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Regulatory woes mount for Dr Reddy's

Resolution of these issues will be a long-drawn process: Analysts

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Investor concern on Dr Reddy's Laboratories has deepened with details from the warning letter issued to the company by the US Food and Drug Administration (FDA) coming into the public domain.

The worry on the three facilities in question — at Nalgonda in Telangana and at Srikakulam and Visakhapatnam in Andhra Pradesh — getting FDA 'import alerts' has increased, say analysts. Most of them have downgraded their target prices and stock ratings for the company. Sales contribution from these facilities to the US market are 10-12 per cent of Dr Reddy's total sales or $250 million, estimates Motilal Oswal Securities.

What's added to these concerns is their arising at a time when the Street's sentiment for Dr Reddy's was at new highs. In the first week of November, the stock was a shade below its all-time high of ₹4,382.95 on October 20. Unlike some of its larger peers, the company had strong growth in the September quarter, despite limited approvals in the US.

As a result, the stock has significantly fallen. It dropped 8.2 per cent on Thursday, taking the total loss to 27 per cent since November 5. It is now trading at a 11-month low of ₹3,110.35 and is not far from its year's low of ₹3,010. Analysts believe this pressure will continue for quite a while.

Analysts at HSBC say the FDA raised serious concerns on alleged data manipulation, compromised control for potential contamination, improper data handling and other deviations from GMP (good manufacturing practices) in the recently published warning letter, citing issues at the three facilities. The regulatory agency also expressed dissatisfaction with the nine responses so far from Dr Reddy's, questioning the corporate quality systems in place.

Analysts also point to the FDA issues being faced by Wockhardt, Sun Pharmaceutical's Halol unit, etc, and the long timelines for clearance. Sarabjit Kour Nangra at Angel Broking says these quality issues will take some time to get resolved.

This is not good news for Dr Reddy's. New drug filings and approvals from these sites are likely to be delayed. For oncology products, there are four or five pending approvals from the Vizag facility, say analysts. The company will now have to make filings through partners and for getting approval on product launches, go for site transfers or outsource basic raw materials (like Aactive Pharma Ingredients). Site transfer filings will elongate the time of receiving approvals while outsourcing of API can lead to lower margins.

Some respite comes from the fact that the company already has approval for site transfers for the Srikakulam facility, despite this being under the regulator's scanner for some time. It had even got approval for launch of generics of a multi-billion heartburn drug, Nexium, in September through site transfer. However, Dr Reddy's is currently in litigation with AstraZeneca for the launch.

A key positive is that the crucial product segment of injectables is already being outsourced. So, analysts at Motilal Oswal Securities say the impact on sales and profitability in this segment will be minimal. Injectables contribute only about a fifth to sales but its profitability is very high. Yet, this is unlikely to be enough for offsetting the possible impact of delay in new launches.

Overall, there are challenges in the days to come and the company will have to enhance efforts on multiple fronts to manage US sales and new approvals. Especially as North America contributes 47 per cent to sales. There are also the cross-currency headwinds it is facing in Russia, Venezuela, etc.

Analysts at HSBC assume no new FDA approvals in the next six to nine months. So, they expect some key opportunities to materialise only in FY18 (essentially, assuming flat US growth in FY17). They have reduced their FY17 and FY18 estimates by 9.5 per cent and 2.3 per cent, respectively, and lowered their target price to ₹3,604 from the earlier ₹4,271. Analysts at Motilal Oswal, having a target price of ₹3,500, say the long-term fundamental will be intact but the stock will remain range-bound in the near term due to regulatory concerns.

AVERAGE WARNING LETTER RESOLUTION PERIOD

Company	Facility location	Resolution period
Aurobindo Pharma	Unit III, Hyderabad	13 months
Cadila Healthcare	Moraiya, Ahmedabad	13 months
Claris Life sciences	Vasana, Ahmedabad	19 months
Dr Reddy's	Mexico	16 months
Lupin	Mandideep	7 months
Wintac	Bangalore	16 months
Sun Pharma (Taro)	Canada	24 months
Sun Pharma	New Jersey	11 months
Average		**15 months**

Source: HSBC