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ANDAs remain pillar of Indian pharma

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The US Food and Drug Administration (FDA) has approved a record 741 generic drugs so far in the calendar 2018, with Indian pharma companies accounting for nearly 50% of the approvals.

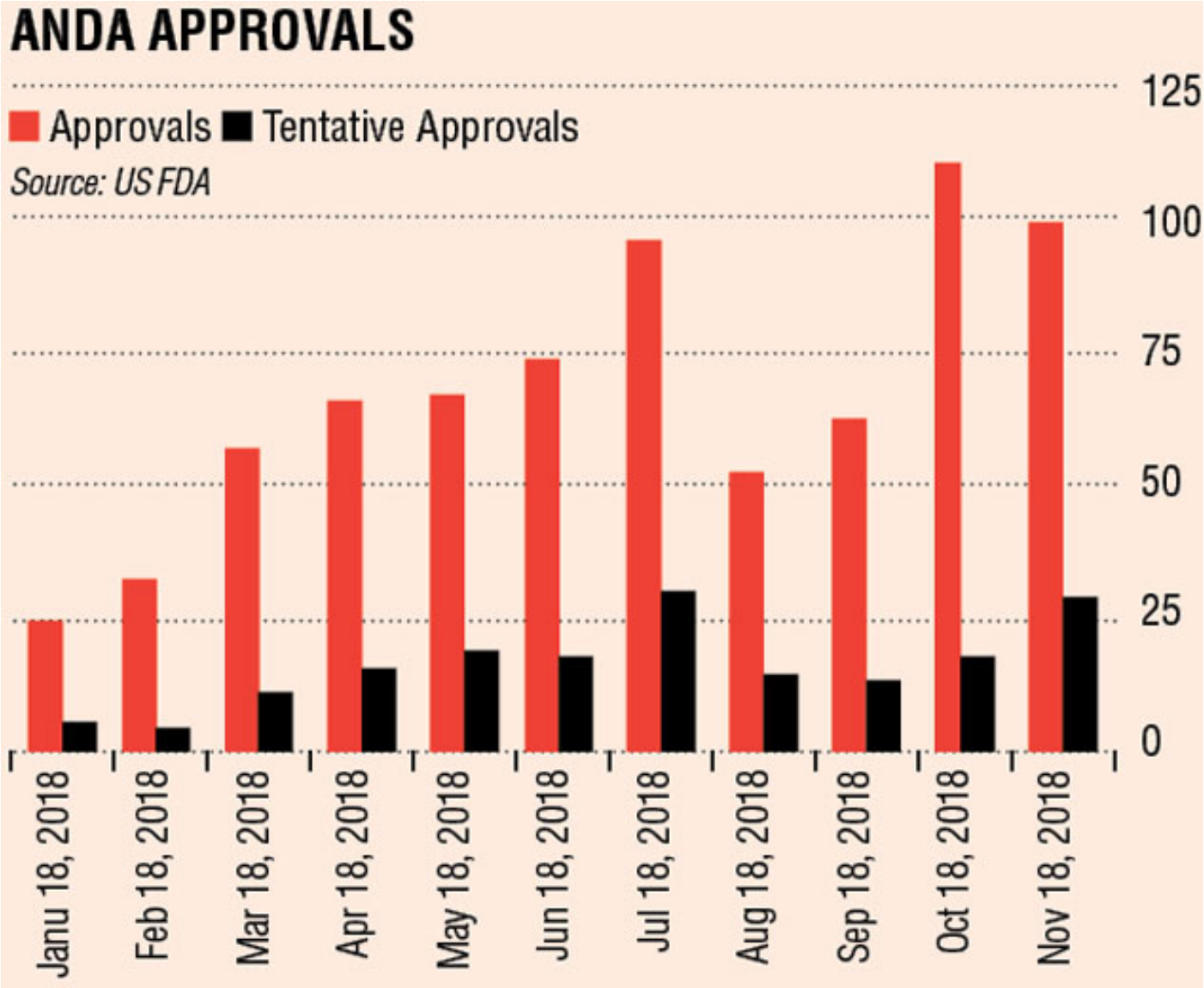
Among the abbreviated new drug applications (ANDAs) filed with the US FDA in 2018, 95 are first-time generic drug approvals and 31 of them were received by Indian companies and their subsidiaries.

Certain ANDAs are deemed "first generic" for the purposes of review prioritisation. A first generic application can be categorised as any received ANDA, which is a first-to-file ANDA eligible for 180-day exclusivity, or for which there are no blocking patents or exclusivities; and for which there is no previously-approved ANDA for the drug product.

According to the latest Activities Report of the Generic Drug Program of the FDA, 741 generic drugs were approved till November 2018 against 740 approvals for the full year of 2017. Till November 2018, the regulator also gave 180 tentative approvals compared with 184 approvals in 2017.

For the fiscal 2017-18, the FDA has approved 781 generic drugs and given tentative approval to 190 such drugs, compared to 763 approvals and 174 tentative approvals in 2016-17. The US follows October to September as fiscal year.

While the US FDA's report did not share country-wise details, an analysis of the monthly company-wise generic drug approvals available on the drug regulator's website indicated that Indian pharma companies received a tota of 415 product approvals in 2018 and 73 tentative approvals. In 2017, a total of 304 approvals were given to Indian companies and 61 tentative approvals.



Among Indian firms, the pace of drug approvals was strong for Aurobindo Pharma Ltd, Cadila Healthcare Ltd, Lupin Ltd and Cipla Ltd.

Total filings of ANDAs for generic drugs with the US FDA, however, dropped to 1,044 in 2017-18 from 1,306 a year ago, as per the regulator's report. For calender year 2018, 935 ANDA filings were submitted as against 1,128 such filings for the full year 2017.

According to a November 2018 research report on the Indian pharmaceutical sector by Nishith Desai Associates, domestic manufacturers are looking to tap into the international generic market with high margins. The ANDAs by the US FDA is increasing every year.

The report, however, added that the industry is witnessing a paradigm shift as the focus is shifting from the manufacturing of generic drugs to drug discovery and development (Sun Pharma, Cadilla Healthcare and Piramal Life Sciences have applied for conducting clinical trials on for numerous new drugs). Recently, Lupin has also partnered with US-based AbbVie Inc for a "first in class" drug discovery programme for blood cancer treatment.

Edelweiss Securities in its latest report said that a large chunk of incremental investments by Indian pharmaceutical companies has been in complex and specialty drugs. The sector's R&D spends have more than doubled over FY14-18 to $1.6 billion per annum coupled with $15 billion cumulative investments, which have mor than doubled the gross block. However, these investments will take some more years to fructify.

However, the report also said that the natural pace of evolution for generic pharma companies, which thus far relied on expanding geographical presence and product basket, will not translate into sustained profitable

growth.

Over the next five years, the nature of the challenges will shift from pricing pressure and soaring investments to changing opportunity mix wherein biologics and complex chemistry will constitute 65% (35% now) of the overall pie.

Going forward, only companies with the ability to adapt fast, milk past investments and transform business models with changing landscapes will endure.

On the earnings front, more consensus downgrades are in store and the sector still trades at a 45% premium to the Nifty, the Edelweiss report said.