



Celebrating 10 years and more...

NPPA
Welcomes
All Participants & Invitees
to
The Seminar
on

“Pharmaceutical Pricing
& Regulatory Framework for Affordable Medicines”

New Delhi, the 12th April 2008

Pricing & Availability

*The Regulatory Framework in
India*

Drug Regulation in India

Drugs & Cosmetics Act, 1940

Manufacture,
Quality, Sales
& Distribution

DCGI

DPCO, 1995

Scheduled
Drugs, Prices
& Availability

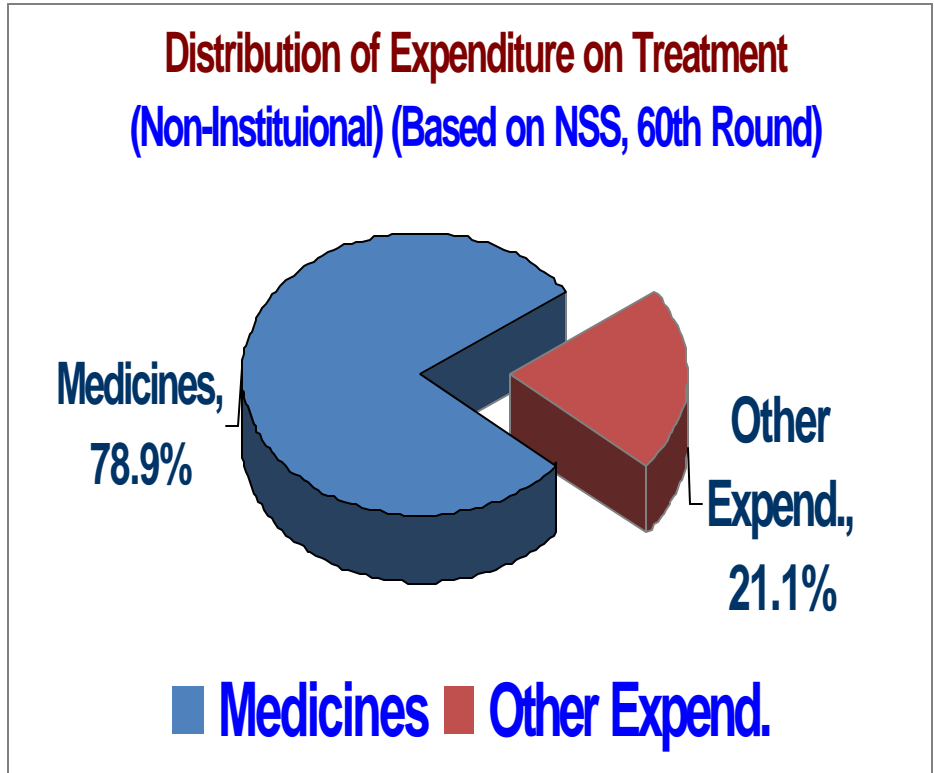
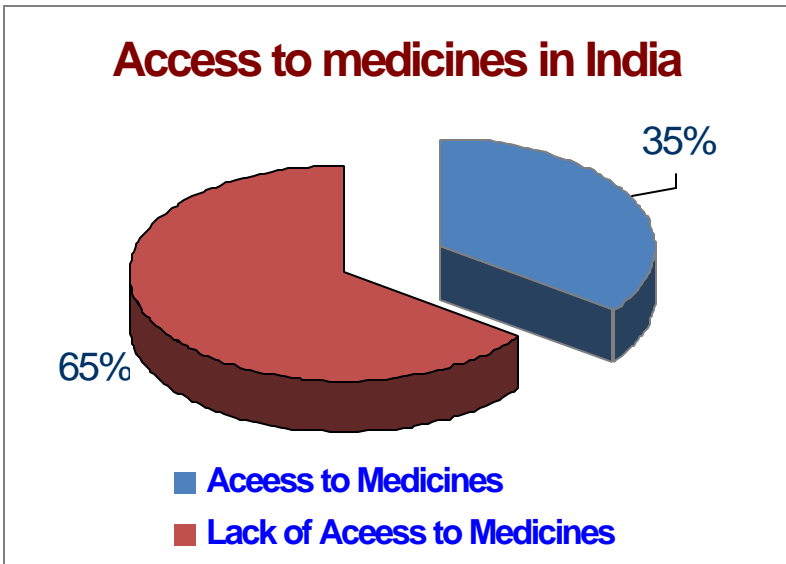
NPPA

State Drug Authorities

**A Perspective on
Regulation for Control,
Pricing & Availability of
Drugs in India**

As per WHO study 650 Million people (65%) in India lack access to modern medicines.

