Pharmaceuticals

Pricing policy – The risk is significantly higher than it appears

Sector Update

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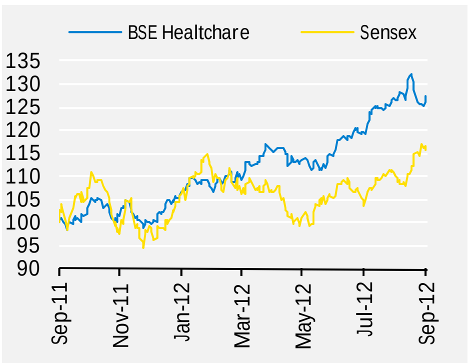
Sensex v/s BSE Healthcare



Source: Bloomberg

Stock Performance

(%)	1M	6M	12M
Sensex	**5.1**	**9.6**	**16.5**
BSE Healthcare	**(0.6)**	**15.4**	**26.2**
Cadila Healthcare	(5.0)	14.1	5.6
Cipla	(1.1)	25.6	26.6
Dr. Reddy's	(1.6)	(0.5)	11.4
IPCA	6.6	30.3	61.5
Lupin	0.2	14.8	25.8
Ranbaxy	(3.5)	29.2	10.1
Sun Pharma	1.6	17.4	44.8
Torrent Pharma	1.9	14.0	28.7

The New Pharma Pricing Policy (NPPP) proposed by the Department of Pharmaceutical in October 2011 was opposed by various NGOs and Health ministry as it is believed that the pricing based on Top 3 brands would not actually reduce the prices to the affordable level for masses. Following the same, the Government formed a Group of Ministers (GOM) on the pharma pricing policy, headed by Mr. Sharad Pawar, to work on an alternative policy. We believe that the new policy may be more detrimental to the industry than the one which was proposed earlier as pricing cuts will be steeper. Apart from impacting profitability, the new policy can significantly de-rate the valuation of leading Indian Pharma companies.

- **GOM in action following instructions from the Supreme Court; final outcome and implementation timelines still uncertain:** The GOM on pharma pricing has swung into action based on the order from the Supreme Court to decide on pricing policy for essential drugs as listed in National List of Essential Medicines (NLEM) 2011. The GOM met on Thursday but could not arrive at any decision as it has called for more data to take a call on market-based pricing formula. However, the GOM is expecting to meet on September 27 and take a final decision within next few days.

- **The new policy can be marginally better on coverage of drugs but harsher in terms of pricing compared to NPPP 2011:** According to some of the media reports, the GOM came to a consensus that the regulation should be limited to 348 medicines and their 614 dosages and combination drugs will not be included in the price control. This will be beneficial to the industry as it would reduce the price control to 60% of the market as per some industry sources (v/s 75% including combination drugs). However, the pricing formula, though market based, will be much harsher in its impact on top companies. As per various proposals, Weighted Average Price (WAP) of all the brands having volume market share of more than 5% or 1% should be considered for price ceiling.

- **Domestic business is of high importance to most of the leading Indian companies:** We note that the domestic formulation business is one of the most profitable business segments for most of the leading pharma companies from India and the new policy is likely to reduce the profitability, return rations and free cash flow generated by the companies from the domestic business. This, in turn, will impact the global growth ambitions of the pharma companies leading to damage to the valuation of these companies. Further, all the leading Pharma companies are trading at a relatively higher valuation leaving little room for margin of safety.

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Pharma pricing policy – The risk is significantly higher than it appears

The NPPP proposed by Department of Pharmaceutical in October 2011 was opposed by various NGOs and Health ministry as it believed that the pricing based on Top 3 brands would not actually reduce the prices to the affordable level for masses. Following the same, the Government formed a GOM on the pharma pricing policy headed by Mr. Sharad Pawar to work on an alternative policy. We believe that the new policy is likely to be more detrimental to the industry than the one which was proposed earlier as pricing cuts will be steeper. Apart from impacting profitability, the new policy can significantly de-rate the valuation of leading Indian Pharma companies.

Background of Drug Price control in India

Price control on drugs was first introduced in 1963. This was followed by Drugs Prices Control Order (DPCO), 1966 and 1970, 1978, 1979 and 1987. All these were formed to control the prices of bulk drugs and essential drugs. The current DPCO was introduced in 1995 which controlled the prices of drugs based on cost of production with allowance given for post-manufacturing expenses. The pricing policy of 1995 was on products where market share of dominant producers are beyond a particular level. Accordingly, a list of 74 bulk drugs was identified and these drugs as well as the formulations based on these drugs (currently about 1577 in number) were brought under the price control regime.

