LORD GANESHA WELCOMES YOU ALL

By: MUTHU IYER - INDIA
PHARMACEUTICAL INDUSTRY IN CHALLENGE & OPPORTUNITIES

INDIA

- G7
- E7
- BRIC
- ROW
## Global Pharma Market Overview

### Global Pharmaceutical Sales : 2006

<table>
<thead>
<tr>
<th>World Audited Market</th>
<th>Sales (US$BN)</th>
<th>Global Sales (%)</th>
<th>% Growth Year over-Year (Constant US$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>North America</td>
<td>$289.9</td>
<td>47.7%</td>
<td>8.0%</td>
</tr>
<tr>
<td>Europe</td>
<td>181.8</td>
<td>29.9</td>
<td>4.8</td>
</tr>
<tr>
<td>Japan</td>
<td>56.7</td>
<td>9.3</td>
<td>-0.7</td>
</tr>
<tr>
<td>Asia, Africa &amp; Australia</td>
<td>52.0</td>
<td>8.6</td>
<td>9.8</td>
</tr>
<tr>
<td>Latin America</td>
<td>27.5</td>
<td>4.5</td>
<td>12.9</td>
</tr>
<tr>
<td><strong>Total IMS Audited</strong>*</td>
<td><strong>$607.9</strong></td>
<td><strong>100%</strong></td>
<td><strong>6.5%</strong></td>
</tr>
</tbody>
</table>

**Note:**

1. China 12.3% $\uparrow$ to $13.4bn in 2006
2. India 17.5% $\uparrow$ to $7.3bn in 2006

*Source: IMS MIDAS®, MAT Dec2006*
Global Pharmaceutical Market

- Leading therapy groups
  - Lipid Regulators
  - Oncologists
  - Respiratory Agents
  - Autoimmune Agents

- Looking Ahead
  - Patients becoming co-managers
  - New demands by payers
  - Need to rebalance the market place
  - Industry getting redefined
Walk Through

- Shifts in Global Market
- Forces Shaping The Global Market
- Drivers for Global Pharma Market
- Global Initiatives
- Predictable Scenario
# Global Economic Shifts & Impact

<table>
<thead>
<tr>
<th>Countries</th>
<th>GDP*</th>
<th>Consumer Prices*</th>
<th>Unemployment Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States</td>
<td>+ 2.0</td>
<td>+ 2.4</td>
<td>4.6</td>
</tr>
<tr>
<td>Japan</td>
<td>+ 2.6</td>
<td>- 0.2</td>
<td>3.7</td>
</tr>
<tr>
<td>China</td>
<td>+ 10.5</td>
<td>+ 5.6</td>
<td>9.5</td>
</tr>
<tr>
<td>Britain</td>
<td>+ 2.8</td>
<td>+ 1.9</td>
<td>5.4</td>
</tr>
<tr>
<td>Canada</td>
<td>+ 2.5</td>
<td>+ 2.2</td>
<td>6</td>
</tr>
<tr>
<td>Euro Area</td>
<td>+ 2.7</td>
<td>+ 1.8</td>
<td>6.9</td>
</tr>
<tr>
<td>Switzerland</td>
<td>+ 2.4</td>
<td>+ 0.7</td>
<td>2.5</td>
</tr>
<tr>
<td>Australia</td>
<td>+ 3.6</td>
<td>+ 2.1</td>
<td>4.3</td>
</tr>
<tr>
<td>India</td>
<td>+ 8.4</td>
<td>+ 5.7</td>
<td>7.6</td>
</tr>
<tr>
<td>South Africa</td>
<td>+ 4.8</td>
<td>+ 7.0</td>
<td>25.5</td>
</tr>
</tbody>
</table>

*% change on year ago

Source: The Economist Sept 07
Economic Growth Drivers

- Borderless Economy
- Increased purchasing power
- Free mobility of capital
- Easier access to technology
- Free Trade Agreements
- M&A’s
Global Demographic Shifts & Impact

Population Growth of Specific Age Groups:

Population in 100 mio

Male Female

2050 2002

Age-Sex Structure of World Population: 2002 and 2050
Global population will change markedly over the next 50 years

Source: U.S. Census Bureau, International Programs Center, International Data Base.
...India is the world largest birth cohort, bigger than China & 5 times that of United States or 4 times that of Europe...

