

Third International Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum

May 28 2009 Rome

Pre-conference I - International Compliance Program Basics

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International Compliance Program Basics

- How can we maintain a robust Compliance Programme in the current difficult economic environment?
- How can we maintain a robust Compliance Programme in the changing internal environment of the pharmaceutical industry?

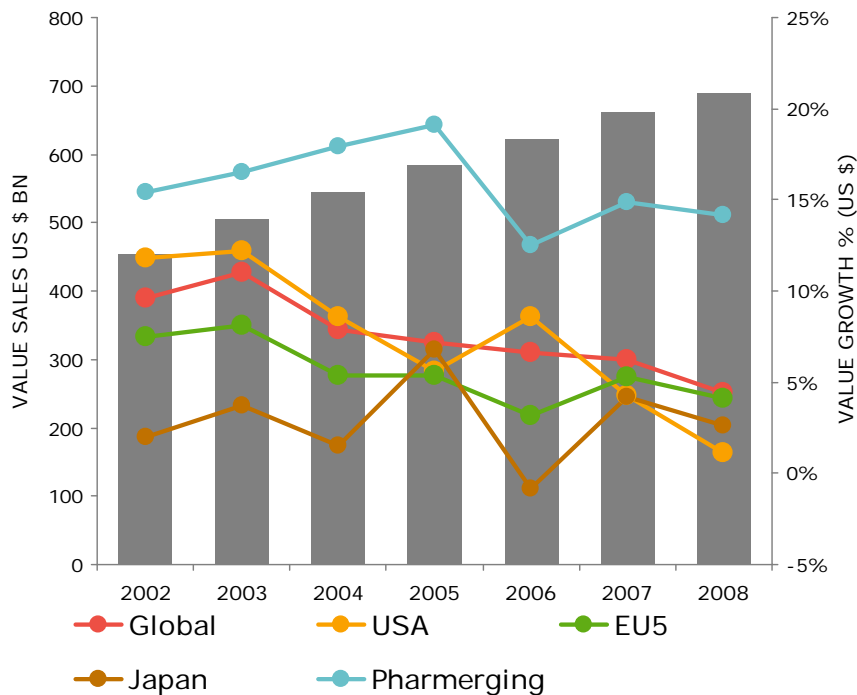
Let's begin by taking a look at the external environment...

