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According to the outlook report outlook on 'Pharma Industry' for 2014 by the Dun & Bradstreet, the Indian pharma industry has exhibited a stellar performance in the past and has grown unabated at an estimated CAGR of ~13% during FY 2009-13. Both, domestic and export led demand contributed towards the robust performance of the sector. Lower cost of production and availability of highly skilled labor pool at low cost has helped Indian pharmaceutical companies to innovate and develop generic substitutes of patented drugs at a fraction of cost incurred in developed markets.

Though the pharma industry has remained shock proof to recession in the past, currently companies in this sector are also facing the heat of slowing economic growth. The domestic economy continued to grow at a subdued GDP growth rate of 4.7% during first three quarters of 2013 as against 5.2% in the previous year period. The cumulative sale for first nine months of CY2013 grew by just 9% against 17.4% in the previous year. Moreover, the industry is facing stringent regulatory and quality norms both at global and domestic front. Increasing government intervention is expected to impact industry's performance in the near term; however such interventions are necessary to bring India at par with global standards. Some of the key developments influencing the industry performance in CY2014 include:

Implementation of New Pricing Policy is likely to translate in weak domestic revenue generation:

Implementation of Drug Policy Control Order (DPCO) 2013 by New Pharmaceutical Pricing Authority (NPPA) with effect from 15th May 2013, which put a cap on the prices of 348 essential drugs, is likely to impact domestic revenue generation of both home grown and multinational drug manufacturers in CY2014. Impact of New drug pricing policy and regulatory intervention has already started influencing the growth performance of the overall pharma industry. Slowing quarterly net sales growth to 9% and 12% during Q2 & Q3 of CY2013 (period during which DPCO was implemented) respectively against 15% plus growth during the same period in previous year well reflect the impact of DPCO as well as slowdown in demand. Compliance to this regulation may continue to create the pressure on pharma companies' profitability in 2014.

Imposition of Quality Issue Norms by the respective US and UK regulating authorities likely to impact export performance:

India is one of the largest exporters of pharmaceutical products in the US & European region. The US and the Europe account for 25% and 7.0% share respectively of pharmaceutical exports of India. The share of exports revenue in total industry revenue has increased to more than 50% in FY13 from 42% in FY09. India has the largest number of US FDA approved facilities (currently 169) outside the US which points to the quality standard achieved by Indian pharmaceutical companies. However, currently pharmaceutical exports from the country are plagued by quality issues, primarily in the US market. There have been multiple instances of product recall from the US market in past couple of years.

The recent adverse rulings by US FDA are expected to impact the export of pharma products from the country which has reported a phenomenal growth of over 19% during the period FY 2009-13. In the light of these adverse rulings, US FDA might impose tighter quality norms which would delay Indian pharmaceutical companies launching their products in the US market. Since the US is the largest export market for Indian pharmaceutical companies, any delay in exports to the US due to adverse rulings by the regulating authorities would have a significant impact on the sector.

Hike in US FDA generic drug user fee is expected to hit hard the Indian drug manufacturer too

In August 2013, US FDA hiked the generic drug user fee sharply for generic drug with a view to reduce the backlog of pending applications and cut down on the average time required to review generic drug applications for safety. However, this hike is likely to put financial burden on generic drug manufacturer across the world while its impact on India is likely to be felt in a big way as it is the second largest exporter of generic drug to US holding a 10% share in US generic drug market. Enactment of Proposed Bill 'Small Manufacturer Protection Act of 2013' in US may benefit small generic drug player including Indian manufacturers.

On 2nd December 2013, Small Manufacturer Protection Act of 2013' was proposed in the House of Representative. This bill has been proposed in order to protect small generic drug manufacturers against the recent hike announced by US FDA in the generic drug user fee for all generic drug manufacturers including small manufacturers which typically face cash-crunch problems. Thus, if this legislation is passed it will have a provision for allowing waivers and refunds of user fees to small generic drug manufacturers and is likely to benefit Indian generic drug manufacturers too since the bill does not discriminate between domestic and foreign generic drug manufacturer.

India with growth in ageing population and low healthcare penetration will continue to be an attractive market for global Pharma Companies:

Despite an adverse regulatory environment, India will continue to remain the attractive pharma market for global pharmaceutical companies on the back of growing ageing population and low penetration of healthcare. As on 2009, approximately 15% of total population in the country was in this age group of 50 and above, and by 2016 this proportion is expected to be ~18.0%. Consequently, demand for pharmaceutical products would go up. Other factors like rising income, greater awareness of personal health and hygiene, easier access to high-quality healthcare facilities, rising penetration of health insurance and media are some of the important factors expected to drive the pharmaceutical industry in India. To access the untapped opportunity in growing domestic pharma business, multinational pharma companies are entering into strategic alliances with domestic generic manufacturers.