IPA Meeting with the FDA

“Desire to Work Together”

by
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Secretary General
Indian Pharmaceutical Alliance

Washington DC
13 April 2015
Desire to Work Together

Outline of Presentation

- About IPA
- McKinsey View of Indian Pharmaceutical Industry
- India’s Contribution to Affordable Healthcare in USA
- Partnering with the FDA
- What IPA Offers
Indian Pharmaceutical Alliance
About IPA

Current Members (20)

- Alembic
- Alkem
- Cadila Healthcare
- Cadila Pharmaceuticals
- Cipla
- Dr Reddy’s
- Glenmark
- INTAS
- IPCA
- J B Chemicals
- Lupin
- Mylan
- Micro
- Natco
- Panacea Biotech
- Sun
- Torrent
- Unichem
- USV
- Wockhardt
About IPA

Contribution

- 85% of Private Sector Spend in R&D
- 60% of Exports of Pharmaceuticals
- 43% of Domestic Sales*
- 75% of Exports to USA
- 43% of Total NLEM Sales*

* AIOCD Pharmasoftech AWACS Pvt Ltd, MAR MAT 2014

Pharmacy of the World
McKinsey View of Indian Pharmaceutical Industry

Industry has also grown to become 8th largest country globally and continues to have one of the highest growth rates

Country wise pharma markets 2013

<table>
<thead>
<tr>
<th>2013 Industry size</th>
<th>2008–13 growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>USD billion</td>
<td>Percent</td>
</tr>
<tr>
<td>Domestic market</td>
<td>Net exports</td>
</tr>
</tbody>
</table>

- **2013 Industry size**
  - **USD billion**
    - United States: 347, Domestic market: -26, Net exports: 321
    - Japan: 113, Domestic market: -17, Net exports: 96
    - Germany: 87, Domestic market: -12, Net exports: 75
    - France: 87, Domestic market: -12, Net exports: 75
    - United Kingdom: 45, Domestic market: -10, Net exports: 55
    - Switzerland: 38, Domestic market: -1, Net exports: 54
    - Italy: 35, Domestic market: -1, Net exports: 43
    - Brazil: 16, Domestic market: -5, Net exports: 26
    - India: 8, Domestic market: 8, Net exports: 43
    - China: 9, Domestic market: 2, Net exports: 21
    - Russia: 8, Domestic market: 8, Net exports: 43

- **2008–13 growth**
  - Percent
    - United States: 2%
    - Japan: 4%
    - Germany: 3%
    - France: 25%
    - United Kingdom: 7%
    - Switzerland: 7%
    - Italy: 7%
    - Brazil: 3%
    - India: 16%

**Source:** United Nations Comtrade Database DESA/UNSD, BMI, Individual country industry associations

**Courtesy:** McKinsey & Co.
### McKinsey View of Indian Pharmaceutical Industry

**Global Leadership**

*Industry will also grow to become the 3rd largest globally by 2030*

#### Comparison of top 10 global pharma markets between 2010-2030

<table>
<thead>
<tr>
<th>Country</th>
<th>2010 (USD Billion)</th>
<th>2013 (USD Billion)</th>
<th>2030 (Estimate) (USD Billion)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>312</td>
<td>300-330</td>
<td>400-450</td>
</tr>
<tr>
<td>Japan</td>
<td>96</td>
<td>90-100</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>70</td>
<td>80-90</td>
<td></td>
</tr>
<tr>
<td>France</td>
<td>57</td>
<td>70-80</td>
<td></td>
</tr>
<tr>
<td>UK</td>
<td>46</td>
<td>50-60</td>
<td></td>
</tr>
<tr>
<td>China</td>
<td>40</td>
<td>40-45</td>
<td></td>
</tr>
<tr>
<td>Switzerland</td>
<td>34</td>
<td>40-45</td>
<td></td>
</tr>
<tr>
<td>Brazil</td>
<td>22</td>
<td>20-25</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>20</td>
<td>27-32</td>
<td>160-200</td>
</tr>
<tr>
<td>Israel</td>
<td>7</td>
<td>8-10</td>
<td>20-25</td>
</tr>
</tbody>
</table>

1 Pharma market defined as Domestic Consumption + Exports - Imports

SOURCE: UN Comtrade, BMI, Local industry association data, team analysis

Courtesy: McKinsey & Company
However, India currently has nascent position in these innovation spaces.

