



# Pharmaceutical Industry-The challenges and the opportunities

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# Thank You For This Opportunity



Question: Can you think of 5  
innovative countries?

Hold on to those ideas/thoughts  
and we will compare with my list!

# About me!

- Professor of Pharmaceutical Innovation at King's College London and Director of Rainbow Medical Engineering, this is Europe's largest centre of health education, with world renowned clinical services and research in physical and mental health.
- I was a former GSK employee and occupied many roles in GSK from Senior Director of Preclinical and Pharmaceutical Development for Emerging Markets and Asia Pacific at GlaxoSmithKline to the development of dosage forms to the design and successful implementation of technological platforms.
- Professor Martini is a Pharmacist and received his PhD in Drug Delivery from the University of Manchester. Professor Martini obtained his MBA with Distinction from the University of Liverpool, specialising in SME business failures and success
- President of the European Industrial Pharmacists Group visit [www.eipg.eu](http://www.eipg.eu)

# Organisation

- First Industrial Pharmacist Teaching Practitioner in the UK!
- My Chair is split between King's College Campus in Waterloo and at my company Rainbow Medical Engineering Ltd based in Herts
- My university focus is forge links between Industry and academia to help the development process
- My Rainbow focus is to help medical and pharmaceutical companies manufacture products using ultrasonic processing technology
- Effectively, I span 3 sectors –academia, pharmaceutical and medical

## Who I work with?

- Large Multinationals Companies both Pharmaceutical and Medical
- Generic Companies
- SME's and Spin-off organisations
- Regulatory Agencies
- Other Universities and Research Organisations
- *Interesting trend is that I have been funded by many organisations in Emerging Markets*
- *Interesting trend is that a large number of PhD requests come from overseas (Emerging Markets)*

# The Industry Today-The perfect storm



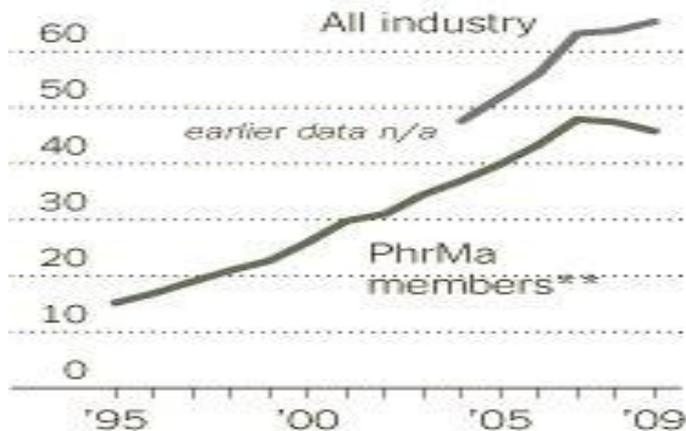
# Productivity is down and costs are rising!

## Fewer New Drugs Gain Approval

Pharmaceutical companies have spent more on research and development over time, but have discovered fewer novel drugs good enough to gain F.D.A. approval.

