



INDIAN PHARMACEUTICALS INDUSTRY

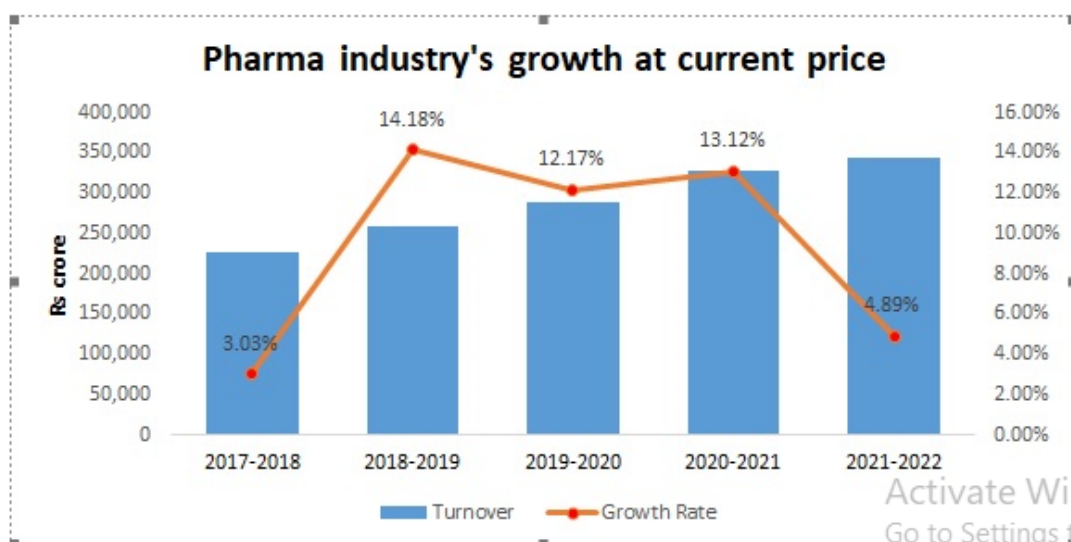
MAY - 2023



The Indian Pharmaceuticals industry plays a prominent role in the global pharmaceuticals industry. It ranks third globally in pharmaceutical production by volume, 14th by value. India is one of the biggest suppliers of low-cost vaccines in the world and it is also the largest supplier of generic medicines. It offers lower cost without compromising on quality as is reflected by the fact India has the highest number of United States Food and Drug Administration (USFDA) approved pharmaceutical plants outside the US and also a significant number of World Health Organization (WHO) Good Manufacturing Practices(GMP)-compliant plants as well as plants approved by regulatory authority of other countries.

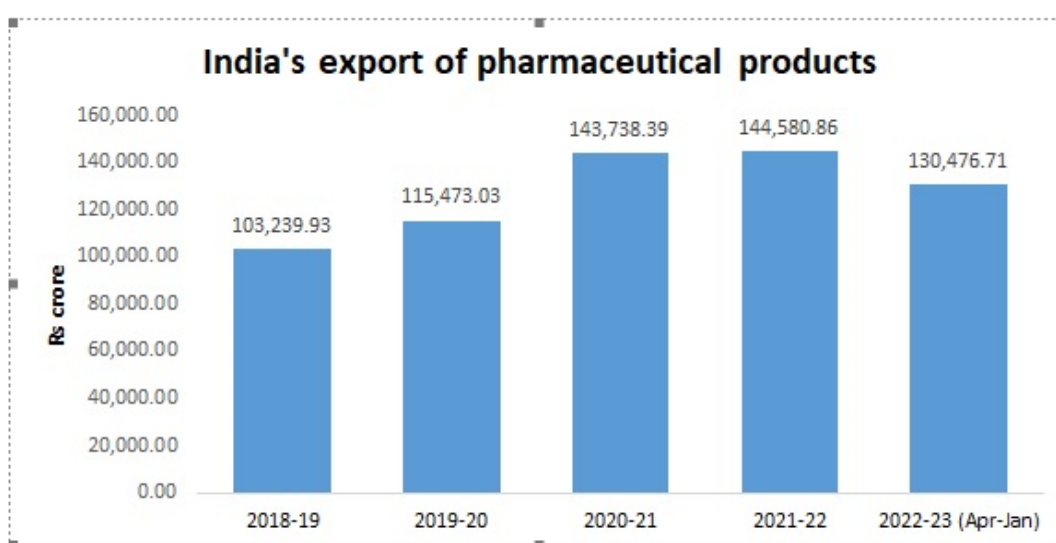
The industry contributed to around 1.32% of the Gross Value Added (at 2011-12 constant prices) of the Indian Economy in 2020-21. The total annual turnover of Pharmaceuticals in the fiscal year 2021-22 was Rs 3,44,125 crore (\$42.34 billion). Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. India is a global leader in the supply of DPT, BCG, and Measles vaccines.

