

# INDIAN PHARMACEUTICAL INDUSTRY: An Update

The proposed NPPP 2011: Price reductions imminent but industry dynamics to ensure relatively limited impact on most companies

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ICRA RATING FEATURE

## Summary

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The Department of Pharmaceuticals has recently released the draft note on the National Pharmaceutical Pricing Policy (2011), which if accepted would replace the present Drug Policy introduced back in 1994<sup>1</sup>. The proposed policy has been put up for review by stakeholders until November 30, 2011 after which it will be presented to the Group of Ministers for final approval. In its proposed form, the policy framework aims at widening the ambit of medicines under price control as it proposes to include all of the 348 essential drugs listed in the National List of Essential Medicines (NLEM) as compared to the 74 bulk drugs, which forms part of the present policy regime. It is estimated, that the new policy in its proposed form would bring approximately 60% of the Rs, 48,200 crore domestic formulation industry under the pricing control compared to ~20% earlier. The market-based pricing mechanism proposed by the policy also marks an important shift over the current framework wherein prices are decided through a cost-based approach. The policy also aims at only regulating the prices of formulations as compared to formulations and bulk drugs in the present regime. With the proposed policy expected to cover nearly 60% of the domestic formulations industry, the impact of price control is likely to expand considerably across therapy segments and result in price reduction across the board. According to estimates, about 52% of drugs included in NLEM 2011 could face a reduction of 0-5% in prices of the highest price band, while 32% of the medicines could see a reduction of 20%+. The impact for the balance 16% of the segment is likely to be between 5-20%. However, in ICRA's view the overall impact on the industry would be limited as intense competition ensures that the prices remain below/at par with ceiling prices for most of the highly competitive therapeutic segments. Companies with higher dependence on the domestic formulations, especially on premium priced products are however likely to have higher impact. Overall, the policy hints at adopting a more practical and transparent mechanism for arriving at prices, which would be positive for the industry over the long-term.

## Background

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Price control over drugs was first introduced in India in 1962-63. Thereafter, a series of price controls have been implemented on several occasions in 1966, 1970 (under the Essential Commodities Act), 1978, 1979 and 1987. All these policies were broadly based on the principle of effecting control over prices of key bulk drugs and their formulations through various different principles, in which the span of control of prices as well as the nature of control varied. The present Drug Policy of 1994 was implemented through the Drug Price (Control) Order (DPCO) in 1995 which brought a major change in the way in which the key drugs were identified for price control. The policy based the selection process on the market share of different companies in the context of total sales of various drugs. Thus, drugs with annual sales at a particular level where the market share of leading players was beyond a particular level were brought under the ambit of price control.

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<sup>1</sup> Implemented through Drugs Prices (Control) Order, 1995

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Around 74 bulk drugs and formulations (~1,580) based on these drugs were brought under the control with price arrived on cost-based approach. Later in 2000, a new policy was introduced, however the policy was never implemented as it was challenged by Karnataka High Court and later the Supreme Court directed the Government to ‘consider and formulate an appropriate criteria for ensuring essential and life saving drugs’. In accordance with the Supreme Court’s directives, the Ministry of Health formulated a list of essential drugs (earlier notified in 1996) and after a series of revisions has brought 348 medicines under the ambit of National List of Essential Medicines (NLEM) in 2011. This compares to the 74 bulk drugs and their formulations under price control through DPCO 1995. The recently proposed policy aims at including all the essential medicines (listed in the National List of Essential Medicines (NLEM)) and their combinations under the gamut of controlled prices through a market based pricing mechanism. The policy also aims at including only the formulations in comparison to formulations as well as bulk drugs implemented in the present regime.

## The Proposed National Pharmaceutical Pricing Policy (2011)

**Salient Features of the proposed policy:** The proposed National Pharmaceutical Pricing Policy (NPPP) of 2011 is structured around three key principles of (i) essentiality of drugs; (ii) market-based pricing approach and (iii) covering only formulations under controlled pricing.

### How does the NPPP of 2011 differ from the earlier policy?

**Table: Snapshot of the proposed policy**

Parameters	Drug Policy (1994)	Proposed Policy (2011)	Comments
<b>Coverage of medicine</b>	On basis of Market Share Principle	On basis of essentiality of drugs	<p><b>Proposal</b> The proposed policy aims to include drugs under the pricing control based on their essentiality rather than market share principle implemented earlier; The coverage is drawn from the National list of essential medicines (NLEM) finalized in 2011</p> <p><b>Impact</b> Inclusion of all essential drugs and its combinations would significantly expand the gamut of drugs under price controls and as per estimates would cover <b>~60% of the domestic pharmaceutical industry compared to ~20% at present</b>; List of essential drugs includes a considerably higher number of medicines (i.e. 348) compared to 74 in the present list</p>
<b>Pricing Mechanism</b>	Cost-based pricing	Market-based pricing	<p><b>Proposal</b> The new policy aims to replace the cost-based pricing mechanism with market-based pricing approach wherein a ceiling price would be formulated based on the weighted average price (WAP) of the top-3 brands in a segment. Prices would be allowed to be revised annually up to the limit of the change in Wholesale Price Index (WPI) for manufactured goods. In case of decline in WPI a corresponding reduction in the ceiling price will be obligatory</p> <p><b>Impact</b> The impact on prices is likely to be limited as intense competition ensures that prices remain below/at par with ceiling prices. Market-based pricing is more practical in approach as it would bring in transparency in estimating ceiling prices and also reduce complexities involved in computing prices through cost-base approach</p>

