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Indian pharma cos secure approval for 88 ANDAs from US FDA in first half of 2012

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The investments in R&D is yielding better results for the Indian pharmaceutical companies and their subsidiaries with higher approvals for ANDAs despite existing stringent approvals norms of US FDA. Indian companies managed to get 88 ANDA approvals from US FDA during the first half ended June 2012 which worked out to 41.1 per cent of the total approvals of 214 ANDAs. During first half of 2011, US FDA approved a total 238 ANDAs, out of which Indian companies received 88 final approvals.

Further, Indian pharma companies obtained 21 tentative approvals during January-June 2012 from US FDA as against 19 in the corresponding period of last year. The total tentative approvals were 49 during the first half of 2012 as compared to 50 in the last period.

Sun Pharma and its subsidiaries, including Taro Pharmaceuticals, received highest final ANDA approvals for 12 products during the first half of 2012. Aurobindo Pharma, Dr Reddy's Laboratories and Strides Arcolab got 9 final approvals each. During 2011, US FDA approved 431 ANDAs, out of which Indian companies grabbed 144 final approvals.

Similarly, in the tentative approval segment, Cipla received five tentative approvals followed by Micro Labs three ANDAs and Hetero Labs Ltd, Lupin, Mylan Laboratories, Sun Pharmaceutical and Torrent Pharma two approvals each. The total tentative approvals were 49 during the first half. US FDA issued 117 tentative approvals during year ended December 2011, out of which Indian companies captured 49 approvals.

The growth in approvals is mainly due to investment in R&D activities by major companies. Sun Pharmaceuticals' R&D expenditure for the year ended March 2012 went up to Rs.440 crore, equivalent to 5.5 per cent of sales. The company and its subsidiary Taro Pharmaceuticals filed cumulative ANDAs for 397 products upto end of March 2012 and it received total approvals for 250 ANDAs. As at the end of March 2012, ANDAs for 147 products awaits US FDA approval, including 19 tentative approvals.

DRL's R&D expenditure increased by 16.8 per cent to Rs.591 crore during the year ended March 2012 from Rs.506 crore in the previous year. Its generic revenue from North America went up by 62 per cent to Rs.3,190 crore on account of new product launches of ziprasidone, fondaparinux, amoxicillin clavulanic acid, products from Shreveport facility and market share expansion in existing products of lansoprazole and omeprazole Mg OTC. DRL launched 16 new products in North America and it filed 17 ANDAs during 2011-12 Cumulatively it has 80 ANDAs pending for approval with US FDA.

Aurobindo Pharma received 9 approvals from US FDA during the first half ended June 2012. It filed 30 ANDAs in USA during the year ended March 2012 and its cumulative filings reached at 239. Lupin's R&D expenditure increased to Rs.523 crore during the year ended March 2012 from Rs.483 crore, a growth of 8.3 per cent. It filed 25 ANDAs during the year and its cumulative ANDA filings with the US FDA rose to 173 with the company having received 64 approvals.

Ranbaxy Laboratories, a Rs.9,958 crore leading pharma major, has received two ANDA approvals for Pantoprazole sodium and morphine sulfate during the first half ended June 2012. The company posted strong financial performance during the first quarter ended March 2012 on account of launch of Atorvastatin and Amlodipine in US and other markets, strengthening of Rupee against US Dollar, foreign exchange gains and resumption of exports to the USA from its Indian facility. However, the company cut down its R&D expenditure during the year ended December 2012 to Rs.470 crore from Rs.498 crore in the previous year.

Strides Arcolab's Agila Specialties division commercialized 9 products in US during first quarter ended March 2012. Agila will continue to focus on expanding regulatory filings in established markets like Canada, Australia and Europe, while pharma would focus on niche US product filings. Agila filed 5 ANDAs during first quarter and its cumulative ANDA filings reached at 152. It received 9 ANDA approvals during first quarter and cumulative ANDA approval worked out to 70 including 4 tentative approvals. The cumulative ANDA filed by its pharma division reached at 39 as at the end of March 2012. The company's R&D expenditure during the year ended December 2011 increased to Rs.104 crore from Rs.74 crore in the previous year.

Glenmark Pharmaceuticals and its US based subsidiary Glenmark Generics Inc., continued to maintained the product filing in highly regulated market. In the FY12, Glenmark was granted approval of 14 ANDAs. These were mainly in the niche and high entry barrier segments of dermatology, oral contraceptives, modified release categories. It filed 12 ANDAs during FY'12. Its portfolio as at the end of March 2012 consists of 80 products authorized for distribution in the US marketplace and 38 ANDAs pending approval with the US FDA.

Indian companies are stepping up investment in R&D during last couple of years to grab more market share in the highly regulated markets like US, Europe and Japan. The higher number of approvals from highly regulated markets will help to spread market presence in the lucrative markets and it will help to en-cash upcoming opportunities with the expiration of patents.