

Group of Ministers

**Impact Assessment
Of
National Pharmaceutical Pricing Policy 2012**

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Impact Assessment

Presentation Outline

- Enlarged Span of Control
- Deeper Price Cuts
- Trade Margin: Industry in Limbo
- Retrospective Price Changes
- Future Availability at Stake

Enlarged Span of Control

Projected v/s Actual

Particulars	Total IPM Rs Cr	NLEM 2011		
		Value Rs Cr	No of Medicines	Span of Control %
As Projected in May 2012*	48,200	8,758	351	18.17
Actual As of Sep 2013^	67,261	9,977	291	14.83

*Source: Draft NPPP 2011 (Pg 13) and IMS Health MAT Mar 2011

^Source: NPPA Notifications and IMS Health MAT May 2012

Total No. of Medicines in NLEM is 654

Enlarged Span of Control

Inclusion of NDDS Products

- ❑ *“The Span of Price Control shall be as per the dosages and strengths as listed in NLEM 2011”*
[Para 4 (iii) of NPPP 2012]
- ❑ NDDS Products Specified in NLEM 2011 are:
 - Acetyl Salicylic Acid as *Dispersible* Tabs,
 - Nifedipine as *Sustained Release* Tabs/Caps,
 - Glyceryl Trinitrate as *Sublingual* Tabs
- ❑ However, Inclusion of All Non-specified NDDS Products will Enlarge Span of Control

Blow to Innovation and R&D

Enlarged Span of Control

What Are NDDS Products

- Uses Innovative Technology
- Eliminates/Reduces Side Effects
- Improves Treatment/Reduces Risks
- Patient Convenience
- Better Compliance

Inclusion of All NDDS Products Will Discourage Innovation

Enlarged Span of Control

NDDS Differentiates Products

- ❑ Amphotericin 10mg

Conventional Dosage: Once a Day 1mg/kg
High Nephro Toxicity

Liposomal (NDDS) Dosage: Once a Day Upto 5mg/kg
Bigger Dose, Still Significantly Less Nephro Toxicity

- ❑ Metoprolol 25/50mg

Conventional Dosage: Twice a Day

Extended Release (NDDS) Dosage: Once a Day

Innovation for Patient Benefits

Deeper Price Cuts

Inclusion of Generic and Clubbing of Brands - 1

- ❑ 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

Deeper Price Cuts

Inclusion of Generic and Clubbing of Brands - 2

- ❑ However, Pricing Formula is Modified to Include:
 - Generic Version; and
 - Low Price Brands of the Same Company;
- ❑ Both These Are Pulling Down Ceiling Price; and
- ❑ Disturbing the Delicate Balance

This is Tweaking of Formula Approved by GoM

Deeper Price Cuts

Impact of Generic and Clubbing of Brands – Alprazolam Tabs 0.25mg

Sr No	Brand	SKU	Company	MAT Value @ PTR Rs.	MS %	PTR/Tab Rs
1	Restyl	Restyl Tabs 0.25 mg x 15	Cipla	7,56,59,953	13.32	0.86
2	Restyl	Restyl Tabs 0.25 mg x 10	Cipla	29,26,737	0.52	0.76
3	Tranax	Tranax Tabs 0.25 mg x 10	Cipla	7,85,699	0.14	0.17
4	Tranquil	Tranquil Tab Uncoated 0.25 mg x 10	Cipla	1,14,429	0.02	0.16
5	Zolax	Zolax Tabs 0.25 mg x 10	Intas	60,65,931	1.07	1.02
6	Anxit	Anxit Tab Uncoated 0.25 mg x 15	Micro	4,84,23,795	8.52	1.49
7	Anxit	Anxit Tab Uncoated 0.25 mg x 10	Micro	2,03,75,816	3.59	1.19
8	Anxit	Anxit Tab Uncoated 0.25 mg x 20	Micro	1,56,543	0.03	0.7
9	Tensyl	Tensyl Tab Uncoated 0.25 mg x 10	Micro	104	0	0.61
10	Alprazolam	Alprazolam Tabs 0.25 mg x 10	Ranbaxy	41,388	0.01	0.36
11	Anxinil	Anxinil Tab Uncoated 0.25 mg x 10	Ranbaxy	1,10,59,108	1.95	0.25
12	Besquil	Besquil Tab Uncoated 0.25 mg x 10	Ranbaxy	348	0	0.74
13	Zolam	Zolam Tabs 0.25 mg x 10	Stadmed	97,66,102	1.72	0.98
14	Alzolam	Alzolam Tab Uncoated 0.25 mg x 10	Sun	6,38,72,671	11.24	1.31
15	Alprax	Alprax Tab Uncoated 0.25 mg x 15	Torrent	19,13,30,969	33.68	1.18
16	Alprax	Alprax Tabs Mou.Dis 0.25 MG x 15	Torrent	2,17,368	0.04	1.2
17	Trika	Trika Tabs 0.25 mg x 15	Unichem	11,11,70,722	19.57	1.04
Total				54,19,67,683		12.81
MAT Value - Rs Cr.			Summary		Reduction	MRP/Tab
Considered for Price Fixation		54.20	As Notified by NPPA		35%	0.96
Without Generic & Clubbing of Brands		54.10	Without Generic & Clubbing		22%	1.16
Difference		0.09	Difference		13%	0.20

