# Establishing a Culture of Compliance in Emerging Markets

"Set your expectations high, find men and women whose values you respect, get their agreement on a course of action, and give them your ultimate trust."

John Akers

Compliance is an outcome...

Integrity is about doing the right thing, even when no-one is watching.

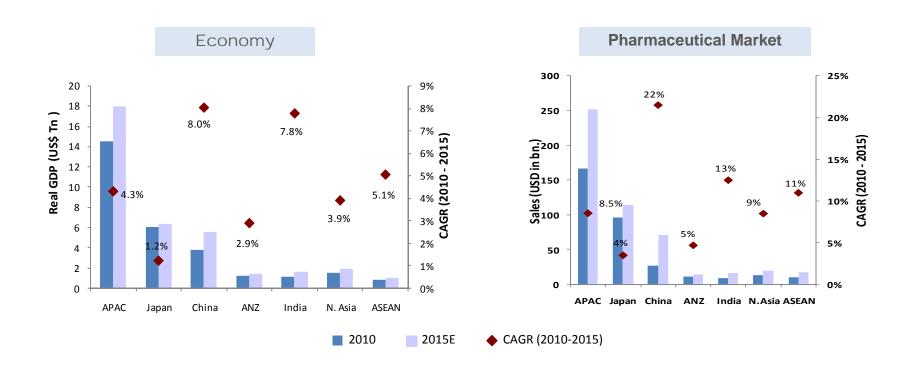
Expectation + People + Process

## **Expectations**

 Heavy investment by multinational companies in emerging markets

#### Continued Global Shift Towards Asia Pacific

17% of global healthcare market today and forecast to reach ~25% share by 2018.



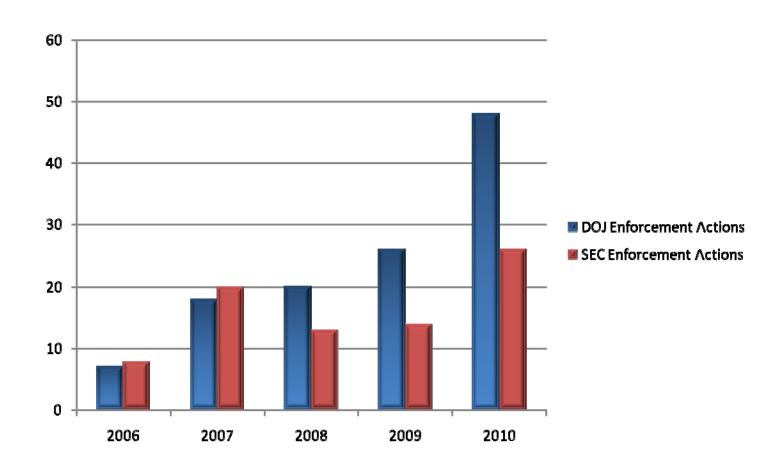
Source: EIU, Espicom;, F&S, Secondary Research

## **Expectations**

 Heavy investment by multinational companies in emerging markets

- Increasing regulation in response to financial crisis
  - Enhanced enforcement capabilities (FBI, DOJ, KFTC, AIC ...)
  - New and far reaching regulatory structures (e.g. UK Bribery Act 2010)

## **Enforcement Actions Brought by DOJ & SEC**



## **Expectations**

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- Increasing regulation in response to financial crisis
  - Enhanced enforcement capabilities (FBI, DOJ, KFTC, AIC ...)
  - New and far reaching regulatory structures (e.g. UK Bribery Act 2010)
- Compliance lapses are costly
  - Multi-million dollar fines are common
  - Loss of reputational capital
  - High remediation costs

## People

- Tone at the top: leadership modelling behaviours
  - Clarity & consistency
  - Accountability
- Recruitment
  - Attract talent exhibiting the right values and behaviours
- Education
  - What (industry / company codes, regulations)
  - Why (ethics and business integrity)
  - How (processes and procedures)
- Communication and reinforcement
  - Integrity in delivering business results
- Encouragement to speak up

## **Process**

Programme

Governance

Transparency

## Compliance Programme

- Dedicated resources
- Documented clear policies and procedures
- Effective education & training
- Reporting mechanism (Hot Line)
- Monitoring
- Corrective action
- Enforcement & support

#### Governance

- Compliance Committee
  - Appropriate structure
    - Single (small operations) vs.
    - Multiple bodies (larger more complex organisations)
  - Membership
    - Includes business leader
    - Chaired by Compliance Officer
    - Cross-functional
  - Clear responsibility and objectives

## Transparency

#### Promotional activities

- On-label vs. off-label (strictly prohibited)
- Congresses, exhibitions & Speaker engagements

#### Education

- Meeting genuine needs
- Bona fide programmes
- Venues and location

#### Third Party Intermediaries

- Compensation
- Operational management
- Due diligence

### Hospitality & gifts

- Set standards (modest and customary)
- Management and control

#### What Can Make The Difference

- Depth of knowledge of cultural norms & nuances
- Disproportionate investment in risk management resources vs business size
- Balanced commercial decisions
- Foundation of values & integrity

Healthcare compliance...

It's the right thing to do.

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