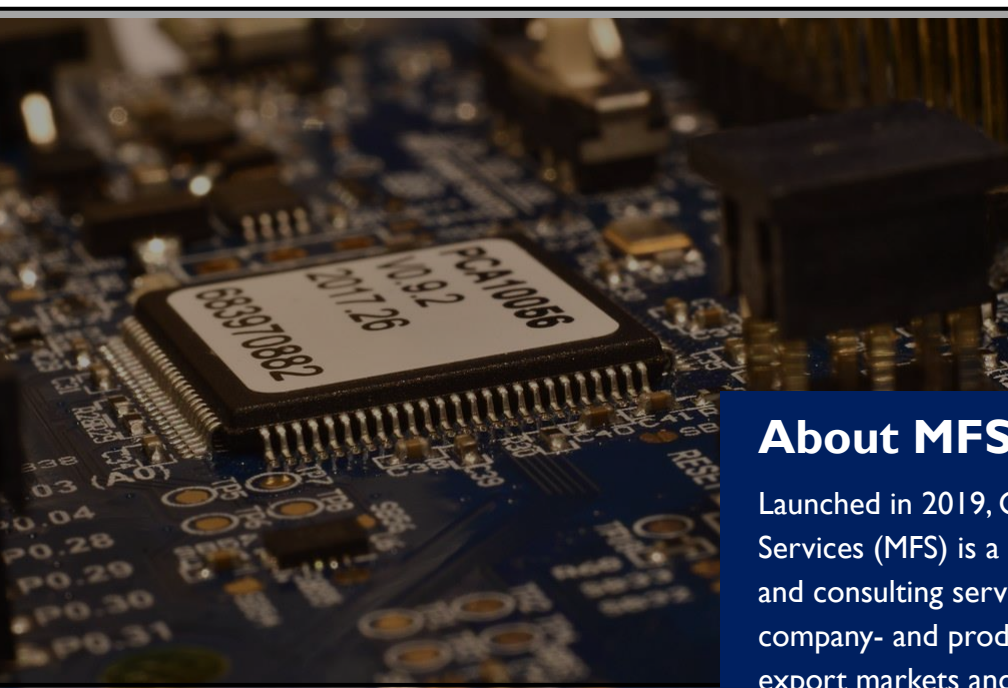


India is one of the world's leading pharmaceutical manufacturing hubs, renowned for its large-scale production capacity, cost efficiency and high-quality standards. It is the largest supplier of generic medicines, accounting for over 20% of global exports in generics. India houses the highest number of USFDA-approved plants outside the US, along with manufacturing approvals from international agencies such as WHO-GMP and EU-GMP.



About MFS

Launched in 2019, CII's Market Facilitation Services (MFS) is a bespoke market research and consulting service that undertakes company- and product-specific research on export markets and investment destinations, for both outbound and inbound companies.

Scope of Analysis

NAICS 3254 (Pharmaceutical and Medicine Manufacturing)

The North American Industry Classification System (NAICS) is an industry classification standard developed by the US, Canada and Mexico for the purpose of collecting and analysing statistical data on the business economy. NAICS 3254 is the code for companies involved in the manufacture of pharmaceutical and medicine products. The products within this category include prescription drugs, over-the-counter (OTC) drugs, biologics, diagnostic substances and other supplements.

Sub-categories:

325411 Medicinal and Botanical Manufacturing

325412 Pharmaceutical Preparation Manufacturing

Tablets, capsules, ointments, solutions, antibiotics, painkillers, cardiovascular drugs, prescription and OTC drugs

325413 In-Vitro Diagnostic Substance Manufacturing

Reagents and test kits for medical laboratories, diagnostic substances used in testing human body fluids or tissues, products used for pregnancy, glucose, or infectious disease tests

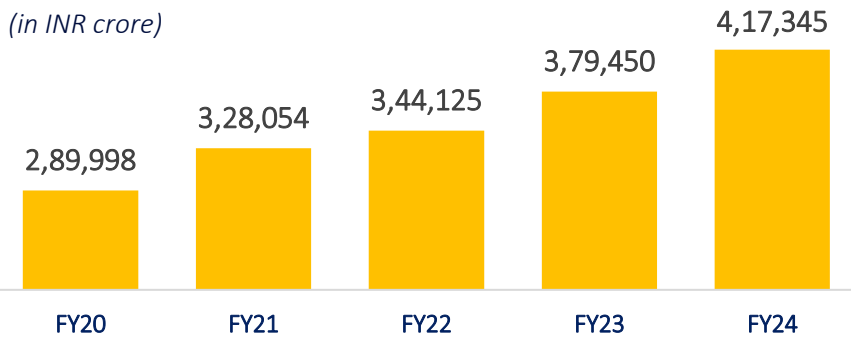
325414 Biological Product (except diagnostic) Manufacturing

