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INDUSTRY OUTLOOK

INDIAN PHARMACEUTICAL INDUSTRY - SUSTAINED GROWTH IS HERE TO STAY

26 September 2023

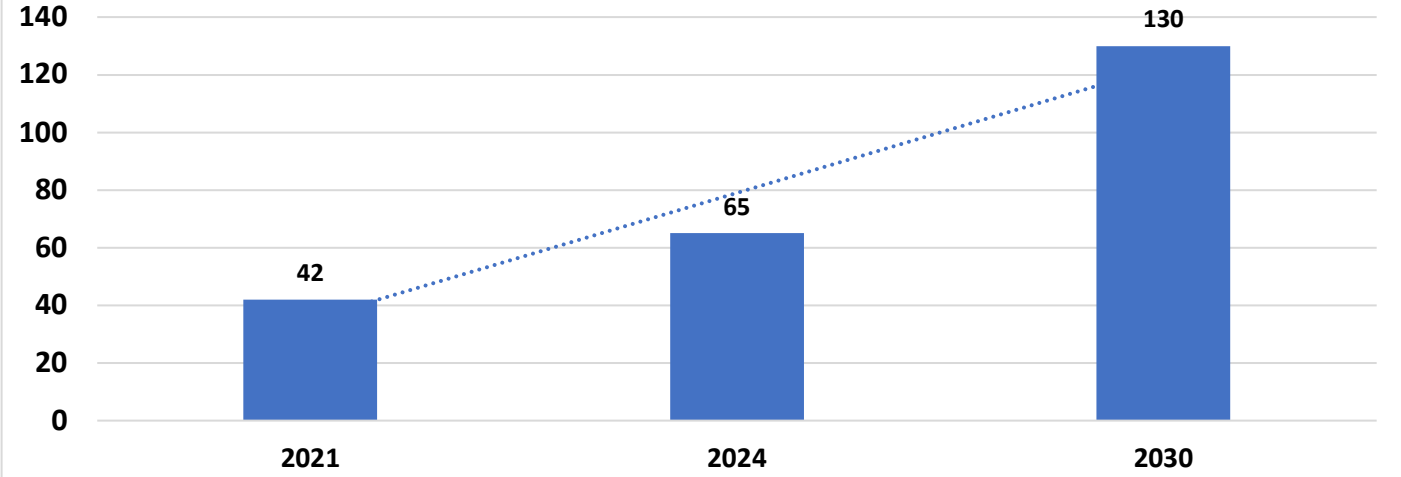
Introduction

The Global Economic Outlook report [1] published by the International Monetary Fund (IMF) showed that the global GDP (Gross Domestic Product) growth decreased from 6 per cent in 2021 to an approximately 3.5 per cent in 2022. In 2022, advanced economies (AE) grew by 2.7 per cent but emerging market and developing economies (EMDE) grew by a far higher rate of 4.0 per cent. The expected global growth is anticipated to decrease from an estimated 3.5 per cent in 2022 to 3.0 per cent in both 2023 and 2024.

The projected outlook for the year 2023 shows a modest increase compared to the previous projection given in the April 2023 World Economic Outlook (WEO). It is anticipated that the global headline inflation rate would decline, decreasing from 8.7 per cent in 2022 to 6.8 per cent in 2023, and further to 5.2 per cent in 2024. The anticipated trajectory of underlying (core) inflation indicates a more gradual decrease, whereas the projections for inflation in 2024 have been adjusted upwards. Despite global challenges, the Indian economy grew 6.9 per cent in FY 2022-23. The rise was fueled by robust demand, government-supported investment, and efforts to improve transit infrastructure, logistics, and the business environment. The Indian pharmaceutical market is expected to grow at a CAGR of 10.7 per cent and is expected to reach US$ 65 billion by 2024, and ~US$ 130 billion by 2030. Meanwhile, the global market size of pharmaceutical products is estimated to cross the US$ 1 trillion mark in 2023. [2]

According to the government data, the Indian pharmaceutical industry is worth approximately US$ 50 billion with over US$ 25 billion of the value coming from exports. India exports 20 per cent of the global demand for generic drugs. [3] The figure 1 below gives the size of the Indian pharmaceutical industry with projections.

Figure 1: Indian Pharmaceutical Market in Value (US$ Bn)



Source: https://www.ibef.org/industry/pharmaceutical-india

The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. The sector contributed to around 1.32 per cent 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 ₹ 3,44,125 crore (US$ 42.34 billion). Major segments of Indian pharmaceutical industry include generic drugs, OTC (over-the-counter) medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics.