Expenditure on Medicines constitutes 79% of healthcare expenditure (non-institutional)



Relevant Observations of the National Commission on Macro Economics & Health, August, 2005

- **Probability of the poor falling sick is 2.3 times more.**
- **A Rs. 1000 increase in per capita income increases life expectancy at Birth by 3 years.**
- **An Estimated 3.3% of the population is getting pushed below poverty line on account of medical treatment.**

***The Indian Pricing
Regulator
NPPA***

What & How!

Regulation for Pricing & Availability in India

DPCO, 1995

**Formulation Prices
as per formula**

**For Indigenous
drugs=Cost + 100%
MAPE**

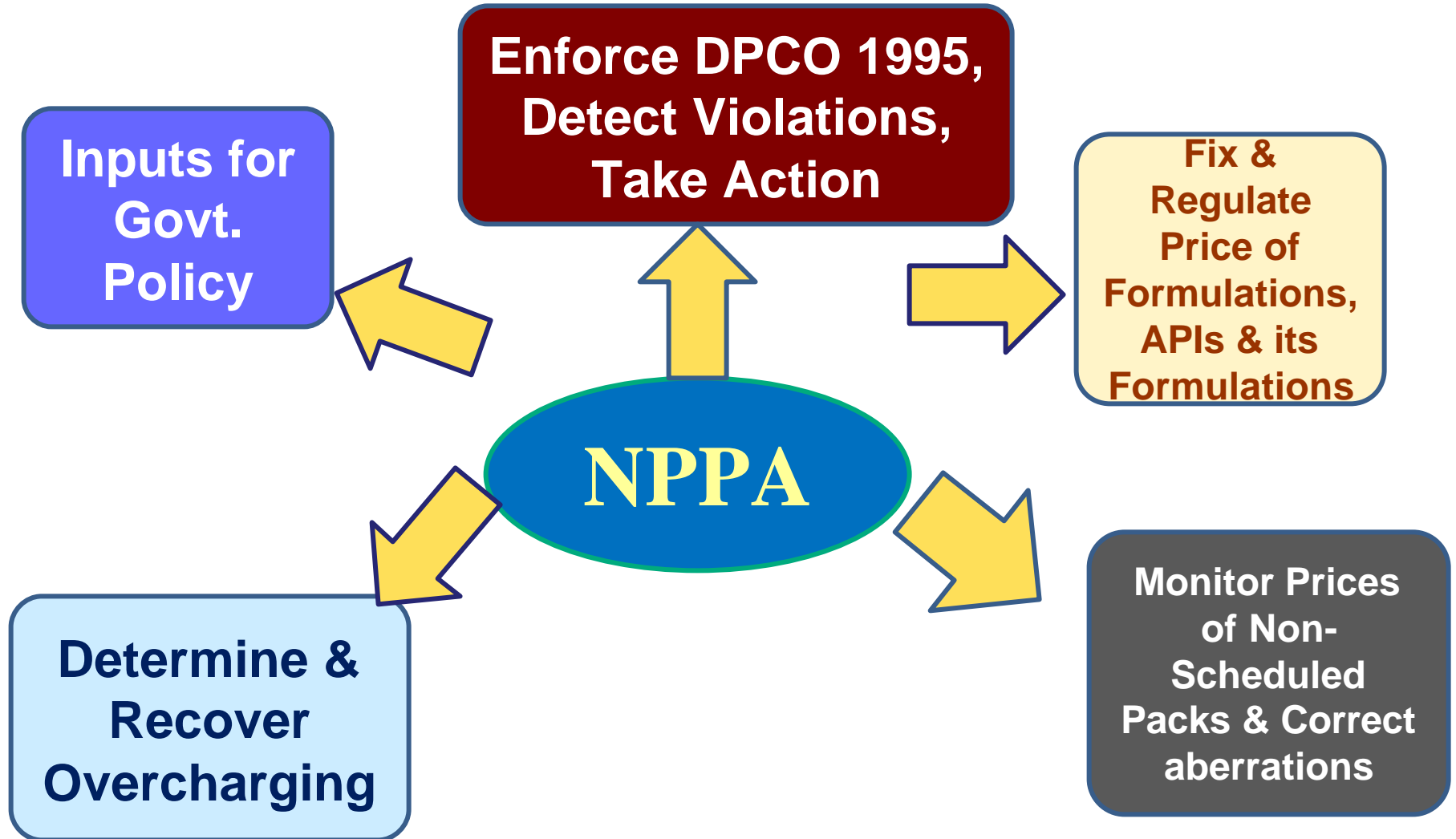
**For imported
drugs=
Landed price+50%
margin**

