمد جواد خليفة وسامي حداد وسفراء الولايات المتحدة الأميركية جيفري فيلتمان وفرنسا برنار إيميه والاتحاد الأوروبي باتريك رينو وعدد من مسؤولي الوزارتين. وخصص الاجتماع لبحث الموضوع المتعلق بالمواد التي تصنع منها الادوية من خلال تنظيم العلاقة





# Government Investigations in our Backyard

### 1. Government Investigation in Egypt

- A MNC MR/DSM videotaped passing money to a doctor
- Possible criminal penalties – imprisonment

### 2. U.N. Iraqi Oil-for-Food Program

- El Paso Corp., Textron, Akzo Nobel
- Multiple Industries (humanitarian goods, oil)
- But same pattern: mischaracterized “after sales service fees”



# How To Enhance Compliance Across the Industry in MEA?

- Enforcement of internal control with training and auditing:
  - Code of conduct
  - Internal promotional polices
  - FCPA
- Develop / launch a Local Industry Code of Promotional Practices
- Design and Implement a SELF-REGULATORY mechanism of enforcement
- Make public (including Government Agencies) and transparent the functioning of the Local Industry Code
- Partner with Regulatory Authorities



# MEA Code of Promotional Practices

- The Middle East Africa Committee (MEAC) is a representative body of the pharmaceutical industry in the Middle East & Africa.
- Written by a task force chaired by Wyeth and included Lilly and Merck
- Approved by MEA LAWG - effective July, 1<sup>st</sup> 2005
- Replaced all currently existing local codes of practice
- Signed by all LAWG members, other companies are encouraged to sign
- The MEA Code is based on a premise of voluntary control of promotional activities of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise, consistent with international standards and practice.



**MEA Regional Code of Pharmaceutical  
Promotional Practices**



## The Principles of the MEA Code

The Code is founded on the following principles:

- All marketing activities should be conducted with highest ethical standards
- Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine or pharmacy.
- We should foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients.
- Companies have an obligation and responsibility to provide accurate, balanced and fair information about its prescription drugs to healthcare professionals.
- Standards of ethical behavior shall apply equally to marketing of prescription medicines in all countries, regardless of the level of development of their economic and health care systems.



# Applicability of Other Codes

- The MEA Code sets out the minimum standards that the MEA LAWG considers must apply to promotional practices in the Middle East and North Africa areas.
- In a manner compatible with applicable national laws and regulations, country associations must, at a minimum, implement the standards and the provisions contained in the MEA Code.
- Member companies must also comply, and must ensure that their respective subsidiaries comply, with other applicable codes and any laws and regulations to which they are subject.
- Member companies must also ensure that their respective agents or representatives are aware and comply with applicable codes





# Applicability of Other Codes

- In the event of a conflict between the provisions of other applicable codes, the more restrictive of the conflicting provisions shall apply.
- The spirit, as well as the letter of the provisions of the MEA Code must be complied with.
- The MEA LAWG also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers Associations (“IFPMA”) Code of Pharmaceutical Marketing Practices and the European Federation of Pharmaceutical Industries and Associations (“EFPIA”), where applicable.



## MEA Code – Articles

- **Article 1:            MARKETING AUTHORIZATION & APPROVED LABELING**
- **Article 2:            PROMOTION AND ITS SUBSTANTIATION**
- **Article 3:            DIRECT TO CONSUMER COMMUNICATIONS**
- **Article 4:            USE OF QUOTATIONS IN PROMOTION**
- **Article 5:            ACCEPTABILITY OF PROMOTION**
- **Article 6:            DISTRIBUTION OF PROMOTION**
- **Article 7:            TRANSPARENCY OF PROMOTION**
- **Article 8:            NO ADVICE ON PERSONAL MEDICAL MATTERS**
- **Article 9:            EVENTS AND HOSPITALITY - CONGRESSES - SYMPOSIA -  
MEDICAL EDUCATION**
- **Article 10:           EDUCATION AND SPONSORSHIP OF HEALTHCARE  
PROFESSIONALS**
- **Article 11:           GIFTS AND INDUCEMENTS**
- **Article 12:           SAMPLES**
- **Article 13:           CONSULTANTS**
- **Article 14:           PHARMACEUTICAL COMPANY STAFF**

