# How did India reach pharmaceutical self-sufficiency?

The Indian pharmaceuticals market has characteristics that make it unique. First, **branded generics dominate, making up for 70 to 80 per cent of the retail market,** despite the fact that this country is the single largest provider of generic drugs globally. India is **supplying over 50% of global demand** for various vaccines, 40% of generic demand in the United States, 25% of all medicine in United Kingdom and extremely low-cost medicine to African nations. Second, **local players** have enjoyed a **dominant position** driven by formulation development capabilities and early investments. Third, **price levels are low,** driven by intense competition. While India ranks tenth globally in terms of value, it is ranked third in volumes. These characteristics present their own opportunities and challenges.

Under the Pharma vision 2020, the government commitment to make India into a global leader not only in the production of low-cost generic medicines but also end-to-end drug discovery and development. Although a quick observation at the pharma industry points to success and the industry has seen a continued growth, with a **lack of public and private capital available and government tax incentives yet to have much effect, R&D has lagged behind.** While India's pharma industry growth has been impressive, it has fallen short of fulfilling Pharma Vision 2020. There are clear examples where rising competition in pure generics globally has led a number of the top Indian pharma companies to focus on specialty and complex generics, including complex injectables and oral solids, new drug delivery systems and biosimilars. However, true innovation in the shape of an end-to-end drug delivery and development infrastructure is some way off. The human talent and academic system is in place, but R&D numbers need to increase. The Indian Pharmaceutical Alliance (IPA), which submitted its Vision 2030 in July 2019 underlining plans to make India into an innovation leader by building a strong innovation pipeline, has urged the government to set up a large fund to boost technological innovation in pharma, biotech and healthcare startups. But with capital funding missing, it is not likely to change any time soon as the capital intensity and high risks associated with the creation of novel molecules do not bode well in the current domestic and global economic climate.

## India approach towards pharmaceutical self-sufficiency over the years

**1960 - 1970**

- Government effort to encourage drug manufacturing by Indian companies in the early 1960s culminates in **The Patents Act of 1970** which **removed patent protection**

**1990 - 2005**

- India is a major destination for generic drug manufacturing
- **Patent (Amendment) Act 2002** introducing provision of 20 years uniform term of patent
- Approval of **Patents (Amendment) Act 2005** was implemented, which led to **re-adoption of product patents in India.**
- 2005: India has the world's **third-largest API manufacturing industry**

**2010 - 2015**

- Increased patent filing by pharma players
- 2012- 13: **The National Pharmaceutical Pricing Policy** and the Drug Pricing Control Order lead reduction of drug prices by 80%
- 2014: 100% FDI allowed in medical device industry under automatic route
- 2015: India reaches 10,500 manufacturing units and over 3,000 pharma companies
- National Health Policy Draft to increase expenditure in health care

**2016 - 2019**

- Union Budget 2016, FDI increased to 74% in existing pharmaceutical companies.
- **Pharma Vision 2020** aimed at transforming India into a global leader in end-to-end drug manufacturing
- Approval time for new facilities is reduced to boost investments

**2019**

- 2019: Indian Pharmaceutical Alliance (IPA) submits its **Vision 2030** underlining plans to make India into an innovation leader by building a strong innovation pipeline.

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## Growth factors that contributed to the success of India's pharmaceutical industry

