

Pharma cos get 113 ANDAs approval from US FDA in Jan-Sept

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MAJOR Indian pharmaceutical companies and their subsidiaries have set to get higher Abbreviated New Drug Application (ANDAs) approvals during 2015 with rising investment in research and development. Indian companies already secured final approvals for 113 ANDAs from US FDA during the first nine months ended September 2015 and 32 tentative approvals. This worked out to over 30 per cent of the total approvals by US FDA. The US FDA has approved total 372 final ANDAs during January-September 2015 and

102 tentative ANDAs.

The overall approval rate of US FDA during 2015 will be higher as compared to full year 2014. In 2014, it approved 416 ANDAs of which Indian companies secured 122 final ANDA approvals.

Aurobindo Pharma and Lupin received highest number of 21 ANDA approvals each during the first nine months ended September 2015, followed by 8 ANDA approvals each by Alembic Pharmaceuticals, Glenmark Pharmaceuticals and Hetero Laboratories. Jubilant Life Sciences, Macleods Pharma and Sun Pharmaceuticals grabbed 6 ANDA approvals each during first nine months of 2015. Torrent Pharmaceuticals and Orchid Chemicals and Pharma-

ceuticals got 4 and 5 ANDA approvals each.

The higher approvals shows that Indian companies are well set to stepped up their presence in the highly regulated market like US, Europe and also in emerging markets by offering new generic products. Patent expiration in coming years may generate higher demand for these products.

Aurobindo Pharma, which secured approval for 21 ANDAs between January-September 2015, has incurred an R&D expenditure of Rs.359.88 crore during the year ended March 2015 as against Rs.270.80 crore in the previous year. The company has filed 192 DMFs and 376 ANDAs with the US FDA upto March 2015 and it received 193

ANDA approvals and 183 ANDA approvals are awaiting.

Lupin's R&D expenditure moved up by 16.7 per cent to Rs.1,118.54 crore during the year ended March 2015 from Rs.958.28 crore in the previous year. It filed 18 ANDAs for the US market during 2014-15 and its cumulative total reached at 210 ANDAs. Currently it has 99 ANDAs pending for approval. It has 15 exclusive first-to-file ANDAs addressing a market size of US\$ 2.5 billion. It also filed 435 patent applications including 97 new inventions taking the cumulative total of 2,197 patents filed.

Sun Pharmaceutical, after acquisition of Ranbaxy Laboratories, pushed its consolidated R&D expenditure at Rs.1,955 crore during the fiscal year

ended March 2015 as compared to Rs.1,042 crore in the previous year. Its five major R&D centres are located in India, Israel, Canada and USA and strengthening the speciality pipeline including patented products and complex generics. Sun's cumulative filings of ANDAs reached at 597 and it received cumulative approvals for 438 ANDAs till March 2015. The company and Taro Pharma received final approval for 8 ANDAs during January-September 2015 and 2 tentative approvals.

Besides above pharma majors, Ajanta Pharma, Dr Reddy's Laboratories, Emcure Pharma, Granules India, Natco Pharma, Strides Arcolab, Wockhardt, Zydus Pharma received approvals for ANDAs. ◆