**74 APIs & Its
Formulations
under Price
Control**

**Cost based
pricing of
APIs**

**Price Control of
any Pack in
Public Interest**

The Indian Pharma Pricing Regulator



Pricing

NPPA
ISO 9001 : 2000 Certified

Price Fixation

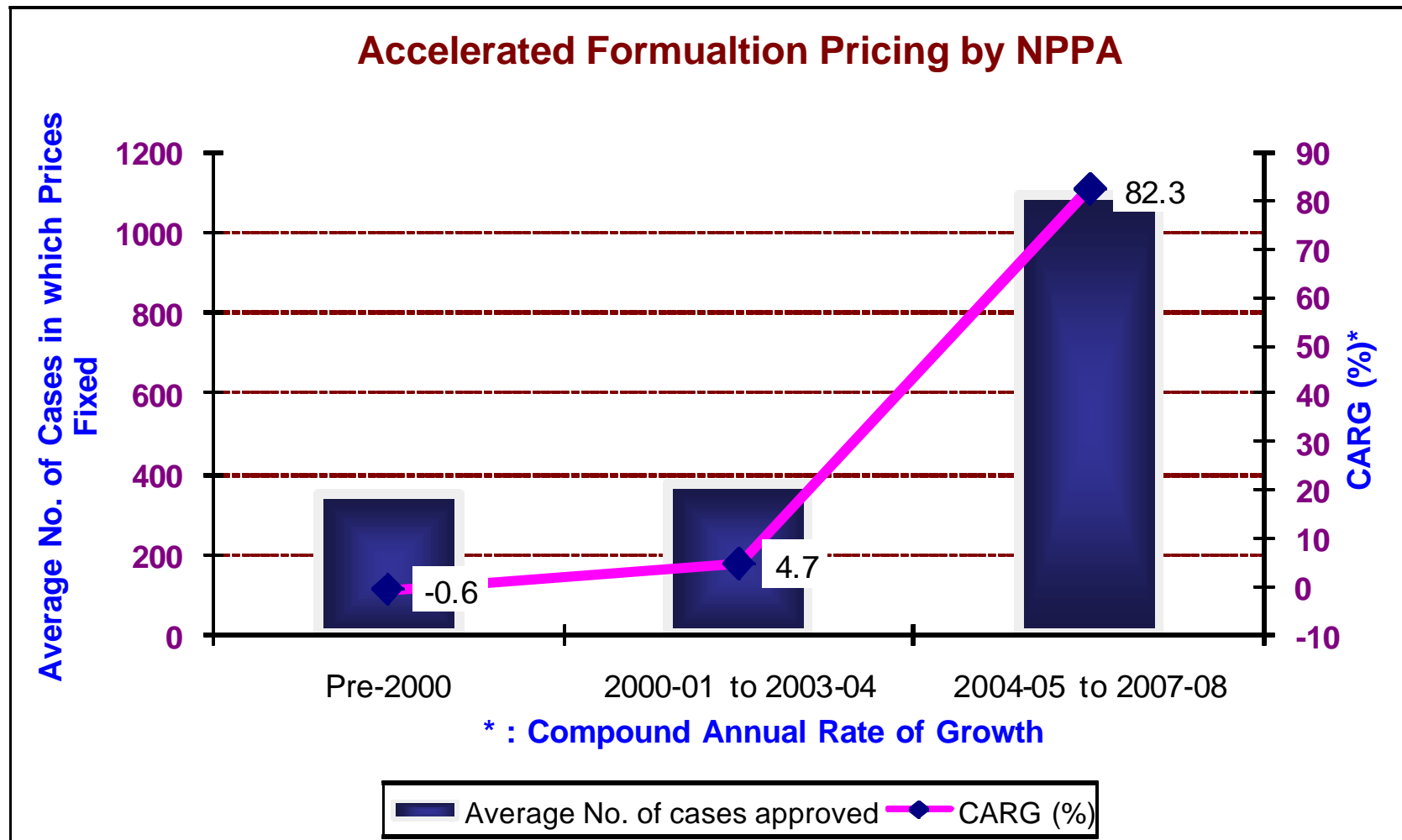
