USFDA observations beneficial in long run: Dr Reddy's

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Mumbai: US health regulator's observations are "unmistakably" beneficial in the long run and have helped the company accelerate the pace of quality reforms, pharma major Dr Reddy's Laboratories has said.

"The remedial actions triggered by the USFDA observations are unmistakably beneficial to us in the long run and it has helped us accelerate the pace of quality reforms across our plants. We believe that the shift in the US regulator's approach from 'what has gone wrong' to 'what can go wrong' is for the long term good of the industry," Dr Reddy's Labs Chairman K Satish Reddy said in the company's annual report.

Based on its corrective actions, the USFDA reinspected the company's three plants between February and April 2017. It had received some observations from the regulator thereafter and subsequently submitted a detailed response. The company is awaiting the USFDA's views on its latest set of responses.

Since November 2015, the company has significantly invested in processes, automation, detailed documentation of each batch and standard operating procedures and further strengthened its quality management systems.

However, the warning letter put on hold the company's approval of several key drugs, including high value added injectables and complex generics, to the US from the last quarter of 2015-16 and throughout 2016-17. This pipeline blockage affected revenues, margins and profits. Additional costs of conducting remedial work, including the use of international consultants, also reduced profits, he added.

Going forward, the drugmaker believes that the pricing pressures in the US market will be less severe and more calibrated in 2017-18. "We also have an excellent pipeline of complex generics to be introduced to the country in 2017-18 and expect to do better through this effective upgrade of our portfolio mix," Reddy said.

"We also believe that there are enormous opportunities across emerging markets and are playing actively to increase our presence in these territories through complex generics and biosimilars. The Russian and CIS markets are on a moderate upswing," Reddy added.

According to the pharma major, in the domestic market, threats of government-induced pricing pressure remain. "We are seeing greater offtake of generics - both relatively simple and complex - and oncological biosimilars, the latter through greater hospital and institutional sales. We believe that emerging markets will again get back to double-digit growth. Despite government induced pricing pressures on pharmaceutical products, India remains a high growth market," stated the report.

In 2016-17, revenues grew by 9 per cent over the previous year.

The first quarter of 2017-18, the chairman said, may see a temporary decline in sales due to de-stocking by trade on implementation of the Goods and Services Tax (GST). "Post normalisation, we expect to grow in low double digits in 2017-18 and for the foreseeable future," Reddy said.