Vaccines (for human and animal use), blood and plasma derivatives, toxins, antitoxins, serums, cell therapies and immunotherapies (excluding diagnostic uses)

Market Overview

Pharmaceutical Sector Turnover

(in INR crore)



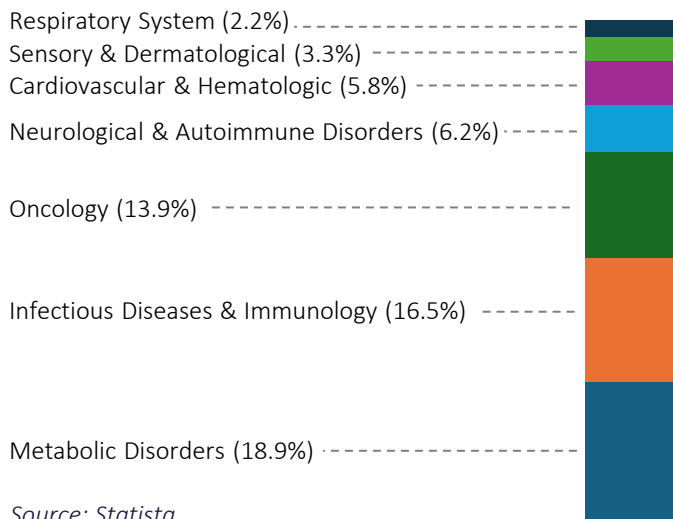
Source: Department of Pharmaceuticals – Annual Reports

Being third-largest global market by volume and 14th-largest by value, the Indian pharmaceutical market recorded a turnover of INR 4,17,345 crore in FY24 with a CAGR of 9.5% between FY20 and FY24. With a production base that manufactures 60,000 generic brands, India owns 20% of the global supply of generic drugs.

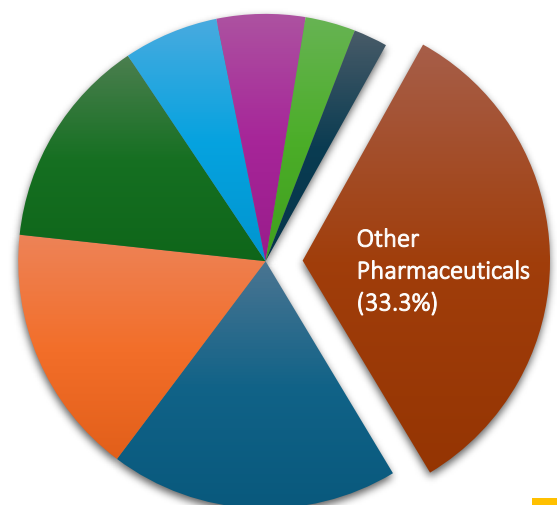
India has the highest number of United States Food and Drug Administration (USFDA) complaint pharma manufacturers outside the US — by FY 25, India had 1,136 plants compared to 1,331 plants in the US. India accounts for the largest share of low-cost vaccine supplies in the world — 60% of total vaccines supplied to UNICEF were manufactured by Indian companies. Further, nearly 90% of the World Health Organisation's (WHO) measles vaccines are supplied by Indian pharma companies, along with 40% to 70% of its DPT and BCG vaccines' demand.

2024 Share of Revenue, Categorized by Therapeutic Area

According to a 2017 report by ICMR, PHFI and IHME, titled *India: Health of the Nation's States*, non-communicable diseases (NCDs) accounted for 55.4% of India's health burden, compared to 32.7% on account of communicable diseases (CDs). Reflecting this trend, NCDs contributed approximately 48% to the total pharma sector revenue in 2024. With the rising number of people living with diabetes and pre-diabetes, India is facing a significant challenge. In a survey report (*India Fit 2022*) by healthcare solutions provider, GOQii, 13.2% of respondents had diabetes in 2021 compared to 7.9% in 2017. Reflecting the same trend, metabolism disorders-based pharma products accounted for the maximum share (18.9%) of 2024 pharma sector revenues. Medications linked with infectious diseases and immunology accounted for the second-highest share of 16.5% revenue., followed by other disorders such as oncology, neurologically, etc., as can be seen in the figure below.