Review of Prices

Intervention

Check & Correction

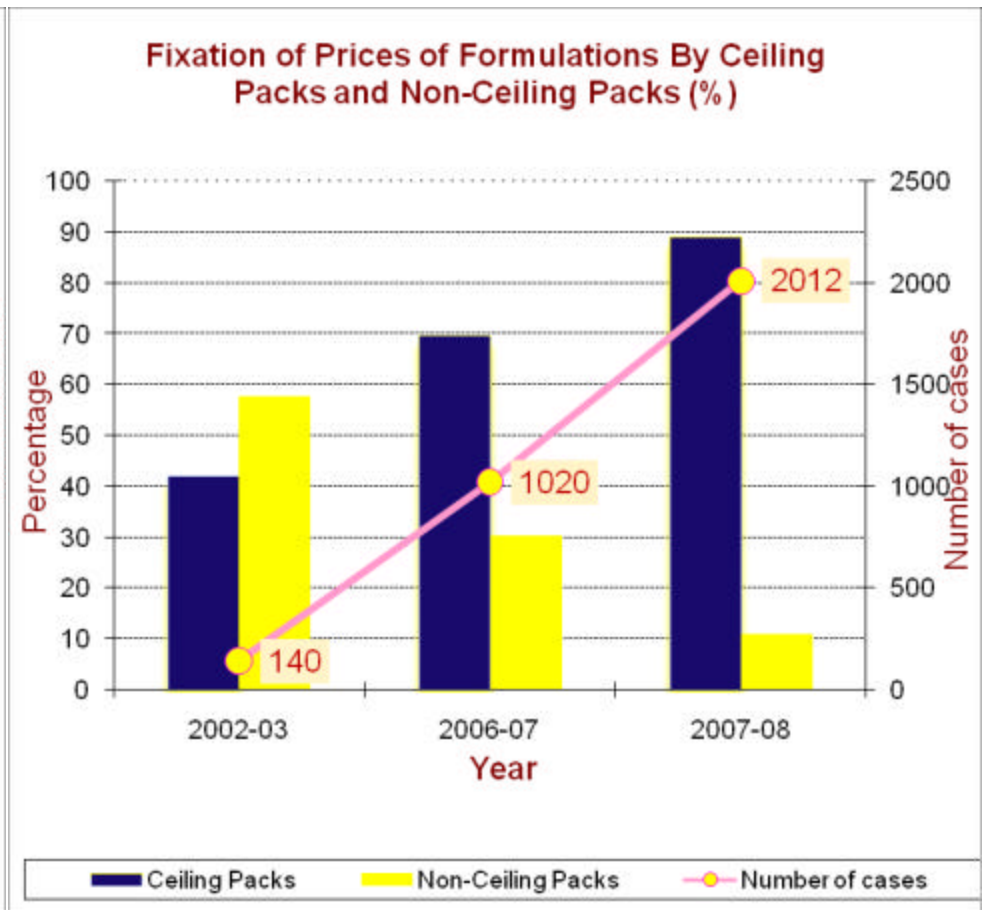
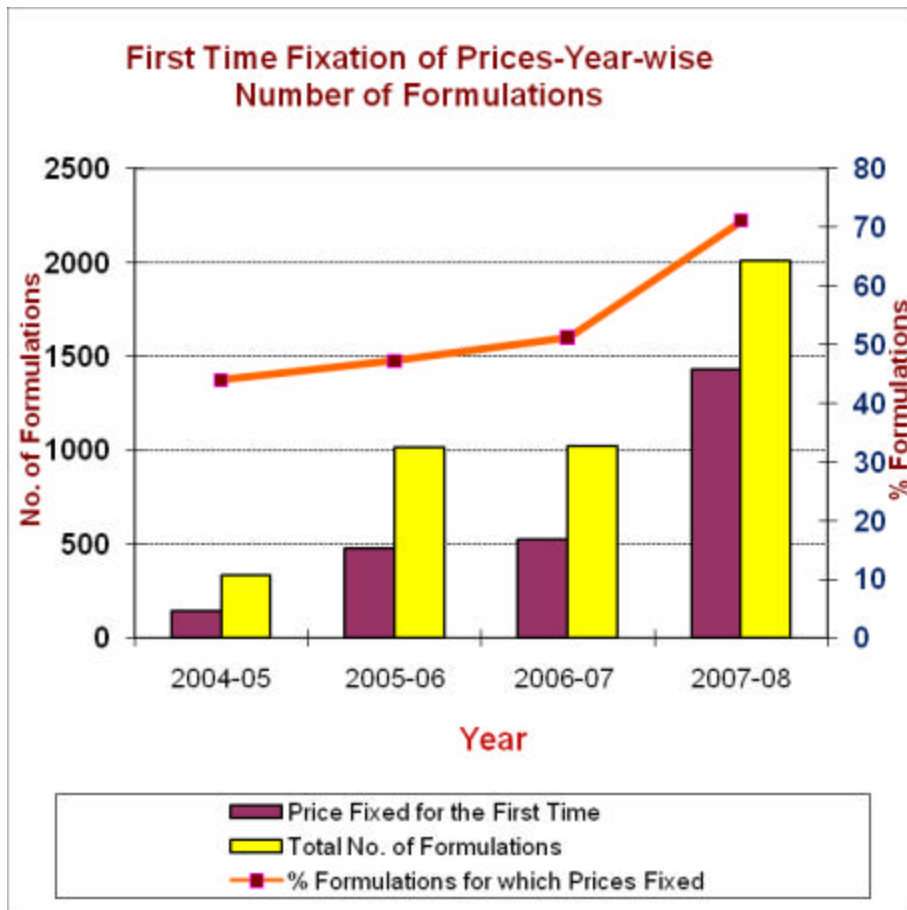
Enforcement