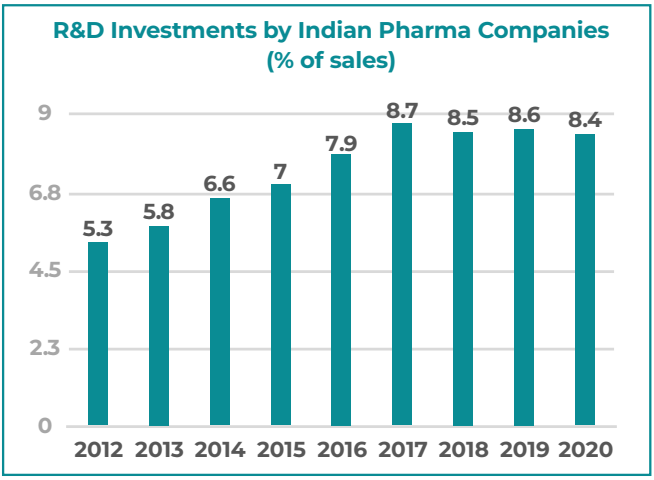
Over the past years, India's pharmaceuticals market has grown in confidence and firmly moved on to an accelerated growth path. This growth is owing to several factors.

### Cost efficiency

- The low cost of production and R&D boosts efficiency of Indian pharma companies considering that the cost of production is approximately 33 per cent lower than that of the US. The country has explored ways to reduce production costs in order to reduce the dependence on imports from China.

### Increasing investment

- An increase in private sector investments in R&D and acquisitions has boosted the pharma market in India (Although the overall growth in R&D has fallen short of the Pharma 2020 vision). In 2017, Indian pharmaceutical sector witnessed **46 merger & acquisition deals** worth US$1.47 billion. Also, the Government of India is supporting industry with tax incentives for R&D. The PTUAS is being implemented to encourage more SMEs to get international approvals.




- **100 per cent FDI** was allowed in this sector up to 2016, which led to many global companies investing in Indian pharma industry. Over 96% of the total FDI in the sector between 2012 and 2013 flowed into brownfield pharma companies. This, however, reduced to 74 per cent in 2016

### Policy support

- Such as needs innovation, partnerships and training, as explained in following section.

### Economic Drivers

- Rising income levels and improved drug affordability
- Increasing penetration of health insurance to drive expenditure on medicine as health insurance penetration is expected to reach 50% (from 34% in Jan 2019), thanks to the National Health Protection Scheme
- Growth in medical infrastructure and increasing penetration of pharmacies, especially in rural India, making OTC drugs readily accessible
- Rise in the prevalence and treatment of chronic diseases, acceptance of biologics and preventive medicine, as well as population growth of around 1.3 per cent every year, resulting in an increase in the patient pool

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## Government has presented various policies over the years to support the local market

The government of India has been promoting this growth by implementing various innovation policy models, such as needs driven innovation, drug regulation and partnerships.

### a) Needs driven innovation

Government promotes needs-driven innovation that protects access by **supporting complementary R&D,** and then makes attempts to **make costs transparent to negotiate a fair price while also guarding the mechanism in the framework of international trade rules.** Government **monitors the innovation profile of the country through estimating its innovation index** which is determined by the number of innovations of new chemical entities. As well as:

- **Biotechnology Industry Research Assistance Council:** BIRAC has been established to promote research & innovation capabilities in India's biotech industry. The council will provide funding to biotech companies for technology & product development. BIRAC under Small Business Innovation Research Initiative (SBIRI) scheme supports innovations in biotechnology.
- **National biopharma mission:** The Industry – Academia mission was launched in June 2017 to boost development of biopharmaceuticals by translating research concepts into viable products.
- **Reduction in approval time for new facilities:** Such as steps taken to reduce approval time for new facilities and NOC for export license issued in two weeks compared to 12 weeks earlier
- **Foreign direct investment:** 100 per cent FDI was allowed in this sector up to 2016, which led to many global companies investing in Indian pharma industry. This, however, reduced to 74 per cent in 2016. Between April 2000 and Dec 2018, Indian drug and pharmaceutical market has received FDI worth USD15 billion.
- **Eliminating pharmaceutical product patent protection** in 1970s encouraging local manufacturing and production. However, since then, India has transitioned to a pharmaceutical product patent production regime

### b) Drug Regulation

- Government maintaining a system of **price controls** on essential medicines.
- Government promoting the concept of the **pharmaceutical cluster,** which provides exemption from import duties for products that are exported, and from local taxes (depending on the state government). The net benefit from producing in a cluster from a tax standpoint is about 14% (the ordinary 34% corporate rate is reduced to 20%).
- A compulsory license to a patented pharmaceutical product.