India is a global leader in the supply of low-cost DPT (diphtheria, tetanus, and pertussis), BCG (Bacillus Calmette–Guérin), and Measles vaccines. India accounts for 60 per cent of global vaccine production, contributing 40 to 70 per cent of the WHO demand for DPT and BCG vaccines, and 90 per cent of the WHO demand for the measles vaccine. [4] The sector has been growing at a healthy rate. The trend in annual turnover in the sector over the last five years may be seen in table 1.

Table 1: Pharma Sector's Growth at Current Prices

Financial year	Turnover (₹ in Crore)	Growth Rate
2017-2018	2,26,423	3.03
2018-2019	2,58,534	14.18
2019-2020	2,89,998	12.17
2020-2021	3,28,054	13.12
2021-2022	3,44,125	4.89

Source: Pharmatrac/NPPA/DGCIS, Kolkata. National Accounts Statistics-2021, Ministry of Statistics and Programme Implementation, Annual Report 2022-23, Ministry of Ministry of Chemicals & Fertilizers Department of Pharmaceuticals, Government of India, https://pharmaceuticals.gov.in/sites/default/files/Annual%20Report%202022-23%20Final-3.pdf

The Active Pharmaceutical Ingredients (APIs), sometimes referred to as drug actives or Bulk drugs, play a crucial role in providing therapeutic effects in the ultimate formulation of a medication. According to IQVIA, formerly known as Quintiles and IMS Health, Inc., the worldwide API market reached a valuation of around US$ 210 billion in 2022, with the small molecule API sector accounting for over US$ 174 billion. The worldwide consumption of APIs saw a compound annual growth rate (CAGR) of 5 per cent over the last five years and is projected to increase by 6 per cent over the next five years. The API market is propelled by many factors, including the escalation in chronic illnesses and the growth of the geriatric population. Additionally, favorable government regulations pertaining to API production, augmented research and development expenditures, and improvements in API manufacturing contribute to the expansion of this market. [5]

Over the last two years, the Indian pharma sector has developed and supplied COVID-19 vaccines and medications worldwide. The Indian vaccine industry created the COVID-19 vaccine utilizing indigenous technology in conjunction with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) in record time.

Some of the major structural factors responsible for the steady growth are ageing of the population, rising lifestyle or chronic diseases, healthcare awareness and insurance penetration apart from increasing government spending under various schemes.

Trade

Drug shortage in United States

The drugs & pharmaceuticals exports are expected to increase in FY 2023-24. The growth in exports will be supported by the drug shortages in the United States (US), trade agreements and the PLI scheme. According to the data from the University of Utah, while there are active shortages for more than 300 drugs in the US, Drug Information Service and Chemotherapy Drugs are among the most affected.[6] This presents an opportunity for Indian pharma companies to meet the demand for generic drugs in this US$ 527 billion market and expand exports in the coming years. In the US, pharmaceutical companies faced persistent pricing pressures. The impact of pricing pressure was exacerbated by fewer new drug launches and fewer Abbreviated New Drug Application (ANDA) approvals. The pending regulatory inspections of Indian sites by the United States Food and Drug Administration (USFDA) impacted exports. Postponed inspections meant that new product approvals were delayed, which impacted pharmaceutical companies' US revenues.

According to the National Cancer Institute,[7] it is estimated that cisplatin and other similar platinum-based drugs are prescribed for an estimated 10 per cent to 20 per cent of all cancer patients. A survey published in June 2023 showed that there is a shortage of carboplatin and cisplatin,[8] which are used in combination to cure many types of cancer. Currently, India exports majority (around 30 per cent; as shown in table 2) of its drugs to USA.

Exports

India's pharmaceutical sector forms a major component of the country's foreign trade and has been consistently making trade surplus. During 2021-22, total exports of pharmaceuticals stood at ₹ 1,74,955 crore (US$ 23.5 Bn) while total imports were to the tune of ₹ 60,060 crore (US$ 8.06 Bn) resulting in a trade surplus of ₹ 1,14,895 crore (US$ 15.44 Bn).[9] As per CMIE data, total exports of pharmaceuticals stood at US$ 25392 during 2022 – 23.