Global Pharma growth declining for the past 5 years

And now the financial crisis has affected GDP prospects

Global Pharma Historical Market Dynamics & Current Economic Environment

Global Sales and Market Growth



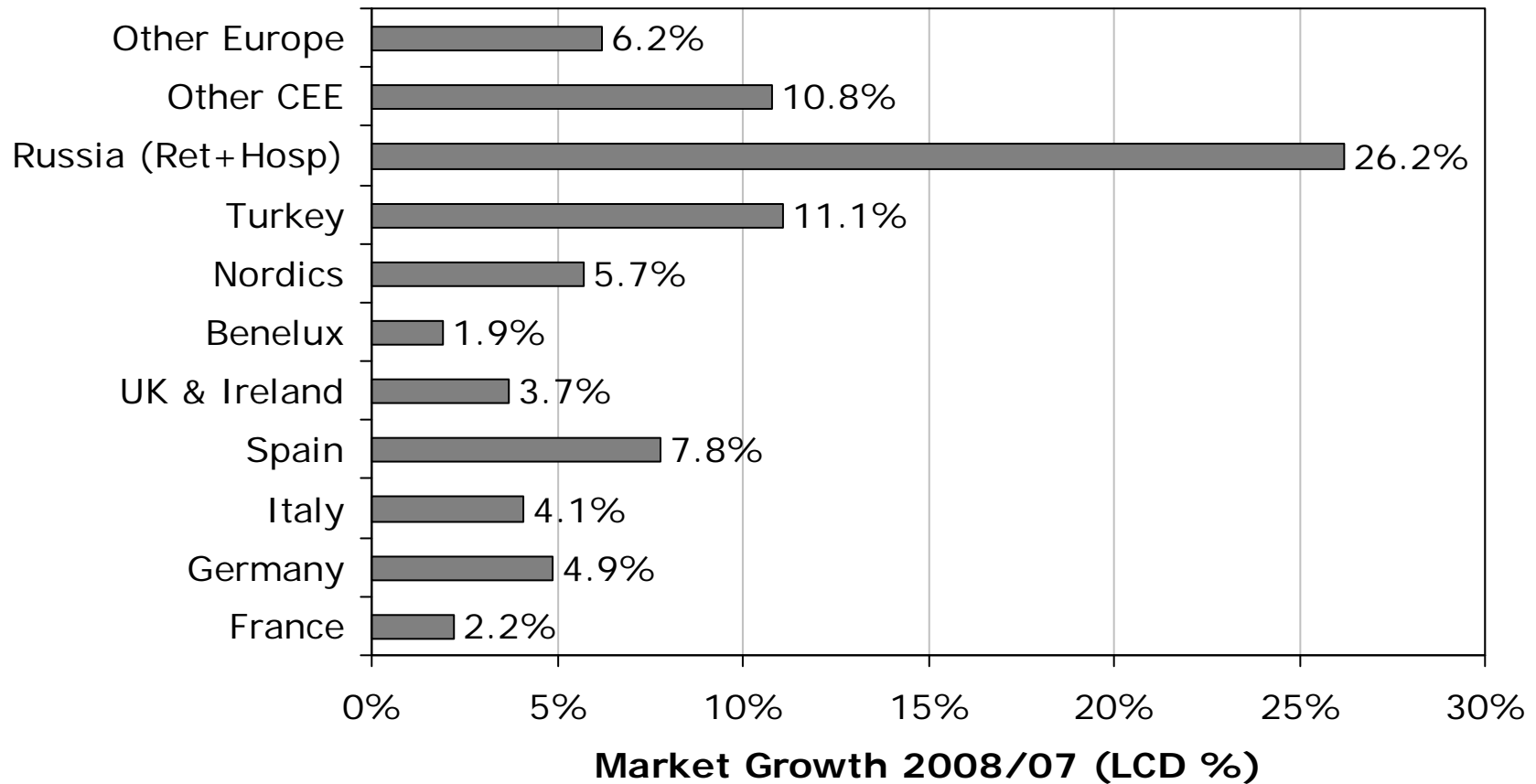
Financial Crisis

- Many banks facing imminent collapse
- Public funds currently channelled to prop banking system
- Global GDP growth forecasts revised*
 - 2008 from 3.1% to 2.4%
 - 2009 from 3.4% to 0.2%
 - 2010 from 3.3% to 1.7%
- Lack of liquidity in the system impacting large industries
 - Automotive
 - Retail

How will the crisis impact an industry already facing low growth?

