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The reform booster shot that transformed India into the pharmacy of the world

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The reform booster shot that transformed India into the pharmacy of the world

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Few industries better illustrate the transformation in the country since the reforms of 1991 than pharmaceuticals.

Today, India supplies medicines to more than 200 countries, accounts for about 20 per cent of global generic medicine supply, contributes roughly 60 percent of global vaccine demand, and hosts the largest number of US Food and Drug Administration (USFDA)-approved manufacturing facilities outside the United States. And, in FY26, India's pharmaceutical exports rose to a record $31.12 billion.

Yet, the journey is also one of paradoxes. India became the world's pharmacy by mastering reverse engineering, process chemistry, affordable manufacturing and generics. Despite its scale and global reach, though, it has produced relatively few breakthrough drugs of its own.

35 years of liberalisation

Indeed, the pharma industry's transformation over the past 35 years of economic liberalisation is not just a tale of exports and market share, it is one of scientific ingenuity and entrepreneurial ambition reshaping a largely domestic business into a global healthcare force.

Product to process patents

The foundations of the sector's transformation were laid long before 1991.

In an interview at the Harvard Business School, Cipla's Non-Executive Chairman Yusuf Hamied, who turned 90 recently, recalled how Indian pharmaceutical companies spent years pushing for changes in the country's patent framework. It had argued that the prevailing system constrained domestic industry.

The eventual shift in India's patent regime, from product to process patents, created the conditions for local companies to develop expertise in process chemistry and affordable drug manufacturing.

That shift proved transformational.

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The reform dose that transformed India pharma

35 years of liberalisation

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Nilaya Varma, co-founder and CEO of public-policy and management consulting firm Primus Partners, describes the 1970 Patents Act as one of the most important policies that aided Indian pharma's rise. The law enabled domestic companies to master reverse engineering and process chemistry at a time when the market was dominated by multinational drugmakers. It would eventually help create one of the world's most competitive generic-drug industries.

Economic historian Chinmay Tumbe has described the Indian pharma industry's rise as being underpinned by "technocratic entrepreneurship", where pioneers such as Hamied and K Anji Reddy combined scientific expertise with business ambition.

Speaking at a conference last year, Tumbe argued that while the Patents Act of 1970 created the opportunity, it was first-generation entrepreneurship that made the story distinctive.

Reflecting on the challenges entrepreneurs faced before liberalisation, Anji Reddy has said in his memoir, titled *An Unfinished Agenda*, that he entered an industry that was "woefully short of technology" to manufacture many basic medicines. But Reddy's ambitions extended well beyond generics. In 1993, when most Indian companies were focused on reverse engineering and off-patent drugs, Dr Reddy's launched one of the country's earliest serious drug-discovery programmes.

The company invested heavily in research on new chemical entities and licensed several experimental compounds to multinational companies. Though none of them ultimately became a globally marketed breakthrough medicine, the effort underscored a larger ambition: That Indian pharma should not be content manufacturing affordable drugs, it must discover them. In many ways, that remains the industry's unfinished agenda.

By the time the shackles on Indian industry began to be removed from 1991, the pharma industry already possessed something many other sectors lacked: A domestic manufacturing base, scientific talent and a generation of entrepreneurs capable of competing globally.

Broadened horizon

Before the reforms, most Indian pharmaceutical companies were focused primarily on the domestic market. When the economy opened, those firms invested in creating world-class manufacturing processes, chasing exports and competing in highly regulated markets such as the US and Europe.

Looking back, Nandini Piramal, chairperson of Piramal Pharma, says the biggest change is ambition. "If you think back to the 1980s, we were protected and very focused on our own market. The ambition changed and people realised that they could compete with the best in the world, not just on cost but also on quality," she says. Of course, that shift required a profound cultural transformation. "The kind of manufacturing that we did for the domestic market, in terms of scale, quality and automation, was completely different from what was needed for the West," she adds.

Piramal believes India's advantage today extends beyond low costs. "Cost is important, but it is also scale and quality. The ability to manufacture at scale, at cost and with quality is not easy. And I would add ambition," she says.

After the reforms, the industry effected one of the most remarkable corporate transformations in post-liberalisation India. Companies such as Sun Pharmaceutical Industries, Dr Reddy's, Ranbaxy, Lupin and Aurobindo moved into the world's most tightly regulated pharmaceutical markets. Acquisitions, abbreviated new drug application (ANDA) filings and USFDA approvals became the new markers of success.

Few events symbolised that transformation better than Sun Pharma's acquisition of Ranbaxy in 2014. The deal not only created India's largest pharma company, but also marked the coming of age of the industry that had evolved from import substitution to global scale.

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1. Y K Hamied, now the non-executive chairman of Cipla, visiting a facility in Goa in 2002; 2. Dr Reddy's opens a branch in Russia in 1992; 3. Kiran Mazumdar-Shaw at the National Stock Exchange, Mumbai, on the day Biocon went public in 2004

PHOTOS: CIPLA, DR REDDY'S LABORATORIES, AND BIOCON

The generic tryst

The industry's biggest success story, and something it has become synonymous with, is generic drugs.