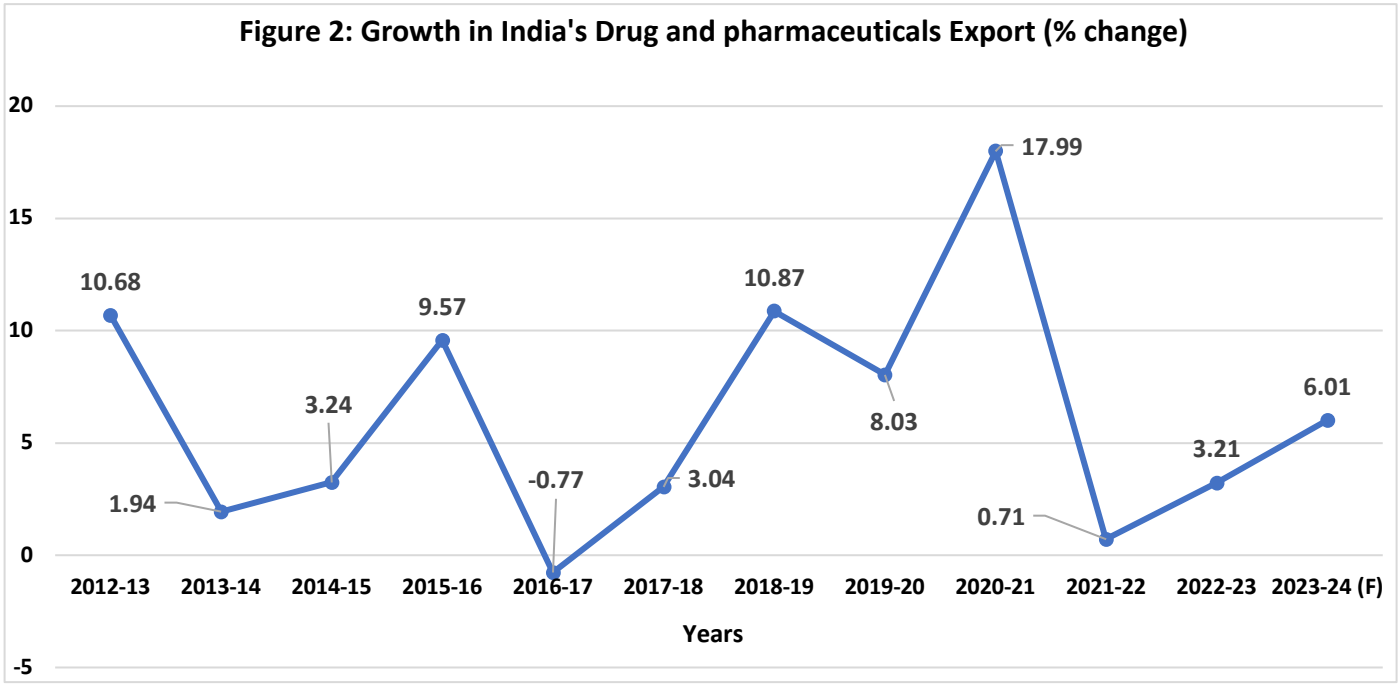
Table 2: Country-wise Exports of Drugs & Pharmaceuticals		
2022-2023		
	Exports (US$ million)	% share
World	25392	100.00
USA	7543	29.71
Belgium	716	2.82
South Africa	658	2.59
UK	648	2.55
Brazil	644	2.54
Netherlands	592	2.33
Russia	574	2.26
France	571	2.25
Germany	523	2.06
Nigeria	515	2.03
Canada	507	2.00
Australia	423	1.67
Kenya	363	1.43
China	348	1.37

Source: CMIE database

Table 3: Category wise Export Data (US$ Million)					
S. No.	Segment	Exports	% Share	Exports	% Share
		2020-21	2020-21	2021-22	2021-22
1	Consumables & Disposables	1290	51%	1378	47%
2	Surgical Instruments	54	2%	71	2%
3	Electronics Equipment	985	39%	1163	40%
4	Implants	99	4%	135	5%
5	IVD Reagent	104	4%	176	6%
	Total	2532		2923	

Source: EEPC (Engineering Export Promotion Council) India, Ministry of Commerce

The Pharmaceuticals Export Promotion Council of India (Pharmexcil) forecasts that India's exports will increase during the current fiscal year, despite the fatalities attributed to cough syrups produced in India. The drugs and pharma export registered 5.13 per cent and 5.10 per cent growth in both June 2023 and April to June 2023 respectively as compared to same period last year.[10] The graph below illustrates the expansion of India's drug exports.



