Industry Perspective

by
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Secretary General
Indian Pharmaceutical Alliance

New Delhi
12 December 2014
Outline of Presentation

- About IPA
- Major Threats
- Opportunities

Support National Industry to Realize its Full Potential
About IPA

Indian Pharmaceutical Alliance

Innovation, Quality and Global Reach
About IPA

Current Members (20)

- Alkem
- Cadila Healthcare
- Cadila Pharmaceuticals
- Cipla
- Dr Reddy’s
- Glenmark
- INTAS
- IPCA
- J B Chemicals
- Lupin
- Mylan
- Micro
- Natco
- Panacea Biotech
- Ranbaxy
- Sun
- Torrent
- Unichem
- USV
- Wockhardt
### Market Share & Growth

<table>
<thead>
<tr>
<th>No</th>
<th>COMPANY</th>
<th>IPM</th>
<th>Domestic</th>
<th>Rs Cr</th>
<th>Growth %</th>
<th>MS %</th>
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<td>SUN</td>
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<td>1,891</td>
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<td></td>
<td>1,610</td>
<td>5.4</td>
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<td>250</td>
<td>5.23</td>
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<tr>
<td>19</td>
<td>NATCO</td>
<td></td>
<td>13</td>
<td>-34.78</td>
<td>0.02</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>MYLAN</td>
<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
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<tr>
<td></td>
<td><strong>IPA Members</strong></td>
<td></td>
<td><strong>32,645</strong></td>
<td><strong>9.4</strong></td>
<td><strong>43.13</strong></td>
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</tbody>
</table>

Source: AIOCD Pharmasoftech AWACS Pvt Ltd
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
Major Threats

- **Internal**
  - Compromised Drug Regulatory Regime
  - TRIPS Plus IPR Regime
  - Unpredictable Pricing Regime

- **External**
  - Challenge from China
  - Trade Agreements
  - UNODC Model Legislation
Compromised Drug Regulatory Regime

Key Areas of Concern

- Consistent Negative Assessment of CDSCO by Parliament, Judiciary & Executive
- Serious Damage to Credibility of CDSCO Impacting Image of Domestic Pharmaceutical Industry
- Demoralization of CDSCO Officers & Staff
- Sharp Decline in Approvals of Generics and Biosimilars Delaying Access to Affordable Medicines
- Push Back to Clinical Trials Denying Access to New Drugs and Treatments
- FDCs - Entangled in Committees and Courts

“Snake Pit of Corruption”
Compromised Drug Regulatory Regime

Road Blocks to Growth

Aging Schedule of Pending Applications

<table>
<thead>
<tr>
<th>No</th>
<th>Particulars</th>
<th>NCEs</th>
<th>Generic Medicines</th>
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<td></td>
<td></td>
<td></td>
<td>Domestic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Export</td>
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<tr>
<td>1</td>
<td>More than 60 Days</td>
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<td>61 to 90 Days</td>
<td>1</td>
<td>22</td>
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<td>3</td>
<td>91 to 120 Days</td>
<td>1</td>
<td>17</td>
</tr>
<tr>
<td>4</td>
<td>121 to 150 Days</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>151 to 180 Days</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>6</td>
<td>&gt; 180 Days</td>
<td>8</td>
<td>29</td>
</tr>
<tr>
<td>7</td>
<td>Total</td>
<td>11</td>
<td>103</td>
</tr>
</tbody>
</table>

Source: IPA Compilation: Data of 13 Companies as of 30th November 2013

Need for Urgent Attention

30% of Generic Applications Pending for More Than 5 Months
Compromised Drug Regulatory Regime

Undoing Growth - Rolling Back Sales

- FDCs are Relevant and Medically Useful
- Necessary for Patient Benefit
- Safety & Efficacy Already Proved by 30-Year Old FDCs
- Where Doubts Exist, Undertake Quick Scientific Appraisal

Need to Understand Why Developed Countries Do Not Have Many FDCs, Before Blindly Imitating Them
TRIPS Plus IPR Regime

Big Pharma & USTR Pressure

- Dilute Patentability Criteria
- Abolish Compulsory License
- Provide Data Exclusivity
- Introduce Patent Linkage

US Compliant IPR Regime will Compromise Both Access & Growth
TRIPS Plus IPR Regime

Data Exclusivity (DE)
A Substitute for “Weak” Patents

- TRIPS Require Data Protection, Not Exclusivity
- DE Means Monopoly Beyond 20-Year Patent Period
- Ensures Monopoly Even if Patent is Invalidated
- Secures Monopoly Even for Off-Patent Drugs
- Incentive to Delay Launch of New Products in India
- Destroys India’s Competitive Edge in Exports
- Makes India Less Attractive Destination for FDI by Global Generic Companies

DE will Put India on a Slippery Slope
TRIPS Plus IPR Regime

Patent Linkage
Linking Regulatory Approval to Patent Status

- A Ploy for Delaying Entry of Generics
- Exceeds India’s Obligation under the TRIPS Agreement
- Inconsistent with Role of Drug Regulatory Authority (DRA)
- Will Embroil DRA in Litigations Galore
- Even in the USA, Court Decides Patent Validity, Not FDA
- Any Linkage Will Deny/Delay Access to Generics
e.g. Glivec (Novartis); Tarceva (Roche)

Should Government Take Responsibility for Protection of Private Property Rights?
Unpredictable Pricing Regime

Creating Trust Deficit

- Deeper Price Cuts
- Going Beyond NLEM
- Myths Driving the Policy
- Revision to NLEM 2011
- Linking Price Approval to Regularization of FDCs

*Tilting Delicate Balance Between Access and Availability*
Unpredictable Pricing Regime

Deeper Price Cuts
Inclusion of Generic and Clubbing of Brands

- Methodology: “Simple Average Price of All Brands Having More Than and Equal to 1% Market Share of the Total Market Turnover of that Medicine”. [Para 4 (iv) of NPPP 2012]

- The Purpose of Limiting to Brands Having Greater Than 1% Market Share Was to Ensure that Only Brands Which are Representative of the Market are Considered.

