

## The Pharma story

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India's first pharmaceutical company, Bengal Chemicals and Pharmaceutical Works, came up in Kolkata in 1930. But bulk of the drugs were imported. The pharma industry came into existence in the 1970s, thanks to a government policy initiative. A decision to amend the Indian Patents Act, 1970 in 1971, which disallowed product patents in pharma and agrochemicals and instead grant five-year patents to processes spurred Indian entrepreneurship in the pharma sector.

The rest is history.

In 35 years, India's pharma industry has scaled several heights. India is today the fourth largest in the world in pharma product volumes. And is ranked thirteenth globally in terms of sales revenues. This ranking is low mainly because the generics-based industry earns roughly one-fortieth of the price of a similar product in the developed market.

A series of government policy interventions spurred entrepreneurship in the pharma sector. The National Drug Policy of 1986 provided a coherent policy framework to encourage the evolution of a domestic pharma industry to make available affordable medicines the citizens.

Subsequently, the policy was revised in 1994, after the economic liberalization started in 1991. This followed the recommendations of the Prime Minister's Advisory Council on Trade and Industry to treat pharma as a knowledge-based industry in which India has a comparative advantage.

The economic liberalization process also initiated some major changes that helped the industry. These were:

- Abolition of industrial licensing to manufacture all drugs and pharmaceuticals except for bulk drugs produced using the recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids and specific cell/tissue targeted formulations.
- Private sector allowed to manufacture five bulk drugs from 1999 which were earlier reserved only for the public sector pharma units
- Automatic approval for foreign direct investment (FDI) increased to 100 percent
- Automatic approval for technology imports for all bulk drugs, intermediaries and formulations, except biotech drugs
- Promotion of R&D by increasing weighted deduction of 150 percent in income tax for R&D investments by companies.

As Indian pharma companies began to establish their presence in the global markets to emerge as key generics manufacturers, policy makers stepped in once again to tweak the policy regime to further boost the industry.

India was expected to switch to the product patent regime when the World Trade Organization (WTO) was set up in 1995. India's government fought hard to get a 10-year 'grace period' to introduce the product patent regime under the TRIPS (Trade Related Intellectual Property Services) guidelines, mainly to prepare the Indian pharma industry for this. The product patent regime came into force in January 2005 after suitable amendments to the Indian Patent Act, 1970. Here too, the incremental innovation definitions adopted by India favors domestic pharma industry.

### National Pharma Policy 2002

In 2002, the pharma policy was further revised to make it more industry-friendly. One of the key initiative was to set up a Pharmaceutical Research and Development Committee, chaired by the Director-General of CSIR. Subsequently, a Drug Development Promotion Fund (DDPF) and a Pharmaceutical Research & Development Support Fund (PRDSF) were set up. These funds get over Rs 200 crore every year from the R&D cess levied on technology imports which are now used to promote drug research and development by companies.

A revised National Pharma Policy which will aim to make available life saving drugs at affordable rates is also in the works now.

- Market share of MNCs in 1970: 70 percent; Market share of MNCs in 2007: 30 percent
- Investments in pharma in 1970: Rs 250 crore; Investments in 2007: Rs 8,000 crore
- Annual industry growth rate in 1970s: 3 percent; Growth rate in 2007: 9 percent
- Today India has the second largest USFDA-approved pharma manufacturing plants outside the US. The last count: 84 in November 2007
- India drug prices are among the lowest in the world
- Indian companies like Serum supply more than half the annual global requirements of pediatric vaccines