Presentation
On
Pharmaceutical Sector in India

by
Sudarshan Jain
Secretary General
Indian Pharmaceutical Alliance

Mumbai
30 May 2019
Indian Pharmaceutical Alliance

Outline of Presentation

- Indian Pharmaceutical Industry
- Importance of Europe
- Possible Opportunities and Threats with Brexit
Indian Pharmaceutical Industry

Pharmacy of the World

- 60%+ of global vaccine production
- Annual UNICEF supply globally: 30%
- 60%+ of global supply of ARV drugs
- Annual UN purchases: 60-80%

SOURCE: Press Information Bureau by Gol, "Indian Vaccine market report 2013"
Indian Pharmaceutical Industry

Contribution to WHO PQ

APIs

On PQ List
- Out of 123: 70
- India: 57%
- RoW: 43%

Under Assessment
- Out of 44: 30
- India: 68%
- RoW: 32%

Courtesy: Presentation by Vimal Sachdeva, WHO
Indian Pharmaceutical Industry

Contribution to WHO PQ

**FPPs**

**On PQ List**

- 31%
- 69%*
- 368 Out of 533

**Under Assessment**

- 36%
- 64%
- 80 Out of 125

*Includes those that are listed based on alternative listing route.

Number of Prequalified by WHO Under Full or SRA Route:

270 out of 427 = 63%

Courtesy: Presentation by Vimal Sachdeva, WHO
Towards Excellence in Quality 1/4

IPA Initiative

IPA QF Mission

Be the conduit of change through thought leadership, knowledge development, and best practice sharing

Measure, benchmark, and publicise the achievements of the Indian Pharma Industry in Quality

Expand the size and base of Quality talent in India

Deepen, and strengthen the industry’s relationship with key stakeholders – both within and outside India

Provide platforms for members and other stakeholders to interact and network

The IPA Quality forum was setup 3 years back, by a group of 6 founding member companies, and supported by McKinsey & Company as their knowledge partner

IPA: 11/18

Opportunities and Threats with EMA

Towards Excellence in Quality 3/4

- **50+** Days of Quality Forum CEOs time
- **500+** Days of senior Operations, R&D leadership time
- **20+** Plants covered for the benchmarking exercises
- **25K+** Employees covered for culture & capability assessment
- **25+** Crore financial contribution for Quality Forum activities

Dedicated McKinsey Team working with IPA QF for the last 2.5 years

SOURCE: IPA QF sub-groups

The industry has continued to show progress. Inspection outcomes in India have improved and are now more in line with global outcomes.

### Towards Excellence in Quality 2/4

#### Outcomes of inspections

<table>
<thead>
<tr>
<th>Year</th>
<th>Global</th>
<th>India</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OAI</td>
<td>VAI</td>
</tr>
<tr>
<td>2014</td>
<td>875</td>
<td>136</td>
</tr>
<tr>
<td>2015</td>
<td>974</td>
<td>165</td>
</tr>
<tr>
<td>2016</td>
<td>1,042</td>
<td>148</td>
</tr>
<tr>
<td>2017</td>
<td>894</td>
<td>165</td>
</tr>
<tr>
<td>2018</td>
<td>1,228</td>
<td>53</td>
</tr>
</tbody>
</table>

**Indian inspections as a share of global**

- 2014: 6%
- 2015: 11%
- 2016: 9%
- 2017: 9%
- 2018: 14%

**Data from Jan – Dec cycle (February 25, 2019)**

**FDA inspection data for CDER and Drug Quality Assurance projects, for Jan – Dec cycle (February 25, 2019)**

**IPA: 5/19**

**SOURCE:** FDA inspection data for CDER (Drug Quality Assurance), data pull on Feb 25, 2019.
Indian Pharmaceutical Industry

India’s Exports of Pharmaceuticals (Mn USD)

Source: Pharmexcil Data Handbook
Opportunities: European Market is Growing at Healthy Rate

Forecast for Major Markets: IMS ’16-’21 vs. BCG ’17-’22 Gross sales CAGR (% p.a.)