Source: Statista

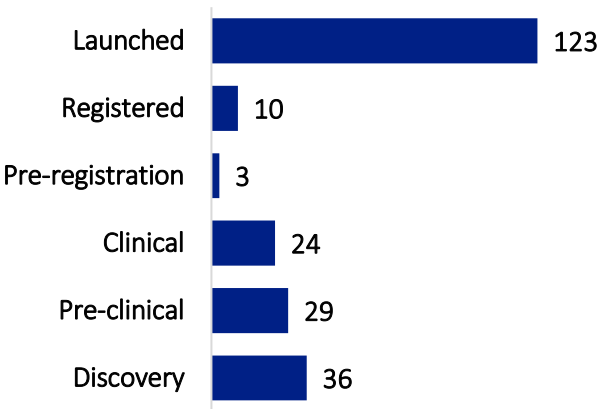


Key Sub-Sectors

Biosimilars

India has historically been a global leader in the biosimilars market, with the approval of ‘similar biologic’ (biosimilars) in 2000 for Hepatitis B, well before Europe, which approved its first biosimilar in 2006 and later the US in 2015. The Biotechnology Industry Research Assistance Council (BIRAC), set up by Department of Biotechnology (DBT), in a 2019 report (*India: The Emerging Hub for Biologics and Biosimilars*), highlighted that India accounted for ~28% share of globally approved biosimilars, with 123 launched and 102 in pipeline. Through India’s universal healthcare programme, biosimilars for cancer, diabetes and other immune-mediated diseases are easily available for the financially-weak sections of society.

Pipeline of biosimilars for Indian pharmaceutical companies



Source: BIRAC

Gene Therapy

India’s gene therapy market holds significant growth potential, driven by advancements in biotechnology and a high prevalence of genetic disorders. In 2023, India took a major leap by making cell therapy accessible to patients. This breakthrough treatment was developed through a collaboration between IIT Bombay, Tata Memorial Hospital and ImmunoACT (a biotech company specialising in gene therapy), marking a critical advancement in cancer therapy. Further strengthening its position, India approved a second CAR-T cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin’s lymphoma. In 2024, the gene therapy market in India was valued at over US\$ 500 million, with projections estimating it will reach US\$ 2 billion within the next 8 to 10 years, according to IMARC, a market research firm.

Biotech-driven pharmaceutical innovation

India is today one of the fastest-growing biotechnology markets globally, witnessing a remarkable 13-fold increase in market value from US\$ 10 billion in 2014 to US\$ 130 billion in 2024, according to a press release issued by the Press Information Bureau (PIB) in 2024. Innovation is primarily concentrated in Tier-I and metropolitan cities. Based on current trends, the market is projected to reach US\$ 300 billion by 2030. In terms of infrastructure, India has nine DBT-supported biotech parks and 73 BIRAC-supported bio-incubators, providing strong institutional support for R&D.

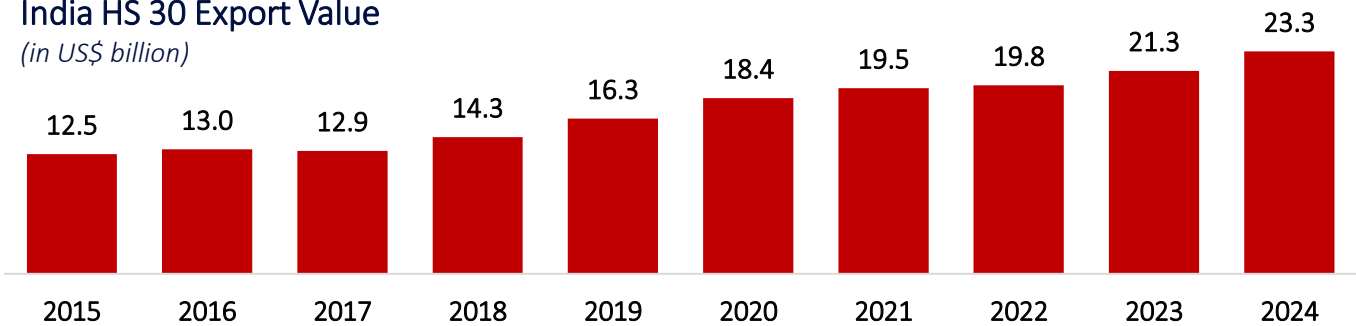
Notably, the start-up ecosystem has flourished, with over 6,000 biotech start-ups established by 2023, reflecting a vibrant and dynamic innovation environment beyond large corporations.

