

Road Map for Universal Access
Carefully Calibrated Policy to Avoid Adverse Trade Offs

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Road Map for Universal Access

Presentation Outline

- Regulatory Infrastructure
- Post-TRIPS IPR Regime
- Public Spending on Drugs
- Procurement & Distribution
- R&D Focus
- Medicine Prices & Policy

Regulatory Infrastructure

Calibrated to Suit Country's Social Goals

- Transparent and Accountable
- Promotes Entry of Generics
- Encourages Innovation
- Focuses on Menace of Spurious Drugs
- Adopts Pathway for Improvements

Not to Blindly Imitate Regulatory Norms of Developed Countries

Post-TRIPS IPR Regime

Challenge to India's Sovereignty

- ❑ Section 3 (d) : Patentability Criteria
- ❑ Section 84 : Compulsory Licensing
- ❑ Section 25 : Pre-Grant Opposition

***Pressure from Agro-chemicals and Biotech Industries
for Data Exclusivity and Patent Linkage***

Public Spending on Drugs

Pricing Policy in Perspective

Current Annual Expenditure (0.1 of GDP)	Rs 6,000 cr
Proposed Increase of 2½ Times in 12 th Plan	Rs 15,000 cr
Proposed Increase After 10 Years (0.5 of GDP)	Rs 30,000 cr