<table>
<thead>
<tr>
<th>Country</th>
<th>IMS Prognosis</th>
<th>BCG Market Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td>4.2%</td>
<td>4.4%</td>
</tr>
<tr>
<td>UK</td>
<td>4.8%</td>
<td>4.9%</td>
</tr>
<tr>
<td>France</td>
<td>5.8%</td>
<td>2.9%</td>
</tr>
<tr>
<td>Italy</td>
<td>9.3%</td>
<td>5.2%</td>
</tr>
<tr>
<td>Spain</td>
<td>3.5%</td>
<td>4.4%</td>
</tr>
<tr>
<td>Poland</td>
<td>5.8%</td>
<td>5.0%</td>
</tr>
<tr>
<td>Romania</td>
<td>n.a.</td>
<td>3.3%</td>
</tr>
<tr>
<td>Czech</td>
<td>1.9%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Europe</td>
<td>5.0%</td>
<td>4.3%</td>
</tr>
</tbody>
</table>

Market Size: € - FY 2016

- Germany: 6.4
- UK: 5.0
- France: 4.1
- Italy: 3.4
- Spain: 2.6
- Poland: 1.7
- Romania: 0.6
- Czech: 0.5
- Europe: 29.4

Source: BCG Analysis, IMS
Opportunities and Threats with EMA

GMP Inspections Performed by EU Inspectorates in India: 2014-17

Source: EudraGMDP data 9th January 2018

Courtesy: Presentation by Andrei Spinei, EMA
Opportunities in EU Market

- Ageing population with a rise in prevalence of chronic and other diseases (e.g. cancer)

- Increased acceptance among consumers, physicians and pharmacists of generics as equivalent of branded pharmaceuticals

- Increasing pharmaceuticals spending

- Ongoing cost-containment measures and increasing pressure from expensive innovative treatments
Business Landscape

- Uncertainty arising out of Brexit: Next steps?
  - Who will take over supervision of the manufacturing sites of medicinal products in third countries previously supervised by UK authorities?
  - What happens to manufacturing site for which the Union GMP certificate has been issued by UK authorities?

- 28 countries, each country with its own nuance; with Brexit complications may increase

- Different regulatory procedures and timelines

- Different patent landscapes

- Multiple SKUs and small volumes
Indian Pharma industry: Going forward

• Large Indian Companies are best suited to deal with market complexities of EU
• Product portfolio and customised approach will help in leveraging the opportunity
• Brexit and aftermath will be key area to decide the way forward
• EU is high priority market for many Indian companies
THANK YOU

sudarshan.jain@ipa-india.org
# Indian Pharmaceutical Alliance

## Current Members (23)

<table>
<thead>
<tr>
<th>Abbott</th>
<th>IPCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajanta</td>
<td>J B Chemicals</td>
</tr>
<tr>
<td>Alembic</td>
<td>Lupin</td>
</tr>
<tr>
<td>Alkem</td>
<td>Micro</td>
</tr>
<tr>
<td>Cadila Healthcare</td>
<td>Mankind</td>
</tr>
<tr>
<td>Cadila Pharmaceuticals</td>
<td>Natco</td>
</tr>
<tr>
<td>Cipla</td>
<td>Panacea Biotech</td>
</tr>
<tr>
<td>Dr Reddy’s</td>
<td>Sun</td>
</tr>
<tr>
<td>Emcure</td>
<td>Torrent</td>
</tr>
<tr>
<td>Glenmark</td>
<td>Unichem</td>
</tr>
<tr>
<td>INTAS</td>
<td>USV</td>
</tr>
<tr>
<td></td>
<td>Wockhardt</td>
</tr>
</tbody>
</table>
Indian Pharmaceutical Alliance

Contribution

- 85% • Of total private sector investment in pharmaceutical research and development

- 80% • Of exports of drugs and pharmaceuticals

- 62% • Of price controlled drugs (NLEM)

- 57% • Of domestic sales

* IQVIA MAT Mar 2019