### c) Partnership

- Increasing **private sector investments in R&D** and acquisitions, where in FY18, Indian pharma companies invested 8.8 per cent of their sales in R&D.
- In 2017, Indian pharmaceutical sector witnessed **46 merger & acquisition deals** worth US$ 1.47 billion.
- Between 2008-18, the S&P BSE Healthcare Index has grown at 16.72 per cent.

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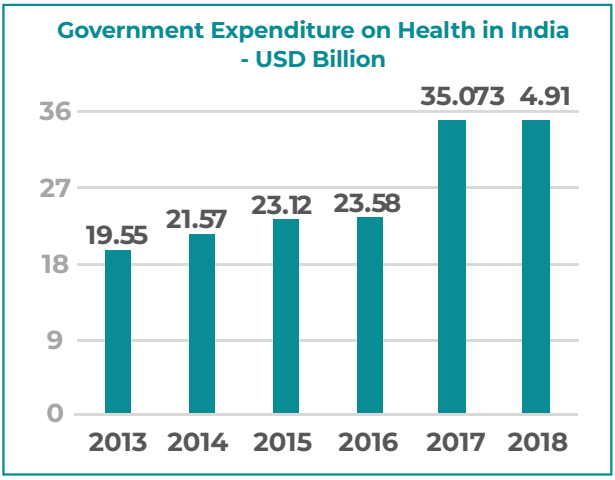
## d) Investments

- **Pharma Vision 2020:** a government commitment to make India into a global leader not only in the production of low-cost generic medicines but also end-to-end drug discovery and development. It also aimed to place India as one of the top five pharmaceutical innovation hubs, which would involve launching one out of every five to ten novel drugs, globally. For this, the government promised a multi-billion-dollar investment plan with a 50% public funding commitment through a public-private partnership model.




- Union budget 2019-20
  - The allocation to the Ministry of Health and Family Welfare increased by 13.1 per cent to US$ 8.98 billion.
  - The National Health Mission Scheme is the largest government funded healthcare programme, which is expected to benefit 7.31 million poor families in the country by providing a cover of up to USD7,314.22 per family per year on floater basis in the impaneled hospitals across India.
  - The government has allocated USD4.64 billion towards the National Health Mission under which rural and urban people will get benefited.

- **Budget 2019-18:** allocation to the Ministry of Health and Family Welfare increased by 13.1 per cent to USD 8.98 billion

## e) Training

- **Biotechnology based programme for women:** Programme on application of biotechnology for women was done to provide employment, skill development, awareness generation, health improvement & socio-economic upliftment of the women population

- **Educational system in terms of developing and promoting scientific talent:** Including a number of high-level public education institutions with entry based on competitive testing. In addition, India has established a network of pharmaceutical industry-specific educational institutions, principally for post-graduate research, referred to as NIPERs. Top Indian students also received post-graduate training at educational institutions in the United States and Europe. In general, the availability of scientifically trained personnel is a strength of the Indian pharmaceutical industry.