India accounts for 60% of global vaccine production, contributing 40 to 70% of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette-Guerin (BCG) vaccines, and 90% of the WHO demand for the measles vaccine. There are 500 API manufacturers contributing about 8% in the global API Industry. It manufactures about 60,000 different generic brands across 60 therapeutic categories and accounts for 20% of the global supply of generics. Access to affordable HIV treatment from India is one of the greatest success stories in medicine. Because of the low price and high quality, Indian medicines are preferred worldwide, making it 'pharmacy of the world'.



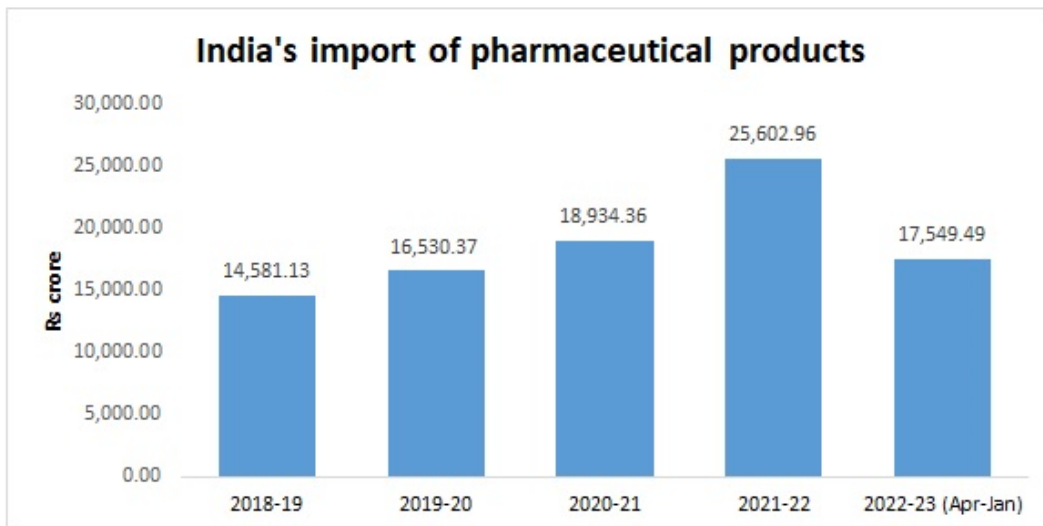
EXPORTS:

India's Pharma exports contributed around 5% of merchandise exports. The country's export of pharmaceutical products stood at Rs 130,476.71 crore for the April-January period of fiscal year 2022-23 (FY23). In the fiscal year 2021-22, India exported pharmaceutical products worth Rs 144,580.86 crore which was slightly higher (0.59%) as compared to Rs 144,580.86 crore exported in the FY21. The pharma exports in 2021-22 sustained a positive growth despite the global trade disruptions and drop in demand for COVID related medicines. In the FY21, the pharmaceutical products have registered notable growth of 24.48% over FY20 when export was Rs 115,473.03 crore driven by COVID-19-induced demand for critical drugs and other supplies made to over 150 countries.