<table>
<thead>
<tr>
<th>Year</th>
<th>India Population</th>
<th>Age Groups 0-14</th>
<th>Age Groups 15-59</th>
<th>Age Groups &gt; 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>1.01 B</td>
<td>348 M</td>
<td>596 M</td>
<td>77 M</td>
</tr>
<tr>
<td>2010</td>
<td>1.18 B</td>
<td>354 M</td>
<td>728 M</td>
<td>101 M</td>
</tr>
<tr>
<td>2020</td>
<td>1.33 B</td>
<td>350 M</td>
<td>840 M</td>
<td>142 M</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>China Population</th>
<th>Age Groups 0-14</th>
<th>Age Groups 15-59</th>
<th>Age Groups &gt; 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>1.27 B</td>
<td>316 M</td>
<td>830 M</td>
<td>129 M</td>
</tr>
<tr>
<td>2010</td>
<td>1.36 B</td>
<td>264 M</td>
<td>922 M</td>
<td>169 M</td>
</tr>
<tr>
<td>2020</td>
<td>1.42 B</td>
<td>262 M</td>
<td>918 M</td>
<td>244 M</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Europe Population</th>
<th>Age Groups 0-14</th>
<th>Age Groups 15-59</th>
<th>Age Groups &gt; 60</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>715 M</td>
<td></td>
<td></td>
<td>185 M</td>
</tr>
</tbody>
</table>

Source: [http://esa.un.org/unpp](http://esa.un.org/unpp)

**ADVANTAGE INDIA:**
- Stability of birth cohort
- Large young working population
- High Purchasing Power
- Low Healthcare burden due to relatively lesser elderly population

**Source:** [http://esa.un.org/unpp](http://esa.un.org/unpp)

**Polpharma**
Global Regulatory Shifts & Impact

- It’s Advisory Committee rejected Merck’s Arcoxia in US for side effects such as heart attacks.
- > 27,250 personal injury law suits in Texas over pain medication Vioxx
- Deplored poor rate of reporting in Pharmaco-vigilance

Emerging Concerns
- Patient Safety
- Side Effects
- Adverse Action Reporting

Source: interlink
Global Regulatory Shifts & Impact

- Petition filed by bulk pharmaceuticals taskforce
- Filed a citizen’s petition with the FDA in 2006, asking the agencies to oversee foreign firms more aggressively.
- Grievance of low USFDA inspection
- Senate (May 9, 07) Legislation - Additional powers to FDA to regulate drugs after approval
- Advised to print “black-box” warning about congestive heart failure to be added to GSK’s Avendia & Takeda’s Actos

- Deaths sentence for its former top drug regulator
- New measures to ensure safety of drug products & productive procedures

Emerging Issues
- Stronger Clinical Evidence
- Strengthening Harmonisation
- Strengthening Regulatory Vigilance
Global Regulatory Shifts & Impact

- Central Drug Authority planning to streamline the licensing system across the country
- Proposed good distribution practices for transporting/storing/selling medicines
- National Pharmaco-vigilance Committee
- Move to regulate Fixed Dose Combinations
Global R&D Shifts & Impact

- Global market for outsourcing (October 2006)
  - Contract research support services – $14.5 bn
  - Drug discovery outsourcing - $4.1 bn
  - Clinical research outsourcing - $9.57 bn

- Decline in R&D productivity forcing global pharma companies to explore low cost options for research.

- New Business Models like risk reward partnership and de-risking by making R&D units as SBUs
Global R&D Growth Drivers

- Genome Project
- New Technology Tools
- Search for better treatments
- Availability of outsourced research
- Pool of scientific talents
- New Business Models
  - Risk-reward partnership
  - De-risking
  - Co-development
- Harmonisation of Regulatory Norms

Source: interlink
Forces Shaping The Global Market
Scenario Building
Forces Shaping the Global Market

- Core Strengths of Global Market
- Disease Incidence
- Health Infrastructure
- Health Insurance
- Alternative Medicine
- Patents
- Science to Business

Source: interlink
Drivers of the Global Pharma Market
Drivers of the Global Pharma Market

R&D Investment
- Increased focus on New Chemical Entities, Improved Chemical Entities, Novel Drug, Delivery System.