A new pharmaceutical policy was introduced in 2002, which further liberalized the span of control over pricing. The turnover limit for price control was raised from Rs40m to Rs250m. All drugs under the unit price up to Rs2 were excluded from the ambit of price control. The 2002 Drug Policy was challenged in the Karnataka High Court and a stay was issued on the implementation of policy. This order was challenged by the Government in the Supreme Court which vacated the stay. In the light of the order of the Supreme Court, it was decided to formulate a fresh Pharmaceutical Pricing Policy and accordingly the 2002 Drug Policy was never implemented and the 1995 Drug Policy continued to be applicable which continues even today. In accordance with the guidelines given by the Supreme Court, the Ministry of Health revised the list of medicines in the NLEM earlier notified in 1996. The revised list was notified as NLEM 2003. In 2011, the Ministry of Health revised the NLEM and notified new NLEM 2011. The Government has enunciated the NPPP 2011 which seeks to replace the Drug Policy 1994 and will consider the pricing of Essential Drugs as laid down in NLEM 2011. NPPP proposed a cap on the prices of 348 essential medicines and their formulations based on the weighted average price of Top 3 brands. These drugs currently account for around 60% of the domestic pharma market.

Except for the last proposed DPCO in 2006, all the previous DPCOs have resulted in reducing bulk drugs under price control. Till 1987, prices of 347 drugs were controlled. In 1987, price control on drugs was reduced to be applicable to 142 drugs and then in the last revision in 1995 it came down to 74 drugs. This was further proposed to be reduced to just 30 drugs in 2002 but the Supreme Court also wanted life-saving drugs to be under price control. As a result, a NLEM 2003 was constituted which had 354 drugs.

A brief about NPPP 2011

Government had proposed the NPPP 2011. In November 2004, the government set up a Task Force under the Chairmanship of Principal Advisor, Planning Commission, Dr. Pronab Sen, to look into the issue of price control. The Pronab Sen Committee submitted its recommendations in September 2005. The NPPP was primarily based on the Pronab Sen Commission recommendations.

The policy was significantly different from the existing policy. The new policy proposed to replace the existing pricing policy of 1995. Drugs brought under price control are determined based on essentiality for which NLEM 2011 has been considered. In the past, the criteria for selection of drugs under price control were based on sales and market share to prevent monopoly in the market. Another major difference was in the pricing formula which was based on market-based pricing rather than cost-based pricing as per the existing policy. The NPPP acknowledged that the market is competitive enough to keep margins and profitability of pharmaceutical companies in check. The departure from a cost-plus method would have been a big relief for the industry as the negative impact of price control would have been relatively less. Further, the NPPP proposed price revision for drugs based on change in WPI versus existing practice of annual assessment of costs. The existing DPCO 1995 was expected to remain in existence for two more years from the date the new pricing policy is adopted. Only 34 out of the 74 drugs in the current DPCO list are part of NLEM. The remaining drugs have therefore moved out of price control post expiry of the two-year period.

As per the NPPP, almost 60% of the India Pharma market would come under price control. However, the policy was shot down by various NGOs and health ministry as they felt that the policy did not bring down the prices of drugs at the affordable level to masses.

GOM in action following instructions from the Supreme Court – Final outcome and implementation timelines still uncertain

The GOM on pharma pricing headed by Mr. Sharad Pawar has swung into action based on the orders from the Supreme Court to decide on pricing policy for essential drugs as listed in NLEM 2011. The GOM met on Thursday but could not arrive at any decision as it has called for more data to take a call on market-based pricing formula. However, the GOM is expecting to meet on September 27 and take a final decision within next few days.

We believe that, despite the rapid activities taking place in the ministry to formulate the new policy, the final outcome (cost based/market based) and timelines remain uncertain as post the GOM proposes the new policy, the opinions of various stake holders will be invited which may delay the implementation. The new policy can be marginally better on coverage of drugs but harsher in terms of pricing compared to NPPP 2011.

According to some of the media reports, the GOM came to consensus that the regulation should be limited to 348 medicines and their 614 dosages and the combination drugs should not be included in the price control. This will be beneficial to the industry as it would reduce the price control to 60% of the market as per some industry sources (v/s 75% including combination drugs). However, the pricing formula, though market based, will be much harsher in its impact on top companies. As per various proposals, WAP of all the brands having volume market share of more than 5% or 1% should be considered for price ceiling.

As per NPPP 2011, which decides ceiling price based on Top 3 brands, 32% of the 348 drugs would have seen the price of top brand falling by more than 20% as indicated in the table below. However, the below analysis does not quantify the impact on industry as it does not take into account the size of the molecule.

Exhibit 1: Pricing impact on highest priced brands as per NPPP 2011

Decrease in the price of highest priced brands	% of molecules under NLEM
0-5%	52%
5-10%	7%
10-15%	5%
15-20%	4%
> 20%	32%

Source: DOP

Possible Pricing Formula

Out of the six options suggested to the GoM by different stakeholders, three have been shortlisted - one was suggested by the Prime Minister's Economic Advisory Committee (PMEAC). As per the PMEAC suggested pricing:

- If a drug is widely purchased by the government through tender process, the MRP should be linked to the tender price.
- For the remaining drugs, the retail price could be fixed at: (a) 1.25 times the 50th percentile (median price) of a particular drug or (b) the price which 80% of the consumers are paying, whichever is less.