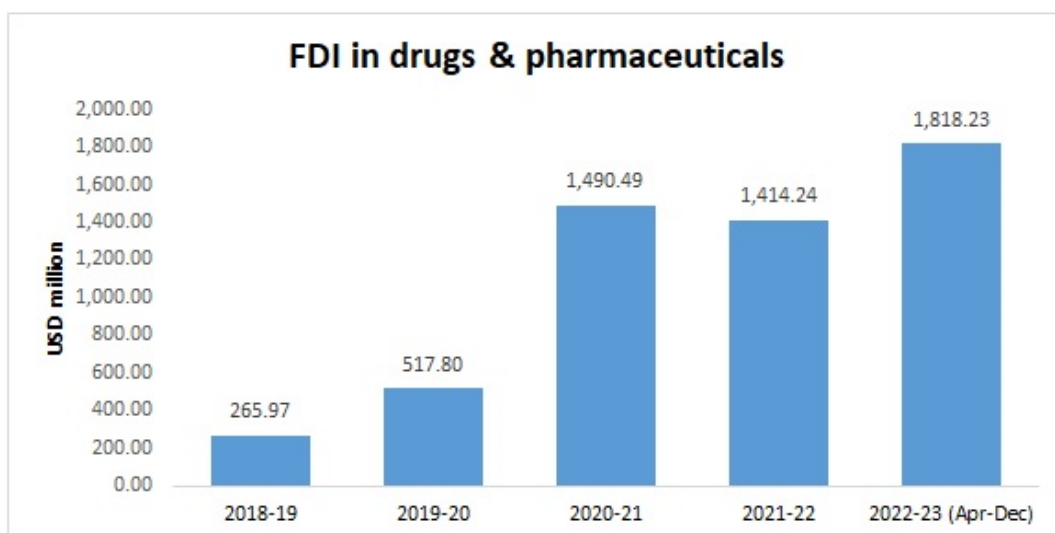
IMPORTS :

India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19. The imports of pharmaceutical products are continuously increasing from 2018-19 when it was Rs 14581.13 crore to Rs 25602.96 crore in 2021-22. In the fiscal year 2021-22, it registered growth of 35.22% as compared to Rs 18,934.36 crore imported in 2020-21. Whereas, in the year 2019-20 imports was Rs 16530.37 crore. In the fiscal year 2022-23, the country imported pharmaceutical products worth Rs 17549.49 crore during April 2022 to January 2023 period.



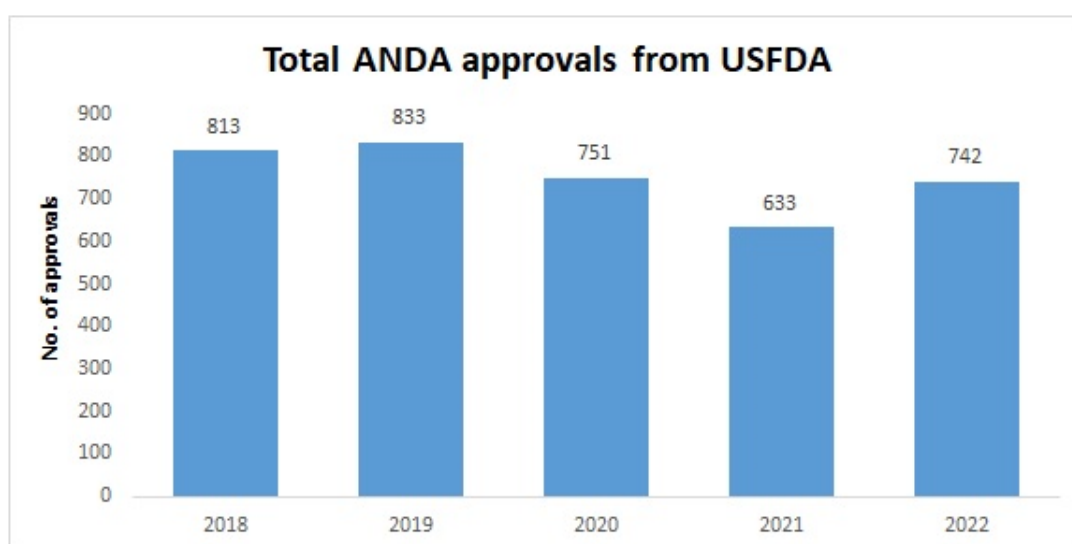
FDI IN DRUGS & PHARMACEUTICALS:

India's pharmaceutical sector forms a major component of the country's foreign trade and is one of the top ten attractive sectors for foreign investment in India. It contributes about 3.71% of total Foreign Direct Investment (FDI) inflows in the country across various sectors. In the just nine-month period (April–December) of fiscal year 2022–23, the FDI equity inflows into the pharmaceutical industry in India have surpassed the full financial year 2021–22 FDI. Inflows jumped to \$1,818.23 million in the April–January period of fiscal year 2022–23 (FY23), whereas for the entire fiscal year 2021–22 the foreign fund inflows was \$1,414.24 million. The FDI showed tremendous growth in past few years, as inflows surged from just \$265.97 million in 2018–19 to \$1,490.49 million in 2020–21, a growth of over 5-fold. This was supported by the government's investor-friendly FDI policy to promote investment in the industry.