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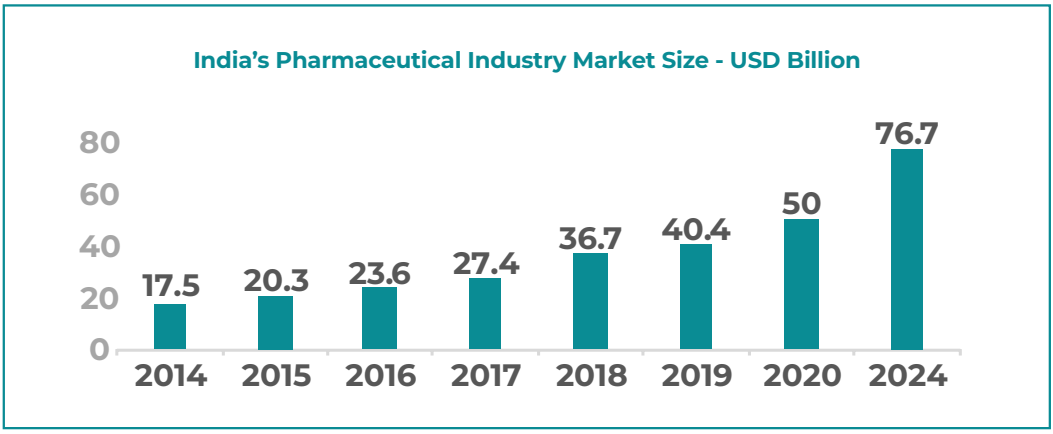
## The pharmaceutical industry market size in India is expected to reach USD 76.7 billion by 2024



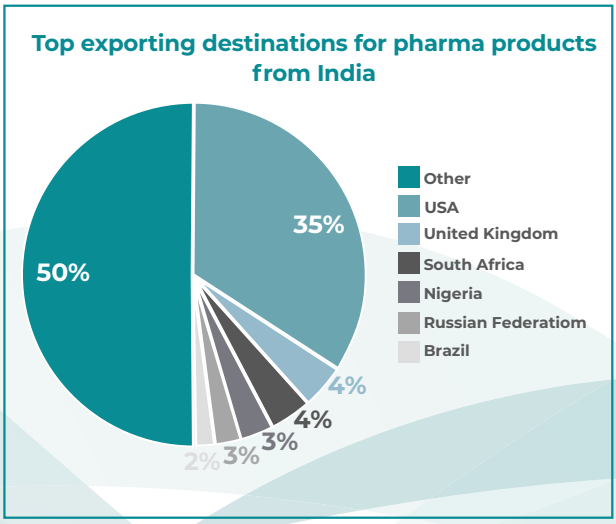

India's pharma market is expected to reach USD 50 billion by end of 2020, driven by a steady increase in affordability and a step jump in market access. It is also predicted to reach USD 76.7 billion by 2024, growing at a CAGR of 15.9% from 2016. The domestic generics market alone is expected to reach USD 27.9 billion by 2020. The lower growth in 2019 was due to a drop in volumes of most manufacturing segment.

## India exported USD14.2 billion worth of pharmaceutical products in 2018

India accounts for 20 per cent of global exports in generics. India's pharmaceutical exports stood at USD 14 billion in 2018.

Indian drugs are exported to more than 200 countries in the world, with the US as the key market. The next biggest export destinations are UK, South Africa, Nigeria and Russia.

This country's API exports and imports in 2018 were USD 1.8 billion and USD 2.22 billion respectively. Top import origins, for APIs to India, in 2018 were China, USA and Italy.

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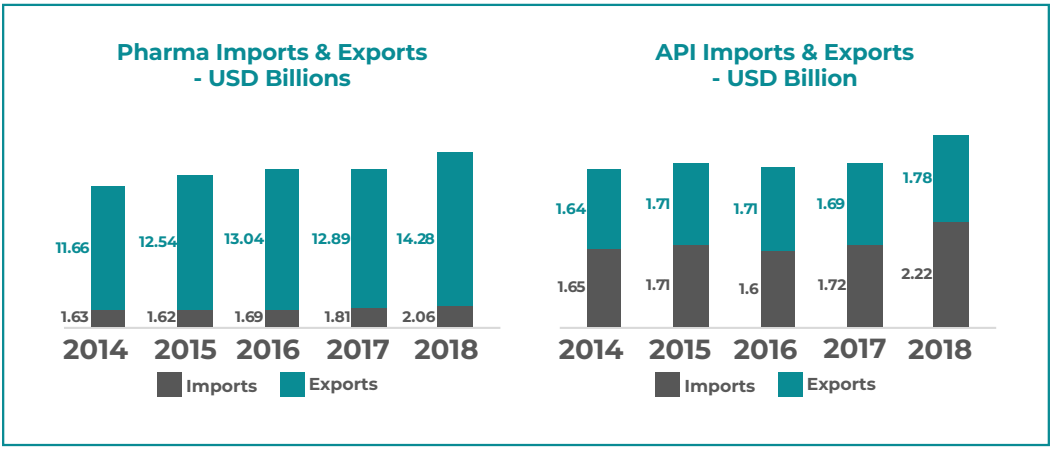


