Mexico Pharma Market & Regulation.

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- Presence of Indian Pharmaceutical companies in Regulated markets
- Mexican Pharmaceutical Market.
- Global Trade of Drugs & Pharmaceuticals; Mexico
- India’s export of Drugs & Pharmaceuticals to Latin America
- India-Mexico Bilateral Trade in Drugs & Pharmaceuticals
- Top Exported Commodities from India to Mexico
- Pharmaceutical Import Regulation in Mexico.
- Time for Registration Approval & Fees
- Prospects in Mexican market
Indian Pharmaceutical Industry – Current Status

- Indian pharmaceutical industry is amongst the world’s largest and most developed.

- The Indian domestic pharmaceutical market size is estimated at US$10bn (Rs.55,454 crores) in the year 2008 growing by health 10%. [IMS Health]

- Drugs & Pharmaceuticals is consistently the fifth largest principal commodity exported from India.

- There are about 1,000 WHO cGMP approved pharmaceutical plants in India.

- India has Proven chemistry & manufacturing skills and is the third largest supplier of Bulk drugs.

- Finished generics supplied from India account for 20% of the global generics market. [PricewaterhouseCoopers]

- India is the leading supplier of medicines to several international healthcare organizations like United Nations Children’s Fund (UNICEF), International Dispensary Association (IDA), the Global Fund, the Clinton Foundation and Medicine Sans Frontiers (MSF).
Presence of Indian Pharmaceutical companies in Regulated markets.

- The largest number of US FDA approved facilities outside US are in India.

- 8.73% of all registered pharmaceutical products in US are from India.

- India has filed largest number (30%) of Drug Master File (DMF) for Bulk drug with US.FDA

- India has received highest number (21.47%) of Certificate of Suitability (CEPs) for Bulk Drug registration granted by European Directorate of Quality Medicine (EDQM).

- The country has about 150 EDQM approved facilities.
Mexican Pharmaceutical Market.

- Mexico Pharmaceutical market Stood at 11bn in 2008. [IMS Health]

- Rank 11th largest Pharma market in 2008; expected to grow at 1-5% during next five year. [IMS Health]

- Considering lower level of income of Mexicans among OECD countries the prices of medicines are 5 times the level of income adjusted prices in US.

- Low competition from generic sector allows higher prices for medicines.

- Per-capita spending on Pharmaceuticals in Mexico is highest in Latin America.

- Mexico is characterized by overwhelming health inequalities – reflecting the large regional differences in income and health.

- The top three causes of death in Mexico are diabetes, heart disease and cerebrovascular disease (in parallel with the worrying rates of obesity, especially in the northern states).
Almost all of the major multinational research-based pharmaceutical companies are present in Mexico. These firms accounted for 84% of the total value of pharmaceutical sales in Mexico in 2003.

Senosiain, The top domestic company ranked fifteenth overall and demonstrating almost negligible growth.

Majority of the Market is occupied by Branded products with generics accounting for just 4% of total pharmacy sales.

Despite fairly strong intellectual property rights protection, low R&D spending on the development of pharmaceuticals in Mexico has meant there is little in the way of innovative activity in this sector.

The degree of product market competition, as measured through an indicator on product market regulations for 2003 shows Mexico to have one of the tightest regulated markets among OECD countries.
## Global Trade of Drugs & Pharmaceuticals; Mexico

### Top 5 Partners in Import [US$mn]

<table>
<thead>
<tr>
<th>Rank</th>
<th>Partner Country</th>
<th>2007</th>
<th>2008</th>
<th>% Growth</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>977.59</td>
<td>1,206.50</td>
<td>23.42</td>
<td>27.02</td>
</tr>
<tr>
<td>2</td>
<td>Germany</td>
<td>574.36</td>
<td>798.23</td>
<td>38.98</td>
<td>17.88</td>
</tr>
<tr>
<td>3</td>
<td>France</td>
<td>317.32</td>
<td>363.34</td>
<td>14.50</td>
<td>8.14</td>
</tr>
<tr>
<td>4</td>
<td>Switzerland</td>
<td>261.77</td>
<td>351.92</td>
<td>34.44</td>
<td>7.88</td>
</tr>
<tr>
<td>5</td>
<td>United Kingdom</td>
<td>193.45</td>
<td>232.97</td>
<td>20.43</td>
<td>5.22</td>
</tr>
<tr>
<td>15</td>
<td>India</td>
<td>81.19</td>
<td>78.61</td>
<td>-3.19</td>
<td>1.76</td>
</tr>
</tbody>
</table>