ANDA APPROVALS FROM USFDA:

The United States Food and Drug Administration (FDA or US FDA) has total approved 742 abbreviated new drug application (ANDA) during the calendar year 2022, as compared to 633 ANDA approvals in 2021, a growth of 17%. In the year 2022, pharma companies reverse their declining trend witnessed over last couple of years, as in the year 2019, 833 approvals were granted which fell to 751 in 2020 and 633 in 2021. Indian players contributed a large proportion of total approvals. India received 355 ANDA approvals in the calendar year 2022, which was 47.84% of total approvals. In the year 2022, the country received 88 more approvals as compared to previous year, a growth of 32.96%. In the year 2021, the country got 267 approvals, which was 42.18% of total approvals. India was followed by the US, China, Europe, and Israel, in that order, in the number of ANDA approvals. Companies accelerated filings, even during the ongoing waves of the COVID-19 pandemic, resulting in a higher number of ANDA approvals across all dosage forms, competition levels, and product complexity including drug-device combination products.



Production Linked Incentive (PLI) scheme for pharmaceuticals:

The objective of this scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification towards high value goods in the pharmaceutical sector. The scheme covers pharmaceutical goods under following three categories-

- Category 1: Biopharmaceuticals; Complex generic drugs; Patented drugs or drugs nearing patent expiry; Cell based or gene therapy drugs; Orphan drugs; Special empty capsules like HPMC, Pullulan, enteric etc.; Complex excipients; Phyto-pharmaceuticals; Other drugs as approved.
- Category 2: Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates (except for the 41 eligible products already covered under the “PLI Scheme for promotion of domestic manufacturing of critical KSMs / DIs / APIs” at sl.no.(i) above).
- Category 3: (Drugs not covered under Category 1 and Category 2): Repurposed drugs; Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs; In vitro diagnostic devices; Other drugs as approved; Other drugs not manufactured in India.

The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2028-29. The scheme provides for incentives on incremental sales to selected participants under these categories at varying rate over the years ranging from 10% to 3%. The scheme is likely to bring in investment of more than Rs 17,000 crore in the pharmaceutical sector, promote the production of high-value products in the country and increase the value addition in exports. The support under PLI schemes is expected to promote the production of high-value products in the country as well as generate employment for both skilled and unskilled personnel, estimated at 20,000 direct and 80,000 indirect jobs.

RIISING COVID-19 CASES, VIRAL INFECTIONS IN THE COUNTRY TO PUSH UP SALES OF PHARMA :

After months of consistent decline, COVID-19 cases are surging again across India. On March 30, 2023, the country reported 3,095 fresh Covid-19 cases, the highest single-day rise in infections in 2023. On April 07, 2023, India recorded 6,050 fresh coronavirus cases, the highest in 203 days, with 28,303 active cases. The death toll has increased to 5,30,943 (over 5.3 lakh) with 14 new fatalities while the daily positivity rate has been recorded at 3.39%. The surge being attributed to a new Covid-19 sub-variant, XBB.1.16, which has been circulating through India for last few months. Further, on April 13, the country reported 11,109 fresh cases in a single day. Levels of XBB.1.16 are also rising in the U.S., Singapore, and Australia, among other countries. The variant has so far been identified in 29 countries, and reported sequences of it more than doubled from the last full week of March to the first partial week of April.

Besides, in the month of February and March 2023, the volume of anti-infectives, respiratory and pain medicines increased due to fast spreading of flu, covid-19 and other viral infections. Thus, this sudden rise in coronavirus cases and many viral infections in the country as well as globally may push domestic sales and exports of anti-infective and pain medication. With this, overall sales of pharma industry may grow. Meanwhile, the government may fast-track the vaccination of coronavirus in the country.

GOVERNMENT INITIATIVES:

- **Govt announces programme to promote R&D in pharmaceuticals**

The government has said that a new programme to promote research and innovation in pharmaceuticals will be taken up through various centers of excellence. It said 'We shall also encourage industry to invest in research and development'. It added 'Dedicated multidisciplinary courses for medical devices will be supported in existing institutions to ensure availability of skilled manpower for future futuristic medical technologies, high end manufacturing and research'.

- **Govt to introduce incentive scheme to boost R&D by pharma industry**

The Centre is all set to introduce a research-linked incentive programme shaped on the lines of the production-linked incentive (PLI) scheme to boost research and development of biotech products in the country. PLI scheme aims to give companies incentives on incremental sales from products manufactured in domestic units.

