

**Roundtable Symposium  
on**

**The Emerging Legal & Policy Landscape of  
Intellectual Property Protection for Pharmaceuticals in India**

**The National Pharmaceutical Pricing Policy 2011**

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# The National Pharmaceutical Pricing Policy 2011

## Presentation Outline

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  - Key Principles
- ❑ Current Cost-Price Fixation System
  - Bulk Drugs
  - Formulations
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# NPPP 2011

## Preamble

- ❑ Goal of enabling industry growth with attendant socio-economic benefits.
- ❑ Balancing the declared objective of making available essential medicines at reasonable prices.
- ❑ Meet the challenges brought about by the competitive international pharmaceutical industry in a globalised economic environment.

# NPPP 2011

## Objective

“The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – “essential medicines” – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of industry, thereby meeting the goals of employment and shared economic well being for all.”

# NPPP 2011

## Key Principles of Pricing Policy

- Essentiality of Drugs
- Market Based Pricing
- Focus on Formulation Prices

# Current Cost-Price Fixation System

## Bulk Drugs

- ❑ Price fixation/revision for the 44-month period (April 2008 to November 2011) reflect the static approach of the current system.
- ❑ 101 price fixation/revision orders issued during the period average about two orders per month.
- ❑ Break-up by frequency of price changes is given below:

<u>Frequency</u>	<u>No. of Bulk Drugs</u>	<u>No. of Fixation/Revision</u>
Once	60	60
Twice	16	32
Thrice	<u>3</u>	<u>9</u>
Total	<u>79</u>	<u>101</u>

- ❑ This 44-month period witnessed severe inflationary pressures, dramatic fluctuations in exchange rate, significant increases in the fuel and electricity charges and phenomenal rise in interest burden. Yet prices of as many as 60 out of 79 bulk drugs were revised once only.

Source: NPPA

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# Current Cost-Price Fixation System

## Formulations

**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	
<b>3</b>	<b>Total RM + PM</b>	<b>2.32</b>	<b>2.27</b>	<b>2.20</b>
4	Conversion Cost	2.50	1.11	1.11
5	Packaging Charges	2.19	0.55	0.55
<b>6</b>	<b>Total CC + PC</b>	<b>4.69</b>	<b>1.66</b>	<b>1.66</b>
<b>7</b>	<b>Total Cost (3+6)</b>	<b>7.01</b>	<b>3.93</b>	<b>3.86</b>

**Disallowance 65%**

\*Actual Cost is as per Cost Audit Report

# Current Cost-Price Fixation System

## Formulations

**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	
<b>3</b>	<b>Total RM + PM</b>	<b>9.41</b>	<b>8.65</b>	<b>4.81</b>
4	Conversion Cost	1.08	1.47	1.47
5	Packaging Charges	0.97	1.33	1.33
<b>6</b>	<b>Total CC + PC</b>	<b>2.05</b>	<b>2.80</b>	<b>2.80</b>
<b>7</b>	<b>Total Cost (3+6)</b>	<b>11.46</b>	<b>11.45</b>	<b>7.61</b>

**Disallowance 44%**

\*Supported by Purchase Bills Certified by Cost Auditor



# Key Elements of Policy Making

## IPA Submission

- Evidence Based;
- Evidence of substantive nature, not anecdotal;
- Validate data; and
- Impact analysis on prices of medicines (Social) and profitability of industry (Economic) for ensuring sustained availability.

