Global Pharmaceutical Industry and Trends

The outlook for the global pharmaceutical market is marked by greater cost pressures and a higher bar for product innovation that reflects an increased demand for value from both regulators and payers. Weak growth in developed markets, the continued rise of emerging markets, and a shift to specialty medicines are forecast to be significant outcomes over the next five years.

By 2017, 50% of drugs by volume are forecast to be in pharmerging markets, and the US and Europe each respectively will account for only 13% of pharmaceutical volume by 2017.

Led by China, the BRIC countries (Brazil, Russia, India, and China) will account for 70% of all pharmerging market sales by 2017 on a value basis and strategically will continue to be the important engines of growth among emerging markets.

It is projected that the Indian market would grow at a compounded annual growth rate of 12 to 14 per cent to become a USD 20 billion to USD 24 billion market by 2015.
### Market share and Compound Annual Growth Rate (CAGR) in Global Pharmaceutical Markets from 2013-2017.

Total Global Market: $1.135 – 1.235 Trillion
Global CAGR: 3 – 6%

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>US</td>
<td>31%</td>
<td>1 – 4%</td>
<td></td>
</tr>
<tr>
<td>EU 5</td>
<td>13%</td>
<td>(-1%) – 2%</td>
<td>Germany, Finance, Italy, Spain, UK</td>
</tr>
<tr>
<td>JAPAN</td>
<td>9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Č Č CHINA</td>
<td>15%</td>
<td>13 – 16%</td>
<td>22%</td>
</tr>
<tr>
<td>BRIC</td>
<td>8%</td>
<td>10 – 13%</td>
<td>16%</td>
</tr>
<tr>
<td>TIER 3</td>
<td>10%</td>
<td>6 – 9%</td>
<td></td>
</tr>
</tbody>
</table>

Č Including traditional Chinese Medicines.

Source: IMS
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3. MFN Status – Threat or Opportunity?
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   – - Infrastructure
5. Likely Outcomes if MFN Granted Today
6. Possible Solutions
Pakistani Pharmaceutical Sector:

• $2.3 Billion Industry

• 15.69% CAGR IN PKR, 9.98% IN US$ (IMSQ2, ‘14)

• Total Domestic Investment of $500 Million

• Foreign Direct Investment of $100 Million

• The largest employer of University Graduates in Semi-urban and Rural Areas.
BENEFITS OF LOCAL PHARMA MANUFACTURING SECTOR

**Direct**
1. Self Reliance
2. Foreign exchange Saving
3. Employment generation
4. Employment for Females
5. Skill Upgradation
6. FDI
7. Transfer of Tech. & Know How
8. Critical Support in Man Made & National disasters

**Indirect**
1. Indirect employment
2. Investment
3. Skill Acquisition
4. Technology spillovers
5. BRAIN DRAIN REVERSAL

**1. indigenous growth**
2. Productive Diversification
3. Human development
4. Revenue generation for govt.
Comparison with India & Bangladesh

Why Compare:
1. Part of tier 2 & 3 Pharmerging Countries
2. Similarities of market factors (Population, people behavior & economic conditions)
3. Medical Infrastructure
5. Growing markets with low cost of production like Pakistan
Industry Evolution –10 Years India vs. Pakistan

2002:

*Indian Pharma’s Domestic Sales were $ 4 Billion*

*Pakistan Pharma’s Domestic Sales were $ 1.2 Billion*

2012:

*Indian Pharma Market crossed $ 16 Billion*

(300% Growth in a Decade or 18% per annum)

*Pakistan Pharma Market reached $ 2 Billion*

(66% Growth in a Decade or 4% per annum)
<table>
<thead>
<tr>
<th>Description</th>
<th>Pakistan</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Pharma Market</td>
<td>USD 2 Bn</td>
<td>USD 14 Bn</td>
</tr>
<tr>
<td>Growth Rate</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Intl. Ranking Value Wise</td>
<td>45</td>
<td>15</td>
</tr>
<tr>
<td>Manufacturing Plants</td>
<td>&gt;700</td>
<td>25,000</td>
</tr>
<tr>
<td>USFDA / MHRA approved Plants</td>
<td>None</td>
<td>&gt;150</td>
</tr>
<tr>
<td>Pharmaceutical Exports</td>
<td>&gt;USD 190mi</td>
<td>&gt;USD 20,000mi</td>
</tr>
<tr>
<td>Raw material(API) supply to own country</td>
<td>Negligible</td>
<td>70%</td>
</tr>
<tr>
<td>Pharmaceutical Machinery Manufacturing</td>
<td>20-25%</td>
<td>90%</td>
</tr>
</tbody>
</table>
History of Pharmaceutical Regulation in India:

