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Indian pharma companies obtains 144 ANDA approvals from US FDA in 2011

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Research based Indian pharma companies are set to capture a major share of the US domestic market with increasing number of filing of Abbreviated New Drugs Applications (ANDAs). During 2011, 28 Indian companies and their subsidiaries or joint ventures have grabbed 144 ANDA approvals from US FDA and 49 tentative approvals. The US FDA approved a total 431 ANDAs and 117 tentative approvals during 2011. Thus Indian companies obtained over 33 per cent of US FDA approvals in 2011.

The US FDA has approved total 2,244 ANDAs during last five years from 2007 to 2011, of which Indian companies received final approval for 694 ANDAs. This worked out to 31 per cent of total approvals. Similarly during the same period aggregate tentative approvals reached at 518 and Indian companies secured 200 tentative approvals, around 39 per cent of total tentative approvals. The approval rate is falling continuously during the year 2007 to 2010 and improved marginally during 2011. In 2007, US FDA approved 492 ANDAs which declined to 483, 419 and 418 during 2008, 2009 and 2010 respectively. However, there was small recovery in approval in 2011 which stood at 431 ANDAs.

Sun Pharma, a Rs.5,700 crore plus Vadodara based pharma giant, and its Israel based newly acquired Taro Pharmaceuticals, have received total 19 ANDA approvals from US FDA during 2011. Sun Pharma received 14 approvals and Taro Pharma got 5 approvals. Similarly, Strides Arcolab and its subsidiary Onco Therapies received total 18 approvals, of which Onco Therapies received 10 approvals. This was followed by Aurobindo Pharma, a Hyderabad based Rs.4,375 crore plus pharma giant, with 16 approvals, Dr Reddy's Laboratories 14, Glenmark Pharma 12 and Lupin 11 approvals during 2011. Further, Torrent Pharma, Zydus Pharma and Wockhardt got approval for 9, 7 and 6 ANDAs respectively.

Dr Reddy's Labs (DRL) secured 10 tentative ANDAs approvals during 2011. DRL launched 28 new generic products and filed 17 new product registration and 11 DMFs globally. It received final approval of its olanzapine 20 mg tablets,the generic version of Eli Lilly's Zyprexa from the US FDA. As at the end of September the cumulative ANDA filings reached at 177 and a total of 76 ANDAs are pending for approval with the US FDA. Its research and development (R&D) expenditure for the quarter touched to Rs.145.94 crore as compared to Rs.126.98 crore, a growth of 14.9 per cent.

DRL's revenues from North America improved by 43.2 per cent to Rs.630 crore from Rs.440 crore in second quarter ended September 2011. The growth is led by new product launches in the last twelve months and market share improvement in key products. It launched five new products

in US, including limited competition products such as fondaparinux and fexofenadine pseudoephedrine D24 OTC.

Sun Pharma filed 5 ANDAs and its cumulative total reached at 388 products. It received US FDA approval for 6 products during the quarter ended September 2011 taking the total number of approvals to 238 and 150 product are awaiting approval. It filed cumulative 210 DMF/CEP application, with 138 approved so far. The total number of patent applications submitted up to the end of September 2011 stands at 551 with 254 patents granted so far.

Aurobindo Pharma's R&D expenditure during the year ended March 2011 increased by almost 71 per cent to Rs.173 crore from Rs.101 crore in the previous year. This reflected in its final approvals of ANDAs from US FDA. Aurobindo now has a total of 139 ANDA approvals (110 Final approvals and 29 Tentative approvals) from US FDA. It received final approval from the US FDA to manufacture and market gabapentin tablets USP 600mg and 800mg during October 2011.

Glenmark Generics, a US based subsidiary of Glenmark Pharmaceutical, received 12 approvals during 2011 from US FDA and two tentative approvals. As at the end of September 2011, Glenmark’s portfolio consists of 73 products authorized for distribution in the US marketplace. The Company has over 40 ANDA’s pending approval with the US FDA. In addition to these internal filings, GGI continues to identify and explore external development partnerships to supplement and accelerate the growth of the existing pipeline and portfolio.

The R&D expenditure of Pharmabiz sample of 30 leading companies went up by 18.7 per cent to Rs.3,770 crore during 2010-11 from Rs.3,177 crore in the previous year which is assisting these companies to file more and more ANDAs in the highly regulated markets like US, Europe and Japan. Dr Reddy's Laboratories has incurred highest R&D expenditure during 2010-11 and the same was increased by 52 per cent to Rs.592 crore followed by Lupin at Rs.530 crore, Ranbaxy Laboratories' R&D spending touched to Rs.498 crore and that of Cadila Healthcare reached at Rs.302 crore. With higher investments in R&D, the Indian pharma companies are set to launch several new products in highly regulated markets and prepared strong product pipeline to overcome stiff competition.