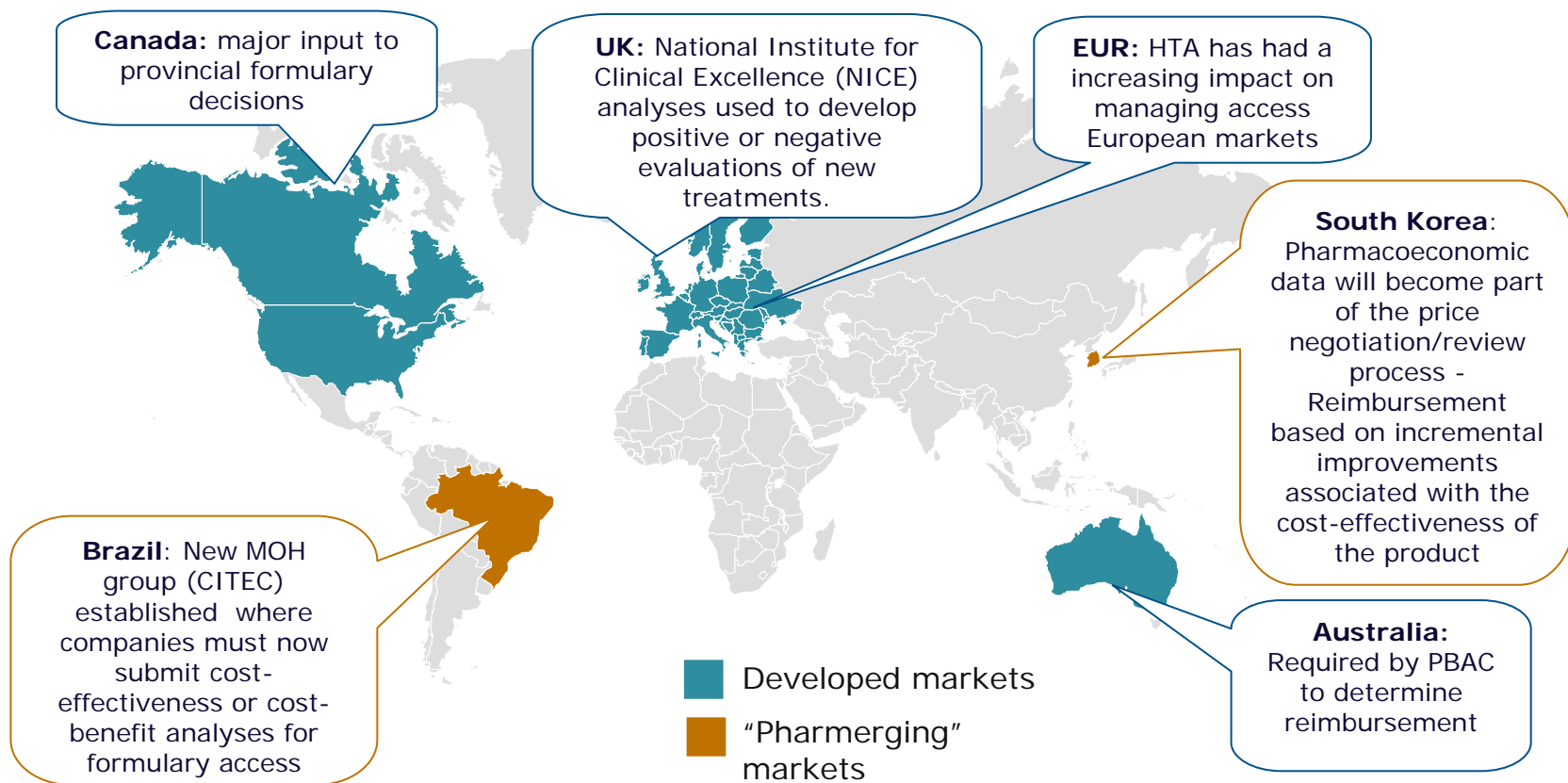
Source: IMS Health MIDAS MAT December 2008, Pharmerging markets = China, India, Russia, Brazil, Mexico, Turkey and South Korea.

Major European markets closed 2008 with low single digit growth while CEE continued in double digits



Source: IMS MIDAS Full year 2008

The Payer is emerging as a key decision maker; Health Technology Assessment will play a central role



This is particularly driven by the aging population

Payers are increasingly fragmented within key markets, as decision making becomes increasingly 'localised'

Local managed care (style) influence develops in Europe



UK: PCTs power & influence varies resulting in divergent prescribing behaviour & implementation of national guidelines



France: Recent health reforms decentralisation process will create *Agences Regionales de Sante (ARS)* and consolidate control over both primary & hospital care. Potential impact is more control over GP prescribing & increased efficiency



Spain: Decentralised healthcare in 2002 to **17 autonomous regions**. Over half of spending in 4 key regions Andalusia (16.4%), Catalonia (15.5%), Valencia (2.9%) and Madrid (10.6%). The 17 regions all pursue variable policies but reference pricing is now nationwide.



Germany: Contracting with the different sick funds has increased regional variability. **Regional sick funds** are partnering with corps to issue treatment guidance with preferred therapy, becoming key decision makers.