- “Both High and Low Price Brands with Negligible Volumes May be an Unrepresentative Benchmark and May Reflect a Predatory Pricing Aimed at Eliminating Competition”. Hence, They were Excluded.

GoM Sought to Achieve Delicate Balance by Excluding High and Low Price Brands

IPA: 12/14
Unpredictable Pricing Regime

Going Beyond NLEM

- Expanding the List of Essential Drugs
- Violating Key Principles of Pricing Policy
- Lack of Transparency in Selection of Drugs
- Compromising Stability and Predictability of Pricing Policy

*Give NLEM 2011/ DPCO 2013 a Chance to Work Before Tinkering with Them*
Unpredictable Pricing Regime

Myths Driving the Policy

Information Asymmetry:

“Patients End up Paying for High-Priced Medicines”

“Doctors Prescribe the Most Expensive Medicines”

There is No Evidence to Support These Perceptions
# Unpredictable Pricing Regime

## Myths Driving the Policy

### Impact of Price Reduction on Prescriptions

<table>
<thead>
<tr>
<th>Sr No</th>
<th>Product &amp; Strength</th>
<th>NLEM Ref #</th>
<th>Brand &amp; Company</th>
<th>Price Reduction %</th>
<th>Volume Growth %</th>
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<tbody>
<tr>
<td>1</td>
<td>Amoxycillin + Clavulanic Acid Tablets 625mg</td>
<td>133</td>
<td>Augmentin - GSK</td>
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<td>32</td>
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<tr>
<td>2</td>
<td>Cefixime Tablets 100mg</td>
<td>137</td>
<td>Taxim O - Alkem</td>
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<td>20</td>
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<tr>
<td>3</td>
<td>Azithromycin Tablets 100mg</td>
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<td>Azee - Cipla</td>
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<td>34</td>
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<tr>
<td>4</td>
<td>Ceftriaxone Injection 250mg</td>
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<td>Maczone - Macleods</td>
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<tr>
<td>5</td>
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<td>Met Xl - Ajanta Pharma</td>
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<td>43</td>
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<td>Calchek - Ipca</td>
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<td>Plavix - Sanofi</td>
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<td>Metadoze-IPR - Biocon</td>
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<td>26</td>
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<td>Losartan Tablets 25mg</td>
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<td>Losaral - Alkem</td>
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<td>311</td>
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<td>Pantoprazole Injection 40mg</td>
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<td>Pansec - Cipla</td>
<td>1</td>
<td>63</td>
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</table>

Source: AIOCD Pharmasoftech AWACS Pvt Ltd, MAT JUNE 2014

^ PTR/Unit - Before and After DPCO 2013  
* Jan-Jun 2014 over Jan-Jun 2013

**Price-Demand Elasticity Proves that “Market Failure” is a “Myth”**

*Doctors Care for Their Customers (Patients)*
Unpredictable Pricing Regime

Revision to NLEM 2011

- Violating Key Principles of Pricing Policy
- “Mass Consumption” is Not True Indicator of “Essentiality”
- Let Expert Committee Decide Core Principles of “Essentiality”
- Do Not Compromise Expert Committee’s Consultative Process

Consistency of “Essentiality” Criteria Key to Stability and Predictability of Policy
Unpredictable Pricing Regime

Linking Price Approval to Regularization of FDCs

- FDCs: A Case of Centre-State Dispute
- Issues Are Far too Complex to Resolve by Pricing Dictate
- FDCs Need Scientific Evaluation, Not Pricing Dictate
- Pricing Dictate Will Undo Years of Growth

*Let Not Pricing Decide the Fate of FDCs*
Challenge from China

Policies Favouring Imports

- SSI Reservation
- Fragmentation of Capacity
- Penalizing Efficiency
- Short-Term View of Patient Welfare

*Over a Decade to Realize the Damage, But ....*
Factors Impacting Domestic Production

- Poor Infrastructure
- High Cost-Structure: Land/Power/Utilities
- Lack of Incentive for Process Development
- Stand Alone Facilities

*Private Sector Alone Cannot Reverse the Damage
Need Concerted Policy Initiatives*
Challenge from China

A Word of Caution on Policy Initiative

- Focus on Raw Materials, Not APIs
- Do Not Create Redundancies
- Avoid Dominance of Raw Material Producers
- Solution Must Not Rely on Perpetual Subsidies

*Aim for Commercially Viable PPP Model*
Trade Agreement

FTAs Outside Multilateral Framework

- Trans-Pacific Partnership Agreement (TPPA)
- Trans-Atlantic Trade and Investment Partnership (TTIP)

Context

- Developed Countries Partnering with Developing and the Least Developed Countries to Isolate and Encircle India
- Harmonization of IPRs Between US & EU
- Bonding May Facilitate Push for TRIPs Plus IPR Regime in the Multilateral Forums (WTO/WIPO)

Need of A Long Term Well Conceived Plan
To Strategically Counter These FTAs
UNODC Model Legislation

United Nations Office on Drugs and Crime (UNODC)

- A Model Legislation to Provide Teeth to “protect public health and combat organized crime”

- Empowers Member States to Define “fraudulent medical products”

- Provides Powers to seize Products in Transit and Criminally Prosecute Manufacturer, Distributor, Agent, etc.

Yet One More Forum to Curb Generic Exports
THANK YOU

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