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Deeper Price Cuts

Impact of Generic and Clubbing of Brands – Folic Acid Tabs 5mg

Sr No	Brand	SKU	Company	MAT Value @ PTR Rs	MS %	PTR/Tab Rs
1	Fol	Fol Tab Uncoated 5 mg x 10	Zydus Cadila	3,63,08,233	3.49	1.32
2	Folera	Folera Tab Uncoated 5 mg x 30	Maneesh	1,03,80,232	1.00	1.23
3	Folinal	Folinal Tab Uncoated 5 mg x 10	Alembic	3,60,984	0.03	1.21
4	Folinal	Folinal Tab Uncoated 5 mg x 30	Alembic	2,83,28,540	2.72	1.32
5	Folly	Folly Tabs 5 mg x 10	Zydus Cadila	8,37,518	0.08	0.29
6	Folvite	Folvite Tabs 5 mg x 10 x3	Pfizer	70,425	0.01	1.12
7	Folvite	Folvite Tab Uncoated 5 mg x 30	Pfizer	89,82,21,101	86.37	1.90
8	Sysfol	Sysfol Tab Uncoated 5 mg x 10	Systopic	14,18,827	0.14	1.05
9	Sysfol	Sysfol Tab Uncoated 5 mg x 30	Systopic	2,18,43,824	2.10	1.15
10	Zyfolic	Zyfolic Tab Uncoated 5 mg x 10 x50	Zydus Cadila	22,530	0.00	0.14
11	Zyfolic	Zyfolic Tab Uncoated 5 mg x 10	Zydus Cadila	35,676	0.00	0.13
Total				99,78,27,890		10.86
MAT Value - Rs Cr.			Summary		Reduction	MRP/Tab
Considered for Price Fixation			99.78	NPPA Notified Price	39%	1.15
Without Generic & Clubbing of Brands			99.69	Without Generic & Clubbing	22%	1.49
Difference			0.09	Difference	17%	0.34

Deeper Price Cuts

Distribution Analysis of Price Reduction

Reduction from Highest Price	As Projected in May 2012*		Actual As of Sep 2013^	
	No.	%	No.	%
Upto 5%	140	52	9	3
Between 5% and 10%	19	7	20	7
Between 10% and 15%	14	5	30	10
Between 15% and 20%	11	4	27	10
Over 20%	86	32	205	70
Total	270	100	291	100

Reduction from Highest Price	Actual As of Sep 2013^	
	No.	%
Between 20% and 35%	94	32
Between 35% and 50%	74	26
Over 50%	37	13

*Source: Draft NPPP 2011, Page 28

^Source: NPPA Notifications and IMS Health MAT May 2012

Deeper Price Cuts

Loss of Sales & Profits - 1

Impact on Sales

Based on Notified Prices of 291 Medicines Only	Rs Cr
Sales Value @ PTR* Before Price Reduction	9,977
Sales Value @ PTR* After Price Reduction	8,370
Loss of Sales Value	1,607
Loss of Sales - %	16.11