Key Factor in Universal Access

Procurement & Distribution

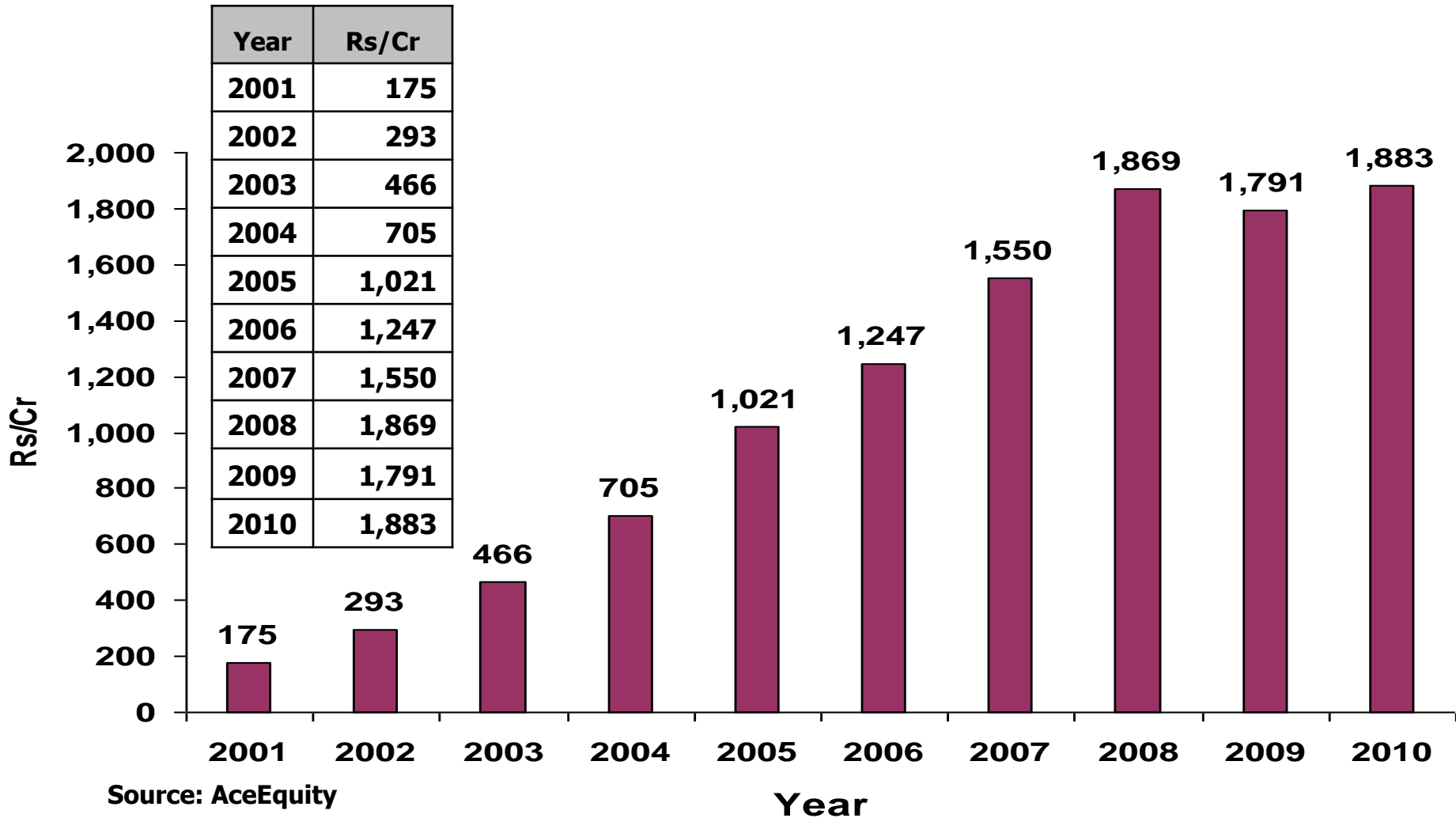
Essential Requirements of System

- Standard Treatment Guidelines (STG)
- Focus on STG Medicines
- Transparent Tendering Process
- Compliance with GMP Norms
- Adherence to Quality Standards
- Assured & Timely Payment