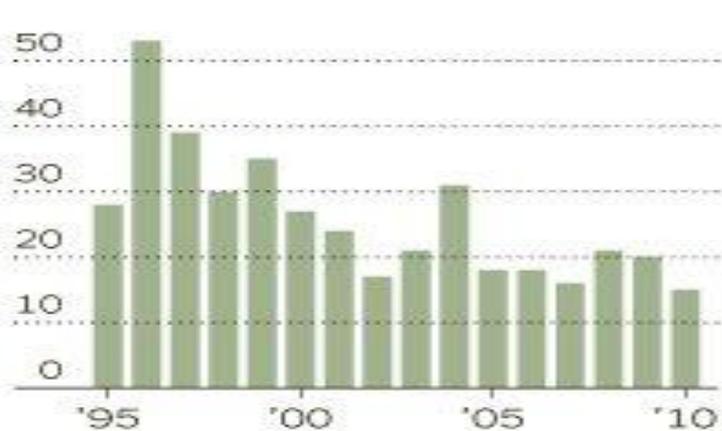
### PHARMACEUTICAL R&D EXPENDITURES

\$ 70 billion



### NEW DRUGS APPROVED\*

60

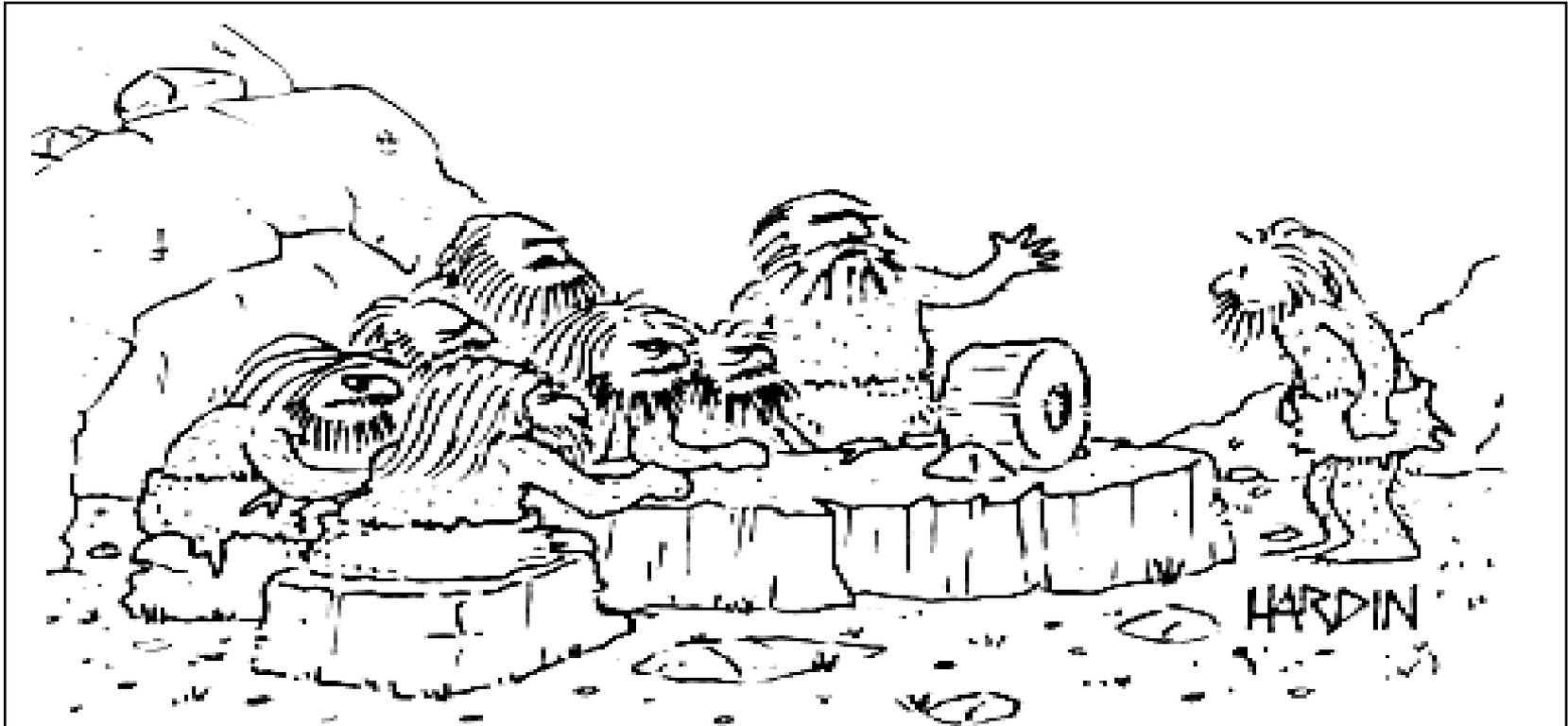


\* Does not include biologics. \*\*Pharmaceutical Research and Manufacturers of America, or PhRMA, includes most of the major U.S. pharmaceutical research and biotechnology companies.

Sources: Food and Drug Administration; Pharmaceutical Research and Manufacturers of America



# Growing Regulatory Conservatism: Application of the “Precautionary Principle”



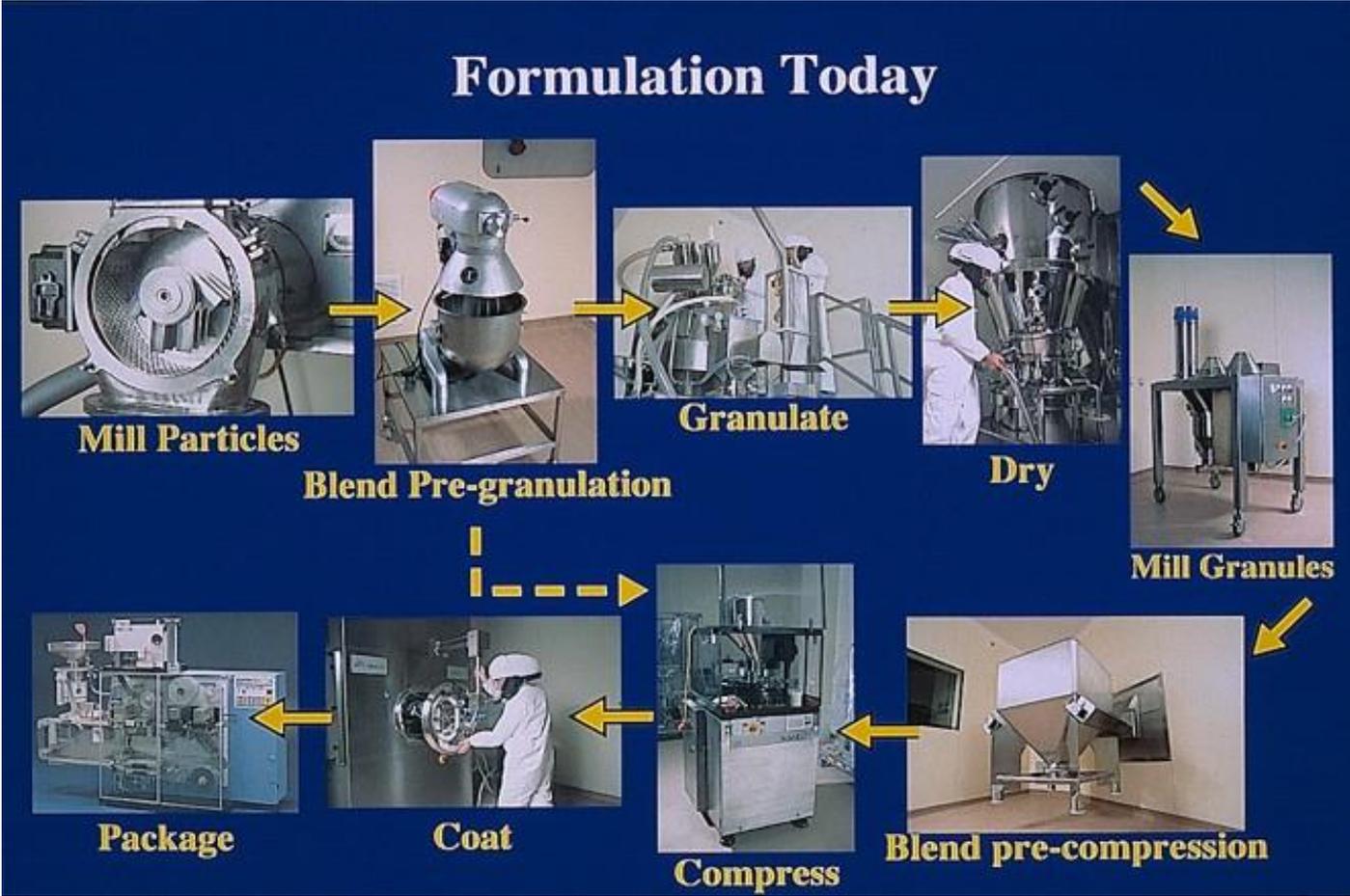
“The Committee’s decided to ban further research until it can be proven your ‘wheel’ poses no threat to the environment, society or public health”

How well do we innovate with respect to Drug Development?