Source: CMIE database

Imports

India is critically dependent on China for supplies of bulk drugs and drug intermediates with China accounting for about two-thirds of the total imports.[11] India's pharmaceutical industry heavily relies on China for 43 per cent of its overall imports, which raises worries in light of the ongoing geopolitical tensions. The imports of bulk drugs in July 2023 were higher by 7,083.5 tonnes compared to the imports recorded in the corresponding year-ago month. This represented a 20.7 per cent growth in imports to 41,233.6 tonnes. Taken together, April 2023-July 2023 saw imports of bulk drugs rise by 10 per cent to 148,679.5 tonnes (CMIE figures). The Table below shows the Country wise imports of drugs and pharmaceuticals.

Table 4: Country-wise Imports of Drugs & Pharmaceuticals (2022-23)

	Imports (US$ million)	% share in total
World	8,100	100.00
China	3,500	43.21
USA	816	10.07
Switzerland	436	5.39
Belgium	360	4.44
Germany	329	4.06
Netherlands	272	3.36
Singapore	231	2.85
Denmark	199	2.46
Italy	183	2.26
France	179	2.21
Japan	133	1.64
UK	132	1.63
Spain	128	1.58
Indonesia	122	1.51

Source: CMIE database

Table 5: Category wise Import Data (US$ Million)					
S. NO.	Segment	Imports 2020-21	% share 2020-21	Imports 2021-22	% share 2021-22
1	Consumables & Disposables	1471	24%	1624	19%
2	Surgical Instruments	104	2%	169	2%
3	Electronics Equipment	3569	57%	5441	64%
4	Implants	226	4%	423	5%
5	IVD Reagents	872	14%	883	10%
	Total	6242		8540	

Source: EEPC India, Ministry of Commerce

Imports of drug formulations in July 2023 were higher by 89 tonnes compared to the imports recorded in the corresponding year-ago month. This represented a 4.4 per cent growth in imports to 2,104.9 tonnes. Taken together, April 2023-July 2023 saw imports of drug formulations rise by 13.3 per cent to 7,598.3 tonnes. (CMIE figures)

Foreign Direct Investments (FDI)

The Economic Survey 2022-23, released on January 31, 2023, ahead of the Union Budget 2023, pointed out that the FDI inflows into the pharmaceutical sector rose four-fold over five years until September 2022, to US$ 699 million. The sector witnessed significant growth in FDI of 58 per cent in the last financial year. [12]

The Government has put in place an investor friendly FDI Policy regime for pharmaceutical sector to bring in global best practices through technology, innovation, and skilling for accelerated economic growth and development; supplement capital for up scaling domestic productivity, increase competitiveness and employment generation amongst other benefits.

As per the extant FDI Policy, 100 per cent foreign investment is allowed under automatic route in greenfield pharmaceutical projects. In brownfield pharmaceutical projects, FDI up to 74 per cent is allowed under the automatic route and Government approval is required for investment beyond 74 per cent. [13]

Data from the Commerce and Industry Ministry shows that from April 2000 to March 2023, cumulative FDI inflows into the pharma sector was US$ 21.46 billion. The cumulative FDI equity inflow into the hospital and diagnostic centers sector stood at US$ 8.73 billion from April 2022 to the end of March 2023, growing from US$ 7.92 billion reported at the end of March 2022. In 2022-23, the hospital and diagnostic centers sector received fund infusion of US$ 810 million, as compared to US$ 697 million inflow in 2021-22. The medical and surgical appliances sector has seen the FDI equity inflow almost doubling during the fiscal year 2023. The foreign investment into the sector stood at US$ 397 million during the fiscal year, as compared to US$ 208 million in the 12 months of the previous fiscal year. The cumulative foreign investment flow from April 2000 to March 2023 in this sector stood at US$ 2.80 billion, while till March 2022 was US$ 2.19 billion. [14]

As per official data, the FDI equity inflow into the pharmaceutical sector hospital and diagnostic centers sector reported a decline of 82 per cent [15] in the first three months of the current fiscal year, as compared to the corresponding period of the previous year. The decline comes after a significant growth of 45 per cent [16] reported for the 12-month period ended March 2023, according to official data.

The FDI equity infusion during the last quarter of the financial year, ending March 2023, reported a growth of 14 per cent at US$ 240 million as compared to the US$ 210 million registered during the same period of previous fiscal year.