All These Need Serious Attention

R&D Focus

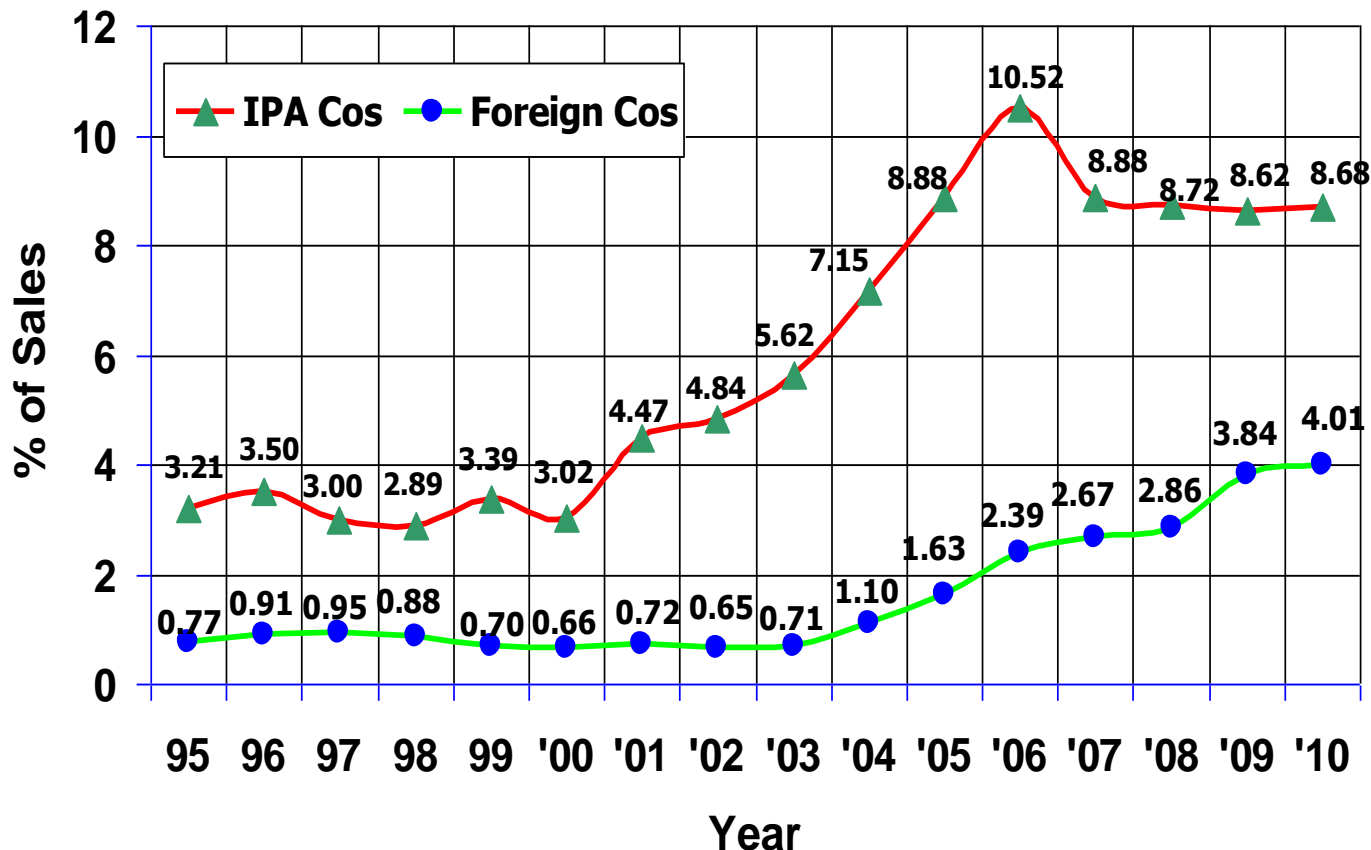
Need for Enabling Environment



Balancing Short –Term Profitability with Sustainable Long-Term Growth

R&D Focus

R&D Expenditure as % Sales – 1995 to 2010



Source : CMIE – Analysis of Indian Pharmaceutical Industry

Three-Fold Growth in R&D by IPA Companies

Medicine Prices & Policy

Prices Rise Trends Between 2004-05 and January 2012

All Commodities	Manufactured Products	Drugs & Medicines
57.2%	41.2%	21.3%

Source : PM EAC's Report on NPPP 2011

***Price Rise in Drugs Only 37% of All Commodities
and about Half of that for Manufactured Products***

Medicine Prices & Policy

Price Rise Trends Between 2005-06 to September 2011

- ❑ Sample Size : 60,000 Packs
- ❑ Market Share : 87% Value
- ❑ Product Range : 70% to 80%

Price Behavior	Distribution %
Month-to-Month Stability	97.14
Showed Price Increase	1.65
Showed Price Decreased	1.21
Total	100.00

Source : IMS Health/PM EAC's Report on NPPP 2011

Medicine Prices & Policy

Price Rise Trends 1996 to 2006 – 10 Year Period

- ❑ Sample Size : 118 Drugs – 54% of IPM

Annual Price Increase

- ❑ Essential Drugs List* : 1.4%
- ❑ Drugs & Medicines : 3.4%
- ❑ WPI : 4.9%

***22 of 67 EDL Selected were Under Price Control**

Source : Sengupta et al-2008 Price Indexation Study/PM EAC's Report on NPPP 2011

Unfounded Apprehensions - 1

Ceiling Prices will Lead to Increase in Prices – Not True

- All Price Increases are Subject to WPI;
- Market Dynamics Do Not Permit Such Increases;
- Nothing Prevents One from Doing So Even Today;
- Companies in Low-Price Segment Will Face Pressure to Reduce Prices Further.

Truth Lies Elsewhere

Medicine Prices & Policy

Unfounded Apprehensions - 2

Policy Does Not Bring Reduction in Prices – Not True

Reduction in Prices of Highest Priced Brands	% of NLEM Medicines
Upto 5%	52
Between 5% and 10%	7
Between 10% and 15%	5
Between 15% and 20%	4
Over 20%	32

Source: NPPP 2011

Prices of Many of These Products are Fixed Under DPCO 95

Myths About Pharmaceutical Industry

- ❑ Patients End up Paying for High-Priced Medicines Due to Information Asymmetry; and
- ❑ Doctors Prescribe the Most Expensive Medicines.

Evidence Do Not Support These Contentions

Medicine Prices & Policy

Illustrative List of Top 10 Therapeutic Categories & Highest Selling Formulation in Each TC

Sr No	Therapeutic Category (TC)	Contribution to IPM		Major Molecule in Each TC	Contribution to TC	
		Rs Cr	%		Rs Cr	%
1	Anti-infectives	8,060	17.2	Cefixime Oral Sol.	586	7.3
2	Cardiac	5,318	11.4	Atorvastatin	518	9.7
3	Gastro Intestinal	5,099	10.9	Rabepra.+ Domperid.	216	4.2
4	Respiratory	4,080	8.7	Cough Prep. Ethicals	923	22.6
5	Pain / Analgesics	4,038	8.6	Diclo.Comb.Oral Solids	300	7.4
6	Vitamins / Minerals / Nutrients	3,625	7.7	Calcium Oral Solids	363	10.0
7	Anti Diabetic	2,743	5.9	Human Insulins	705	25.7
8	Gynaec.	2,658	5.7	Conv.Iron Liquid	414	15.6
9	Neuro / CNS	2,633	5.6	Alprazolam	151	5.7
10	Dermatology	2,554	5.5	Emollients, Protectives	205	8.0
11	Top 10 Segments	40,808	87.2		4,381	10.7
12	Others	5,979	12.8			
13	Total IPM	46,787	100.0			