### Generics

**ANDA approvals**

- **Percent share, 2011-13**
  - India: 37%
  - US: 37%
  - Europe: 12%
  - Israel: 5%
  - Others: 9%

**Strong position comparable to US, achieved in just 10 years**

### Specialty generics

**ANDA approvals**

- **Percent share, 2011-13**
  - US: 57%
  - India: 22%
  - Iceland: 6%
  - Europe: 4%
  - Others: 10%

**Strong emerging presence in areas such as derm, topicals etc.**

### New therapeutic entities

**505(b)2 approvals**

- **Percent share, 2011-13**
  - US: 59%
  - India: 11%
  - Europe: 15%
  - Others: 6%

**Position primarily driven by ARVs; Potential to explore incremental innovation in other areas**

### New molecular entities

**NCE approvals**

- **Percent share, 2011-13**
  - US: 51%
  - U.K: 35%
  - Japan: 8%
  - Canada: 3%
  - Others: 3%

**Limited advances made thus far; Early movement seen in Indian market**

**Source:** Evaluate, FDA, Robert W Baird & Co survey data

**Courtesy:** McKinsey & Co.
India’s Contribution to Affordable Healthcare in USA

**ANDA Filing Run-Rate of Six Leading Indian Companies**

<table>
<thead>
<tr>
<th>Company</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
<th>FY13</th>
<th>FY14</th>
<th>H1FY15</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Reddy’s</td>
<td>14</td>
<td>7</td>
<td>17</td>
<td>19</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>30</td>
<td>28</td>
<td>22</td>
<td>13</td>
<td>29</td>
<td>15</td>
</tr>
<tr>
<td>Lupin</td>
<td>37</td>
<td>21</td>
<td>25</td>
<td>21</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>Glenmark</td>
<td>13</td>
<td>13</td>
<td>12</td>
<td>18</td>
<td>20</td>
<td>11</td>
</tr>
<tr>
<td>Cadila</td>
<td>14</td>
<td>24</td>
<td>21</td>
<td>25</td>
<td>50</td>
<td>23</td>
</tr>
<tr>
<td>Aurobindo</td>
<td>13</td>
<td>24</td>
<td>30</td>
<td>34</td>
<td>78</td>
<td>42</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>121</strong></td>
<td><strong>117</strong></td>
<td><strong>127</strong></td>
<td><strong>130</strong></td>
<td><strong>210</strong></td>
<td><strong>110</strong></td>
</tr>
</tbody>
</table>

Source: Company Reports / J P Morgan

*India Files Over 40% of Total Generic Applications*
India’s Contribution to Affordable Healthcare in USA

Price Changes in 2014 Over 2013
Illustrative Sample of 582 Products of Six Leading Indian Companies

<table>
<thead>
<tr>
<th>Company</th>
<th>Products Evaluated</th>
<th>No. of Products</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No Change</td>
</tr>
<tr>
<td>Lupin</td>
<td>71</td>
<td>53</td>
</tr>
<tr>
<td>Dr Reddy’s</td>
<td>101</td>
<td>75</td>
</tr>
<tr>
<td>Ranbaxy</td>
<td>97</td>
<td>84</td>
</tr>
<tr>
<td>Sun Pharma</td>
<td>143</td>
<td>136</td>
</tr>
<tr>
<td>Aurobindo</td>
<td>108</td>
<td>100</td>
</tr>
<tr>
<td>Cadila</td>
<td>62</td>
<td>54</td>
</tr>
<tr>
<td><strong>Total - Nos</strong></td>
<td><strong>582</strong></td>
<td><strong>502</strong></td>
</tr>
<tr>
<td><strong>Total - %</strong></td>
<td><strong>100</strong></td>
<td><strong>86</strong></td>
</tr>
</tbody>
</table>