Table 6: FDI inflow in Pharma sector	
Years	(₹ crores)
2018-19	2950
2019-20	5846
2020-21	11526
2021-22	12097
2022-23 (up to September 2022)	8081

Source: DPIIT

The FDI Inflows into the country were led by the services sector with US$ 631.98 billion (16.3 per cent), followed by computers and software & hardware (14.85 per cent), trading (6.20 per cent), telecommunications (6.08 per cent), automobile industry (5.44 per cent), construction (infrastructure) activities (4.72 per cent), construction development (4.08 per cent), and drugs and pharmaceuticals (3.34 per cent), between April to June 2023. [17]

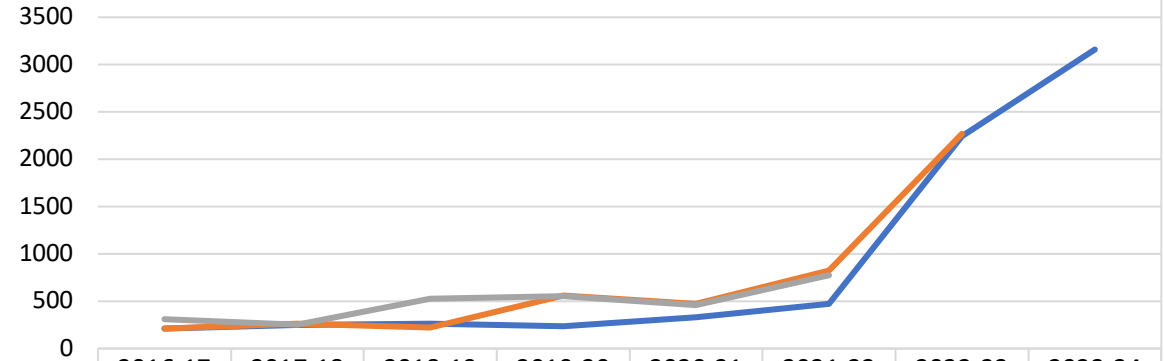
Institutional Initiatives

The DoPs (Department of Pharmaceuticals) launched several new projects and initiatives in 2022. Some of the department's most notable accomplishments this year include the PLI scheme and the Pradhan Mantri Bhartiya Janaushadhi Pariyojana, both of which aim to increase investment and production in India's pharmaceutical sector to make high-quality generic medicines more accessible to the country's poor and disadvantaged. The division also prioritized bolstering the pharmaceutical sector and encouraging indigenous manufacture of medical equipment.

The Finance Minister, Smt. Nirmala Sitharman spoke on the subject of pharmaceutical innovation by announcing the launch of a new initiative to support pharmaceutical R&D via the establishment of centers of excellence. According to her, the government would also push industries to fund R&D in certain sectors. With respect to healthcare and research and development in the sector, she made the following declarations [18] in her budget speech:

- New nursing colleges will be established, co-located with 157 recently established medical colleges.
- A mission to eliminate sickle cell anemia by 2047 will be launched in 2023-24, involving screening of seven crore people.
- Facilities in select ICMR Labs will be made available for research by public and private medical college faculty and the private sector.
- The allocation of ₹ 1,250 crores has been for the development of bulk drug parks and for the promotion of medical device parks in the country. It includes ₹ 1,000 crore for bulk drug parks, and ₹ 200 crore promotion of medical device parks.

Figure 3: Allocations to Department of Pharmaceuticals From 2016-17 to 2023-24, ₹ crores



	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22	2022-23	2023-24
Budget Allocation	211.4	247.74	261.53	235.51	333.58	470.41	2244.15	3160.06
Revised Allocation	211.4	266.09	220.41	562.33	470.41	823.11	2268.54	
Actual Expenditure	307.57	252.42	523.46	553.5	456.01	774.83		

Source: Union Budget 2023-24, https://www.indiabudget.gov.in/

During FY 2018-19, the actual expenditure was twice the budget estimates. The budget estimates for the year were ₹ 261.53 crores, while the actual expenditure for the year was ₹ 523.46 crores. While the budget estimates for FY 2019-20 were on par with those of the previous year, they were revised to ₹ 562 crores, closer to the actual expenditure incurred in FY 2018-19 (see Chart 3). During the pandemic hit year 2020-21, the initial budget estimates for the DoPs were ₹ 333.58 crores, which the government revised to ₹ 470.4 crores. However, as per the details provided in the Budget documents, the actual expenditure for FY 2020-21 was ₹ 456.01 crores. This is not only slightly lower than the revised estimates but also lower than the actual expenditure for the previous two years.