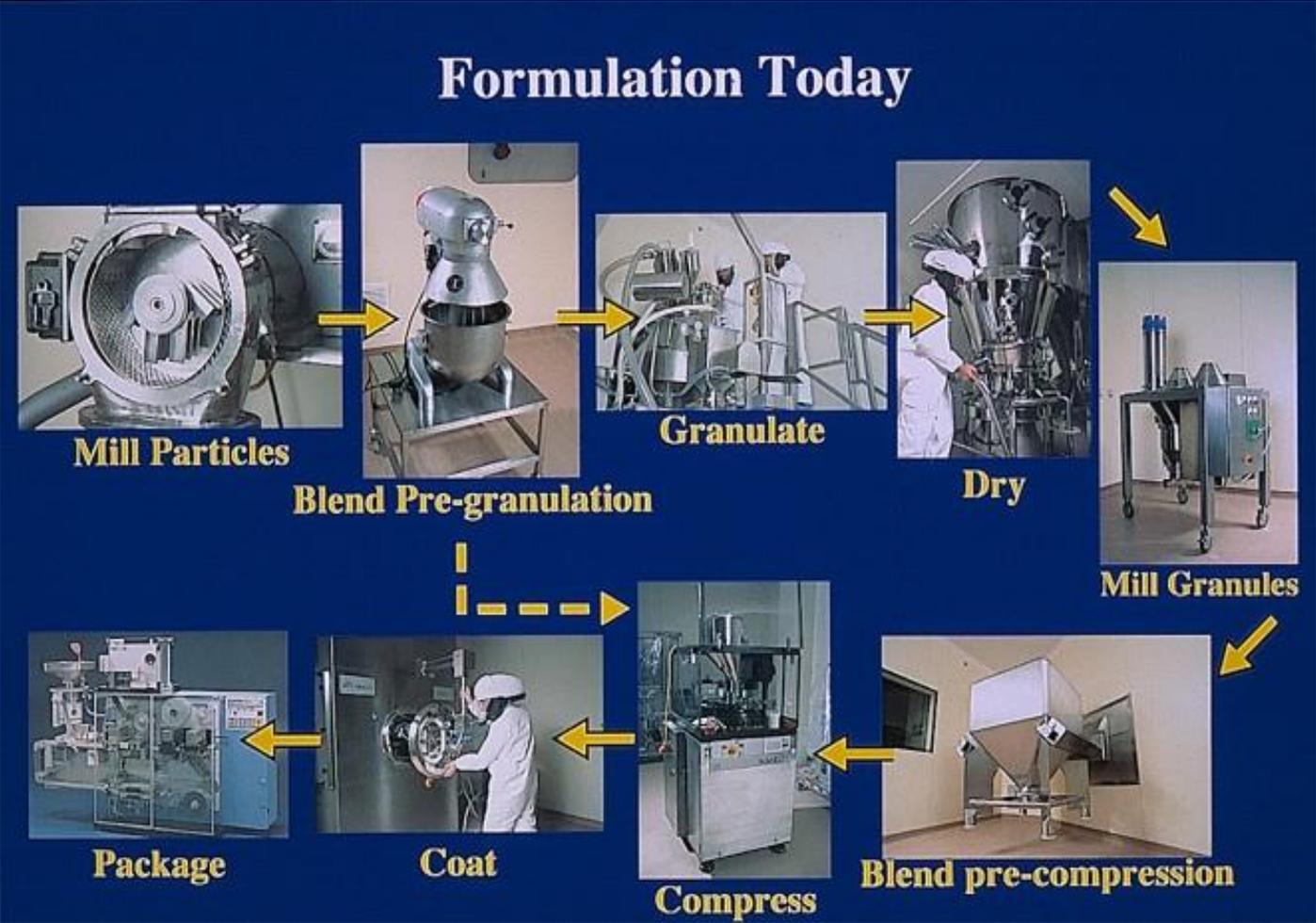
# Pharmaceutical Manufacturing in 2011



# Pharmaceutical Manufacturing in 1990



# Pharmaceutical Manufacturing in 1970



# Pharmaceutical Manufacturing in 1950's



Same hardware but operating at slower speeds!

An operator today would still recognise pharmaceutical manufacturing if they travelled back in time to 1890's!

# Pharmaceutical Product Manufacture (an FDA View)

- Not state-of-art compared to other industries
- Reasonable product quality but at great effort & cost
- For some products, waste as high as 50%
- Inability to predict effects of scale up on final product
- Inability to analyze or understand reasons for manufacturing failures

# Consequences (FDA View)

- High cost due to
  - inefficiencies (time, energy, materials)
  - prolonged manufacturing cycle time due to testing.
  - no improvements based on new technologies
- Drug shortages due to manufacturing problems
- Slows development of investigational drugs

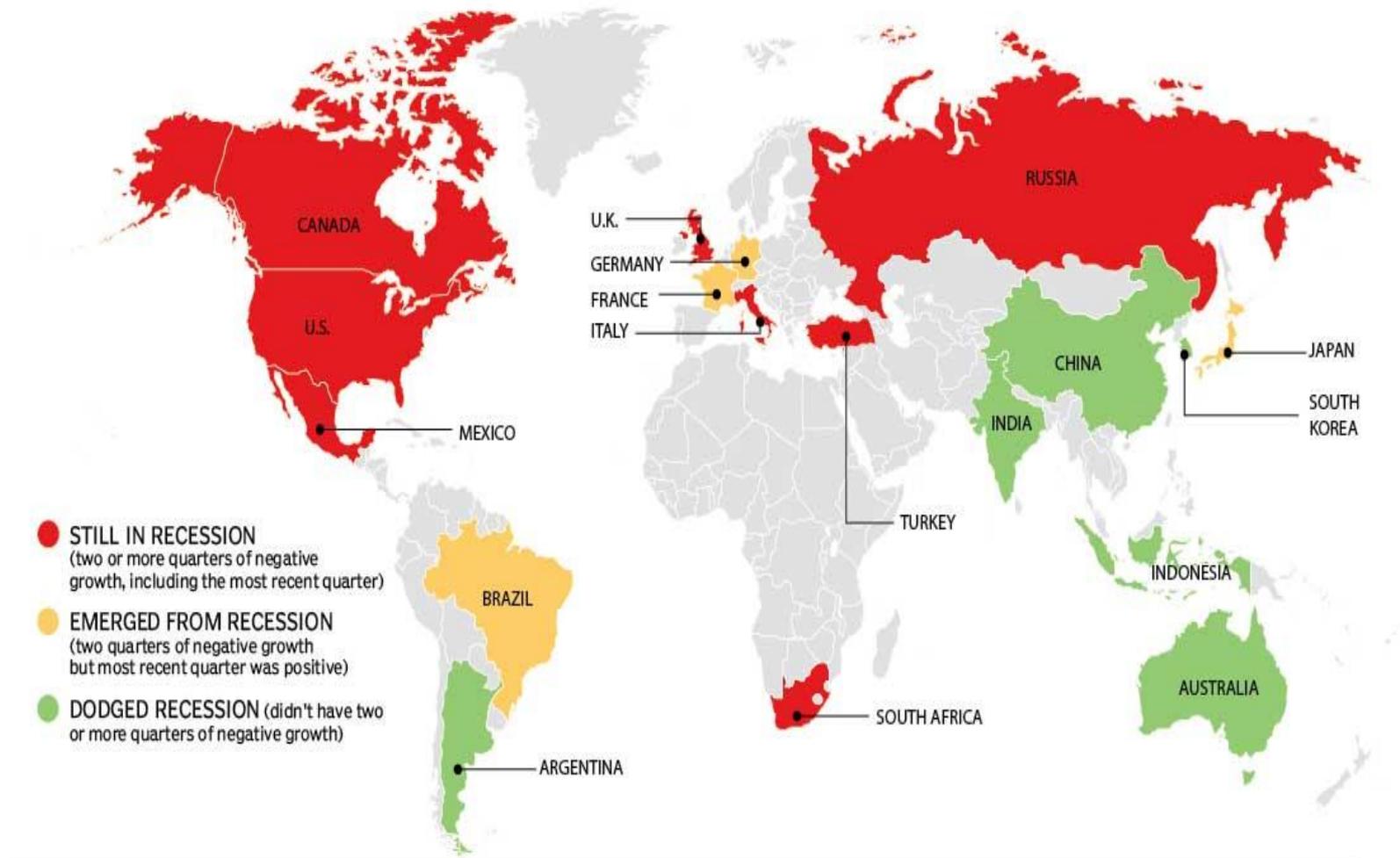
# Is this fair?

