

Indian drug makers gasp with relief as US regulator relaxes inhaler norms



THE US INHALER MARKET

Total US inhaler market pegged at around \$23 billion
Total market for GSK's Advair pegged at around \$8 billion

Advair is the world's third-best selling drug, used for asthma and chronic obstructive pulmonary disorder

While the patent on Advair expired in 2010 in the US, a separate patent on the Diskus (the device for inhaling the medicine) remains in force till 2016

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Indian drug makers are eager to enter the generic inhaler combination business in the US after the drug regulator there eased guidelines for cheaper alternatives to GlaxoSmithKline (GSK)'s blockbuster respiratory drug, Advair.

Even as pharmaceutical giants Lupin, Sun Pharma and Cipla are preparing plans to launch their generics in the US, Glenmark has already launched its Advair generic in emerging markets.

Advair, an inhaled medicine for asthma and chronic obstructive pulmonary disorder,

is the world's third-best selling drug, with a revenue of \$8 billion last year. It currently accounts for a fifth of Glaxo's annual sales. Sector officials say the US alone accounts for \$5 billion a year, while Europe and emerging markets together clock \$2 billion. In India and some other emerging countries, GSK markets the drug under the Seretide brand.

In September 2013, the US Food and Drug Administration revised guidelines for generic drug makers to launch Advair. Under the new norms, long and expensive human tests are not required. Subsequently,

Indian companies have expedited their processes and procedures to seek approval in the US. For instance, Glenmark recently received approval for generic version of the drug in Mexico and the Philippines.

Glenmark and Lupin have also set up research and development (R&D) teams and facilities for inhalers. "The inhaler opportunity is significant and also challenging due to the difficult regulatory pathway even in emerging markets. Being an R&D-driven organisation, we are glad we have been able to raise the bar and get approval in two key emerging markets," said

Glenn Saldanha, chairman and managing director, Glenmark. The company is seeking approval for the Advair generic in 12 other countries, including Russia and Brazil.

Lupin spokesperson Shamsheer Gorwarra said the company had outlined plans to set up a dedicated research facility in the US to begin work on inhalers there. In 2013, the company appointed Xian-Ming Zeng as senior vice-president of research for the purpose. Xian-Ming joined Lupin from Israeli drug maker Teva.

Most Indian drug makers, including Cipla and Ranbaxy, sell the generic version of GSK's drug in the country. However, because of patent protection and lack of clear-cut guidelines in the US until now, they were unable to enter the segment in the world's largest drug market. "With the latest norms in place, there is a huge avenue opening up for Indian drug makers who already have technology to develop a low-cost version of the drug," said an industry analyst.

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Under the new norms, the US Food and Drug Administration does not require generic drug makers to conduct long and expensive human tests for GSK's Advair Inhaler. PHOTO: REUTERS

Regulatory