India Export Overview

For the trade analysis, this newsletter analyses data at the HS4 digit-level, instead of using the NAICS classification. In 2024, India was the 11th-largest exporter of pharma products (HS30) in the world, by export value. Almost 40% of pharma product exports from India are shipped to the US, 18% to European countries, and about 17% to Africa. Nearly 90% of India's pharma exports are of HS 3004 (medicaments, consisting of mixed or unmixed products for therapeutic or prophylactic uses).

India HS 30 Export Value

(in US\$ billion)

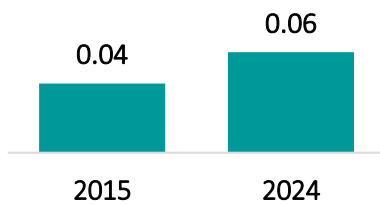


Source: TradeMap



India HS 3001 Export Value

(in US\$ billion)



HS 3001: Dried glands and other organs for organo-therapeutic uses, whether or not powdered; extracts of glands or other organs or their secretions, for organo-therapeutic uses; heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, n.e.s.

HS 3002: Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses; antisera and other blood fractions and immunological products, whether or not modified or obtained by means of biotechnological processes; vaccines, toxins, cultures of micro-organisms (excl. yeasts) and similar products; cell cultures, whether or not modified

HS 3003: Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale (excl. goods of heading 3002, 3005 or 3006)

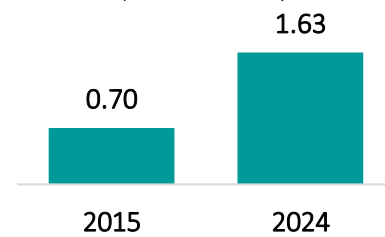
HS 3004: Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006)

HS 3005: Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated or covered with pharmaceutical substances or put up for retail sale for medical, surgical, dental or veterinary purposes

HS 3006: Pharmaceutical preparations and products of subheadings 3006.10.10 to 3006.93.00

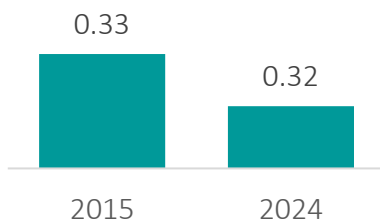
India HS 3002 Export Value

(in US\$ billion)



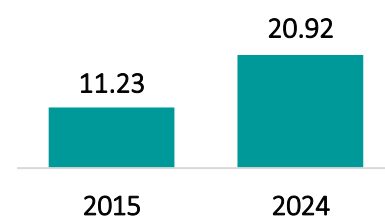
India HS 3003 Export Value

(in US\$ billion)



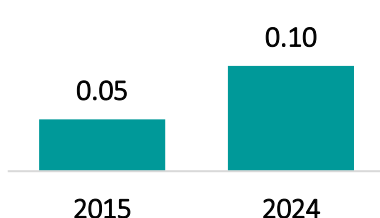
India HS 3004 Export Value

(in US\$ billion)



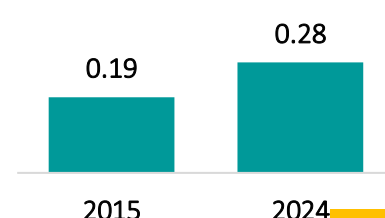
India HS 3005 Export Value

(in US\$ billion)



India HS 3006 Export Value

(in US\$ billion)