Fixation of Formulation Prices



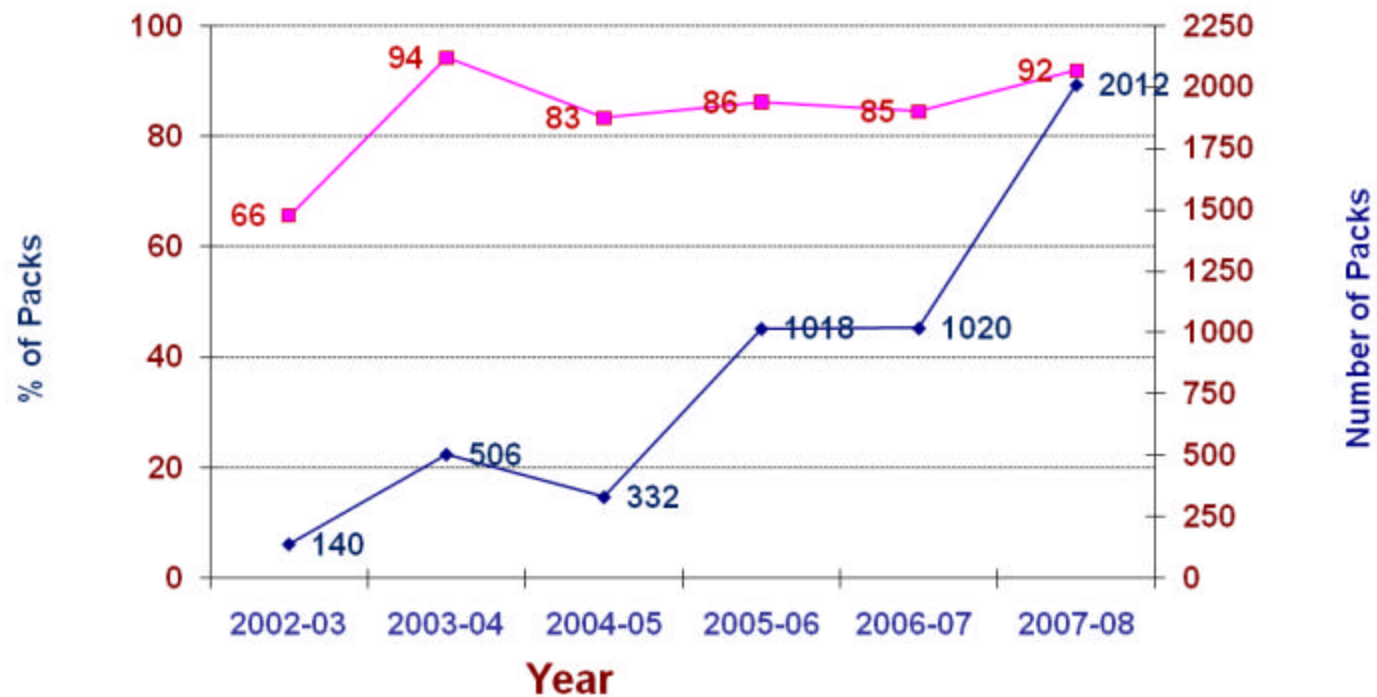
Increase in first time fixation of prices

Increase in ceiling prices from 42% in 2002-03 to 89% in 2007-08



Decrease In Prices

Decrease in Prices- No. of Packs and Its Percentage



—■— % of Packs for which Prices Decreased

—◆— Number of Packs for which Prices Decreased

Scheduled Medicines are Also Top Selling Medicines

***5 out of 10 Top Brands are
for scheduled Medicines***

(Source : OPPI Annual Report 2006-07)

