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Choose pharma stocks with care

While valuations have risen, share prices have been hit by quality concerns and restrictions by international agencies

MARKET INSIGHT

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The Indian pharma industry is in throes of a massive crisis. The tightening of standards by the US Food & Drug Administration has had a negative impact on exports to America and also resulted in a erosion of brand value.

Ranbaxy, Wockhardt, RPG Life Sciences, Aurobindo Pharma and Strides Arcolab are among the big names that have been hit by "import alerts", or seen approvals withdrawn from specific facilities. According to FDA data, so far this year, over 20 drug manufacturing factories across India have been barred from supplying to the US.

The US is the world's biggest drug market by far, contributing around 36 per cent of global sales by value. India is the second-largest supplier to the US. The FDA's regulatory focus has hit sales directly. On top of that, regulators elsewhere tend to emulate the FDA and that could mean higher barriers against Indian pharma in other markets.

The only way to avert this is to pull up standards in Indian facilities and meet the stiffer FDA norms. That will take time. It is also becoming obvious that, given the breadth and scale of the problem that Indian pharma companies will have to undergo a paradigm shift in terms of quality control.

The Indian pharma industry also faces several domestic issues. One is tight price controls on a very wide range of drugs, which means margins are low. The second is regulatory pressure in terms of allowable clinical trials in India. Indian pharma's volumes come from generics – drugs going off-patent. Clinical trials are vital to establish that a generic exactly replicates the action of the drug coming off-patent.

As with other export oriented industries, pharma's cost-competitiveness depends to a large extent on labour arbitrage. Skilled researchers and technicians come relatively cheap in India. But if clinical trials are difficult to conduct and research facilities must be located abroad, that advantage will be reduced.

In one sense, the industry has only itself to blame. As with most other Indian industries, the concept of *jugaad* prevails. There is a great hurry to develop generic versions as soon as a drug comes off-patent. Cutting corners in the conduct of trials is tempting.

In 2012-13, Indian pharma exports to the US topped $4.2 billion. Indian drug makers command a 10 per cent share in the $30-billion US generic market and an about 40 per cent share of over-the-counter prescription drugs sold in the US market. If the FDA had not thrown a spanner in the works, future prospects would have been very bright, given Obamacare and the weak rupee. But there has been an erosion of faith in the processes of Indian pharma majors. There is concern, both domestically and in other markets, about Indian quality controls. While the inability to fully exploit export opportunities is sad, it is not a bad thing that the industry is being forced to pull up its socks

India has much higher than normal death rates in clinical trials and at various times, allegations have surfaced alleging problems in clinical trials. As a result, the Supreme Court has directed the government to codify an improved regulatory regime for trials. In its efforts to do so, the GoI has introduced very elaborate rules.

In 2012-13, Indian pharma exports to the US comfortably topped $4.2 billion. Indian drug makers command a 10 per cent share in the $30-billion US generic market and an about 40 per cent share of over-the-counter (OTC) prescription drugs sold in the US market. If the FDA had not thrown a spanner in the works, future prospects would have been very bright, given Obamacare and the weak rupee.

Given the large scale of exports, the FDA has an inspection team of about 20 personnel that constantly monitors the 150-odd Indian plants, which are FDA-approved for US imports. Although the bans and alerts dominated the news, Indian firms received over 100 new generic approvals from the FDA in calendar 2013.

Inevitably, there has been an erosion of faith in the processes of Indian pharma majors. The number of FDA alerts is alarming and earlier, Ranbaxy was pulled up for falsifying test results. There is a fair amount of worry both domestically, and in other markets, about Indian quality controls.

The inability to fully exploit export opportunities is sad, of course, But it is frightening to realise that drug quality controls have probably always been sub-standard. In that context, it is not a bad thing that Indian pharma is being forced to pull up its socks. However, it is also true that the industry is going to suffer from needlessly complex and unnecessary regulations restricting clinical trials,

Valuations in the industry have been consistently high. Share prices have been impacted by these problems. Is this an opportunity to buy into a highly profitable industry going through temporary difficulties?

My sense is that it will take some time before the problems are definitively sorted out and there may well be more FDA import-alerts before that happens. The FDA's actions will probably induce a quick improvement of quality controls. On the domestic front, it could be years before the issues centred on trials settle down. There would be case-by-case investment opportunities arising over the next couple of years.