Consider the music industry and  
Apple?

Now think of that list again!

Innovation Index (2007)	Innovation Index (2010)	Total Expenditure on R&D % of GDP (2003)	Total Expenditure on R&D % of GDP (2008)	Number of Patents granted to Residents Total, 2002	Number of Patents granted to residents, 2006-2008
USA (6.66)	USA (5.65)	Israel (4.35)	Israel (4.86)	Japan (110,053)	Japan (141,203)
Finland (6.43)	Switzerland (5.60)	Sweden (4.27)	Sweden (3.75)	USA (86,551)	USA (82,284)
Taiwan (6.19)	Finland (5.56)	Finland (3.44)	Finland (3.50)	Taiwan (26,964)	S.Korea (80,688)
Sweden (5.89)	Japan (5.52)	Japan (3.12)	Japan (3.44)	S. Korea (24,984)	China (34,537)
Japan (5.74)	Sweden (5.45)	Iceland (3.10)	South Korea (3.21)	Germany (19,593)	Taiwan (33,402)
Israel (5.38)	Israel (5.30)	South Korea (2.64)	Switzerland (2.90)	Russia (14,454)	Russia (19,943)
Switzerland (5.37)	Taiwan (5.23)	USA (2.59)	Taiwan (2.77)	France (10,737)	Germany (13,691)
16-UK (4.35)	14-UK (4.65)	16-UK (1.88)	17-UK (1.88)	9-UK (4.452)	11-UK (2.369)

# The US/EU Economy is in a mess!



# Europe Not Paying for Pharma Innovation

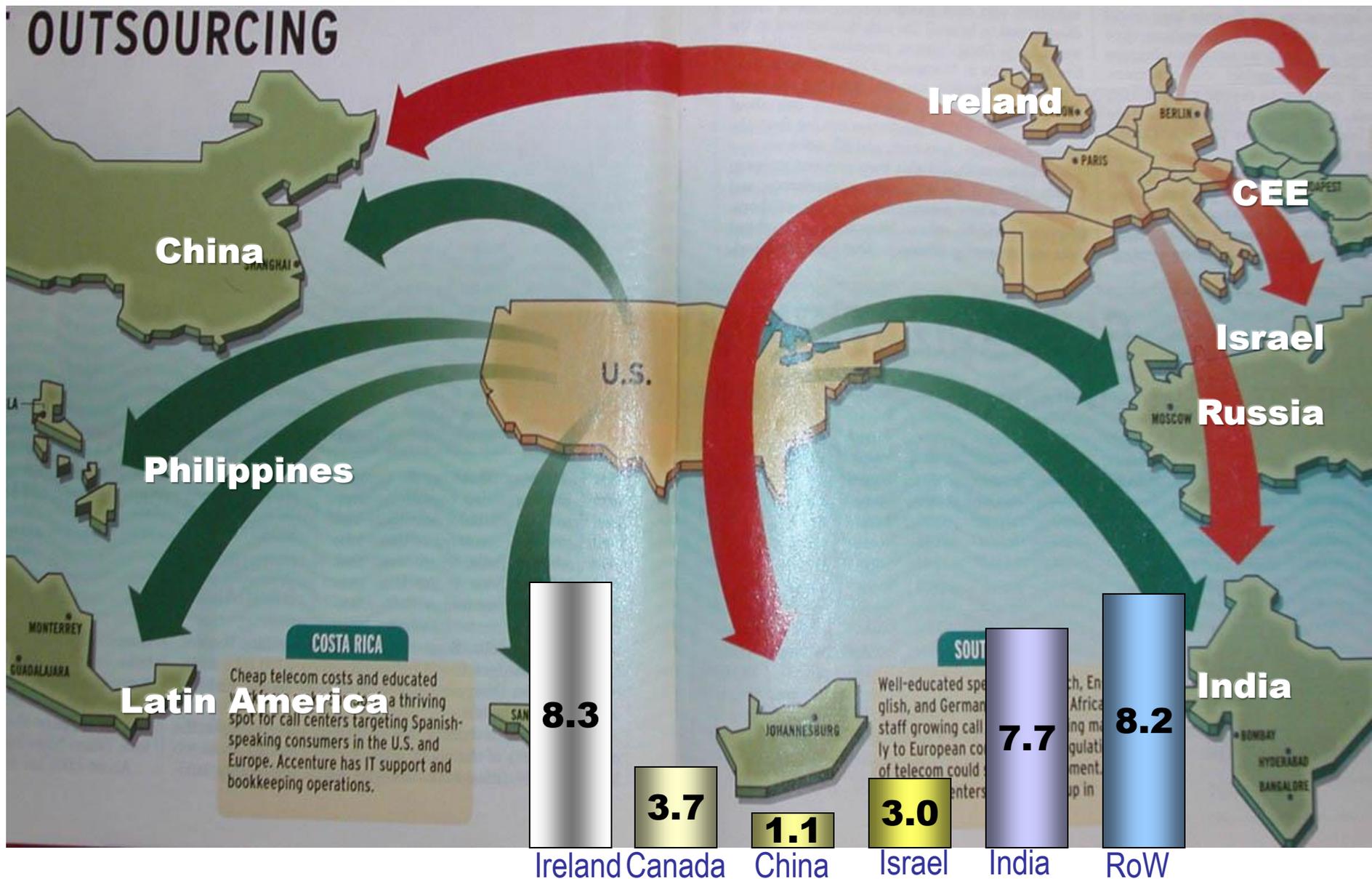
- Hard-pressed healthcare systems can no longer pay premium prices for new drugs. The consequence will be less innovation in Europe says Andrew Witty, CEO of GlaxoSmithKline.
- The consequence is not only that new products are launched first elsewhere, delaying benefits for patients, but also that GSK will do less clinical research in Europe. “We have to take a view and face reality: it’s about the U.S. and excitingly, about Japan in terms of where innovation should be driven,” Witty said.

