



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### Innovation has helped drug firms take on Big Pharma

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India has also emerged a leader in novel drug delivery systems and custom synthesis of new molecules

In November, India's largest drug maker by revenue, Ranbaxy Laboratories Ltd, introduced the generic version of GlaxoSmithKline Plc's (GSK) skin medicine Valtrex (valacyclovir) in the US market. Ranbaxy had a 180-day marketing exclusivity for the generic. Before its exclusivity ended, Ranbaxy achieved a record 74% market share. Piggy-backing on the more-than-expected sales, Ranbaxy's holding company Daiichi Sankyo Co. Ltd, recently revised its earnings forecasts upwards.

Reverse-engineering has been one of the greatest boons to the Indian pharmaceutical industry and is a form of innovation that Indian pharma has mastered. But the story of Indian pharma doesn't end at developing and manufacturing generic versions of branded or patented drugs. In fact, that is where it starts. Its strength in generic manufacturing also gave India the confidence to challenge patents of some of the world's largest pharmaceutical companies. To add to that, India has fast become the hub of research and development outsourcing. It has emerged a leader in novel drug delivery systems, custom synthesis of new molecules, and much of the work done by Indian contract research and manufacturing firms is being patented by MNC (multinational corporation) pharmas.

Until 1998, India had no medicine exports to regulated markets. Today, over 40% of its \$8 billion (Rs. 37,360 crore) exports is to North America and western Europe alone.

According to government statistics, pharma exports were worth Rs. 39,538 crore in 2008-09, growing at a combined annual growth rate of 21.25%. It also accounts for 1,735 drug master files (DMF) according to 2008 US food and drug administration (FDA) data, as against 1,054 from US domestic companies and more than the combined total of European and Japanese companies. In 1998, India filed only three abbreviated new drug applications (ANDAs). In 2009, it filed 181 ANDAs.

"The understanding of market dynamics and adapting to them quickly is a huge strength that India has. This is illustrated in the number of DMF filings alone that Indian pharma has with the US drugs regulator," says Satish Reddy, managing director and chief operating officer, Dr Reddy's Laboratories Ltd.

As per to the investment and technology promotion division of the ministry of external affairs, during 2009-10, pharma was among the few sectors that managed to expand revenue despite the global slump. "The Indian pharmaceutical industry's strengths in the global market are the safe, effective and quality medicines (it provides) at affordable prices," says D.G. Shah, secretary general of the **Indian Pharmaceutical Alliance**. He adds that the pharma industry has a presence in 150 markets, which is more than any other industry in India.

According to the consultancy **KPMG**, from practically non-existent indigenous drug production before the 1950s, the domestic pharma market now ranks fourth in volume terms globally. The market is currently valued at approximately \$21.4 billion and is expected to grow at a CAGR (compound annual growth rate) of about 18% till 2013-2014. "The Indian pharma industry has emerged as one of the most attractive markets as its growth continues to outperform that of the global industry and particularly developed markets such as the US and the EU," says Hitesh Gajaria, executive director, KPMG. A major turning point came in 2005, when India adopted the product patent regime, opening up the market for foreign firms. The move spurred growth in the domestic industry and paved the way for greater regulatory compliance as well as battle for intellectual property within the country. Today, with the pharmaceutical world inching closer to the dreaded patent cliff, Indian pharma has been the saviour for Big Pharma. Sixty-one drugs worth an estimated \$80 billion will go off patent in the US between 2011 and 2013. That is the value of money that Indian generic manufacturers stand to gain.

"With large drug makers facing the approaching patent cliff as major products lose patent protection and face competition from generic versions, many are forging alliances with Indian generic drug makers to capture market share in developed and emerging markets," said Anantharaman Kavassery Viswanathan, principal analyst, healthcare, Datamonitor. In the last two years, India has witnessed strategic alliances between GSK and Dr. Reddy's Laboratories Ltd, Pfizer Inc. and Aurobindo Pharma Ltd, Strides Arcolab Ltd and Claris Lifesciences Ltd, AstraZeneca Plc. and Torrent Pharmaceuticals Ltd and Aurobindo Pharma Ltd and Abbott Laboratories and Cadila Healthcare Ltd, to name a few.

"Generic manufacturing is an area where India has been able to establish a firm foothold. With a market share of 31% in the total ANDA approvals and estimated 50% in the total DMF filings in 2009, India is likely to continue holding a dominant position here," explains Gajaria.

Despite its obvious success in capturing the global generics market through innovation, as well as emerging as a strong hub for contract research and manufacturing, Indian pharma has not had much luck in commercializing a new chemical entity (NCE). Till date there has been no drug discovered by an Indian company that has hit the markets.

Indian companies began investing in NCE research in 1998. Industry watchers believe that a span of 12 years is too short to judge success or failure. "It takes seasoned players 10 to 12 years to get a molecule from lab to market. Give them (Indian pharma) at least 20 years and required funding support before sitting in judgement," says Shah.

The industry's R&D spend increased 17-fold in 11 years—from Rs. 140 crore in 1995 to Rs. 2,380 crore in 2006. However, this amount pales in comparison with the billion-dollar investment needed to complete studies and reach commercialization for a single molecule. Indian pharma doesn't have the financial muscle to develop such drugs, which is why companies such as Glenmark Pharmaceuticals Ltd rely on out-licensing of molecules to fund their research pipeline. "This is a long-term story in terms of value creation. There have been capabilities built in this space but for it to translate into a revenue model will take time. The challenge is not discovery, it is about the number of products that move to phase 3 and finally make it to the market," says Reddy. He admits that while the good thing is that there are candidates coming in, the risk in research is a hurdle.

"New drug discovery and development has not reached its full potential in India. However, the number of compounds in the Indian pipeline and in the advanced stages of development is also increasing. It is therefore not appropriate to say that India has failed in NCE innovation," says Gajaria.

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