Government Initiatives

- ❑ **Scheme for Promotion of Research and Innovation in Pharma MedTech Sector (PRIP):** Launched in 2023 by the Department of Pharmaceuticals, the scheme aims to make India a global R&D hub for pharma and medical technology, with a total outlay of INR 5,000 crore, including INR 4,250 crore for R&D investment.
- ❑ **Scheme for Strengthening of Pharmaceuticals Industry (SPI):** The Department of Pharmaceuticals, along with the Ministry of Chemicals and Fertilizers, has launched this scheme to address demands of support for pharma clusters and MSMEs, to improve their productivity, quality and sustainability. Eligible components include land, building, internal infra, machinery, utilities, margin money for working capital, etc.
- ❑ **Production Linked Incentive (PLI) Scheme for Pharmaceuticals:** With a financial outlay of INR 15,000 crore, for the period FY 2020–21 to FY 2028–29, this scheme provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories for a period of six years.
- ❑ **Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/Drug Intermediates and Active Pharmaceutical Ingredients (APIs):** The PLI scheme for domestic manufacturing of KSMs, DIs and APIs aims to reduce India's import dependence and strengthen supply chain resilience by supporting local production of critical bulk drugs. Launched with an outlay of INR 6,940 crore for the period 2020–21 to 2029–30, the scheme offers financial incentives based on investment and domestic sales thresholds. So far, 249 applications have been received, and 48 projects selected, leading to the creation of manufacturing plants with over 56,000 MT of cumulative installed capacity. The scheme has already surpassed its INR 4,000 crore investment target, driving job creation and positioning India as a global pharmaceutical manufacturing hub.
- ❑ **Scheme for Promotion of Bulk Drug Parks:** This scheme supports the financing of common infrastructure facilities in three bulk drug parks with a budget allocation of around INR 3000 crore for the next five years. Under the scheme, three mega bulk drug parks will be developed in India in partnership with states. The Central government will give grants-in-aid to state governments with a maximum limit of INR 1000 crore per bulk drug park.
- ❑ **Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP):** Launched in November 2016 by the Department of Pharmaceuticals, this scheme aims to provide quality generic medicines at affordable prices through 16161 Janaushadhi Kendras across India. The Kendras offer 2176 drugs and 314 surgical items, with medicines priced 50%–90% lower than branded alternatives.
- ❑ **Pradhan Mantri Jan Arogya Yojana (PM-JAY):** Launched in 2018 under Ayushman Bharat, is the world's largest government-funded health assurance scheme. It provides cashless health coverage of ₹5 lakhs per family per year for secondary and tertiary care hospitalization to over 55 crore poor and vulnerable individuals, based on Socio-Economic Caste Census 2011 (SECC 2011) for rural and urban areas respectively. The scheme covers a wide range of medical services including pre- and post-hospitalization expenses (up to 3 and 15 days respectively), diagnostics, surgery, ICU, and medicines. All pre-existing conditions are covered from day one, with no cap on family size, age, or gender.

MFS Offerings

Export/Import Assessment

- Identification of top importing countries
- Export competitor countries
- Shipment data analysis
- Shipment cost with export pricing strategy
- Supply chain network mapping
- Listing of non-tariff measures (NTMs) and national tariff lines (NTLs)

Market Potential Assessment

- Country geopolitical analysis
- Market feasibility analysis
- Sector SWOT analysis
- End-use sector growth trend
- Location and market entry advisory
- Regulatory and policy insights

Operational Cost Optimisation

- Assessment of operational expenses
- Mapping of expenses with sectoral average
- Deep dive of micro cost components
- Positioning of company with respect to peers
- Future outlay of operational expenses

Benefits For You

- Global Trade Intelligence
- Market sizing reflecting domestic and global demand-supply landscape
- Global reach to government and business stakeholders across countries
- Touchpoints in export markets
- Product-market fitment from a global trade perspective
- Diversification/investment opportunities

Our Knowledge Base

20⁺ Countries

15⁺ Sectors

50⁺ Products

Would you like to
EXPLORE more?

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Confederation of Indian Industry

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering Industry, Government and civil society, through advisory and consultative processes.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, with around 9,000 members from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 365,000 enterprises from 294 national and regional sectoral industry bodies.

For more than 125 years, CII has been engaged in shaping India's development journey and works proactively on transforming Indian Industry's engagement in national development. CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness, and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Through its dedicated Centres of Excellence and Industry competitiveness initiatives, promotion of innovation and technology adoption, and partnerships for sustainability, CII plays a transformative part in shaping the future of the nation. Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes across diverse domains including affirmative action, livelihoods, diversity management, skill development, empowerment of women, and sustainable development, to name a few.

For 2024-25, CII has identified "Globally Competitive India: Partnerships for Sustainable and Inclusive Growth" as its Theme, prioritizing 5 key pillars. During the year, it would align its initiatives and activities to facilitate strategic actions for driving India's global competitiveness and growth through a robust and resilient Indian industry.

With 70 offices, including 12 Centres of Excellence, in India, and 8 overseas offices in Australia, Egypt, Germany, Indonesia, Singapore, UAE, UK, and USA, as well as institutional partnerships with about 300 counterpart organizations in almost 100 countries, CII serves as a reference point for Indian industry and the international business community.

Confederation of Indian Industry

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