Industry Perspective

by
D G Shah
Secretary General
Indian Pharmaceutical Alliance

New Delhi
12 December 2014

Industry Perspective

Outline of Presentation

- About IPA
- Major Threats
- Opportunities

Support National Industry to Realize its Full Potential

About IPA

Indian Pharmaceutical Alliance

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

About IPA

Market Share & Growth

No	COMPANY	MAT Mar-14		
		Rs Cr	Growth %	MS %
IPM	**Domestic**	**75,690**	**6.1**	**100.00**
1	SUN	4,088	17.3	5.40
2	CIPLA	3,761	5.9	4.97
3	ZYDUS CADILA	3,040	8.3	4.02
4	RANBAXY	2,864	-1.6	3.78
5	LUPIN	2,536	12.5	3.35
6	ALKEM	2,357	10.9	3.11
7	INTAS	1,891	8.9	2.50
8	GLENMARK	1,637	16.3	2.16
9	DR. REDDYS	1,610	5.4	2.13
10	MICRO LABS	1,529	9.3	2.02
11	USV	1,395	11.3	1.84
12	TORRENT	1,361	14.6	1.80
13	IPCA	1,326	19.11	1.75
14	WOCKHARDT	1200	0.31	1.59
15	UNICHEM	779	7.51	1.03
16	CADILA PHARMACEUTICALS	610	12.05	0.81
17	JB CHEMICALS	397	14.53	0.52
18	PANACEA BIOTEC	250	5.23	0.33
19	NATCO	13	-34.78	0.02
20	MYLAN	-	-	-
IPA Members		**32,645**	**9.4**	**43.13**

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

No	Particulars	NCEs	Generic Medicines	
			Domestic	Export
1	More than 60 Days		29	37
2	61 to 90 Days	1	22	38
3	91 to 120 Days	1	17	10
4	121 to 150 Days		4	7
5	151 to 180 Days	1	2	2
6	> 180 Days	8	29	14
7	**Total**	**11**	**103**	**108**

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

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

Sr No	Product & Strength	NLEM Ref #	Brand & Company	Price ^ Reduction %	Volume* Growth %
1	Amoxycillin + Clavulanic Acid Tablets 625mg	133	Augmentin - GSK	37	32
2	Cefixime Tablets 100mg	137	Taxim O - Alkem	23	20
3	Azithromycin Tablets 100mg	138	Azee - Cipla	48	34
4	Ceftriaxone Injection 250mg	124	Maczone - Macleods	NA	53
5	Metoprolol Tablets 25mg	363	Met Xl - Ajanta Pharma	7	43
6	Amlodipine Tablets 2.5mg	382	Calchek - Ipca	9	20
7	Clopidogrel Tablets 75mg	366	Plavix - Sanofi	90	383
8	Metformin Tablets 500mg	520	Metadoze-IPR - Biocon	24	26
9	Losartan Tablets 25mg	388	Losaral - Alkem	59	311
10	Pantoprazole Injection 40mg	471	Pansec - Cipla	1	63

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 ....

Challenge form China

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 form 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

dgshah@vision-india.com