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Sector review: Pharmaceuticals

On the road to recovery

Bloomberg

Most Indian pharma companies have posted impressive numbers in the quarter ended December 2013, signalling better times ahead

SOUMONTY KANUNGO

THE Indian pharmaceuticals industry is undergoing a difficult time. With Indian pharma companies battling regulatory issues, both foreign and domestic, the sector may take a while to return to its good old days, despite a visible growth witnessed in the quarterly numbers.

The latest import ban from the US Food and Drug Administration (FDA) on Ranbaxy's Gurgaon-based active pharmaceuticals ingredient (API) facility in Toansa (Punjab) is just a reminder of how stringent the rules of the US regulator are when it comes to compliance issue and how important it is to ascertain interests of the US consumers. Even Mumbai-based Wockhardt is also facing similar regulatory challenges at its manufacturing facilities, which resulted in import alert.

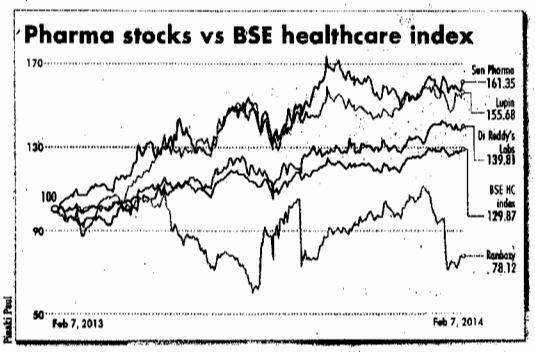
According to a CII-PwC report on the pharma sector, quality and regulatory concerns could also lead to greater US FDA scrutiny in future. Pharma companies will have to step up their quality and manufacturing compliances in line with the global guidelines.

"India has had an efficient pharmaceutical industry. It has been manufacturing affordable drugs for the Indian market as well as exporting them to the rest of world, but off late it has been facing rising FDA scrutiny for quality. The US FDA has increased its scrutiny on the quality coming from manufacturing plants located in India. Indian companies will have to raise their compliance to the US FDA regulations, as they drive their major share of exports from the US market," the report said.

India is the biggest supplier of medicines to the US and according to industry sources, pharmaceutical exports from India to the US rose nearly 32 per cent last year to $4.23 billion. With increasing exports, companies are drawing greater FDA scrutiny for quality and manufacturing compliances.

It is, however, quite obvious that the FDA will keep a strict vigil to ensure safety and quality throughout its supply chain, thanks to 40 per cent of the finished drugs taken by the US patients and 80 per cent of the raw materials (active ingredients) coming from other countries of which India accounts for nearly 10 per cent of the US generic drug market by value.

But not just the FDA, other foreign regulations including the United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA), EU and the Australian regulators are also keeping a close watch on Indian companies. So, unless the pharma companies can actually meet compliance over their manufacturing practices and quality issues, foreign regulators are more likely to continue crackdown on more and more firms, feel experts.



Pratik Paul

In a recent post-earnings conference call, Ranbaxy Laboratories' CEO and MD Arun Sawhney said, "We are actively engaging with all regulators. We have offered clarifications and we welcome other regulators if they want to come and conduct their own investigations." The company posted net loss of Rs 159 crore on the back of one-time write-off inventory cost.

Taking caution of the present regulatory hurdle that the companies are facing with the foreign regulators, the drug controller general of India (DCGI) is also in the process of streamlining drug regulation in the country with some fundamental changes expected to take place soon.

A pharma consultant said, "The major problem is while the foreign regulators are extremely stringent in their regulations the same cannot be said of the domestic regulators. Uniformity should have been maintained across and domestic regulators must set standards equivalent to their global peers."

The DCGI, however, feels that companies cannot be judged by the standards set by the US FDA and the industry may collapse if these stringent norms are followed elsewhere, as quoted by media. Despite regulatory challenges, most Indian pharma companies have posted impressive numbers in the quarter ended December 2013.

Ahmedabad-based Torrent Pharmaceuticals has posted consolidated net profit of Rs 158 crore on net income of Rs 1,015 crore for the December 2013 quarter. The company's US business reported a 61 per cent growth. Bangalore-based biotech major, Biocon has reported 14.41 per cent increase in its consolidated net profit for the third quarter at Rs 104.89 crore.

Glenmark Pharmaceuticals reported Rs 216.2 crore profit for the December quarter compared with Rs 213 crore in the year ago, which included a one-time gain of Rs 49 crore from a research out-licensing deal. Its generic business in the US and Europe increased 19 per cent and 72 per cent, respectively.

Lupin also posted a record net profit at Rs 476.1 crore in the third quarter of the current financial year as against Rs 335.2 crore in same quarter last year a growth of 42 per cent. Cadila Healthcare's consolidated net profit jumped 81.6 per cent YoY to Rs 186 crore in the quarter ended December 2013. Aurobindo Pharma reported over four-fold increase in consolidated net profit at Rs 416.12 crore for the quarter ended December 2013, on the back of improved sales and margins and on account of new launches in the US.

However, big players such as Sun Pharmaceuticals, Dr. Reddy's Laboratories and Wockhardt are yet to announce their results for the December quarter. The quarterly numbers from the Indian drugmakers indicate a revival in the pharma sector after two stressed quarters.

Ranjit Kapadia, senior VP — pharma at Centrum Broking said, "The quarter has shown some improvements mostly on the back of US sales. However, the new drug pricing control order (DPCO), trade related issues continued to impact domestic sales. There is also a slowdown in the Europe and Japan, with the latter likely to see a price cut in April on new products by at least 10 per cent. However, existing products will not be impacted. Besides, regulators have come down heavily on Indian manufacturers with a number of facilities under the FDA scanner." He also added that the US FDA is not encouraging Para-IV which means the first-to-file advantage is slowly ground.

"The US generics market is big and fragmented enough, presenting growth opportunities to Indian pharma players for several years though some moderation may occur due to an already high base. Annual size of the overall US pharmaceutical market is currently about $326 billion at wholesale prices, as per industry estimates. The share of generics is estimated at close to 28 per cent (approximately $95 billion) and comprises both generic generics and branded generics. Generic generics has approximately 55 per cent share in the overall generics market," a pharma report by IIFL said.

IIFL pharma analyst Bino Pathiparampil said, "The domestic market may witness a better growth in the next financial year, as DPCO and trade related issues are likely to get resolved. However, though the quarter numbers are impressive, there remains regulatory pressure on some pharma companies. Also a fluctuating rupee may hamper exports prospect."

India Ratings & Research in a report said, "We believe the strong export growth recorded over FY08-FY13 at a compounded annual growth rate (CAGR) of 22 per cent will continue in the medium term" There are over 125 FDA approved manufacturing facilities in the country; the largest number of FDA approved facilities in any country outside the US.

Pathiparampil said, "Para IV may not be looked as an advantage, since the market is extremely competitive with sometimes six to eight players competing for the first-to-file exclusive right. At times, the market is shared between these players. Besides, this exclusivity is a short-term gain. However, the overall outlook on the sector is bullish."

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