As a result, the top 20 league table will be significantly different in 2013

2003 Rank		2008 Rank		2013 Rank	
1	United States	1	United States	1	United States
2	Japan	2	Japan	2	Japan
3	Germany	3	France	3	<b>China</b>
4	France	4	Germany	4	Germany
5	Italy	5	<b>China</b>	5	France
6	United Kingdom	6	Italy	6	Spain
7	Spain	7	United Kingdom	7	Italy
8	Canada	8	Spain	8	<b>Russia</b>
9	<b>China</b>	9	Canada	9	Brazil
10	Brazil	10	Brazil	10	Canada
11	Mexico	11	<b>Russia</b>	11	United Kingdom
12	Australia	12	Mexico	12	Venezuela
13	India	13	<b>Turkey</b>	13	<b>Turkey</b>
14	Poland	14	India	14	India
15	Netherlands	15	South Korea	15	Mexico
16	Belgium	16	Australia	16	South Korea
17	South Korea	17	Greece	17	Greece
18	<b>Russia</b>	18	Poland	18	Poland
19	<b>Turkey</b>	19	Netherlands	19	Australia
20	Portugal	20	Belgium	20	Belgium

Source: IMS Health Market Prognosis, Jun 2009. Includes revised history and forecast for Russia. Market size ranking in Constant US\$.

# Outsourcing is not new-but this is different!



Source: BusinessWeek February 3, 2003

(Source: McKinsey&Company 2004; Billion US\$)

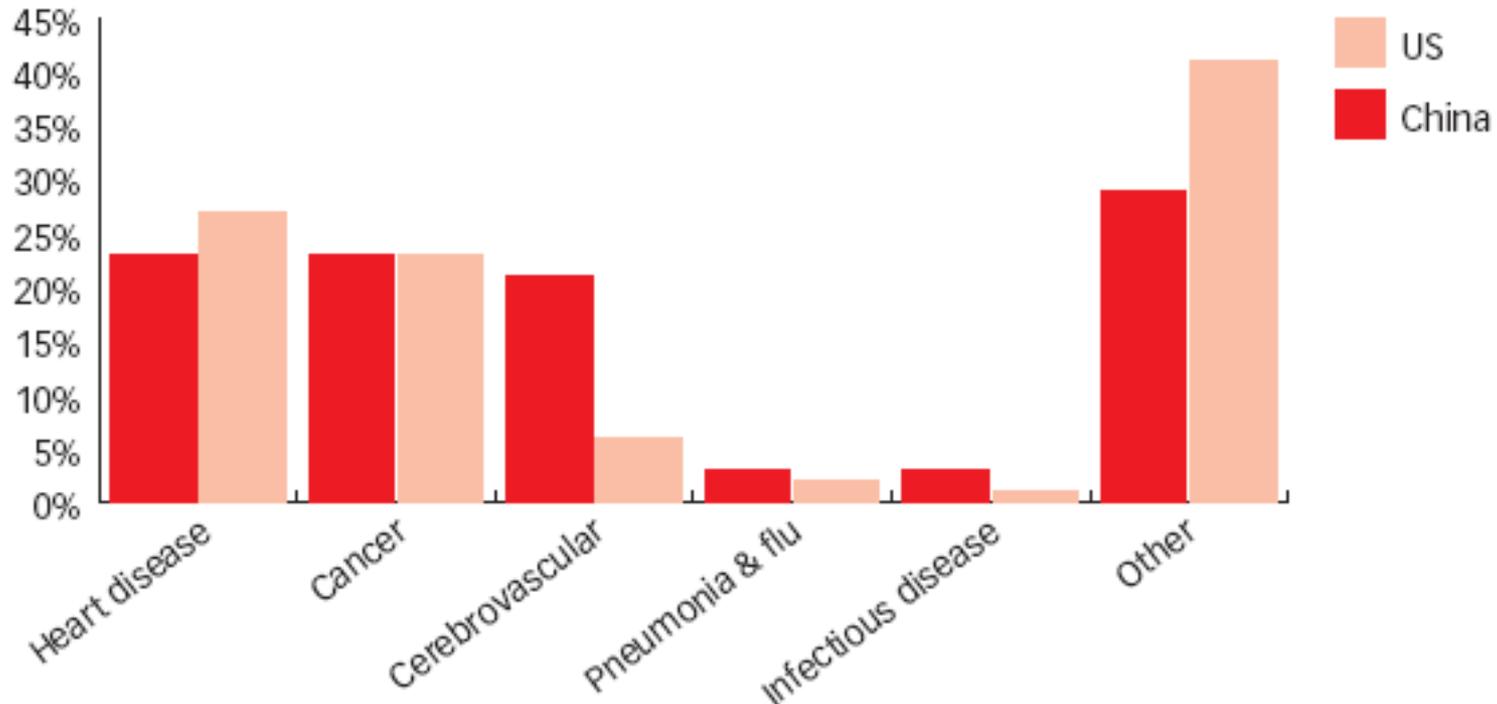
# Note: Rolls Royce Sales 2011



- Rolls-Royce ended 2011 with a bang, reporting its highest annual sales in its 107-year history. The British automaker sold 3538 vehicles in 2011, beating its previous best set in 1978 with 3347 units sold.
- China also surpassed the U.S. as Rolls-Royce's biggest market in 2011, with the U.K. coming in third.
- The sales growth was the trend across the globe, with the Asia Pacific market up a notable 47 percent. The U.K. reported a 30 percent growth, while sales in the Middle East represented a 23 percent increase. Germany and Russia both doubled sales compared to 2010, and North America reported a 17 percent growth

# Major diseases in China

Figure 1: Major causes of death in China and the US (adapted from CDC National Vital Statistics, 2007<sup>2</sup>).