## India currently imports almost 80% of its APIs

Between the early 1970s and the 1990s, the **Government mandated that private enterprises intending to formulate drugs also commit to manufacture of APIs,** thus at this time India was self-sufficient to produce such APIs. However, in the last two decades, the situation has completely metamorphized and today 80% of the API comes from China

Owing to the **low-profit margin on APIs,** Indian drug manufacturers consider it as a viable option to import APIs, make formulation drugs and export them. There are three factors responsible for over-dependence on Chinese imports: **wage cost, infrastructure facilities and tax benefits.**

Most API production units in India run at 30 per cent of their capacity as against capacity utilization of 70 per cent in China. This is mainly due to different competitiveness due to different cost of production: producing APIs in China is about 20-30% cheaper than in India.

This overreliance on China poses as a challenge as it could make the pharma industry vulnerable. Recently, manufacturers have experienced a sharp spike in the prices of these raw materials due to rising labor costs and the Chinese government shutdown of numerous API manufacturing plants due to environmental concerns. Though these Chinese supplies have stabilized now, prices of some APIs have increased.

During this recent situation, India depended on countries like the US, Italy, Singapore and Hong Kong for import. However, this created the opportunity for India to develop APIs and intermediates and fill some of the supply gaps and as a result, China along with 174 destinations started purchasing APIs from India during 2018-19. Though this has not been a continued trend, the aim of the government is to increase local production and decrease its dependency on Chinese imports.

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## Strategies implemented by major players

In the past 3 to 4 years, industry structure in pharmaceuticals has changed with remarkable shifts in the leader board. **Four of the top ten players, including the market leader, are new entrants.**

Furthermore, over the past few years, the **distinction between local players and multinational companies has increasingly blurred.** It is believed that if market leadership is the aspiration, the implications and imperatives will be common for both groups of players. Some samples of strategies implemented by big players in this market are as below:

### Cost leadership

**Sun Pharma** is trying to achieve cost leadership by Vertical Integration. Complex API, which require special skills and technology, are developed and scaled up for both API and dosage forms.

### Differentiation

Players in the sector are trying to strengthen their position in the market and expand themselves by investing heavily in R&D activities, such as **Dr Reddy's** acquired **OctoPlus N.V,** a Netherlands-based company, to get access to the Poly Lactic-CoGlycolic Acid (PLGA) technology for the formulation of complex injectables.

### Focus on new markets

- **Lupin** is making inroads into new markets such as Latin America, Russia and other East European countries
- **Sun Pharma** decided to focus on specialty and chronic therapies such as neurology, oncology, dermatology segments

### Mergers and acquisitions in Biotech

- In Nov 2018, Cipla's subsidiary in the United States has ordered two steps to acquire Avenue Therapeutics Inc. for around an estimated $215 million.
- In October 2016, Advanced Enzyme Technologies, a biotech based firm in Mumbai signed an agreement with JC Biotech - Active Pharmaceutical Ingredient maker in Hyderabad, to acquire 70 per cent stake in the company.