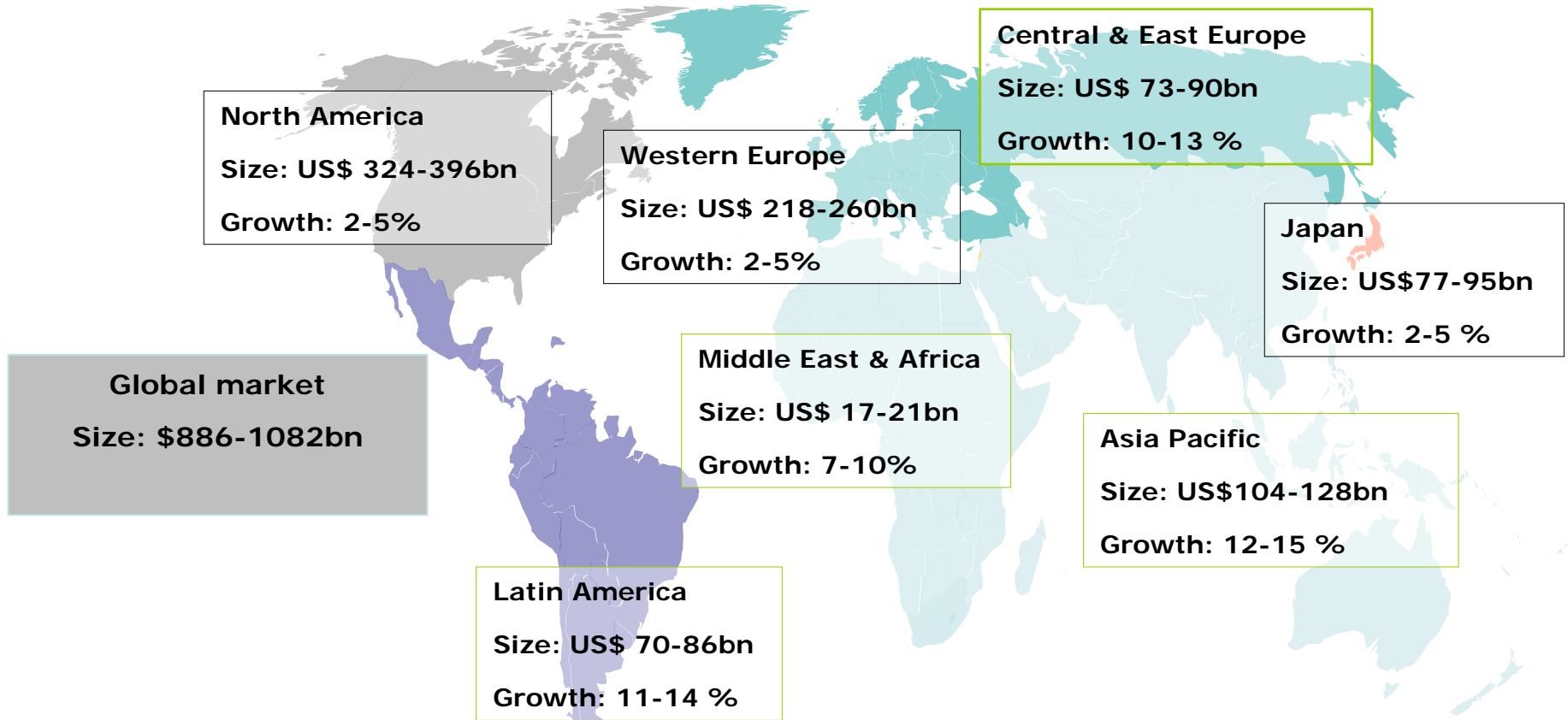


Italy: **Regional governments** taken on increasing healthcare financing responsibility. North-South affluence divide reflected in Lombardy seeking increased responsibilities, whilst Lazio & Sicily struggle with huge deficits and central government disciplinary pacts.