Medicine Prices & Policy

Price Rank of Top 3 Selling Brands by Value MS%

No	Product & Pack	Price Rank of Top 3 Brands Among All Formulators			Total No of Formulators
		1	2	3	
1	Cefixime Oral Solids 200 mg	113	41	127	136
2	Atorvastatin Oral Solids 10 mg	1	2	3	87
3	Rabeprazole + Domeperidone	6	12	22	91
4	Cough Preparation 100 ml	67	166	90	582
5	Diclofenac Combination OS 50 mg	43	45	131	145
6	Calcium Oral Solids 250 IU x 15 (/500)	5	21	11	28
7	Human Insulin 40 IU	6	9	10	36
8	Iron Liquid 200 ml	58	25	73	148
9	Alprazolam OS 0.5 mg	19	10	32	78
10	Emollients & Protectives	NA	NA	NA	361

Source: IMS Health, Aug MAT 2010

Medicine Prices & Policy

MoH&FW Sample – Selected 5 Therapeutic Categories and 15 Formulations

Sr No	Therapeutic Category (TC)	Contribution to IPM		Major Molecule in Each TC	Contribution to TC	
		Rs Cr	%		Rs Cr	%
1	Cardio-Vascular	5,655	10.4	Atorvastatin (10Mg x 10)	328	5.8
2				Losartan+Hydrochlorthiaz (12.5Mg x 10(/50))	201	3.6
3				Atenolol (50Mg x 14)	98	1.7
4	Gastro-Intestinal	6,573	12.1	Pantoprazole (Enter C Tabs 40Mg x 10)	249	3.8
5				Omezaprazole (Caps 20Mg x 25)	171	2.6
6				Antacid+Antiflatulant (Gel/Liquid 170 MI x 1)	138	2.1
7	Central Nervous	3,212	5.9	Phenytion (Tabs Sug. Coa 100Mg x 100)	90	2.8
8				Alprazolam (Tab Uncoated 0.50Mg x 10)	77	2.4
9				Sodium Valportae [Fil C Tab CR 333Mg x 10 (/145)]	0	0.0
10	Anti-Diabetic	3,187	5.9	Human Insulin (Inj SC Vial 40 IU 10MI x 1)	200	6.3
11				Glimepiride (Uncoated 2Mg x 10)	102	3.2
12				Metformin (500 Mg x 10)	55	1.7
13	Anti-Infective	10,905	20.1	Cefixime (Tab 200MgX10)	475	4.4
14				Ciprofloxacin (Tab 500MgX10)	223	2.0
15				Amoxy+Clavulanic Acid (Tab 500/125MgX6)	86	0.8
16	5 Therapeutic Segments	29,531	54.3		2,493	8.4
17	Other Segment	24,826	45.7			
18	Total IPM Market	54,357	100.0			

Source: AWACS MAR MAT 2011

Medicine Prices & Policy

MoH&FW Sample - Price Rank of 15 Selected Formulations

Sr No	Product & Pack	Price Rank of Top 3 Brands Among All Formulators			Total No of Formulators
		1	2	3	
1	Atorvastatin (10Mg x 10)	4	2	18	130
2	Losartan+Hydrochlorthiaz (12.5Mg x 10 (/50)	10	7	3	64
3	Atenolol (50Mg x 14)	3	2	6	52
4	Pantoprozole (Enter C Tabs 40Mg x 10)	22	9	75	248
5	Omezaprazole (Caps 20Mg x 25)	13	10	8	64
6	Antacid+Antiflatulant (Gel/Liquid 170 MI x 1)	10	7	23	80
7	Phenyntion (Tabs Sug. Coa 100Mg x 100)	1	16	2	24
8	Alprazolam (Tab Uncoated 0.50Mg x 10)	10	21	8	108
9	Sodium Valportae [Fil C Tab CR 333Mg x 10 (/145)]	2	1	-	2
10	Human Insulin (Inj SC Vial 40 IU 10MI x 1)	1	2	3	121
11	Glimepiride (Uncoated 2Mg x 10)	1	12	2	80
12	Metformin (500 Mg x 10)	25	13	5	59
13	Cefixime (Tab 200Mg x 10)	30	184	216	239
14	Ciprofloxacin Itab 500 Mg x 10)	14	18	47	187
15	Amoxy+Clavulanic Acid (Tab 500 / 125 Mg x 6)	1	101	44	104