### Incremental product improvement

In India, strategies are still largely focused on incremental product improvement. Yet this too may be changing: Sun Pharma, India's largest domestic drug company, has been buying the Indian rights to drugs still under patent, such as Novartis' Odomzo, or even in trials, like Merck's MK-3222

## Many new opportunities can be observed in the evolving Indian pharma market

Considering the current state of the pharmaceuticals market in India, various opportunities can be seen:

**Patented products:** Launched primarily in four therapies: metabolics, neuropsychiatry, oncology and anti-infectives, which has the potential to reach USD 1.7 billion by 2020.

**Consumer healthcare drugs:** It is expected that the consumer healthcare segment will grow at 14 to 16 per cent to become a USD 14 to 18 billion market by 2020.

**Biologics:** Has the potential to grow to USD 3 billion by 2020.

**Vaccines:** Expected to grow to USD 1.7 billion by 2020.

**The public health market:** Has the potential to grow to USD 4.5 billion by 2020

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## Various changes over the last few years have affected this industry and posed new challenges

Over the last few years, many changes have affected the pharmaceutical sector, which have necessitated a fresh, comprehensive national policy to maintain and enhance its global competitive edge in quality and prices. Although many proposals have been put forward, further deliberations and negotiations are expected. Various challenges that currently exist in this market are:

- The launch of **branded generics** businesses and **significant expansion of market coverage** by multinationals
- **Government pricing controls** and increased regulatory oversight
- **Economic slowdown**
- **Dependence on US market:** In February 2019, the US government considered withdrawing the Generalized System of Preferences (GSP) from India. Withdrawal of the GSP, a scheme developed in the 1970s, would introduce tariffs on Indian exports to the US and ultimately act as a deterrent to the demand for Indian goods and services.
- **Overreliance on China** could make the pharma industry vulnerable. As any changes or issues with the production of these raw materials in China could result in price spikes or shortages, causing problems for Indian manufacturers.

## Conclusion

In the past, the growth trajectory settled by the Government was based on a strict control over the sector: removing patent right, leveling prices downwards and obliging pharmaceutical companies to integrate vertically with basic API manufacturing. In this way, the regulator created room for the arising of a low added value pharma production whose output was easily absorbed by the local demand.

Today, the protectionism strategy seems to have been abandoned. A more market-oriented growth strategy is pursued, where dynamic private companies are better positioned to take advantage of local and international market opportunities through higher added value ventures.

A major driver of revenue growth has been **exporting of generic formulated products to high-value developed country markets,** particularly those of the United States and Europe. The revenues from exports have allowed the major Indian generic producers to invest in upgrading of plant and equipment so as to allow conformity with strict regulatory requirements, enabling export expansion

The Indian pharma industry has been growing at a continuous rate over the past years, however, it has been **facing challenges recently** due to the launch of branded generics businesses and significant expansion of market coverage by multinationals, increased costs related to regulatory compliances, particularly for the US market, price controls across markets and mandatory genericization in India.

For the industry to sustain its robust growth rate, companies will have to rethink their **business strategy,** and the need for **capital investment, both from public and private funds, is essential** in the sustainability and development of such ecosystem.

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## INDIAN PHARMACEUTICAL SECTOR - SWOT

### Strength

- Low cost of skilled man-power
- Large pool of high technical scientists
- Strong marketing and distribution network
- Experience in high technology manufacturing
- Low cost of manufacturing, innovation and operation

### Weakness

- Stringent pricing regulations
- Poor infrastructure
- Lax IP enforcement
- Very competitive environment
- Poor health insurance coverage
- Low quality drugs staining image of industry
- Low R&D investment

### Opportunity

- Rising global demand for generics
- Rising population with sitting lifestyle
- Increasing health insurance
- Significant FDIs in pharma
- Medical tourism
- Cheap, diverse clinical trials
- Can become important outsourcing destination

### Threat

- Changing government regulations
- Competition from countries like China due to their low cost
- Expansion of drug price control order (DPCO)
- Lack of investment in infrastructure
- Wage inflation
- Counterfeiting

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