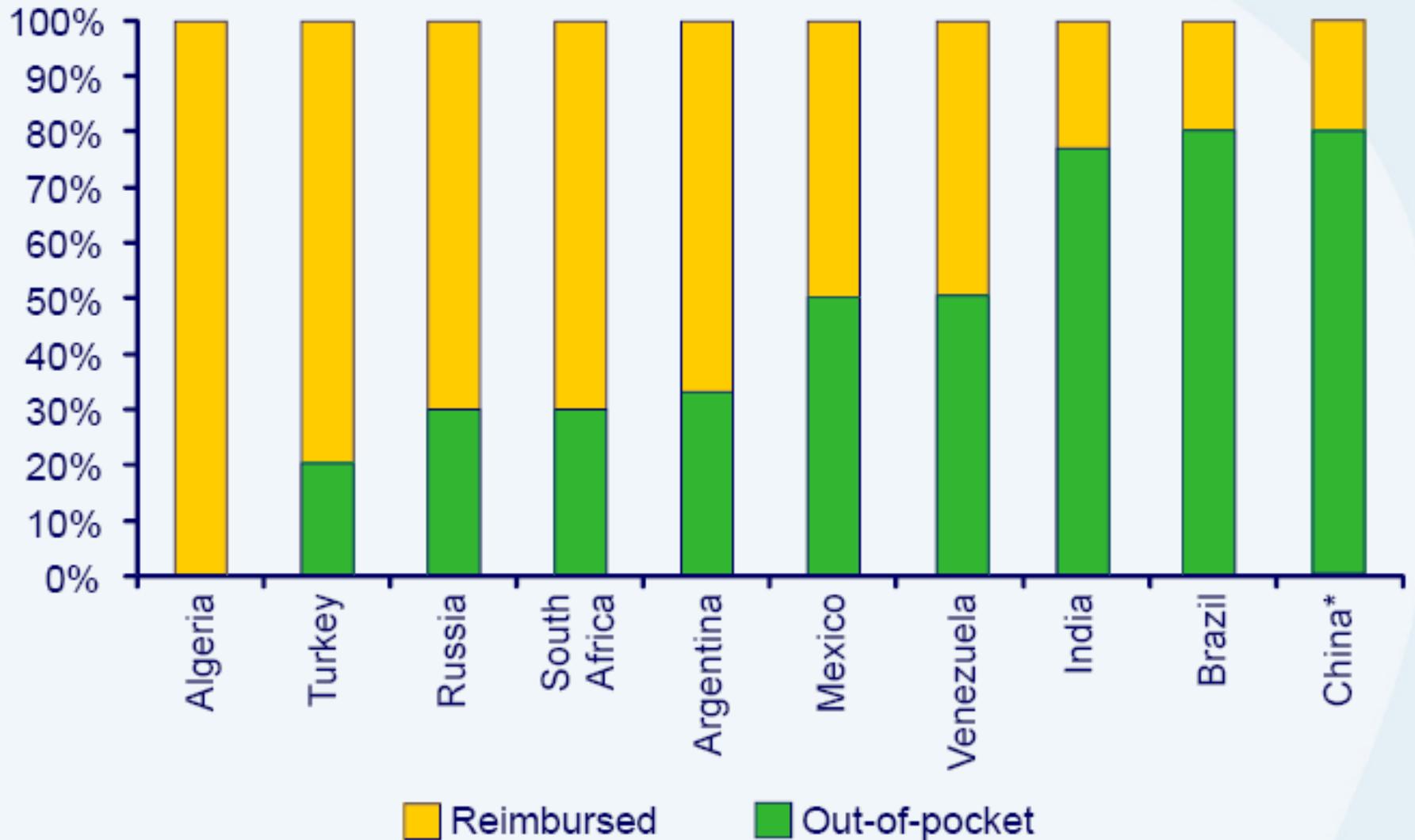


700,000 individuals with HIV, 75,000 full blown AIDS  
170 Million individuals with Hepatitis B – poorly served  
40 Million diabetics  
High incidence of lung, mouth and neck cancers

# So its simple lets access the Emerging Markets

- Not quite that easy, there are many challenges and drivers?
  - Diverse healthcare systems (No NHS)
  - Fragmented markets
  - Complex regulatory systems
  - Cultural and language barriers
  - Increased Competition (local & global)
  - Infrastructure is varied
  - Dynamic situation (regulations and technology changes occur daily)