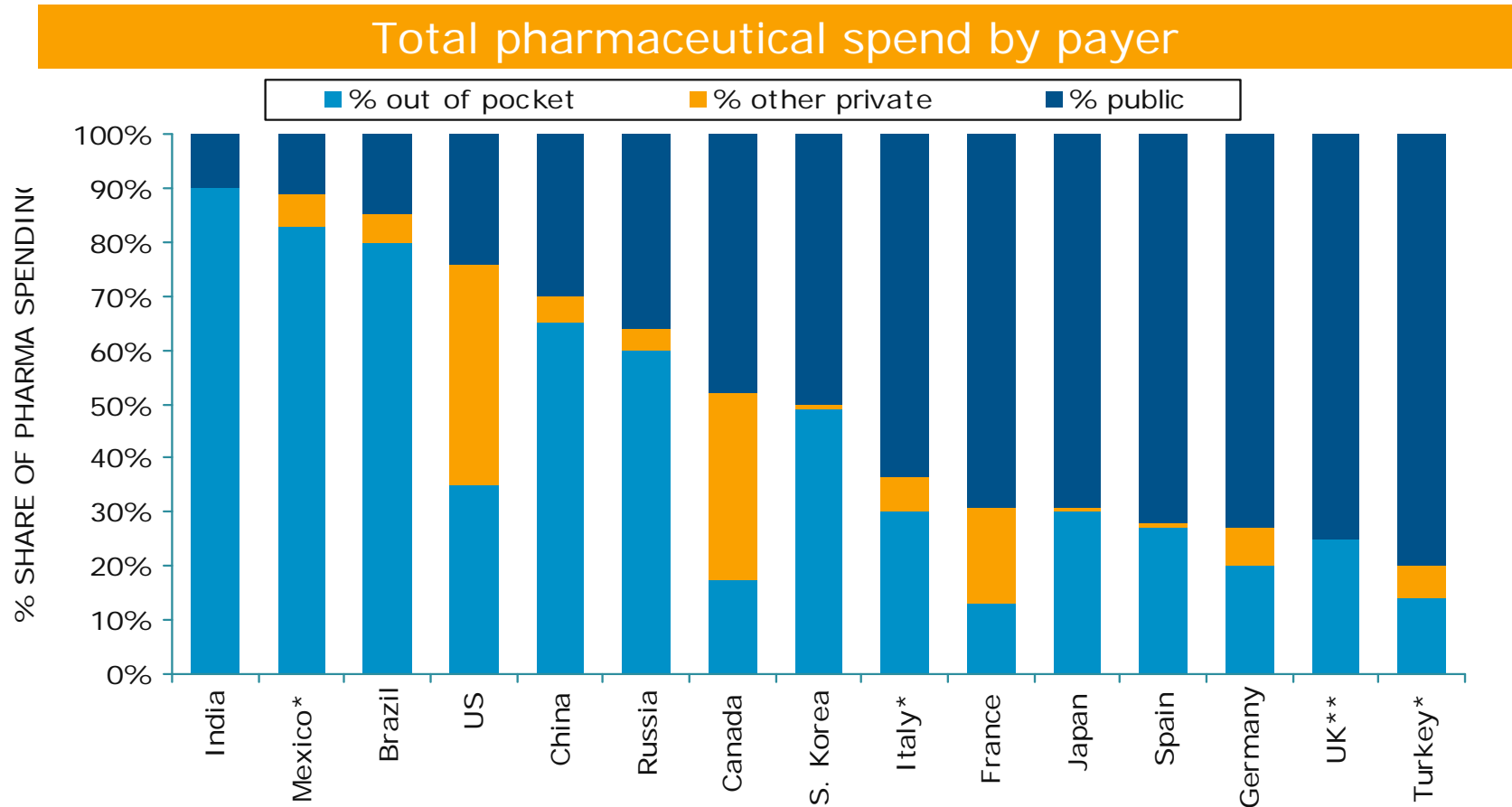
In September 2008, IMS forecasted growth opportunities shifting away from traditional pharma markets over the next five years

Global: IMS Regional Pharmaceutical Outlook in 2012 (US\$ Billions)



Source: IMS Health, Market Prognosis, Sep 2008

Impact on pharma of patient and policy responses is influenced by the relative importance of funding sources