1970: Drug Prices Control Order (DPCO I) passed, placing indirect control on drug Pricing in India

1979: DPCO II put a Price Control on 370 Molecules

1995: DPCO III reduced the number of Molecules under price control to 76

Reasons for Growth of Indian Pharma Sector

1. Deregulation
2. Deregulation
3. Deregulation
History of Pharmaceutical Regulation in Pakistan:

1972: Drugs (Generics) Act passed prohibiting use of brand names/differentiation, instituting 100% control on drug Pricing.

1976: Drugs Act 1976 Passed, allowing for use of Brand Names, but continuing with Draconian Price Controls on 100% of all Pharmaceutical Products.

2001: Last price increase Granted by the Ministry of Health to Manufacturers to allow for inflation, rise in cost of inputs

2011: Devolution under the 18th Amendment led to dissolution of MoH, DRAP not Formed until Feb ’12, Shifted to new Division in April 12, Still not Fully Functional
Reasons for Stunted Growth of Pakistani Pharma Sector

1. Arbitrary Regulations: No price adjustments for inflation in a DECADE.

1. No Vitamin Policy, No policy for Over the Counter (OTC) Drugs. OTC drugs are a large segment for Big Pharma globally, adding to scale and profitability

2. Poor Domestic Regulation and weak government procurement policies that do not encourage investment in quality.

3. Energy Crisis Rendering Sector Uncompetitive. Electricity and Steam are the two Costliest Inputs. No R&D Grants or Tax Benefits to Pharma. No Support on Utilities
Impact of Ad-hoc Regulatory Environment in Pakistan:

• Complete Emphasis on Price Control vs. Quality Control

• Lack of Capacity to Enforce Quality Standards
  10 FID’s to Monitor 600+ Local Facilities

( *India has over 20,000 Registered Manufacturers – Pakistan’s regulatory body does not have the capacity to monitor them for quality)

• Lack of Transparency and Ad-hoc Decision making has discouraged genuine investment.

Result:

Stifled Industry Growth
Depressed Profitability
Discouraged Investment
Restricted Scale of Industry to Uncompetitive Levels
**Misconception:** Drugs are Cheaper Across the Board in India

**Fact:** 16 of the Top 30 Most Used Drugs are Cheaper in Pakistan

<table>
<thead>
<tr>
<th>#</th>
<th>NAME</th>
<th>COMPARATIVE PAK MRP</th>
<th>INDIAN MRP IN PKR</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>AUGMENTIN</td>
<td>91.68</td>
<td>259.27</td>
<td>65%</td>
</tr>
<tr>
<td>2</td>
<td>GLUCOPHAGE</td>
<td>69.14</td>
<td>397.70</td>
<td>83%</td>
</tr>
<tr>
<td>3</td>
<td>PONSTAN</td>
<td>203.31</td>
<td>336.47</td>
<td>40%</td>
</tr>
<tr>
<td>4</td>
<td>AMPICLOX</td>
<td>149.55</td>
<td>235.07</td>
<td>36%</td>
</tr>
<tr>
<td>5</td>
<td>INTERFERON</td>
<td>450.00</td>
<td>1,578.31</td>
<td>71%</td>
</tr>
<tr>
<td>6</td>
<td>ERYTHROCIN</td>
<td>200.86</td>
<td>313.30</td>
<td>36%</td>
</tr>
<tr>
<td>7</td>
<td>HUMULIN70/30</td>
<td>406.54</td>
<td>578.01</td>
<td>30%</td>
</tr>
<tr>
<td>8</td>
<td>PANADOL</td>
<td>31.04</td>
<td>41.12</td>
<td>25%</td>
</tr>
<tr>
<td>9</td>
<td>MOTILUM</td>
<td>125.38</td>
<td>175.68</td>
<td>29%</td>
</tr>
<tr>
<td>10</td>
<td>CALPOL</td>
<td>26.31</td>
<td>35.54</td>
<td>26%</td>
</tr>
<tr>
<td>11</td>
<td>TARIVID</td>
<td>304.31</td>
<td>382.69</td>
<td>20%</td>
</tr>
<tr>
<td>12</td>
<td>DIAMICRON</td>
<td>128.78</td>
<td>150.83</td>
<td>15%</td>
</tr>
<tr>
<td>13</td>
<td>LINCOCIN</td>
<td>114.12</td>
<td>140.88</td>
<td>19%</td>
</tr>
<tr>
<td>14</td>
<td>CECLOR</td>
<td>205.58</td>
<td>227.97</td>
<td>10%</td>
</tr>
<tr>
<td>15</td>
<td>KLARICID</td>
<td>648.53</td>
<td>703.13</td>
<td>8%</td>
</tr>
<tr>
<td>16</td>
<td>HAEMACCEL</td>
<td>275.48</td>
<td>279.64</td>
<td>1%</td>
</tr>
</tbody>
</table>
## Comparison of Industry Environment for Exports