# Impact of Policy - 1

## Summary of Price Reductions Specified Formulations

No	Price Reductions	Distribution	
		No	% of Total
<b>1</b>	<b>0 to 1%</b>	<b>278</b>	<b>36</b>
<b>2</b>	<b>1.1 to 10%</b>	<b>183</b>	<b>24</b>
<b>3</b>	<b>10.1 to 20%</b>	<b>92</b>	<b>12</b>
<b>4</b>	<b>20.1 to 30%</b>	<b>51</b>	<b>7</b>
<b>5</b>	<b>30.1 to 40%</b>	<b>28</b>	<b>4</b>
<b>6</b>	<b>40.1 to 50%</b>	<b>17</b>	<b>2</b>
<b>7</b>	<b>50.1 to 100%</b>	<b>63</b>	<b>8</b>
<b>8</b>	<b>100.1 &amp; Above</b>	<b>52</b>	<b>7</b>
<b>9</b>	<b>Not Available</b>	<b>1</b>	<b>0</b>
<b>Total</b>		<b>765</b>	<b>100</b>

Source: IMS Health Data, Mar MAT 2011

## Impact of Policy - 2

### Illustrative List of Top 10 Therapeutic Categories & Molecules 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	Rabeptra.+ 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
<b>11</b>	<b>Top 10 Segments</b>	<b>40,808</b>	<b>87.2</b>		<b>4,381</b>	<b>10.7</b>
12	Others	5,979	12.8			
<b>13</b>	<b>Total IPM</b>	<b>46,787</b>	<b>100.0</b>			

Source: IMS Health, Aug MAT 2010

## Impact of Policy - 3

### Illustrative List of Top 10 Molecules in Each TC Showing Price Levels & No of Formulators

Major Molecule in Each TC	MRP Per Unit				No of Formulators
	Highest Rs	Lowest Rs	Median Rs	WAP of Top 3 Rs	
Cefixime Oral Sol.	44.23	3.55	14.33	10.57	136
Atorvastatin	8.12	1.02	5.33	7.82	87
Rabepira. + Domperid.	16.19	1.73	4.95	6.77	91
Cough Prep. Ethicals	58.75	7.49	32.25	39.46	582
Diclo.Comb.Oral Solids	8.46	0.23	1.48	0.91	145
Calcium Oral Solids	3.36	0.39	1.97	2.23	28
Human Insulins	162.62	105.34	129.42	144.26	36
Conv.Iron Liquid	288.70	18.15	50.27	55.02	148
Alprazolam	15.68	0.12	1.38	1.85	78
Emollients, Protectives	1,329.78	7.34	62.52	NA	361

Source: IMS Health, Aug MAT 2010

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## Impact of Policy - 4

### Illustrative List of Top 10 Molecules in Each TC Showing Price Rank of Top 3 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	92	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

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# Impact of Policy - 5

## Illustrative List of Top 10 Molecules in Each TC Showing Social Impact

Major Molecule in Each TC	Sales Rs Cr	Price Reductions				No of Formulators
		No of Firms	%	Rs/Tab	Value Loss Rs Cr	
Cefixime Oral Sol.	586	87	76	33.66	23	136
Atorvastatin	518	4	4	0.30	1	87
Rabepra. + Domperid.	216	9	58	9.42	2	91
Cough Prep. Ethicals	923	119	33	19.29	114	582
Diclo.Comb.Oral Solids	300	112	89	7.55	32	145
Calcium Oral Solids	363	9	34	1.13	2	28
Human Insulins	705	7	11	18.36	32	36
Conv.Iron Liquid	414	51	81	233.68	66	148
Alprazolam	151	16	88	13.83	2	78
Emollients, Protectives	205	NA	NA	NA	NA	361
<b>Top 10 Molecules</b>	<b>4,381</b>				<b>277</b>	

Source: IMS Health, Aug MAT 2010

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# Impact of Policy - 6

## Profitability of Drug Industry

No	Particulars	Rs Cr
1	Profit Before Tax (PBT), Net of Prior Period Income and Extraordinary Income	13,371
2	Loss of PBT – Rs	3,000
3	Loss of PBT as % of PBT	<b>22.4%</b>
4	PBT after Price Reductions (1-2)	10,371

Source: CMIE: Industry Financial Aggregates & Rates, Feb 2011

# Summing Up

- ❑ Pharmaceutical is a Very Complex Subject
- ❑ Let Not Aberrations Frame the Policy, Address them Separately
- ❑ Balance Social & Economic Impacts for Sustainable Supply





# THANK YOU

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