

Desi companies see big biz in competitive generics

Target New US Opportunity Amid Tough Mkt

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Mumbai: Faced with pricing pressures and a challenging generics market environment in the US, domestic companies like Zydus Cadila, Dr Reddy's, Aurobindo and Glenmark are eyeing a multi-million opportunity in a relatively new field — competitive generics — to shore up profits in the world's most lucrative market.

The opportunity for domestic companies could cumulatively fetch up to a billion dollars in sales over the next few years and includes complex generics across therapies, which are challenging to develop or get approved by the US regulator. Examples include insulin, asthma control medication and hormonal medicines.

competitive generic therapy (CGT) relates to complex drugs that are hard to copy because of their complex formulation or mode of delivery, and have limited or no generic competition in the US. At present, Glenmark, Torrent and Strides have reportedly got approvals for drugs under the CGT pathway.

Domestic generic companies are keen to focus on this opportunity due to high margins and as an additional segment to grab market share. There may be over 70 potential CGT opportunities where there is only one generic approved and selling in the US. This would be attractive for smaller firms, while larger companies may target those with high complexity, faster approval and 180-day market exclusivity analysis.

In 2017, the USFDA — as part of its efforts to increase availability of generic drugs in the country and bring down overall healthcare costs — issued guidance under CGT. It states that generic competition for that drug, or if

there was not more than one approved drug.

In August 2018, the USFDA approved several strengths of a potassium chloride oral solution as the first CGT, with the permission being granted to Apotex. The USFDA designed this process with a strict agenda to assist the industry in filing and approving drugs in limited competition areas quickly. From three abbreviated new drug applications (ANDAs) filed under CGT at the start of the programme in October-December 2017, the number has now grown to 45 pending approvals globally.

In December last year, Glenmark obtained CGT approval of the generic version of Westcort olumvent, with 180 days of exclusivity upon commercialisation, and a potential to mop up about \$15 million in sales. Torrent recently obtained CGT designation on two products, though nature of the products are undisclosed, and Strides announced two CGT products with potential exclusivity (sales of the two products amounted to \$50 million

in the US, according to market research firm IQVIA).

Real wins under CGT may be only in very complex products — sales could be small but margins are high. "Only a handful (CGTs) have sizeable value to make it attractive for large generics. Smaller companies may file some of these 70-odd products, which may not cost much," an analyst from DSP Merrill Lynch said in a note. The US regulator has drawn up a huge list of drugs that includes formulations, olonimons, injectables and powders classified under the CGT pathway.

Glenmark Pharmaceuticals chairman and MD Glenn Saldanha said, "We are keenly exploring opportunities to get approval under CGT. The FDA has provided another window of opportunity for generic players and we must take upon us the challenge to launch products where there is limited or no generic competition."

An executive from Aurobindo confirmed the company had applied, but declined to give specifics at this stage.

Jet Airways grounds 4 more planes

Mumbai: The financially-stressed Jet Airways on Tuesday said it has grounded another four of its aircraft due to non-payment of lease rentals.

With this, the total number of aircraft taken out of operations due to severe liquidity crunch in the airline and its subsequent failure to pay rentals to various lessors now stand at 32.

However, Jet Airways chairman, in a letter to the airline's equity partner Etihad Airways' CEO Tony Douglas last week said that more than 50 aircraft are grounded.

"As you are no doubt aware, Jet Airways is in a very precarious position, with more than 50 aircraft grounded and increasing arrears of vendors and salaries, which makes the need for interim funding all the more imperative," Goyal said in his letter on March 8.

Jet Airways, in the filing on Tuesday, also said that it is making all efforts to minimise disruption to its network due to the grounding of these planes. AGENCIES

Sensex surps over 481 points on global cues

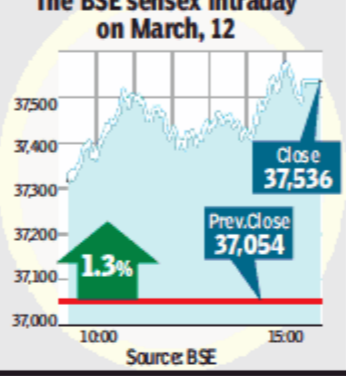
Mumbai: The Sensex on Tuesday rallied over 481 points, riding on a host of positive factors like sustained foreign fund inflows, stronger rupee and chances of the incumbent NDA government returning for a second term. Besides, gains in global equity markets also had its impact on domestic bourses.

The 30-share BSE gauge settled 482 points, or 1.3%, higher at 37,536. The broader NSE Nifty reclaimed the psychological 11,300-level and closed with gains of 133 points, or 1.2%, at 11,301.

In the Sensex pack, Bharat Airtel was the top performer, surging nearly 5%. Other gainers included ICI Bank, IndusInd Bank, L&T, Sun Pharma, RIL, HDFC Ltd, Tata Motors and M&M — climbing up to 3.7%.

Bucking the overall trend, Bajaj Finance, ONGC, NTPC, Coal India, Yes Bank, Bajaj Auto, SBI and Hero MotoCorp fell as much as 1%. IT stocks too came under pressure amid the

IN HIGH SPIRITS



strengthening rupee. Meanwhile, Tech Mahindra and MindTree falling up to 1.2%.

In a constant boost for investor sentiment, the rupee closed with 18 paise gains at 69.71 against the dollar on Tuesday.

Sectorally, the BSE realty index topped the gainers chart, surging 2.6%, followed by telecom, bank, healthcare and finance indices. In March, the Sensex has so far rallied 1,668 points, while the Nifty soared 508 points. The 30-share index has gained 864 points in

the past two sessions, while the broader NSE gauge added 266 points.

Analysts said that the much awaited flows of money from the foreign institutional investors (FIIs) seem to have started at least for the time being, which is a prominent factor leading to this pre-election rally.

The Lok Sabha elections will begin on April 11 and will be held over seven phases followed by counting of votes on May 23.

On a net basis, foreign institutional investors (FIIs) bought shares worth a net of Rs 3.811 crore on Monday, provisional data available with the BSE showed.

Meanwhile, the market breadth on Tuesday was tilted in favour of buyers as 1,653 stocks advanced and 1,067 declined. "Market continued the bullish rally as the investors are expecting the formation of a stable government at the Centre," Vinod Nair, head of research, Gejfit Financial Services, said. AGENCIES

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