Competition, Delay in Drug Approvals May Take a Toll on Pharma Cos' Health

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With global macro-economic scenario turning volatile, Indian players may have to strategise harder to stay ahead

For investors, the export-oriented, defensive pharma sector produced high returns (of over 45%) during 2014. The year was indeed an important one for the sector -the Sun-Ranbaxy Deal, recovery in domestic market in the aftermath of price control, record sales in the US -all resulting in its out-performance on the bourse. With the global macro-economic scenario turning volatile, there are signs that the going may not be as good in 2015.

Sector Outperformance

Pharma sector has been outperforming the Sensex every year since FY10. The export-oriented sector benefited from rupee depreciation over the past four years. With rupee . 60 per dollar continuing to rule over ` and volume growth picking up in the domestic market, the prospects for the sector look promising. However, the outperformance of the sector vis-à-vis the broader indices depends on the performance of the rate-sensitive cyclical sectors and the currency movements in home as well as emerging markets.

M&As to Continue

Has the M&A action in pharma industry peaked with the Sun-Ranbaxy deal? Unlikely. Consolidation has been a regular feature of the highly fragmented sector. While mido-small companies have routinely engaged in M&As, large cross-border deals have happened once in every couple of years. In 2008, Daiichi Sankyo bought Ranbaxy . In 2010, it was Abbott buying Piramal's domestic drug business. Although the high valuations have deterred MNCs from buying attractive targets in India, their interest nevertheless remains unabated.

US - The Biggest Growth Driver

The world's largest pharma market continues to remain the Indian pharma industry's biggest opportunity as well as its biggest weakness. In FY10, Sun earned 28% of its revenues by selling generics in the US. Today , it earns over 60%. Likewise, Dr Reddy's Labs' proportion of revenues earned from the US has increased from 30% in FY10 to 47% in FY14. With such overdependence on the US market, any regu latory or structural issue in that business leads to an amplified impact on the Indian drug companies. In 2014, US FDA injunctions and delay in drug approvals adversely impacted the performance of several Indian drug firms. This phenomenon is likely to remain so in 2015.

Intensifying Competition

As competition intensifies in the global as well as domestic turfs, Indi an drug firms have to strategies harder to stay ahead. As US became a haven for low-cost generic drug companies, large innovator companies turned their attention to the emerging and under-penetrated markets outside the US, EU and Japan. Today , Bayer Healthcare, Sanofi, Merck, GlaxoSmithKline, Novartis, Novo Nordisk, AstraZeneca and Pfizer are the top drug sellers in the emerging markets in Asia, Eastern Europe, Latin America and Africa. As Indian firms expand global footprint outside the US, they are in for real competition from the Big Pharma in most of the `Pharmerging' markets.

Incidentally, currencies of most emerging markets have depreciated against the dollar -leading to high possibility of earnings downgrades for Dr Reddy's, Glenmark Pharma and Aurobindo Pharma. Even in the home turf, competition is intensify . 78,000-crore Indiing further for the ` an pharma market with growing presence of the small regional and unorganised players. These players, armed with state FDA-approved facilities, supply low cost drugs (of questionable quality), thereby eating into the share of the larger established brands. While each of them singularly do not cause much damage for the organised players, taken together they are fragmenting the industry further.

Living With Regulatory Risk
Looming regulatory risk is one of the prime reasons why pharma business cannot be considered to be a defensive sector for investors. Sudden regulatory clamps -on international as well as local front -render a lot of volatility to the growth prospects of a drug company . Import injunctions or delay in drug approvals by US FDA or price control order on drugs sold in India are glaring instances of regulatory risks threatening to spoil the party for investors in the pharma sector. With frequency of the regulatory actions increasing, the companies will be compelled to work on making their business models fungible. For instance, Ranbaxy amidst the resolution of issues with US FDA, entered into a profit-sharing agreement with its rival international generic company Teva in 2011 as a backup measure for gaining approval from US FDA to exclusively market a generic of Lipitor, one of the highest selling drugs.

R&D to Stay On Backburner
The number of brands launched in India has been on a gradual decline in the recent years with those for 2014 being at a five-year low. Despite the drying up of product pipeline, innovative R&D is not still a major priority for pharma firms. The amount spent on selling and administrative expenses is higher than the R&D. Most leading drug companies in India spend 6-8% of their revenues -much lower than the double-digit proportion spent by leading multinational companies.

The year 2014 saw the shutting down of drug discovery business by Piramal Healthcare. In earlier years its rivals -Dr Reddy's and Ranbaxy -too, had reportedly either closed or divested stake in their drug discovery units.