<b>Scope</b>	Covers both Formulations & Bulk Drugs	Proposes to cover only Formulations	<b>Proposal</b> The new policy proposes to regulate the price of formulations only. This is different from the earlier principle of regulated price of specified bulk drugs and their formulations
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Source: Draft Policy Document, ICRA

## Proposals for Non-price controlled drugs

On the non-essential drugs, the new policy proposes that these drugs should not be under a controlled regime and that the prices should be decided by market dynamics unlike in Drug Policy 1994, where companies are not allowed to take a price increase of more than 10% annually. However, the proposed policy does aim to keep the overall drug prices under check and proposes to monitor the prices on regular basis. It suggests that the price hike should not be more than 15% p.a. or the increase in WPI (whichever is higher). For imported drugs, it doesn't propose a differential ceiling pricing mechanism, while it remains unclear on the patented drugs. The prices of bulk drugs and their formulations under the scope of the DCPO will be held constant for two years. Thereafter, the price revision will be linked to the changes in WPI, similar to what is being allowed for NLEM 2011 drugs.

**Table: Other proposals in the Policy**

Type of Drugs	Proposal on Pricing Mechanism
<b>Imported Drugs</b>	There will be no separate mechanism for determining the ceiling prices for imported drugs and will be computed in the same manners as for drugs in NLEM
<b>Patented Drugs</b>	The policy remains silent on the pricing of patented drugs; points out that the prices for patented drugs will be decided by a separate committee constituted by the Government
<b>Drugs under DPCO 1995</b>	The prices of bulk drugs and their formulations under the ambit of the DPCO 1995 will be held constant for two years, post which the price revision will be aligned to the changes in WPI, similar to what is being allowed for drugs in the NLEM 2011 list
<b>Exempted Drugs</b>	Drugs that form part of the Hospital supplies and public health products will be exempted Drugs with weighed average price of less than or equal to Rs. 3 for each unit will also be exempted from price control. For such drugs the ceiling price will be fixed at Rs. 3/unit and any such drug selling at a price higher than Rs. 3/unit will have to bring the price down to Rs. 3/unit. However, this limit will be revised in line with the change in WPI on an annual basis

Source: Draft Policy Document, ICRA

## Other initiatives aim at strengthening the drug distribution system & usage of generics

Besides ensuring affordability of medicines through effective price control mechanism, the proposed policy also aims strengthen the drug distribution and availability mechanism through various measures. Some of the prominent initiatives proposed by the policy include:

- ❖ Streamlining the drugs procurement mechanism of the Government through a strong and transparent drug purchase policy
- ❖ Improving direct healthcare access by expanding healthcare cover through State healthcare systems
- ❖ Promoting usage of generic drugs through various channels including the 'Jan Aushadhi' programme
- ❖ Supporting the industry by introducing policies to support investments in R&D; improve access to capital for start-ups, set up of pharma development parks, rationalize tax structure as well the pharmaceutical retail trade
- ❖ Improving the access to drugs used for specialized treatments particularly anti-cancer, HIV etc

## Impact on the Domestic Pharmaceutical Industry: Price reductions imminent but impact likely to be limited

Share of Domestic Formulations (FY11)	Domestic Formulations Revenues	Share of Turnover
Cipla	2,759	45%
Sun Pharma	2,381	41%
GlaxoSmithKline Pharma*	2,004	93%
Ranbaxy*	1,759	21%
Cadila Healthcare	1,620	38%
Lupin	1,573	27%
Dr. Reddy's Laboratories	1,431	19%
Pfizer**	947	81%
Torrent Pharma	838	38%
IPCA Laboratories	696	37%
Unichem	579	76%
Indoco Remedies	307	64%
Natco Pharma	226	51%

Source: Companies, Industry Estimates, ICRA Research

\* CY Ending; \*\* 16M March 11; Amount in Rs. Crore

Despite having a fragmented structure, the domestic formulations business has been one of the most profitable business segments for the industry, exceeded only by the one-off exclusivity-based opportunities in US generics. Driven by rising instance of lifestyle related diseases, favorable demographic trends, rising awareness levels and improving healthcare infrastructure, the domestic formulations industry has been growing steadily between 14-15% p.a. over the past several years. However, off late the growth levels have been subdued partially contributed by increased competitive intensity and pricing pressures particularly in the acute therapy segments. With the proposed policy expected to cover nearly 60% of the domestic formulations industry, the impact of price control is likely to expand considerably across therapy segments and result in price reduction across the board.

However, in ICRA's view, the overall impact of the proposed NPPP 2011 would be limited, as intense competition ensures that the drug prices remain below/at par with ceiling prices for most of the highly competitive therapeutic segments. Companies with higher dependence on the domestic formulations and premium pricing policy, particularly the MNC pharmaceutical companies are likely to have higher impact. Overall, the policy hints at adopting a more practical and transparent mechanism for arriving at prices, which would be positive for the industry over the long-term.



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