The second option includes taking a WAP of all brands, which have a market share of more than 5% and the third option entails the use of WAP for all the drugs which have a market-share of more than 1%. To decide on at least one of these three options, the GoM has asked for more data analysis. They want to see how drugs have been priced in other emerging countries with similar platforms as India.

We believe that significant reduction in prices may lead to quality issues as companies may focus more stringently on minimizing costs rather than focusing on quality.

Following table indicates the possible changes that may appear in the new policy v/s NPPP 2011. The table has been prepared by taking into account the outcome of last meeting of GoM and opinion of various stake-holders.

Exhibit 2: Possible differences between NPPP 2011 and the new policy to be announced as per our expectation based on industry sources

Parameter	NPPP 2011	New policy*	Comment
Coverage	All the 348 drugs and its combinations to be included in price control	Only the 348 drugs and its 614 dosages to be included and combinations will be excluded	This will be minor positive for the industry as the span of control will reduce from 75%+ market size to ~60% of market size
Pricing Formula	Ceiling Price will be based on WAP of top 3 brands	Ceiling Price will be based one of the 3 proposals described above	This will be significant negative for the industry.
Price Revision	Revision based on changed in WPI every year	Uncertain if the earlier recommendation will be followed	Some of the stakeholders have taken objection to the price hike linked to WPI change.

Source: Industry, PL Research

** New Policy to be announced as per our expectations based on industry sources*

Domestic business is of high importance to most of the leading Indian companies; if the pricing impact is severe based on new policy, it will have unwarranted repercussions for the companies

We note that the domestic formulation business is one of the most profitable business segments for most of the leading pharma companies from India and the new policy is likely to reduce the profitability, return rations and free cash flow generated by the companies from the domestic business. This, in turn, will impact the global growth ambitions of the pharma companies leading to damage to the valuation of these companies.

We are not sure about how severe the impact of this policy will be on the profitability of leading companies, but, it will certainly be a sizable impact which cannot be ignored. The impact on profitability of leading Indian companies will depend on various parameters like percentage of profits derived from domestic formulation business which in most cases are higher than the percentage of revenue derived from domestic formulation business, percentage of domestic revenue covered by the 348 drugs and its formulations and pricing premium the company commands in those drug formulations.

We believe that, the domestic formulation business is high RoCE and high cash-flow generating business for most of these companies due to branded nature of the market and low capital employed. The rapid strides made by most of these companies in the international market have been funded through the domestic formulation business. In fact, for many companies, the international operations are not still profitable. It is the domestic formulation business which subsidized the international operations for many of the companies in the initial years.

Any severe impact of the new policy will have multiple negative repercussions on the business of these companies as mentioned below:

- Overall profitability of the companies may go down significantly which will lead to lower RoCE and RoEs

- The top-line growth in both, the domestic business and international business, will be impacted. The growth in domestic business will come down as prices gets impacted and growth in international business will come down as the companies will be left with lower free cashflows to invest in international business.

- For investors, the above two factors may lead to substantial de-rating of the stocks in the short term and even in the longer term.

Exhibit 3: Importance of Domestic formulation to the companies

Company	Contribution to top-line (%)^	Contribution to EBITDA*
Sun Pharma	40	50
Cipla	45	54
Dr Reddy's Lab	15	23
Ranbaxy	25	70
Lupin	29	35
Cadila	37	45
IPCA	33	41
Torrent Pharma	35	55

Source: Company Data, PL Research
*^ Excluding one-off revenues from US; * Based on PL estimates; Based on FY12 financials*

As shown in the table above, most of the leading companies derive 35-70% of their EBITDA from domestic formulation business. Dr. Reddy's and Lupin have the lowest contribution to EBITDA from domestic formulation business as per our estimates. However, the risk of any adverse outcome is significant for all the players.

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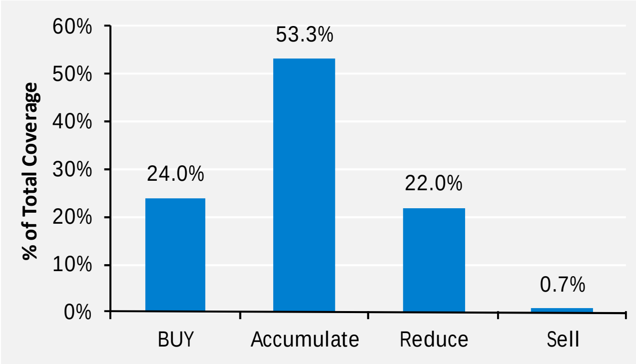

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BUY	:	Over 15% Outperformance to Sensex over 12-months	**Accumulate**	:	Outperformance to Sensex over 12-months
Reduce	:	Underperformance to Sensex over 12-months	**Sell**	:	Over 15% underperformance to Sensex over 12-months
Trading Buy	:	Over 10% absolute upside in 1-month	**Trading Sell**	:	Over 10% absolute decline in 1-month
Not Rated (NR)	:	No specific call on the stock	**Under Review (UR)**	:	Rating likely to change shortly

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