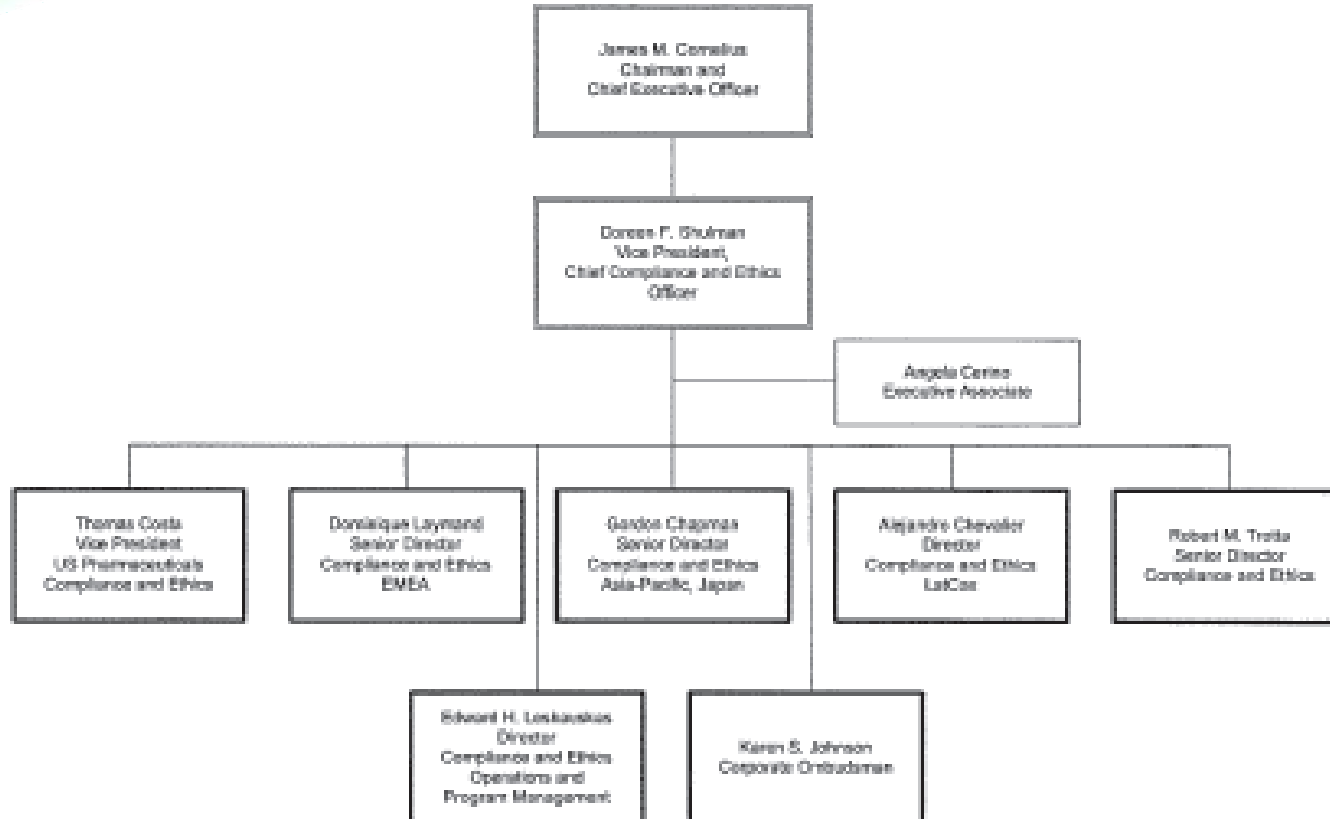
Source: OECD 2008; WHO 2008; Canada, CIHI 2007; *Estimated from available sources; **OOP vs other private not available

Pharmaceutical Companies – Internal environment

- Evolution of organisations in response to the external environment by reducing costs, streamlining internal structures, etc...
- Key components for maintaining a robust Compliance Programme as a business enabler through the approaches of 2 companies:
 - BMS approach Slides 10 and 11
 - AstraZeneca approach Slides 12 and 13



Office of Compliance and Ethics



Office of Compliance & Ethics

MISSION STATEMENT

To establish an effective Compliance & Ethics program that ensures a culture of integrity enabling BMS to conduct its global business with the highest ethical standards, in full compliance with all applicable laws and regulations and our own Pledge and the Standards of Business Conducts & Ethics.

EMEA Business Compliance & Ethics Governance Model Overview

BMS Approach

EMEA Compliance & Ethics Governance Model

EMEA Business Compliance & Ethics Program

Contribution to Productivity Transformation and Continuous Improvement by:

- ▶ A standardized approach on core activities
- ▶ A focus on innovative and new projects

EMEA Business Control Program

- ▶ Continuous assessment of processes in terms of controls and compliance efficiency with the objective of working in a safe environment while removing bureaucracy

Business strategy and Risk-based Approach
Focused on Accountability

Collaborative working process
with Finance Control and Legal Functions

Compliance Programme Basics

AZ Approach

Having clear, written rules

Appointing an LCO and Local Compliance Committee

Carrying out effective training so people know what the rules are

People carrying out their duties with the rules in mind

Monitoring activities detect non-compliance with the rules

People having the confidence and appropriate mechanisms to report problems positively