Source: Morgan Stanley
Partnering with the FDA

Objectives

- Strengthen India’s CDSCO
- Provide an Effective Interface with Government
- Promote Capacity Building
  - Industry
  - Academia
  - CDSCO
- Identify and Resolve Cultural Issues
- Quick Resolution of Quality Issues
Partnering with the FDA

Strengthen India’s CDSCO

- Initiate Structural Changes
- Empower and Elevate Position of DCGI
- Insist on Transparency & Accountability
- Push for PICs Membership
- Define Pathway & Milestones
Partnering with the FDA

An Effective Interface with Government

- India – A Complex Country
- Multiple Ministries/Departments Overseeing Pharmaceuticals
- IPA Can Be an Effective Vehicle to Deal with Multiple Government Agencies
Partnering with the FDA

Capacity Building

- Explains Science Behind the Rules
- Modifying Pharmacy Curriculum for Appropriate Skills
- Exposure of Academia to FDA
- Training of Drug Control Officers/Inspectors

Impact of May 2014 Workshops
Effective Quality Systems

Hyderabad
Goa
Ahmedabad
Chandigarh
**FDA/ CDSCO/ IPA Workshops - May 2014**

**Effective Quality Systems**

**Courtesy FDA**

**Opening Remarks** : Dr Leslie Ball, Assistant Commissioner & Deputy Director
Office of International Program

**Key Note Address** : Mr Howard Sklamberg, Deputy Commissioner
US FDA Global Regulatory Operations and Policy

**Faculty** : Dr Albinus D’Sa, Acting Country Director
US FDA India Office

Alicia Mozzachio, Branch Chief
US FDA Center for Drug Evaluation and Research

Thomas Arista, Drug Program National Expert
US FDA Office of Regulatory Affairs

Farhana Khan, International Program & Policy Analyst
US FDA India Office
Topics Covered

- An Overview of 21 CFR 210/211
- An Overview of ICH Q7 for Active Pharmaceutical Ingredients
- The Roles and Responsibilities of the Quality Control Unit
- An Overview of Personnel Qualifications and Responsibilities
- An Overview of Records and Reports
- OOS, Complaints and Failure Investigations
- An Overview of Process Validation
- An Overview of Data for Manual and Automated Systems and Electronic Records
### Summary of Evaluation for Eight Sessions

**Faculty & Content**

<table>
<thead>
<tr>
<th>Location</th>
<th>Fair</th>
<th>Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyderabad</td>
<td>25</td>
<td>406</td>
<td>295</td>
</tr>
<tr>
<td>Goa</td>
<td>39</td>
<td>331</td>
<td>350</td>
</tr>
<tr>
<td>Ahmedabad</td>
<td>19</td>
<td>256</td>
<td>346</td>
</tr>
<tr>
<td>Chandigarh</td>
<td>23</td>
<td>275</td>
<td>334</td>
</tr>
<tr>
<td><strong>Total - Nos.</strong></td>
<td><strong>106</strong></td>
<td><strong>1,268</strong></td>
<td><strong>1,325</strong></td>
</tr>
<tr>
<td><strong>Total %</strong></td>
<td>4</td>
<td>47</td>
<td>49</td>
</tr>
</tbody>
</table>