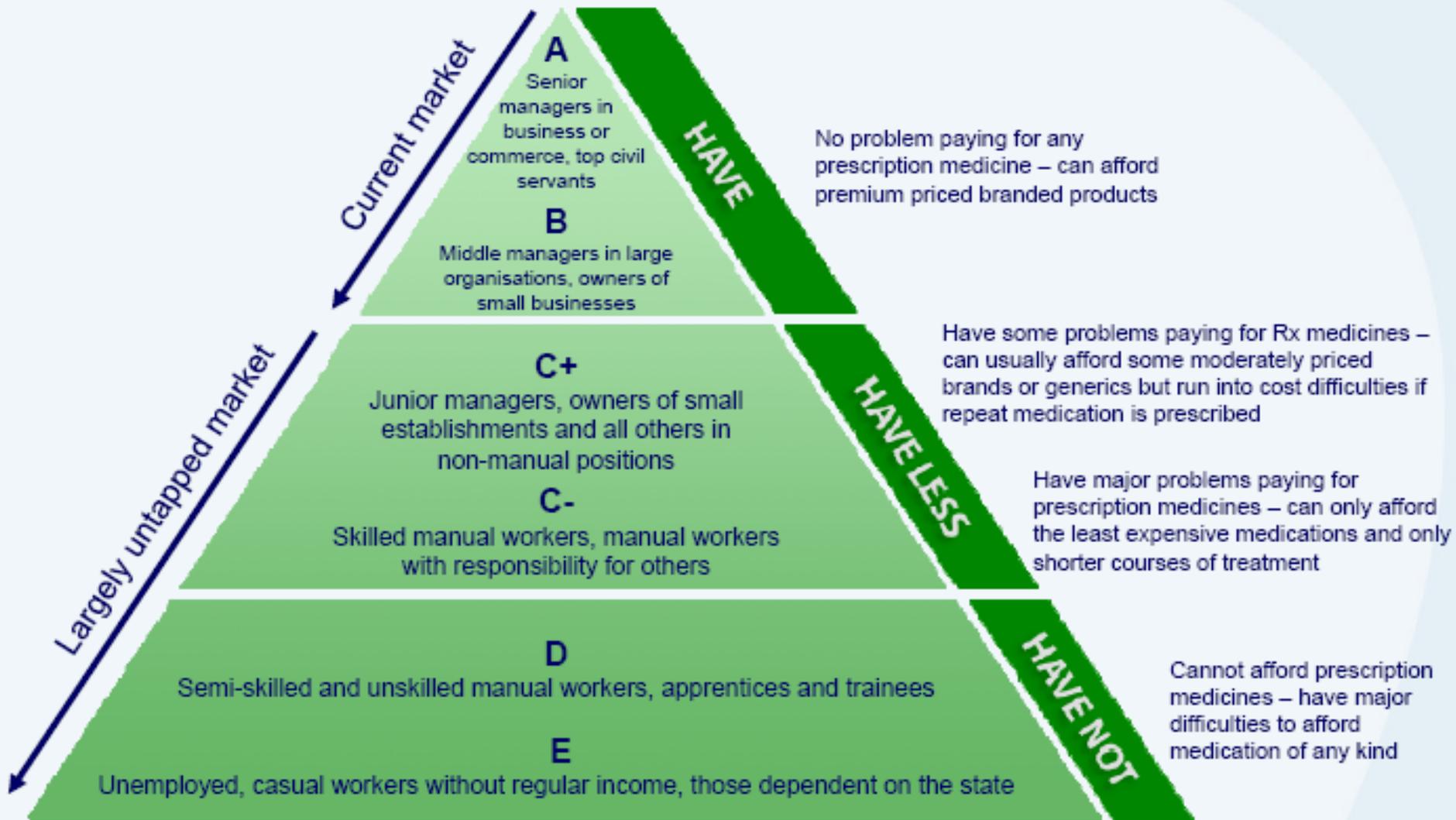
# Pay out-of-pocket



Source: IMS

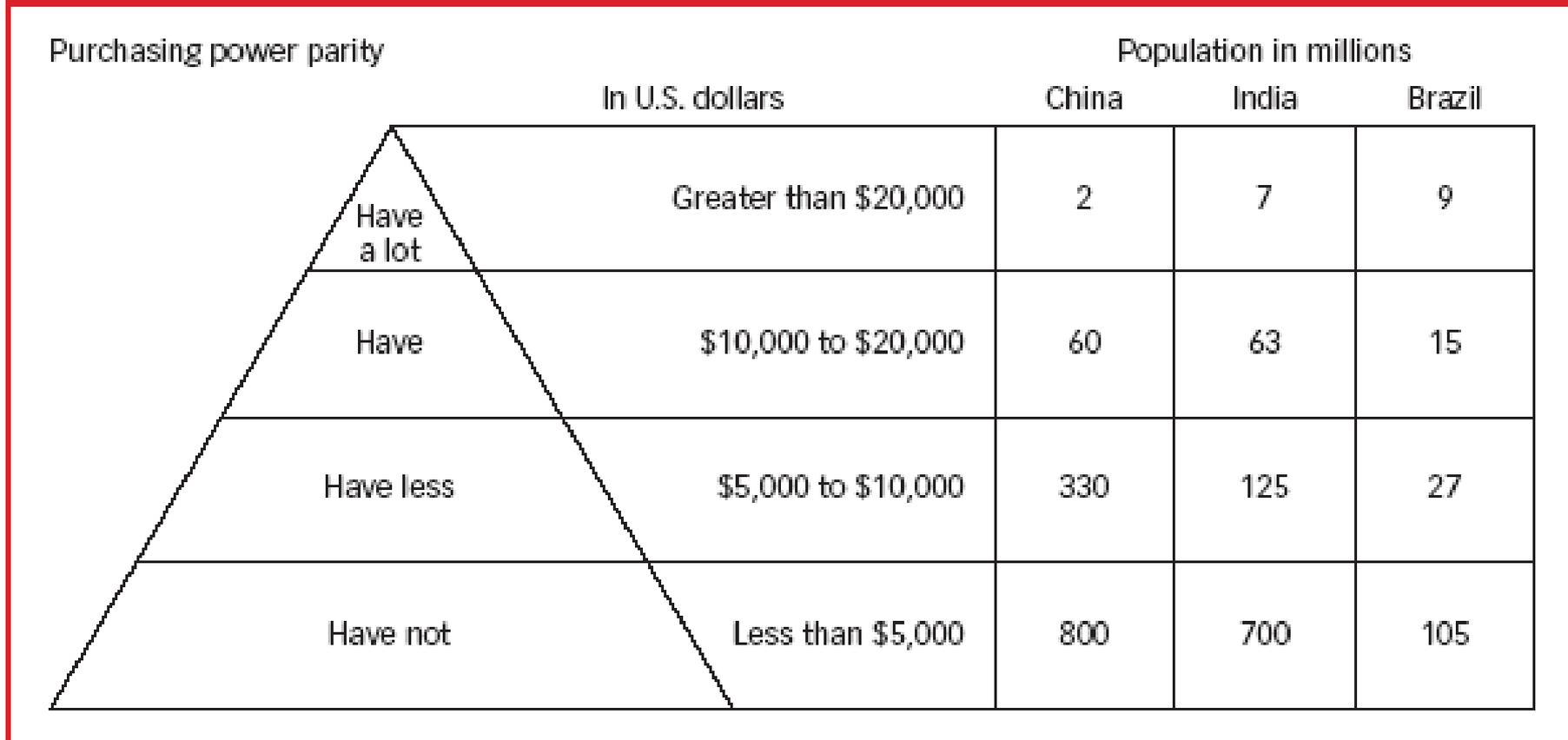
\* China is an estimate.

# The Wealth Pyramid



# Distribution of wealth in key emerging markets

Figure 2: The Wealth Pyramid across the emerging markets (adapted from Prahalad and Lieberthal, 1998<sup>7</sup>).



How do we get affordable healthcare to the 'Have nots'?