The Budget also highlights the substantial increase in focus and allocation to the DoPs in FY 2022-23. The revised estimates for FY 2021-22 increased to ₹ 823.11 crores from the earlier budget estimates of ₹ 470 crores. However, the most important increase was observed in the budget estimates for FY 2022-23 and 2023-24. The Budget estimates for FY 2022-23 for the DoPs stand at ₹ 2244.15 crores, which marked an almost five-fold increase over the budget estimates of FY 2021-22. This was later revised to ₹ 2268.54 crores. Similarly, the Budget estimate for 2023-24 is ₹ 3160.06 crores.

Indian Medical Device Sector

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Union Cabinet, chaired by the Hon'ble Prime Minister Shri Narendra Modi, on 26th April 2023, approved the National Medical Devices Policy, 2023. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19 pandemic through the large-scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Rime Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment (PPE) Kits & N-95 masks. The market for medical equipment in India is a "sunrise sector" that is seeing rapid expansion at the moment. The market for medical devices in India is projected to have a size of US$ 11 billion (roughly ₹ 90,000 Cr) in the year 2020, and its share of the market for medical devices worldwide is projected to be 1.5 per cent. The market for medical equipment in

India is poised for expansion and offers a significant opportunity to realize the dream of self-sufficiency while also contributing to the achievement of universal health care.

It is anticipated that the National Medical Devices Policy, 2023 would make it easier for the medical device industry to expand in a methodical manner, thereby helping it to meet the public health goals of access, affordability, quality, and innovation. It is anticipated that this industry will be able to realize its full potential because of the implementation of synchronized strategies. Such strategies include developing an ecosystem that is conducive to manufacturing while also placing an emphasis on innovation; developing a regulatory framework that is both robust and streamlined; providing support for training and capacity building programs; and promoting higher education in order to cultivate talent and skilled resources that are in conformity with the requirements of the industry.

Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

The DoPs, Ministry of Chemicals and Fertilizers, Government of India launched PMBJP in November 2008 with the goal of making high-quality generic medications accessible at low cost to everyone. The Janaushadhi Kendras are specially designated pharmacies that sell low-cost generic drugs as part of the program. There are 1800 different medications and 285 different surgical products in the PMBJP's product basket. The Pharma & Medical Bureau of India (PMBI) is the society established under India's Societies Registration Act, 1860 that is responsible for carrying out the plan.[19] The target is to increase these Kendras to 10500 by March 2025. With 9,782 outlets already functional, the Health Ministry aims to open 10,000 new Janaushadhi Kendras across the country by the end of the year. With the aim to ensure its presence in 745 districts in the country (including 112 aspirational districts), the Janaushadhi Kendras are to expand to 25,000 outlets by 2028-29, according to government data.[20] The prices of the Janaushadhi medicines are generally 50 to 90 per cent less than that of branded medicines, which are available in the open market. The medicines are procured from World Health Organization – Good Manufacturing Practices (WHO-GMP) certified suppliers only to ensure the quality of the products. [21]

As per a government official [22], Uttar Pradesh has the greatest number of outlets while Ladakh has the fewest; only 651 districts have Janaushadhi Kendras, and online applications are only being invited from 765 districts. The goal is to open 3000 centers every year. The product range will be increased to up to 2,500 medicines and 350 surgical and consumable equipment. The aim is to establish a resilient supply chain by end-to-end solution. There are currently about 25-50 testing labs across India that have National Accreditation Board for Testing and Calibration Laboratories (NABL) accreditation, and the central government is working to identify more good quality suppliers, who will meet the demand for medicines and other equipment.

Table 7: Janaushadhi Kendra

States	No. of centers
Uttar Pradesh	1432
Karnataka	1098
Kerala	983
Tamil Nadu	940
Ladakh	2
Sikkim	5
Andaman and Nicobar Islands	9

Source: www.Janaushadhi.gov.in

A COVID Drugs Management Cell (CDMC) was set up in the DoP in the month of April 2021 to oversee the management of smooth supply of drugs used in COVID-19 management during the pandemic. The CDMC has representatives from National Pharmaceuticals Pricing Authority (NPPA) and the Central Drugs Standards Control Organization (CDSCO) as well.