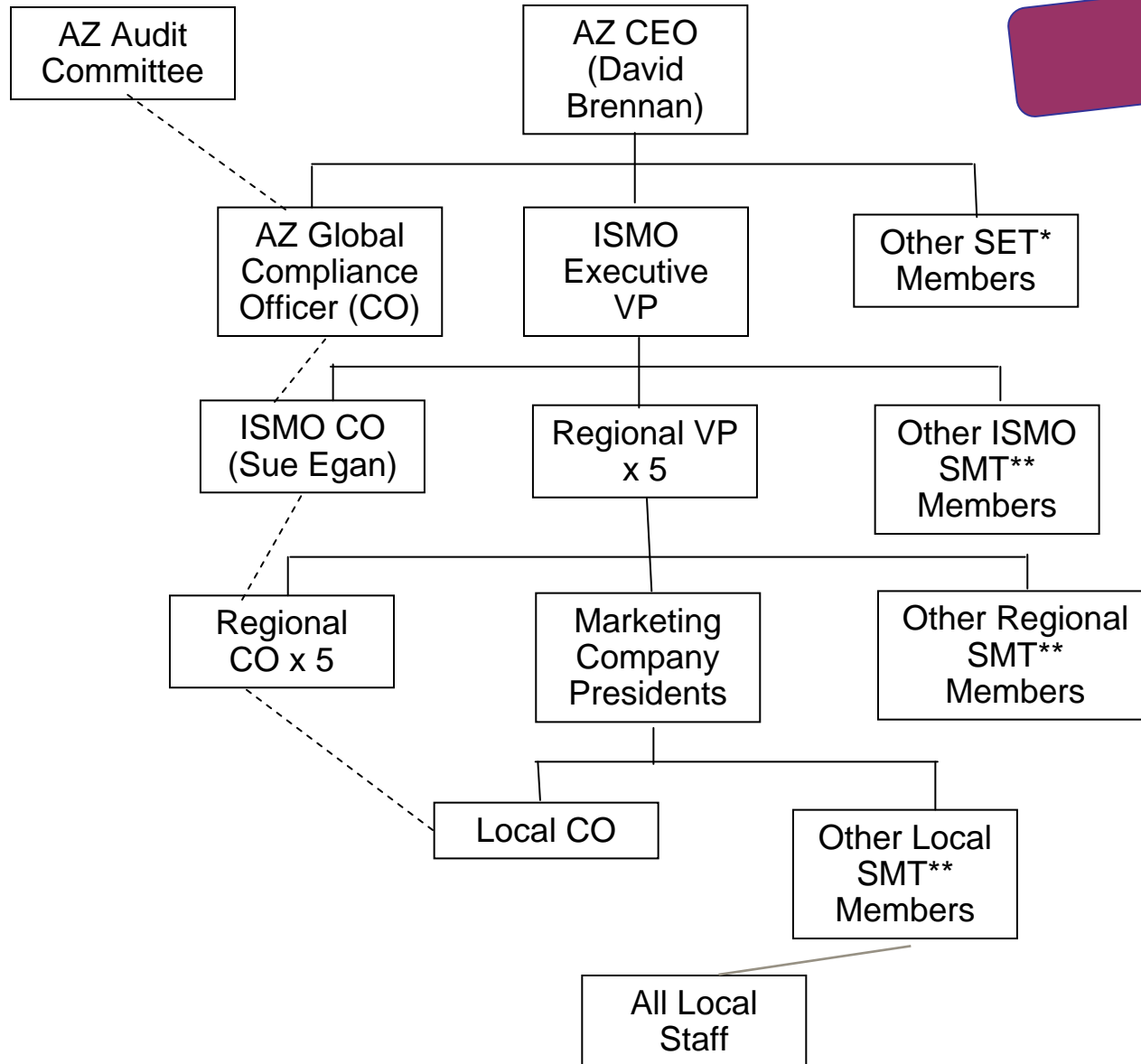
Reasons for non-compliance are analysed and appropriate actions taken, for example

- Rules are clarified / updated
- Re-training
- Bonus impact
- Warning (verbal / written)
- Dismissal

(Based on OIG (Office of Inspector General) – 7 Elements of Compliance)

The AstraZeneca Compliance Team

AZ Approach



*SET = Senior Executive Team

**SMT = Senior Management Team

Examples of what can go wrong

- Too few people in compliance roles
- Decentralised compliance programme
- Over centralised compliance programme
- Insufficient in-depth monitoring
- Ineffective audit programme
- Line managers not taking responsibility
- Culture and language barriers
- Resistance to change
- Others

Discussion

- What works for other companies?
- What changes are you seeing internally?
- What impact will these changes have on our Compliance Programmes?
- Are you seeing a shift in the types of incidents reported in your companies?
- Do you have any questions for us?