<table>
<thead>
<tr>
<th>Parameter</th>
<th>India</th>
<th>Pakistan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price Control</td>
<td>Nominal</td>
<td>100%</td>
</tr>
<tr>
<td>Time to obtain Export License for a Drug</td>
<td>2 weeks</td>
<td>Indefinite</td>
</tr>
<tr>
<td>Utilities</td>
<td>Provided at Base Tariffs (free of GST, IT and other taxes (in SEZ’s))</td>
<td>Intermittent Availability. Lowest priority</td>
</tr>
<tr>
<td>Duties &amp; Taxes on Machinery, Inputs</td>
<td>Zero (in SEZ’s)</td>
<td>5-25%</td>
</tr>
</tbody>
</table>
Comparison with Bangladesh
Bangladesh Regulatory Strategy:

Registration of drugs for import. The application for registration of a drug for import will be taken into consideration only if the drug is registered under the same brand name in at least one of the following developed countries: USA, UK, Switzerland, Germany, France, Japan & Australia.

Bangladesh’s Drug Registration Policy 2005 issued by the Directorate General of Drugs Administration (DGDA) allows for registration of only those imported brands that are manufactured in plants approved by and registered and sold freely in one of the following countries: USA, UK, Switzerland, Germany, France, Japan and Australia.
<table>
<thead>
<tr>
<th>Description</th>
<th>Pakistan</th>
<th>Bangladesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Pharma Market</td>
<td>USD 2.3 Bn</td>
<td>USD 1.5 Bn</td>
</tr>
<tr>
<td>Growth Rate</td>
<td>15%</td>
<td>12%</td>
</tr>
<tr>
<td>Intl. Ranking Value Wise</td>
<td>45</td>
<td>58</td>
</tr>
<tr>
<td>Manufacturing Plants</td>
<td>700</td>
<td>210</td>
</tr>
<tr>
<td>USFDA / MHRA approved Plants</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Raw material(API) supply to own country</td>
<td>Negligible</td>
<td>15%</td>
</tr>
<tr>
<td>Pharmaceutical Machinery manufacturing</td>
<td>20-25%</td>
<td>15%</td>
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</table>
Benefits of Bangladesh Strategy:

By restricting access to imports of the Top FDA/EU -approved companies only, Bangladesh gave space and set a benchmark for Local Industry to raise its standards or be disqualified in the future.

At the same time, by granting MFN status to India and thereby easing access to Indian expertise, training and consultancy, The Bangladeshi Government has helped Industry to grow tremendously in Size, Scope and Scale.

Quality Standards of Bangladeshi plants have accordingly been raised to international levels (Bangladesh has 4 FDA/EU Approved plants, approved in the last 4 years). Exports have gone up from $5 Million in 2003 to $50 Million in 2011.