Overcharging

Detect

Demand

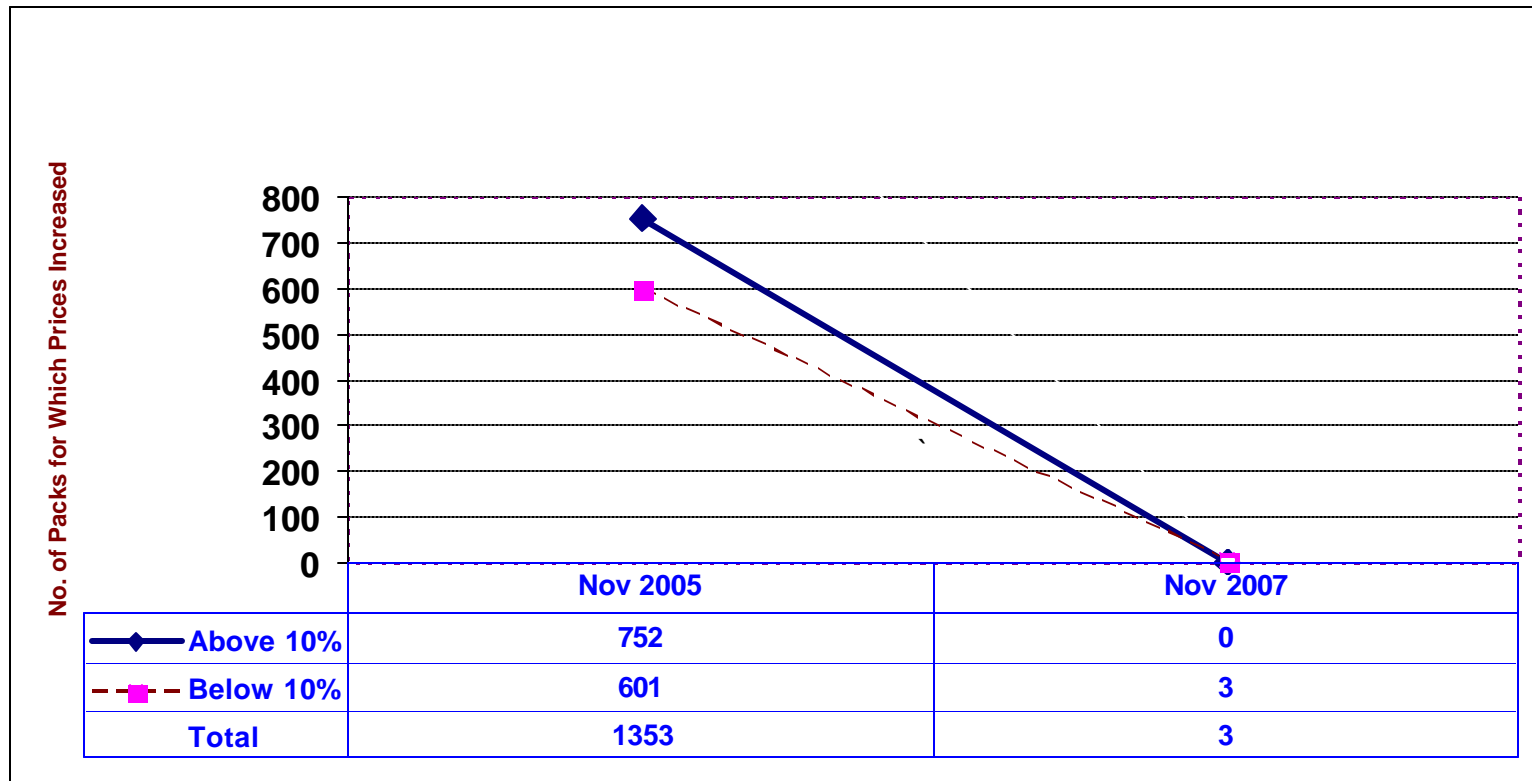
Deposit

Monitoring

- **Monitor Prices**
- **Monitor Availability**
- **Market-Surveillance**
- **Market-Intervention**
- **Maintain Price Line**

Impact of Better Monitoring on Prices of Non-Scheduled Packs (Based on ORG-IMS data)

NPPA
ISO 9001 : 2000 Certified



Price reduction consequent to NPPA's intervention:

- i. Voluntary Price reduction = 60 packs
- ii. Price fixation by NPPA = 24

Total = 84

Pharma Market-Retail Sales

No. of Packs sold: 53998

MAT Value: Rs.31.04 Billion

Building Up Resource Base

To respond to existing and future needs, studies & technical support made or contemplated with:

- **Indian Institute of Science, Bangalore.**
- **Academic & Research support by IIM, Bangalore.**
- **Indian Institute of Packaging, Mumbai.**
- **Pilot Study by IIT, Kanpur.**
- **Administrative Staff College of India, Hyderabad.**
- **Computerization & Support in e-governance by NIC.**
- **FPCI dovetailed with Census of Micro, Small & Medium Enterprises.**

The Bottomline.....

➤ **Policy Prescriptions of the Govt.
And Provisions of DPCO, 1995**

**Not a matter of Choice Nor
negotiable.**

➤ **They must necessarily be
universally complied in the
country.**

**An Important Observation of the National
Commission on Macro Economics & Health,
August, 2005**

***Expand Price Control on all
drugs and mandate use of
only generic drugs in all
publicly funded programmes.
Such price caps will help
contain costs.***

THANK YOU

visit us at <http://www.nppaindia.nic.in>