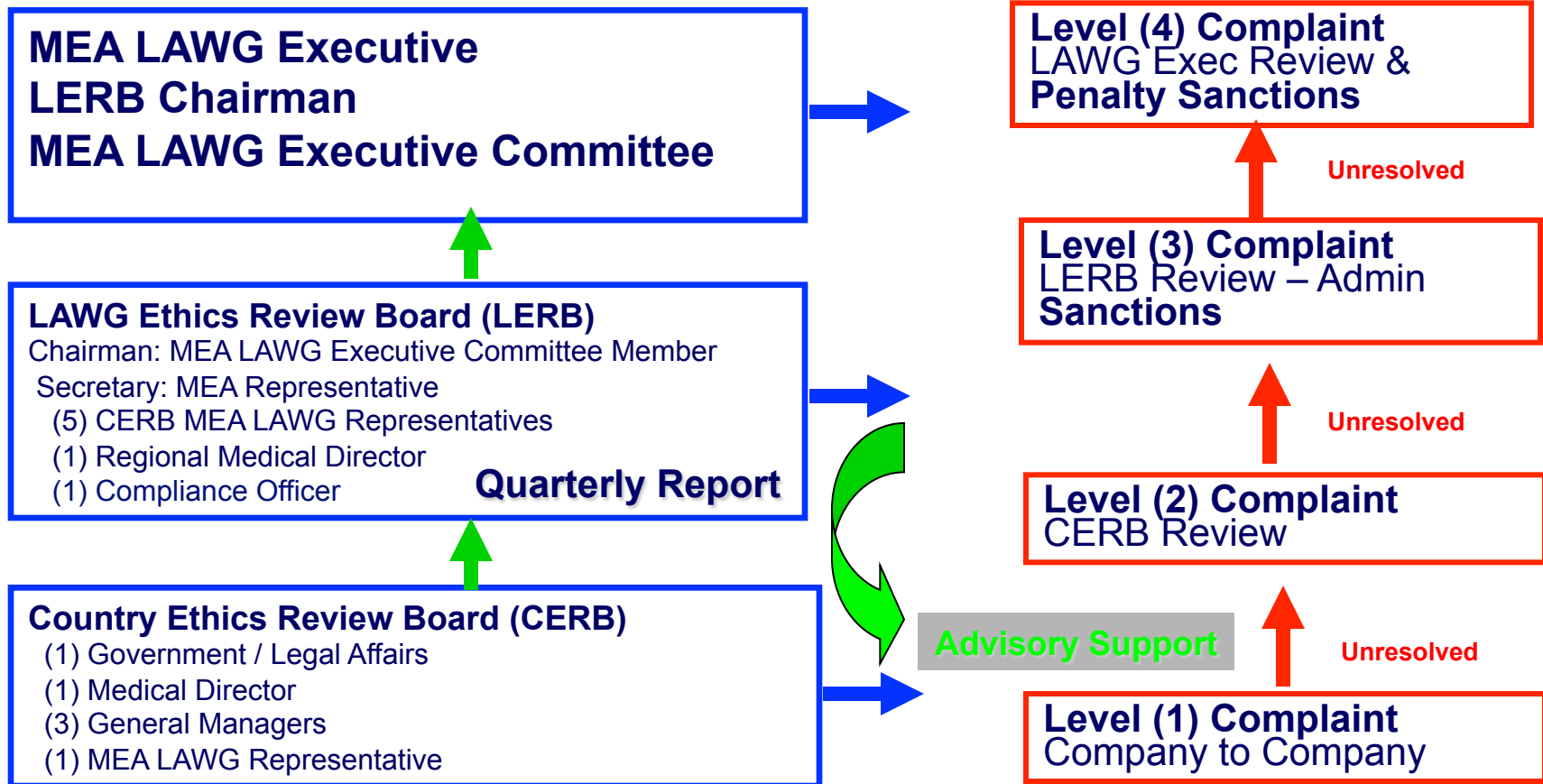


# MEA Code – Launch

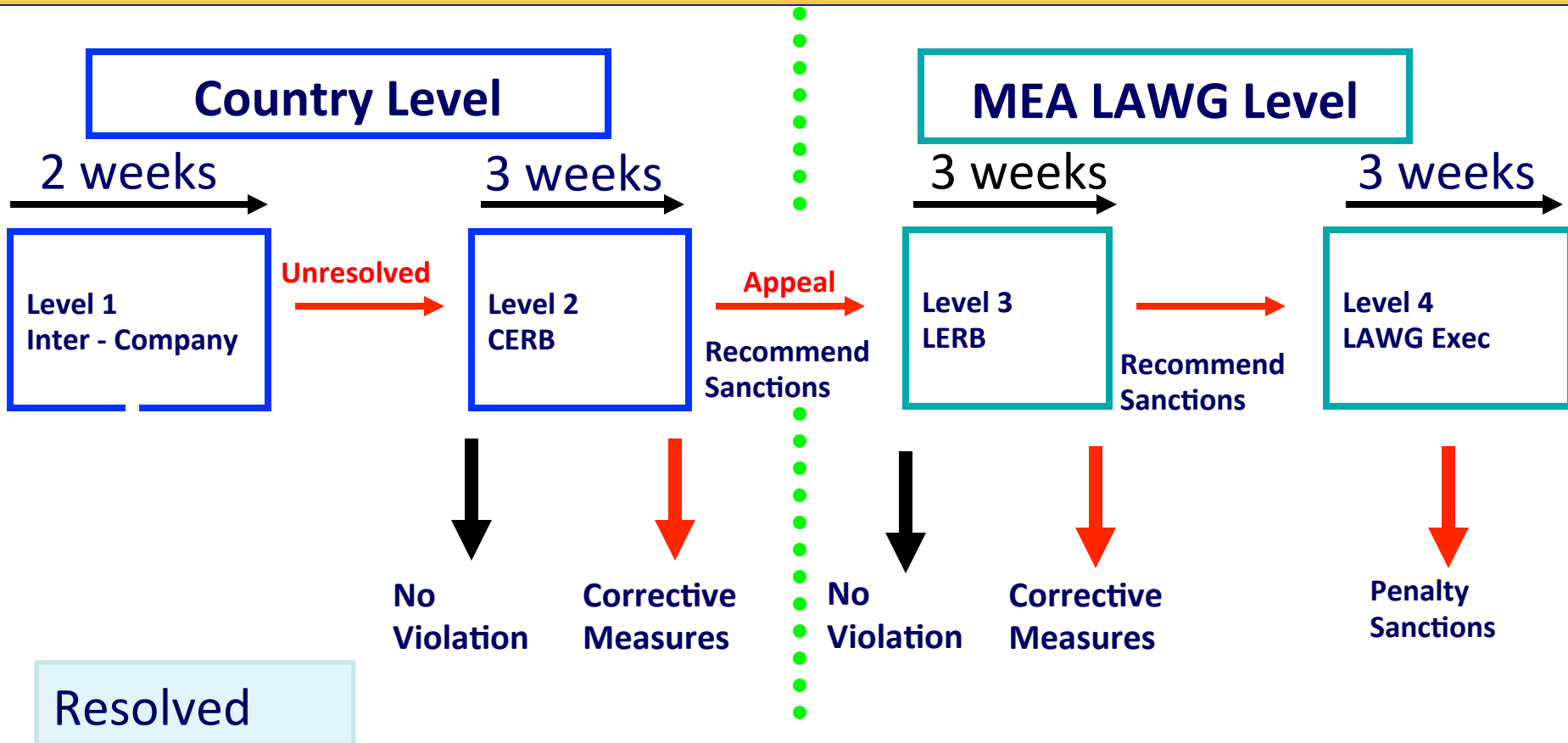
- Printing and distribution in 3 Languages English, Arabic and French.
- Regional commitments obtained from all member companies.
- Nomination of LERB and CERB committees – completed
- Training slide kit sent to all companies
- Training confirmation by all companies
- Q&A follow up



## Reporting Structure & Implementation and Enforcement Procedure



# IMPLEMENTATION AND ENFORCEMENT PROCEDURES



Corrective Measures: Administrative (e.g. Changes to detail aid)  
 Penalty Sanctions: Issued only by LAWG Exec (e.g. Suspend)



## MEA Code – Implementation Challenges

- Wrong interpretation of the code
- Individual behaviors (not in line with the spirit of the code)
- Interpretation of local culture
- Engagement of non PhRMA member companies
- Local industry
- Private Companies
- Medical Profession





## **MEA Code – Next Steps**

- PR & Launch to governments, HCP's, key stakeholders
- Encourage other companies to join and abide by the code
- Connect with IFPMA – Compliance Network
- Partner with Medical Associations and Academic institutions to widen understanding and increase compliance



