

Smaller rivals give US-bound drug majors a scare

DMF Filings By Matrix, Lupin, Cadilla Exceed Those By Ranbaxy, Cipla & Dr Reddy's; Chinese Firms Also In Reckoning

Javed Sayed

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THE US bulk drug market is undergoing a churn. The share of the big three — Ranbaxy, Dr Reddy's, and Cipla — in the DMFs (drug master files) filed by Indian pharma companies with the US Food and Drug Administration (FDA) is falling as smaller companies such as Matrix and Aurobindo have stepped up their filings. Drug Master Files contain information on the processes and facilities used in drug manufacture and storage and are submitted to the FDA for examination.

While India is the global leader in DMF filings and accounts for more than 35% of the DMFs filed, competition from China is gathering momentum. Ghinese fil-

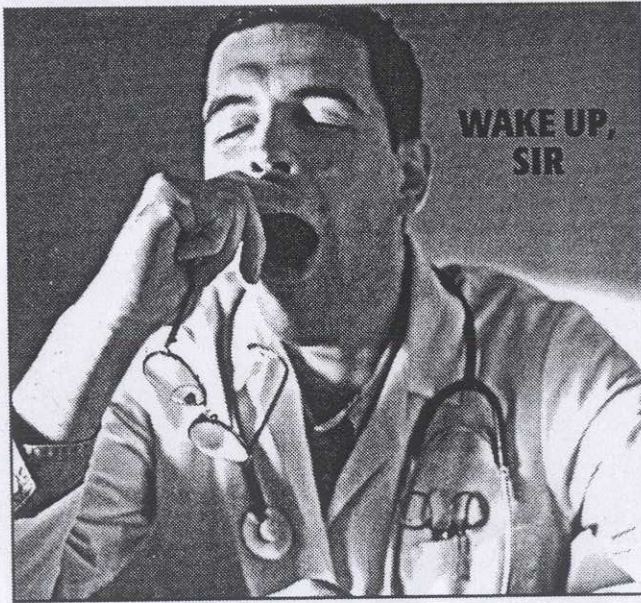
ings in the first two quarters of 2005 have risen to 46 from 15 in the previous two quarters, still much less than India's 152 filings during the same period, but nevertheless comparable with India's tally two years ago.

Moreover, out of the 21 DMFs filed by Chinese companies in the second quarter, 10 have an overlap with Indian APIs (active pharmaceutical ingredients).

In the second quarter of 2005, Indian pharma companies have filed 76 DMFs, and this follows 75 filings in the first quarter.

The staggering growth in the number of filings can be gauged by the fact that for the full year of 2002, domestic companies filed 77 DMFs and as late as the first quarter of 2004, they were averaging around 35 filings a quarter.

This growth is being driven by new entrants such as Matrix,



Lupin, Aurobindo, and Cadilla who have significantly stepped up their filings. Matrix and Aurobindo were two of the three largest DMF filers from India in the second quarter. The gap between the traditional incumbents, Ranbaxy, Cipla, and Dr Reddy's, and the recent entrants is narrowing.

While in the first quarter of 2004, the "big three" accounted for 40% of India's total filings, this number has come down to 15% in the last quarter. "The new entrants are catching up with the incumbents much faster than we thought," says a CLSA report.

The largest filer in second quarter '05 was Matrix (12 DMFs) followed by Dr Reddy's (9), and Aurobindo (7). Interestingly, Cipla filed only two DMFs, and Ranbaxy made no filings at all during this period.

Even as the balance of power shifts within the Indian API industry, competition from China is gathering steam. Against the 7-8 DMFs that Chinese companies filed in the previous quarters, they filed 21 in Q2 '05 and 25 in Q1 '05.

But what will possibly concern Indian drug makers more is the fact that in 10 cases, the Chinese API will be in competition with the Indian variant. For instance, a Chinese company has filed a DMF for simvastatin and has entered into an API supply agreement with Synthron.

This could impact Indian pharma companies such as Biocon, Lupin, and Glenmark which also manufacture simvastatin and expect to benefit from it.

According to CLSA, Chinese players taking away a large marketshare can jeopardise the prospects of Indian firms.