The list [23] of various schemes and programs for the Indian pharmaceutical industry as per the 12th Plan are detailed below:

- Pharma Promotion and Development Scheme (PPDS)
- Intellectual Property Rights Facilitation Centers
- International Pharma Cooperation Initiative (IPCI)
- Up-gradation of SMEs to WHO-GMP standards
- Capacity building through training of 5000 Working Professionals in WHO-GMP
- Up-gradation of SMEs to USFDA/EDQM/TGA and other International Standards
- Setting up of one National and five Regional Formulation Development and Manufacturing standards training centers
- Establishment and up-gradation of 10 Pharmaceuticals Growth Clusters
- Infrastructure support for Cold Chain for high end drugs for exports
- Scheme for environment standards compliance and required infrastructure support including capacity building
- Setting up of National Center for Phyto-pharma development
- GLP/GCP/Animal House Lab Schemes
- Continuing R&D Schemes for National Institute of Pharmaceutical Education and Research (NIPER) Mohali
- Permanent establishment and operation of 6 New NIPERs
- Pharma Venture Capital Fund
- Pharma Innovation and Infrastructure Development Initiative (PIIDI)
- At NIPER Hyderabad: Setting up National Center for R&D in Bulk Drugs at NIPER Hyderabad
- At NIPER Kolkata: National Pharmaceutical Nanotechnology Center
- Setting up National and Regional Bio-similar Expertise Centers
- Creation of NPPA-State Government Coordination Cells in States
- "Scheme for Interaction with States" and "Creation of National Pharmaceutical Pricing Authority (NPPA)-State Government Coordination Cells in States" were originally proposed in 11th Plan but not approved by Planning Commission. Hence proposed for 12th Plan and will help in strengthening the monitoring Objective of drugs prices and strengthening the monitoring objective of drugs prices, resp.
- Pharma Vision 2020
- Make in India
- Assistance to Medical Device Clusters for Common Facilities (AMD-CF)
- Scheme for Strengthening of Pharmaceuticals Industry (SPI)
- Scheme for Promotion of Bulk Drug Parks.
- Scheme for Promotion of Medical Device Parks.
- Scheme of Consumer Awareness, Publicity and Price Monitoring (CAPPM)
- Assistance to Pharmaceutical Industry for Common Facilities
- Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP)

Pharmaceutical parks for Bulk Drugs and medical devices

The DoPs has established a high-level committee to track the development of bulk drug, also Known as API, parks in three states. Shri. Mansukh Mandaviya, Union Minister of Chemical and Fertilizer, oversees the high-level committee. The Minister of State, Shri. Bhagwanth Khuba is vice chairman, and other top officials, including business experts, are also the members of this committee. In October 2022, the Prime Minister of India, Shri Narendra Modi laid the foundation stone of the bulk drug park in Una, Himachal Pradesh. It is expected to generate investment of roughly ₹ 10,000 crores and employ more than 20,000 people. It will also have a positive effect on the local economy. The first bulk drug park in India was set up in Jambusar of Bharuch district, Gujarat. A total of 13 States submitted proposals under the scheme for promoting bulk drug parks. To evaluate the proposals, the DoPs was advised by an advisory committee under the CEO of NITI Aayog. As per the proposals submitted by the States,[24] three states got 'in-principal approval' from the Centre to establish bulk drug parks. Bulk drug parks will be set up in the following States:

- In 1402.44 acres of land at Tehsil Haroli, district Una, Himachal Pradesh
- 2015.02 acres of land at Tehsil Jambusar, District Bharuch, Gujarat
- 2000.45 acres of land at K.P. Puram & Kodhada of Thondagi Mandal of East Godavari District, Andhra Pradesh.

Last year, as per a statement by the Minister of State, Shri. Bhagwanth Khuba in a Lok Sabha session,[25] the scheme for "Promotion of Bulk Drug Parks," has a financial outlay of ₹ 3,000 crores from FY 2020-2021 to FY 2024-25. This scheme provides financial assistance to three states mentioned above for establishing Bulk Drug Parks. He mentioned further that the total financial outlay of "Promotion of Medical Devices Parks" was ₹ 400 crore and the maximum assistance under the scheme for a medical device park would be limited to ₹ 100 crore. In September 2023, the Cabinet approved shifting the Kakinada Bulk Drug project to Nakkapalli in lieu of the Centre's decision to set up the project on government land. [26]

Production Linked Schemes (PLI)

The DoPs have PLI schemes for pharmaceuticals, for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ drug Intermediates and APIs in the country and promoting domestic manufacturing of medical devices. During Union budget 2023, total outlay set aside for the coming year was ₹ 1200 crores. Last year, ₹ 1663.30 crores were allocated as total budget for boosting domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

Table 8: Budget Allocation for the PLI schemes for the Department of Pharmaceuticals 2023 (₹ crores)				
Sr. No.	Production Linked Incentive Schemes	Budget Allocation 2022-2023	Revised Allocation 2022-2023	Budget Allocation 2023-2024
1	Promotion of Bulk Drug Parks	900	900	---
2	Production Linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of Critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India	390	14.61	100
3	Promotion of Medical Device Park	120	32.93	---
4	Production Linked Incentive (PLI) Scheme for Domestic Manufacturing of Medical Devices	216	21.56	100
5	Production Linked Incentive Scheme for Pharmaceuticals	3	694.2	1000
	Total	1629	1663.3	1200

