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Drug firms bank on faster US approvals

OUR SPECIAL CORRESPONDENT

Mumbai, June 21: Domestic pharmaceutical companies are pinning their hopes on faster clearances from the US Food and Drug Administration (USFDA) amid challenges such as compliance issues and customer consolidation.

Experts, however, maintain that it's too early to conclude that the improvement in the pace of approvals from the US regulator in the last couple of months will be sustained.

The US is a key market for Indian pharmaceutical companies, many of which supply close to 40 per cent of their generic and over-the-counter drugs to that country.

However, regulatory actions and a slowdown in new drug approvals have led to a tardy growth in revenues for many companies. A pick-up in the pace of approvals is crucial at a time a consolidation of drug supply chains in the US has given them better bargaining power leading to a pricing pressure on Indian generic drugs.

During the fourth quarter of 2014-15, Lupin witnessed a 12 per cent decline in its US revenues to $211 million from $241 million in the same period last year. The Mumbai-based company said higher price erosion and a slowdown in approvals had an adverse impact on growth. The company has made 210 abbreviated new drug applications (ANDA), of which 111 have been approved. It only received 12 approvals in the previous fiscal.

BITTER PILL

Challenges faced in US

- Compliance issues
- Slow pace of approvals to ANDAs
- Price pressure on generic drugs as a result of consolidation of supply chains in US giving them better bargaining power

Flicker of hope

- Of late, clearances by FDA have been fast-tracked

ANDA is an application to supply a generic drug after the expiry of the patent.

Hyderabad-based Aurobindo Pharma has the largest pipeline of ANDAs (85) pending approval. On the other hand, Dr Reddy's Laboratories, which had filed 220 ANDAs in the US as of March 31, has 68 pending approvals.

The US regulator has also been taking more time to clear applications. According to Lupin, the median ANDA approval timeline has increased to 42 months in 2014 from 32 in 2013. It happened during a year when approvals for Indian companies fell to 76 from 114 in 2013.

To expedite the approval of a generic drug, the USFDA has implemented the Generic Drug User Fee Act (GDUFA) programme in October 2012, wherein the industry pays user fees to supplement the cost of reviewing applications and inspection of facilities. However, its progress has been disappointing.

According to the Generic Pharmaceutical Association, a US-based organisation, while the median approval time in 2015 appears to be tracking at 48 months, approvals by the USFDA, which include tentative and final, have also come down. From 619 in 2011-12, the number has come down to 535 in 2012-13 and 500 in the subsequent year.

About $621 million has been invested in the programme till date and the regulator has hired 950 people.

However, there could be some good news ahead. "The past two months have seen a pick-up in approvals (tentative plus final). We believe this is a healthy development for industry with the USFDA getting its act together," a note from Edelweiss Securities said.

Regulatory