### Top 5 Partners in Export [US$mn]

<table>
<thead>
<tr>
<th>Rank</th>
<th>Partner Country</th>
<th>2007</th>
<th>2008</th>
<th>% Growth</th>
<th>% Share</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Venezuela</td>
<td>208.40</td>
<td>280.83</td>
<td>34.75</td>
<td>19.48</td>
</tr>
<tr>
<td>2</td>
<td>USA</td>
<td>307.85</td>
<td>262.22</td>
<td>-14.82</td>
<td>18.19</td>
</tr>
<tr>
<td>3</td>
<td>Brazil</td>
<td>115.36</td>
<td>112.18</td>
<td>-2.75</td>
<td>7.78</td>
</tr>
<tr>
<td>4</td>
<td>Panama</td>
<td>99.11</td>
<td>101.19</td>
<td>2.10</td>
<td>7.02</td>
</tr>
<tr>
<td>5</td>
<td>Colombia</td>
<td>99.86</td>
<td>96.97</td>
<td>-2.90</td>
<td>6.73</td>
</tr>
<tr>
<td>19</td>
<td>India</td>
<td>3.52</td>
<td>8.76</td>
<td>149.12</td>
<td>0.61</td>
</tr>
</tbody>
</table>

Source: UN Comtrade,
India’s export of Drugs & Pharmaceuticals to Latin America

India's Export in Latin America 2008-09 [US$mn]

- Formulation: 389.76 (54%)
- Bulk Drug: 326.25 (46%)

Top Export Destination in Latin America 2008-09 [US$mn]

- Brazil: 254.61 (36%)
- Mexico: 113.76 (16%)
- Venezuela: 46.42 (6%)
- Colombia: 58.38 (8%)
- Puerto Rico: 49.05 (7%)
- Others: 193.79 (27%)

Source: DGCIS, CMIE India trades
India-Mexico Bilateral Trade in Drugs & Pharmaceuticals

India's export of Drugs & Pharmaceuticals to Mexico [US$mn]

2005-06: 25.01
2006-07: 42.56
2007-08: 34.18
2008-09: 32.31

India's import of Drugs & Pharmaceuticals from Mexico [US$mn]

2005-06: 56.9
2006-07: 56.24
2007-08: 73.08
2008-09: 81.45

Source: DGCIS, CMIE India trades
## Top Exported Commodities from India to Mexico

### Bulk Drug

<table>
<thead>
<tr>
<th>Commodity Name</th>
<th>2008-09 [US$mn]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diloxanide furoate, cimetidine, famotidine</td>
<td>52.46</td>
</tr>
<tr>
<td>Sulphamethoxazole</td>
<td>3.27</td>
</tr>
<tr>
<td>Insulin and its salts</td>
<td>2.75</td>
</tr>
<tr>
<td>Penicillins &amp; their derivatives</td>
<td>2.43</td>
</tr>
<tr>
<td>Ranitidine</td>
<td>1.69</td>
</tr>
<tr>
<td>Other sulphonamides</td>
<td>1.62</td>
</tr>
<tr>
<td>Erthromycin &amp; its derivs slts thereof</td>
<td>1.35</td>
</tr>
<tr>
<td>Ciprofloxacin &amp; its salts</td>
<td>1.18</td>
</tr>
<tr>
<td>Para acetyl aminophenol(paracetamol)</td>
<td>1.17</td>
</tr>
<tr>
<td>Menthol</td>
<td>0.95</td>
</tr>
</tbody>
</table>