Source: AWACS MAR MAT 2011

NPPP 2011 Normative Cost-Based System

- Intrusive
- Lacks Transparency
- Discretionary
- Retards Growth & Investment
- Discourages Innovation & Efficiency

Medicine Prices & Policy

Current Cost-Price Fixation System Does Not Recognize Actual Material Costs

Formulation : Salbutamol and Beclomethasone Capsules
Strength : Salbutamol 400mcg
Pack Size : Bottle of 30 Capsules

No	Break up of Cost	Cost per Unit - Rs		
		Actual 2010-11	Form 3 15/04/2011	Price Notfn 01/07/2011
1	Raw Material*	4.64	4.23	} 4.81
2	Packing Material*	4.77	4.42	
3	Total RM + PM	9.41	8.65	4.81
4	Conversion Cost	1.08	1.47	1.47
5	Packaging Charges	0.97	1.33	1.33
6	Total CC + PC	2.05	2.80	2.80
7	Total Cost (3+6)	11.46	11.45	7.61

*Supported by Purchase Bills Certified by Cost Auditor

Disallowance 44%

Source: Company Documents & Price Notification

Medicine Prices & Policy

Current Cost-Price Fixation System Does Not Recognize Actual Manufacturing Cost

Formulation : Dexamethasone Injection
Strength : Dexamethasone 4mg per ml
Pack Size : 2ml Vial

No	Break up of Cost	Cost per Unit - Rs		
		Actual* 2010-11	Form 3 15/04/2011	Price Notfn 01/07/2011
1	Raw Material	0.86	0.84	} 2.20
2	Packing Material	1.46	1.43	
3	Total RM + PM	2.32	2.27	2.20
4	Conversion Cost	2.50	1.11	1.11
5	Packaging Charges	2.19	0.55	0.55
6	Total CC + PC	4.69	1.66	1.66
7	Total Cost (3+6)	7.01	3.93	3.86

*Actual Cost is as per Cost Audit Report

Source: Company Documents & Price Notification

Disallowance 65%

Medicine Prices & Policy

Profitability: Inter-Industry Comparison 2009-10

Industry	PAT Net of P&E / Total Income Net of P&E	PAT Net of P&E/ Average Capital Employed	No of Companies
Polymers	2.5	2.9	39
Sugar	4.2	4.1	86
Inorganic Chem	3.7	5.9	58
Metals & Met Products	7.7	7.7	703
Steel	7.9	7.8	248
Manufacturing	5.1	8.8	5392
Chemicals	4.6	10.1	1215
Pharmaceuticals	10.2	11.1	332
Pesticides	7.0	12.2	57
IT	19.2	20.8	559
Dairy Products	6.8	35.0	33
Cosmetics	10.4	35.8	62

Source: CMIE: Industry Financial Aggregates & Rates, Feb 2011 P&E = Prior Period Income & Extraordinary Income

Dangers of Overarching Policy

- ❑ Growth in Price Controlled Drugs Has Languished Over a Decade, When Overall Pharmaceutical Industry Has Shown Very Strong Growth;
- ❑ Only 47 of 74 Controlled Drugs Produced in Country;
- ❑ Unavailability is a Realistic Adverse Consequence of Price Control Policy.

Source: PM EAC's Report

Medicine Prices & Policy

Industry Submission

- ❑ Evidence Based Balanced Policy;
- ❑ Evidence of Substantive Nature, Not Anecdotal;
- ❑ Conclusions Based on Validated Data; and
- ❑ Decisions Based on Impact Analysis:
 - Social Impact - Prices of Medicines
 - Economic Impact - Profitability of Industry
- ❑ Ensure Both Access and Sustained Availability.

Carefully Calibrated Policy to Avoid Adverse Trade Offs

THANK YOU

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