- **Govt launches 3 schemes to strengthen MSMEs in pharmaceutical sector**

The government has launched three schemes to strengthen Micro, Small and Medium Enterprises (MSMEs) in the pharmaceutical sector. The schemes envisage technology upgradation, setting up of common research centres and effluent treatment plants in clusters for the pharma MSMEs. Small companies should be able to upgrade their facilities to global manufacturing standards. The government rolled out the schemes under the banner of 'Strengthening Pharmaceuticals Industry' (SPI).

The schemes provide for credit linked capital and interest subsidy for technology upgradation of MSME units in pharmaceutical sector, as well as support of up to Rs 20 crore each for common facilities, including research centre, testing labs and ETPs, in pharma clusters.

The Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS) would facilitate pharmaceutical MSMEs with proven track record to upgrade their technology. Similarly, Assistance to Pharma Industries for Common Facilities Scheme (API-CF) would strengthen the existing pharmaceutical clusters' capacity for sustained growth. Pharmaceutical and Medical Devices Promotion and Development Scheme (PMPDS) would involve preparation of study reports on topics of importance for the Indian pharma and medical device industry. The scheme is aimed at creating a database of pharma and medical device sectors.

RECENT DEVELOPMENTS :

- **Govt exempts customs duty for imported drugs for medical purposes, treatment of rare diseases**

The Central Government has given full exemption from basic customs duty on all drugs and Food for Special Medical Purposes imported for personal use for treatment of all Rare Diseases listed under the National Policy for Rare Diseases 2021 through a general exemption notification. In order to avail this exemption, the individual importer has to produce a certificate from Central or State Director Health Services or District Medical Officer/Civil Surgeon of the district. Drugs/Medicines generally attract basic customs duty of 10%, while some categories of lifesaving drugs/vaccines attract concessional rate of 5% or Nil.

- **NPPA fixes retail price of 74 drug formulations**

The National Pharmaceutical Pricing Authority (NPPA) has fixed the prices under the Drugs (Price Control) Order 2013 based on the decision of the 109th authority meeting held on February 21 this year. The NPPA said it has also revised the ceiling price of 80 scheduled formulations (NLEM 2022) including the one to treat epilepsy and neutropenia. The ceiling price of one tablet (200mg) of Sodium Valproate, used to treat epilepsy and bipolar disorder, has been fixed at Rs 3.20. Similarly, the ceiling price of Filgrastim injection, used to treat low white blood cells, has been fixed at Rs 1,034.51 (one vial).

- **Nepal govt ban import of medicines manufactured by 16 Indian companies**

The Nepal government has said that it would not import medicines manufactured by 16 Indian companies for failing to keep up with the World Health Organization's (WHO) good manufacturing practices. The move comes after the WHO issued an alert on Indian-made cough syrups, which were allegedly responsible for the deaths of children in Gambia. The Department of Drug Administration of Nepal has released a list of 16 Indian pharmaceutical companies, includes the names of Shree Anand Life Sciences, IPCA laboratories, Cadila Healthcare, Dial Pharmaceuticals, Aglowmed and Mackur laboratories, Radiant Parenterals., Mercury Laboratories., Alliance Biotech, Captab Biotec, Aglowmed, Zee Laboratories, Daffodils Pharmaceuticals, GLS Pharma, Unijules Life Science, Concept Pharmaceuticals etc.

OUTLOOK :

The Indian pharmaceutical industry witnessed greater collaboration adopted innovative approach to deliver high quality medicines continuously during the pandemic and beyond. The pharmaceutical industry in the country is a significant part of the nation's foreign trade. Tremendous development in foreign investment, rising exports of pharmaceutical products and rising standards of care to lend support to pharmaceutical industry to continue grow in coming time. With dipper focus on quality manufacturing, rising USFDA approvals, adoption of innovation & technology and the government's continued support to push R&D in pharma sector, the outlook of Indian pharmaceutical industry looks positive in coming time.

Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. Recent rise in coronavirus cases and viral infections to push up sales of pharma products. In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies. An increase in government schemes like PLI scheme and initiatives for manufacturing, skill development and other crucial areas of growth for the industry. All of this can tremendously help the industry's growth rate in coming years, while enhancing India's potential to become the world's preferred pharmaceutical investment destination.



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