Source LG. Martini and S. Macrae (GSK): Pharm Tech 1 May 2010

# Dynamic Environments and the Dangers of Western Thinking consider the



# A picture tells a 1000 words!



**Technology Leapfrogging is the norm!**

# What is the outcome from these drivers?

- Companies have to provide a 'basket of offerings' i.e. a mixed portfolio of new medicines and cheaper (generic) medicines
  - Many multinational companies do not have the experience of playing in the 'generic space'
  - Many multinational companies have to acquire or form joint ventures with local players
    - Accessing existing dossiers and products
    - Registering new dossiers locally or in selected markets
  - Many multinational companies are forming dedicated emerging markets teams and relocating senior people/resources to these regions
  - Local manufacturing is key for registration in many emerging markets!

# Supporting Headlines

- **GSK announces a strategic alliance with Dr. Reddy's to further accelerate sales growth in emerging markets**
- **Merck, Sun Pharma ink JV to bring innovative drugs to EMs**
- **Abbott to pay \$3.7 billion for unit of India's Piramal**
- **Novartis will transfer production technology for three commonly-used vaccines to the new facility under its 20-year agreement with Arabio**

# What are the resulting issues?

- Many global companies struggle with different regulatory standards i.e. Global (US/EU) vs Local Domestic
  - Different registration requirements
    - Many multinational companies work to higher standard than FDA/EU requirements
    - WHO often used as a default
  - Clinical Data
    - For some products 'equivalence' is not enough
    - Clinical study designs being audited (DCGI in India)
    - Requirements in India vs. China vs. Korea
- Pricing products— different systems exist and referencing pricing lists change regularly
  - Competing on price alone for Branded Generics is not enough-eventually margins will be cut
- NICE like systems are being established in Emerging Markets
- Products from certain countries are NOT easily registered in other countries due to historical issues

# We cannot underestimate quality & safety!



## Deadly Heparin Found in 11 Nations

FDA traces tainted Chinese blood thinner that killed 81



Apr 22, 2008 7:17 AM CDT

### Adulterated Products

- Agencies are concerned with sites of manufacturer and are focusing their inspectors in the emerging markets
- Sterile facilities and capability in the emerging markets is also a cause for concern

# Counterfeits



- Supply chain issues in the Emerging Markets cannot be compromised

# Brand Power = Quality and Safety!



- Big Pharma will capitalise on its reputational power and high quality standards

# Changes within Pharma



**SCOTTISH HIGHLANDS**  
*Lucky*

**NORTHERN VIETNAM**  
*Lucky*

Never underestimate the importance of local knowledge.

Flowers mean different things the world over and to understand those differences, it helps to be a local. At HSBC, we have banks in more countries than anyone else. And each one is staffed by local people. We have offices in 77 countries and territories; Europe, Asia-Pacific, the Americas, the Middle East, and Africa. Being local enables them to offer insights into financial opportunities and create service initiatives that would never occur to an outsider. It means our customers get the kind of local knowledge and personal service that you'd expect of a local bank. And a level of global knowledge and widely sourced expertise that you wouldn't.

**HSBC**   
The world's local bank

- Local knowledge is key and working locally is needed
- However, how does this knowledge spread to the rest of the organisation?
- You need Change Agents whose focus is simply Emerging Markets and you also need them throughout the organisation
- Most Pharma companies now have Emerging Markets groups (GSK in R&D)

# Evolving Workplace

- Key areas of change is that scientists will be dealing more with projects that are being developed across national borders
  - drug discovery in Europe with drug development conducted in India and registration executed in Europe or North America or
  - drug discovery occurring in China, developed in China, commercialised in China and then registered and commercialised in Europe or
  - another scenario being drug discovery conducted in China, development conducted in India and commercialised in Europe.
- **Basic Formulation Development for small molecule will be continually developed in a virtual way i.e. outsourced to low cost countries whereas large molecules will be developed in the EU and North America.**

# View of the future workforce

## Seven Skill Sets with Great Future Value

<b>Seven Skill Sets Necessary to Operate in the Pharmaceutical Industry of the Future</b>	
1)	Ability to Manage Decentralized Intellectual Capital Resources
2)	Ability to Work In Joint Ventures and Across Divisions, Cultures and Countries
3)	Ability to Integrate an Understanding of Intellectual Property Laws, Scientific Expertise and Business Strategy
4)	Ability to Spur Creativity While Managing Commercially
5)	Knowledge and Insight on the Decision-Making Dynamics of Payers
6)	Expertise In the Functioning and Decision-Making of Regulatory Agencies
7)	Human Resource Skills to Help Transform Pharmaceutical Companies

# Required Skills for a Translator/Innovator

- **Albani & Prakken, Nature Medicine, Sept 2009**
  - Knowledge of research and development
  - Knowledge of Intellectual Property
  - Knowledge of the various regulatory agencies
  - Understanding Clinical Trials design and supplies
  - Understanding legal and ethical requirements for good business
  - Good communication skills
  - Fundamental skills of networking, team building and strategic thinking

**Working in the Pharmaceutical Industry allows you to gain these valuable and transferrable skills—My time at GSK afforded me the opportunity to acquire and develop these skills**

# What is EIPG?

The E.I.P.G. is a European association representing the national, professional organizations of pharmacists employed in the pharmaceutical and allied industries of the Member States of the European Union.

Its foundation dates back to 1966 and, over the years, it has progressed in its activities in line with the evolution of the European Union.

As a European association having its official seal with the French Order of Pharmacists, EIPG is registered at the Prefecture of Police in Paris.

Today EIPG represents about 10 000 pharmacists working in the European industry.

# Role of EIPG

## Objectives

The main objective of EIPG is to promote and uphold the importance and role of the industrial pharmacist within the pharmaceutical industry. In addition EIPG aims to ensure that it:

- Will influence the evolution of EU regulations and guidelines concerning standards of quality, safety and efficacy of medicinal products
- Works closely with member state industrial pharmacist groups, including representation of their views within an EU context
- Maintains contact with other EU pharmaceutical groups representing community and hospital pharmacy practices
- Consults with European Pharmaceutical Industry Associations

# Next 8 years

- To promote the modern pharmaceutical industry to observers and more importantly to young Pharmacists
- To ensure that educational standards meet the needs of the Industry of 2020
- To provide mentoring and coaching to young Pharmacists who need career advice

But the Industrial Pharmacist of the future needs to think differently!

e.g. Funding will be tight and therefore Lean Innovation is key

# Jugaad



*Jugaad* literally means an arrangement or a work around, which has to be used because of lack of resources.

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The influence of Emerging Markets can even be felt in King's College



**The World Questions and King's Answers!**