*As of MAT May 2012

Impact of 291/654 Medicines Only

Deeper Price Cuts

Loss of Sales & Profits - 2

Five-Year Profitability Data

Year	Total Income Net of P&E Rs Cr	PAT Net of P&E Rs Cr	PAT Net of P&E / Total Income Net of P&E %	No of Companies
2006-07	66,272	7,553	11.4	410
2007-08	77,071	8,111	10.5	408
2008-09	89,334	7,071	7.9	413
2009-10	99,265	10,463	10.5	444
2010-11	1,08,203	13,469	12.4	433

P&E = Prior Period Income & Extraordinary Income

Source: CMIE: Industry Financial Aggregates & Rates, June 2012

Deeper Price Cuts

Loss of Sales & Profits - 3

Impact on Profitability

Based on Notified Prices of 291 Medicines Only	Rs Cr
PAT Net of P&E Before Price Reduction	13,469
Price Reduction	1,607
PAT Net of P&E After Price Reduction	12,862
% Reduction in Profits	11.9

Impact of 291/654 Medicines Only

Trade Margin: Industry in Limbo

Loss of Trade Margin

No	Particulars	Sales Value - Rs Cr		Trade Gain/(Loss) Rs Cr
		@ MRP	@ PTR	
1	Coming-In: 319 Products (approx 9,000 SKUs)	12,409	10,697	-1,176.70
2	Going-Out: (6,094 SKUs)	10,806	8,645	687.00
3	Net Loss	1,603	2,052	-489.70
4	Net Loss as % of Sales @ MRP			-3.95%

Source: IMS Health MAT MAY 2012

Raise Margin to Support Small Chemists

Trade Margin: Industry in Limbo

Coercive Action by Trade Impacting Access

- ❑ The Boycott of NLEM Products and Selective Boycott of Companies by the Trade for Inadequate Margin is Hurting the Patients as the Supply of Essential Medicines is Affected.
- ❑ All Efforts by the Government to Discipline the Trade have not Succeeded as Small Chemists are Unable to Absorb the Loss of Margin

DoP Should Reconsider the Retail Margin

Retrospective Price Changes

A Messy Exercise, Benefits None

"...in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable)." [Para 24 (i) of DPCO 2013]

- Unlike Past Practice, the Price Changes are Made *Retrospective*.
- Manufacturers are Obligated to Reduce Prices of Goods Cleared on Payment of Excise Duty and VAT.
- By This Logic, in Case of Price Increase, Authorities will Demand Differential Excise Duty & VAT on Cleared Goods Also.
- Logistical Nightmare for Trade & Industry.
- No Gain for Consumer, as Old Stock is Sold at Old Prices.

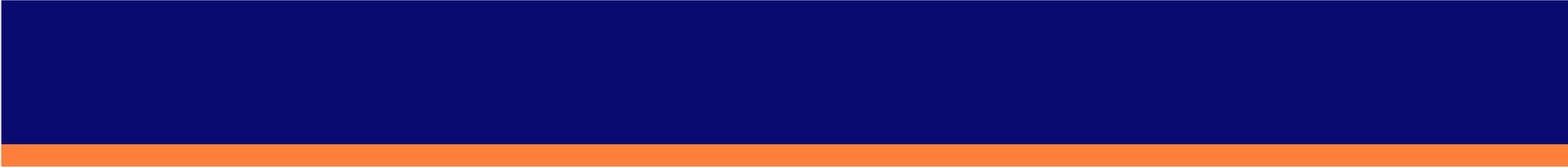
All Price Changes Should be Made Prospective

Future Availability at Stake

Questions to Ponder

- Universal Healthcare, Better Infrastructure and Population Growth Will Drive Demand for Essential Medicines.
- How Will Supply Keep Pace with the Growing Demand?
- Would Companies Make New Investment for Raising Production of Essential Medicines?
- Is Supreme Court Going to Ensure Availability?

70% of Price Fixation Orders Forced Reduction Exceeding 20%



THANK YOU

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