### Formulation

<table>
<thead>
<tr>
<th>Commodity Name</th>
<th>2008-09 [US$mn]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixed vaccines</td>
<td>3.55</td>
</tr>
<tr>
<td>Insulin injection</td>
<td>1.59</td>
</tr>
<tr>
<td>Amoxycyllin in capsules, injections etc.</td>
<td>1.16</td>
</tr>
<tr>
<td>Omeprazole and lansoprazole</td>
<td>1.11</td>
</tr>
<tr>
<td>Anthelmintics drugs;antiamoebic and other antiprotozoal/antifungal drugs</td>
<td>0.94</td>
</tr>
<tr>
<td>Ciprofloxacin (fluoroquinolones)</td>
<td>0.66</td>
</tr>
<tr>
<td>Other fluoroquinolones</td>
<td>0.86</td>
</tr>
<tr>
<td>Salbutamol, terbutaline, ephedrine, salmeterol and methyl xanthimes</td>
<td>0.6</td>
</tr>
<tr>
<td>Dicyclomine, metoclopramide and dexe thatone and ondanetron</td>
<td>0.48</td>
</tr>
<tr>
<td>Cephalexin - formulations thereof, in capsules etc.</td>
<td>0.47</td>
</tr>
</tbody>
</table>
Pharmaceutical Import Regulation in Mexico.

• Authorization for Production, Sale, Import and Export of Drugs is obligatory and comes under the aspects of Ministry of Health (SS) via The Federal National Commission for Protection against Health Risks (COFEPRIS).

• All imported products need to be registered with Secretariat of health prior to distribution in the country.

• In order to export pharmaceutical products to Mexico, the exporting company needs to register and import those pharmaceutical products through a local manufacturer holding a sanitary license for such products.

• Additionally, in order to obtain registration medicines manufactured abroad, it is necessary to include the following documents:

  – The free sale certificate issued by the sanitary authorities of the country of origin;

  – A certificate that the company has a permit to manufacture medicines and a certificate of good manufacturing practices issued by the corresponding authority of the country of origin;

  – The letter of representation, when the manufacturing laboratory abroad is not an affiliate or mother company of the laboratory requesting the registration.
Pharmaceutical Import Regulation in Mexico.

Issues / Trade barrier

• Mexico imposes higher average tariff on finished products than on raw materials.
  – *In pharmaceuticals, although the average tariff rate of the semi-processed products is a litter lower than that of the raw materials, the average tariff rate of the finished products is still much higher than that of the raw materials.*

• North American Free Trade Agreement (NFTA) agreement strengthened IP Rights and provide favorable environment for innovator companies.

• NFTA eliminated import duty for US & Canada.
  – While US & Canada enjoy no import duty (Post NFTA), other country face average tariffs of 18%, providing both US & Canada with a competitive advantage over their overseas exporters.

• In view of no generic drug registration fee in US which is the largest generic market globally; the registration fee for generic drugs in Mexico could be considered high.
• Time for Approval
  – Officially 60 to 90 days / Realistically six to twelve months.

• Fees:
  – US$7,458 for new molecules
  – US$6,992 for new medicines
  – US$4,102 for generic medicines.
Prospects in Mexican market

• Under New regulation (Aug 2008) overseas Pharmaceutical producer no longer need to have local manufacturing facilities in order to operate in Mexico. Such requirement will be phased out over two years [COFERPRIS 2008]
  – *Initially this requirement was introduced to promote investment in the country but have resulted in lack of competition and subsequently higher prices of medicine.*

• The Reform of health supplies regulation, published in official bulletin in Jan.2008 has improved the registration process of Pharmaceuticals.

• Registration are granted for five year period and all the existing drug were proposed to renewed before 24th Feb.2010. There after only innovative drug and bioequivalent generics will be allowed in the market.

• As part of efforts to phase out similares (imitating branded products / Non-interchangeable generics) by 2010, there are now obligatory bioequivalence tests in Mexico and Brazil.

• The combination of government incentives and the introduction of low-cost pharmacy chains like Farmacias Similares and WelMex (Wal Mart in Mexico) are likely to increase the use of generics in Mexico.
Thank You

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(Set up by Ministry of Commerce, Govt. of India)

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