*Over 96% of Participants Rated Good/Excellent*
### Satisfaction Level

<table>
<thead>
<tr>
<th>Location</th>
<th>No. of Forms Received</th>
<th>No Response</th>
<th>Yes</th>
<th>No</th>
<th>Partially</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyderabad</td>
<td>93</td>
<td>5</td>
<td>66</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>Goa</td>
<td>90</td>
<td>0</td>
<td>59</td>
<td>1</td>
<td>30</td>
</tr>
<tr>
<td>Ahmedabad</td>
<td>81</td>
<td>4</td>
<td>64</td>
<td>0</td>
<td>13</td>
</tr>
<tr>
<td>Chandigarh</td>
<td>79</td>
<td>0</td>
<td>60</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>343</strong></td>
<td><strong>9</strong></td>
<td><strong>249</strong></td>
<td><strong>3</strong></td>
<td><strong>82</strong></td>
</tr>
<tr>
<td><strong>%</strong></td>
<td><strong>100</strong></td>
<td><strong>3</strong></td>
<td><strong>72</strong></td>
<td><strong>1</strong></td>
<td><strong>24</strong></td>
</tr>
</tbody>
</table>

72% of Participant Achieved their Objective
## Overall Rating

<table>
<thead>
<tr>
<th>Location</th>
<th>Not Rated</th>
<th>Poor</th>
<th>Average</th>
<th>Good</th>
<th>V. Good</th>
<th>Excellent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyderabad</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>20</td>
<td>54</td>
<td>14</td>
</tr>
<tr>
<td>Goa</td>
<td>0</td>
<td>0</td>
<td>6</td>
<td>25</td>
<td>37</td>
<td>22</td>
</tr>
<tr>
<td>Ahmedabad</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>5</td>
<td>35</td>
<td>31</td>
</tr>
<tr>
<td>Chandigarh</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>26</td>
<td>28</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>12</strong></td>
<td><strong>1</strong></td>
<td><strong>11</strong></td>
<td><strong>76</strong></td>
<td><strong>154</strong></td>
<td><strong>89</strong></td>
</tr>
<tr>
<td><strong>%</strong></td>
<td><strong>4</strong></td>
<td><strong>0</strong></td>
<td><strong>3</strong></td>
<td><strong>22</strong></td>
<td><strong>45</strong></td>
<td><strong>26</strong></td>
</tr>
</tbody>
</table>

*93% of Participants Rated “Good to Excellent”*
Partnering with the FDA

Cultural Issues

- Barriers to Effective Communication
  - Fear
  - American English
  - Accent
- Attitudinal Diversity

*An Effective Vehicle to Address These Issues*
Partnering with the FDA

Quick Resolution of Quality Issues

An Appropriate Mechanism

for

Dialogue Between the Inspected Company and the FDA

to

Provide a Process Similar to One Followed by the District Offices in the USA
What IPA Offers

India Enjoys a Unique Position

- Benefits of Higher Regulatory Scrutiny
- Incorporates Diverse Requirements of All Major Agencies
- Drives Access and Affordability Across the World
- Services Markets of More than 200 Countries
- Offers, Quality, Competition & Stability of Prices
Beyond growth, Indian industry has also made significant contribution to driving access, affordability both in India.

India continues to drive affordability through low priced\(^1\) drugs across markets

<table>
<thead>
<tr>
<th>Drug</th>
<th>US cents per pill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisoprolol (5mg)</td>
<td></td>
</tr>
<tr>
<td>Atorvastatin (20 mg)</td>
<td></td>
</tr>
<tr>
<td>Amlodipine (5mg)</td>
<td></td>
</tr>
<tr>
<td>Saxagliptin (5mg)</td>
<td></td>
</tr>
</tbody>
</table>

1. Average price across brands

SOURCE: Lauer-Taxe (Germany), PriceRx (US), GBI Pharma (China), AIOCD (India), Indiamedline, team analysis

What IPA Offers

... as well globally – Example of essential medications in developing markets

60%+ of global vaccine production

Annual UNICEF supply globally 30%

60%+ of global supply of ARV drugs

Annual UN purchases 60-80%

THANK YOU

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