Product Portfolio Pipeline
- New products in line with the emerging demand patterns
- Strong pipeline essential to sustain future earnings

Market Diversification
- Presence in multiple, regulated markets, good distributions
- Price control getting stricter and larger

Manufacturing Facility
- Low cost manufacturing capability: key strength
- Product quality: systems and processes critical
- Quality of documentation critical
- Backward integration crucial for greater value addition
- Technology up gradation necessary for contract manufacturing
Global Pharma Market
2010 Predictable Scenario
### Global Pharma Industry: Scenario 2010

<table>
<thead>
<tr>
<th>Basic Drivers Forces</th>
<th>Optimistic Scenario</th>
<th>Negative Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Push of Technology</strong></td>
<td>Faster &amp; better medicines</td>
<td>Better but costly medicines</td>
</tr>
<tr>
<td>(Genome related research/ computer aided technology)</td>
<td>Cost Containment</td>
<td>Market Segmentation</td>
</tr>
<tr>
<td></td>
<td>Volume Growth</td>
<td></td>
</tr>
<tr>
<td><strong>Informed Consumerism</strong></td>
<td>Better acceptance of industry contributions</td>
<td>Industry perceived more as profiteer than a health healer</td>
</tr>
<tr>
<td></td>
<td>More Trust</td>
<td></td>
</tr>
<tr>
<td><strong>Genetics</strong></td>
<td>Revolutionary treatment for defined therapeutic interventions (e.g. Cancer, Alzheimer)</td>
<td>Limited outreach</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Distance between science &amp; common man</td>
</tr>
<tr>
<td><strong>Health Insurance</strong></td>
<td>Privatised &amp; liberalised industry</td>
<td>More Restrictive</td>
</tr>
<tr>
<td></td>
<td>More Coverage</td>
<td>Vulnerable population (aged) kept out.</td>
</tr>
</tbody>
</table>

Market Growth (2010-2020) – 7.5% under Optimum Scenario  
Market Growth (2010-2020) – 4% under Negative Scenario  

Source: interlink
“Slow and steady wins the race. This is the version of the story that we’ve all grown up with.”
“Fast and consistent will always beat the slow and steady. It’s good to be slow and steady; but it’s better to be fast and reliable.”
INDIA.... INDIA.... The Twin opportunity

India as a Market

- Significant unmet needs
- 20 B USD by 2015*
- One of the Top 10 markets by 2015
- Top 3 growth opportunity

India as a service India as a service provider

- Resources
- Competence
- Cost Arbitrage
- Experience, Image
- Young population
- Growing economy
- Pharmaceutical expertise
- Democratic set up

McKinsey 2007
**BCG, 2006
India potential across the value chain

**Target Identification & Validation**
- Less developed academic expertise
- Investment incongruity

**Lead Generation & Optimisation**
- Medicinal Chemistry
- Custom chemical synthesis
- Molecular Modelling
- Virtual Screening

**Pre-Clinical Development**
- Pharmacokinetics
- Animal Testing
- Toxicology

**Ph I**
- Limited first in man studies

**Ph II & III**
- Clinical trials
- Data Management
- Central Lab
- Biostats

**Contract Manufacturing**
- APIs
- Formulations
- Finished product
- Clinical trial suppliers
- Bio-equivalence

**Commercialisation**
- Packaging
- Medical Writing
- Legal
- HR and finance support
- Call centres

---

Source: ipa
# IDM Classification

<table>
<thead>
<tr>
<th>Group</th>
<th>Number of Firms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100</td>
<td>Large Firms: Indian and MNC subsidiaries, Brand Recognition, R&amp;D capability. Responsible for recent wave of cross border acquisitions, Exports to regulated, other Export Markets</td>
</tr>
<tr>
<td>2</td>
<td>200</td>
<td>Mid Size Firms: Less Brand recognition, R&amp;D capability in reverse engineering, Low cost manufacturing, Exports to Regulated Markets (Other than US, Japan, EU)</td>
</tr>
<tr>
<td>3</td>
<td>5700</td>
<td>Small Firms: Closures due to new schedule M, No R&amp;D capability, Contract manufacturing for bigger firms.</td>
</tr>
</tbody>
</table>
Future

Indian Pharma Market is likely to triple by 2015

Source: McKinsey
R & D in Pharma Industry

Rising pressures on revenues

Falling trend in R & D productivity

Search of Innovation

Creativity from young minds

Academic Excellence
Academic-Industry interactions

Various types of models used in the western and also eastern world for industry – Academia Interactions
eg. United States, European, Singapore Universities
Research Initiatives in Pharmaceutical Industry

- Synthetic chemistry
- Combinatorial chemistry
- Natural Products
- Pharmacogenomics
- High Throughput Screening
- Biotechnology
- Novel drug delivery systems

8-12 years
USD 850 Mn

Blockbuster Molecule

Source: rubicon
The Need of the Hour

LEADERSHIP

Quality Professionals/Consultants

NEED

Centers of excellence

Skilled Faculty

Centers of Innovations

Superior Infrastructure

Bridges with Industries

Quality Students Prepared To Assume Industrial Responsibilities

Specialized Competencies And Newer Technologies

polpharma
Thank You & All The Best

iyermv@gmail.com