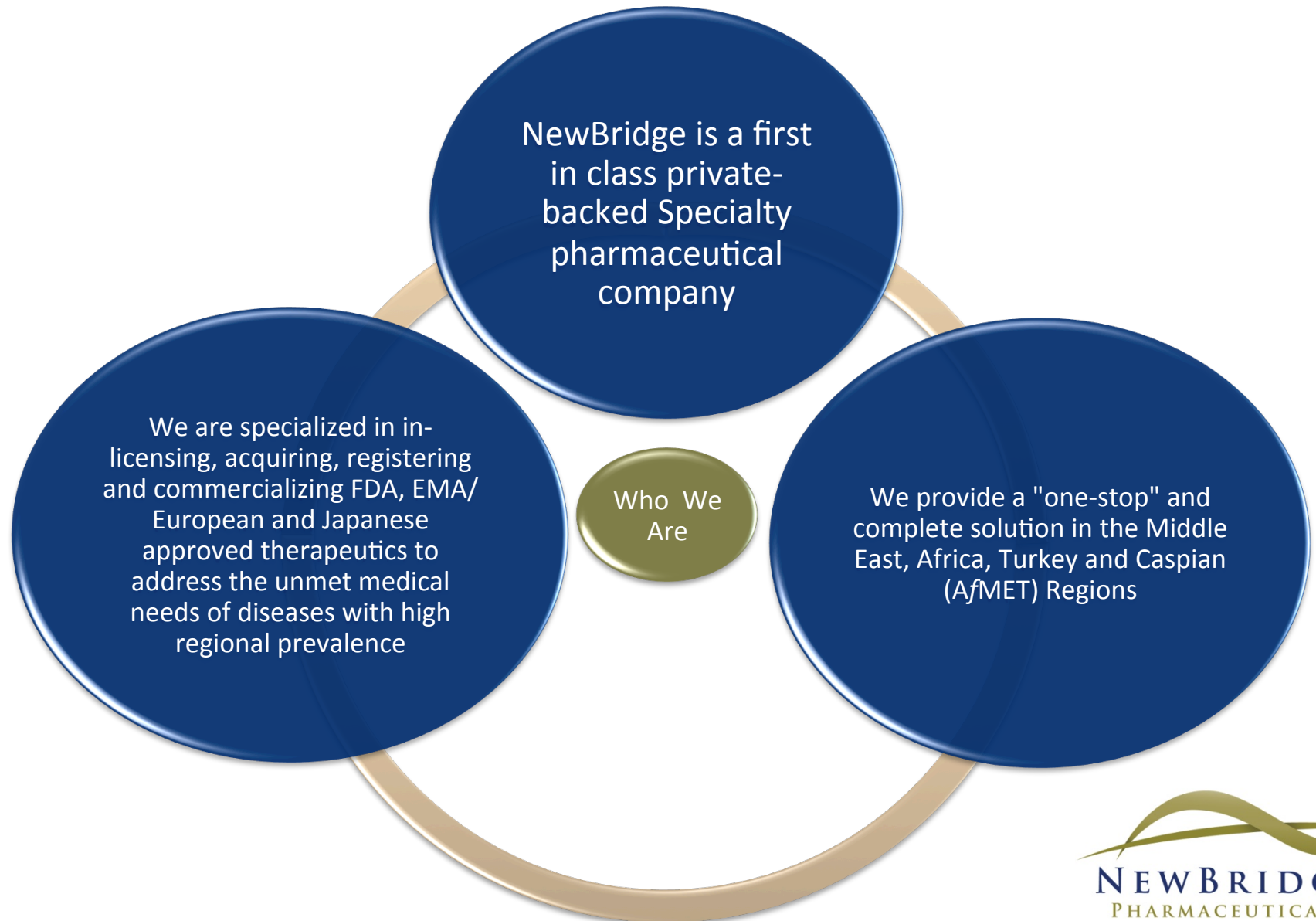
## Transition From Corporate to Private..what does it mean..?

➤ Thinking you may be free from all these forms, restrictions, and codes

... Maybe don't have to deal with long processes or bureaucracies but definitely not Free....!

➤ How in absence of clear local regulations or codes you level plane field..?

# NewBridge Pharmaceuticals



# Our Competencies

Just a few reasons why NewBridge Pharmaceuticals is your Partner-of-Choice



## **NewBridge Team**

is well-connected to a wide range of partners and key stakeholders in and out of the region, and offers a flexible approach to joint-ventures and partnerships



### Why Compliance Still Matters....?

- Regional Players are not in R&D...will always represent and depend in some way on Multinationals.
- There is a growing trend to have regional players get involved not only in manufacturing but also in promotion on behalf of these multinationals – which is a game changer
- It is now a mandate by corporate Pharma - contractual and legal obligations
- Garner respect status among partners, industry, profession and key stakeholders
- Ability to attract the industry talents in a corporate like environment
- Like NewBridge if you want to go public, this will be the only path
- Guarantee to grow and prosper as a key regional player backed by a compliant reputation



## Conclusion

### *Big or Small*

*“Compliance is not just only common business sense,  
it is basically good business period”*