The combination of chemistry skills, manufacturing capabilities and cost competitiveness created an industry that was primed to pounce on a global opportunity. One such opening came with the US creating a streamlined pathway for generic approvals under the Hatch-Waxman Act of 1984. It allowed companies to challenge patents and launch lower-cost alternatives after exclusivity periods expired.

According to Joydeep Ghosh, partner and industry leader – life sciences and healthcare at Deloitte South Asia, Indian pharma's rise was not the result of a single event. "The real success factor was India's ability to combine policy-enabled opportunity with entrepreneurial execution and scientific talent," he says.

Making it affordable

Beyond generics, the industry also focused on expanding access to medicines. One defining moment came in 2001, when Cipla offered a triple-combination HIV/AIDS therapy for less than $1 a day. It dramatically reduced treatment costs for patients in developing countries and challenged the economics of patented medicines. It also shifted the global debate around access to life-saving drugs and cemented India's reputation as a supplier of affordable healthcare solutions.

Another major turning point came in 2005, when India adopted a product-patent regime under the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement. Many feared that the change would weaken the domestic industry's generics-driven growth model. Instead, Indian companies adapted.

Milind Antani, leader of the pharma and healthcare practice at law firm Nishith Desai Associates, argues that the industry's evolution has been aided not only by patent reforms, but also by a broader shift in the regulatory ecosystem. He points to faster decision-making, better understanding of industry needs, the New Drugs and Clinical Trials Rules and newer research-focused initiatives as important building blocks for the next phase of growth.

The big shifts

- **1970 Patents Act:** Process patents created India's reverse-engineering advantage
- **Post-1991:** Domestic drugmakers moved into the US and Europe
- **US generics push:** Indian drugmakers used patent challenges and low-cost manufacturing to scale rapidly
- **2001 milestone:** Cipla offered HIV therapy for under $1 a day
- **2005 product-patent regime:** India ended process-patent-led copying, pushing drugmakers towards patent-compliant generics and innovation
- **2014 Sun–Ranbaxy deal:** The acquisition created India's largest pharmaceutical company
- **Covid-19:** Serum Institute and Bharat Biotech powered vaccine rollout and global supplies
- **Global footprint:** India supplies 20 per cent of generics and 60 per cent of vaccines
- **FY26 record:** Pharmaceutical exports reached $31.12 billion

The industry's global influence expanded beyond generic medicines.

Alongside, India also saw the rise of vaccine makers like Biological E, Serum Institute of India, Bharat Biotech and others, that turned the country into a critical supplier for immunisation programmes worldwide. In parallel, Biocon, founded by Kiran Mazumdar-Shaw in 1978, helped establish India's biotechnology industry, building capabilities in recombinant insulin, biologics and biosimilars.

The Covid-19 pandemic highlighted the scale of those capabilities. India's vaccine manufacturing network became critical to both domestic and global immunisation efforts.

The innovation imperative

The next phase of growth may prove the most challenging yet.

According to Anuj Sethi, senior director at Crisil Ratings, the industry faces a dual challenge. While dependence on China for key starting materials, intermediates and active pharmaceutical ingredients remains a strategic vulnerability, companies must simultaneously preserve the scale and cash flows generated by generics. They must also migrate towards higher-value segments such as biosimilars, complex injectables, specialty medicines and contract development and manufacturing. Meanwhile, pricing pressure in the US generics market and increasing regulatory scrutiny continue to test profitability.

Varma of Primus Partners argues that the next phase of growth will require stronger emphasis on research and development (R&D), deeper industry-academia collaboration, reduced dependence on imported APIs and complex biologics, and a regulatory system that supports innovation.

That brings into focus the industry's biggest challenge: Innovation.

Indian pharma companies have demonstrated remarkable strength in process innovation, manufacturing excellence, vaccines and biosimilars. However, they have struggled to create a steady pipeline of globally successful novel drugs.

Habil Khorakiwala, chairman of Wockhardt, whose novel antibiotic Zaynich recently received USFDA nod, says India needs to think carefully about how innovation is rewarded. "What is ₹100 crore? You need $100 million, $200 million to get a drug out," he says.

For Ghosh of Deloitte, the industry's next phase will be very different from the past. "India's first pharmaceutical revolution was built on the ability to make medicines affordable, accessible and available at a global scale. The next one is expected to shift from a scale-led generics model to an innovation-led healthcare ecosystem," he says.

More than three decades after liberalisation, Indian pharma has largely achieved what Hamied fought for—affordable medicines at global scale. It has also produced globally competitive companies.

The challenge that remains is the one Anji Reddy pursued decades ago and that Khorakiwala continues to speak of today: Can India become a meaningful source of new medicines, not just a manufacturer?

The answer will determine whether India remains the pharmacy of the world, or becomes one of its laboratories as well.