Pakistan exports are already $200 Million. Potential Gains are therefore far greater. Given encouragement and right policies, the industry can achieve $1 Billion export in 3-4 years.
WHAT IS LIKELY TO HAPPEN IF MFN WITH INDIA IS GRANTED TODAY?
CASE STUDY:

BRAZIL

1. Institutional Dynamics of Indo-Brazilian Trade: Reflections from the Pharma Sector.
   - Sandra Sweet, University of Cambridge, 2007
1991: As Part of a Major Trade Liberalization, the Government of Brazil Opened the Pharmaceutical Sector to Imports from India.


“The emergence of Indians as suppliers to the Brazilian government was initially seen as providing important advantages for public health initiatives.”

Indian Companies Engaged in Aggressive Dumping Practices, quoting well below Domestic Indian Prices.
Indian Exports to Brazil and Brazilian Local Production Trends: 1997-2002

Source: ABFINA, 2004
Over 2,000 Brazilian Firms Went Out of Business. Several were Subsequently Acquired by their Indian competitors.

“A problematic strategic dependency on a foreign resource, which, like petroleum or gas, could be disrupted by shifts in the political climate or national interest of supplying countries.”

“In addition to questions of dependency, representatives from Brazilian public laboratories have complained about the level of quality of the Indian [Products] they have been purchasing via the pregão—public call for tender system.”
The Brazilian Government’s Delayed Response:

2007:

Government circumvented tender provisions to buy preferentially from local manufacturers on the basis of quality.

Ministry of Health and the Brazilian National Development Bank (BNDES) Entered into a Strategic Alliance to fund Revival of Brazilian Pharmaceutical Industry through Loans, Grants, Subsidies and Long Term Credits.
Likely Outcome for Pakistan if Trade Opened up Today:

More Severe Impact on Local Production than Brazil

MNC’s will shut down their plants in Pakistan and serve market from their facilities across the border.

Currently a lot of toll-manufacturing for MNC’s is done by Local Pharma Companies. This business, too, will shift to India.

After the initial dumping period in which low-cost players are driven out, prices will go up again as in the case of Brazil.

Pakistani Exports, which are growing by almost 50% per-annum and carry a huge potential, will also suffer.
Way Forward for Pakistan:

Learn from the Brazilian Experience.

**Recommendation I:**
Place a Moratorium on Imports of Finished Products from India by retaining Pharmaceuticals on the **Negative List (HS Code 3004.9099)**.

Reduce import tariffs on Indian Raw Materials (Active Ingredients) to Zero to encourage Indo-Pak Trade and Support Competitiveness of Local Industry.

*Simultaneously, Liberalize the Regulatory Environment for Pakistani Companies. Allow them to Grow and recover from the ‘Lost Decade’ and Compete with India on a Level Playing Field*
Recommendation II:

Amend Drug Registration Policy of the DRAP to allow registration of only those imported brands that are manufactured in plants approved by and registered and sold freely in USA, UK, EU Countries, Switzerland, Japan or Australia.

Simultaneously, Liberalize the Regulatory Environment for Pakistani Companies and improve regulatory standards to match international GMP Requirements.
Pakistan is Sandwiched between the World’s Two Largest Producers of Pharmaceutical Raw Materials (India & China)

This is an Advantage to be Leveraged.

Retain Focus on Formulations and Facilitate Import of Cheaper Raw Materials and Technology Transfer from India.

Encourage Expansion in Quality and Scale of the Pakistani Pharma Sector through Incentivizing FDA Approvals, Giving Industry Space through Deregulation and Liberalization for EXPORTS AS WELL AS FOR LOCAL MARKET.
Despite Severe Odds, the Pakistani Industry has continued to invest in Quality, and in New Areas including Biotechnology.

Through Local Manufacture of Biotech Medicines, we have reduced the cost, through Competition, of Hepatitis C treatment by over 50%, and opened New Avenues of Exports for Pakistan.

Given a Supportive Regulatory Environment and fiscal space, the Industry WILL Invest in Quality, Scale and Innovation.
20 FDA Approved Units

$ 2 Billion Dollars in Exports

By 2020
“WE ARE LIMITED NOT BY OUR ABILITIES BUT BY OUR VISION”