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Pain for big pharma as US FDA warnings double

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18% of new products to be delayed; strong balance sheets cushion credit metrics

Warning letters issued by the US Food and Drug Administration (FDA) to large Indian pharmaceutical firms more than doubled in the first ten months of calendar 2019 compared with 2018. This will impact about 180 abbreviated new drug applications, or 18% of the total pipeline of large drug makers, delaying new product launches, a CRISIL analysis of current regulatory actions, including adverse observations on FDA audit indicates. The US market accounts for more than a third of overall revenue of the big drug makers or Rs 55,000 crore of sales annually.

Says Sameer Charania, Director, CRISIL Ratings, “With intensifying regulatory scrutiny, sales growth from the US market will drop to 10-11% during fiscals 2020-22, compared with a growth of 16% in fiscal 2019. Large players are banking heavily on successful launch of complex generic products – these filings have risen to about 25% of the overall new product pipeline from nearly zero three years ago. A substantial delay in resolution of regulatory issues and/or heightened scrutiny could derail the US growth story.”

A similar trend was noticed in calendar 2015, when FDA scrutiny of Indian drug makers had intensified largely citing data integrity issues by and large. Consequently, US revenue growth had dropped to 6% in fiscal 2017 as new product launches got delayed amid inherent price erosion.

However, the recent FDA observations are relatively less severe and pertain largely to upkeep of facility, cleanliness, and enhanced manufacturing systems. As a result, resolution is expected to be faster. That said, remediation costs to resolve the regulatory observations are likely to increase for big pharma. This is expected to shave off operating profitability by 100-150 basis points over the next two fiscals from the current 19%. Therefore, cost optimisation and rationalisation of research and development expenses will be critical to arrest further decline in operating profitability of these players.

Says Tanvi Shah, Associate Director, CRISIL Ratings, “The players are, however, taking steps to contain the impact of regulatory scrutiny and moderate its impact on exports to the US. De-risking strategies such as dual-product filings from different plants and transfer of high-value products to unaffected plants through FDA approvals, which reduce the dependence on a single plant, may help partially contain the impact.” Besides, steady double-digit domestic sales growth, prudent capital expenditure, and strong balance sheets are expected to help the big pharma companies maintain healthy credit metrics. The debt-to-EBITDA ratio is expected to sustain at 1.6-1.7 times over the medium term.