Source: Demand Numbers 7, Expenditure Budget 2023-24

National List of Essential Assistive Products (NLEAP)

The National List of Essential Assistive Products (NLEAP) was released by the ICMR to prioritize essential assistive products in order to improve the lives of people with functional impairments. The Assistive products (APs) play a vital role in enhancing the quality of life and promoting independence among individuals with functional impairments. The NLEAP is a list of 21 APs and technologies that are deemed essential for individuals with functional impairments to enhance their quality of life and participation in society. [27]

Industry Risk and Challenges

In 2018, Indian pharmaceutical manufacturers received 174 USFDA inspections, 14 per cent of all FDA inspections globally. The USFDA reports that India owns 12 per cent of US pharmaceutical manufacturing, and Indian corporations are approving more ANDAs. This necessitates FDA inspections. Of the 60 Drug GMP warning letters issued between 2013 and 2018, 14 came in 2018. The USFDA plant audits in India for medication quality assurance peaked in 2019 with 239 inspections. While 80 inspections were conducted during the period January to March 2020, the number of such inspections fell to 5 in 2021.

In 2023, the USFDA resumed regular inspections/audits of pharma manufacturing units and issued voluntary, formal, warning letters, and import warnings. For instance, on 20 September 2023, Aurobindo Pharma stated that the USFDA had issued a Form 483 with one observation following an inspection of a formulation production facility of its unit in Andhra Pradesh.

The Drug Controller General of India (DCGI) has issued an advisory against the usage of antacid Digene gel, which is manufactured by Abbott India. The authority issued this advisory after receiving a complaint alleging that one bottle of Digene gel mint flavor is of regular taste and light pink color whereas another bottle of the same batch was of white color with bitter taste and a pungent odor. The products were manufactured in Abbott India's Goa unit. Accordingly, the drugmaker Abbott India voluntarily recalled several batches of antacid Digene Gel in September 2023. The government further plans to suspend the

manufacturing license of Abbott India's popular antacid medicine after inspectors flagged contamination risks and sanitization issues at its factory, government documents show. [28]

In December 2022, the WHO linked Indian-made cough syrups to the acute kidney failure and deaths of 66 children in the West African country. WHO's laboratory analysis said the cough syrups contained "unacceptable amounts of diethylene glycol and ethylene glycol," chemicals often meant for industrial use.[29] The two products were AMBRONOL syrup and DOK-1 Max syrup. The stated manufacturer of both products is MARION BIOTECH (Uttar Pradesh, India). [30] This license was later cancelled. The fatalities of children and adolescents caused by contaminated cough syrups manufactured by Indian companies exposed India's lack of regulation, which enables the excessive consumption of over-the-counter cough syrups in the nation.

According to the DCGI, following alerts from the WHO, the DCGI has instructed the drug controllers of all states and union territories to maintain a strict vigil on the sale and distribution of falsified version of two drugs, the liver medicine Defitelio and Takeda's cancer medicine Adcetris (injection). These products are usually available at the patient level and distributed in unregulated supply chains, primarily online. The WHO reported that there are at least eight different batch numbers of falsified versions in circulation.

The Indian pharma is now experiencing a strict control over the price of pharmaceuticals by the government. If we look at it from the other angle, then things apparently seem to be in order since citizens are able to get pharmaceuticals of high quality at more affordable costs. This, however, creates a barrier for the innovative potential and motivation of pharmaceutical companies, especially for the start-ups. If there is not a great deal of certainty of receiving returns on the investment (as sunk cost) that has already been spent on R&D, then pharmaceutical businesses will be hesitant to spend significant sums in the R&D departments of their companies for the purpose of drug development.

India has a competitive advantage that is conducive to favorable FDI regulations, industrial expansion, and a trained labor force. However, the demographic attributes of the skilled workforce in the pharmaceutical sector are deficient in terms of appropriate employment opportunities, incentives, training, resources, and other supportive functions. India is a country, where annually, over 400,000 pharmaceutical graduates emerge, including individuals with degrees such as B.Pharm, M.Pharm, Pharm.D, pharmaceutical MBA, and others. However, a discrepancy exists between the kind of academic subjects offered and the practical demands of the industry. As a result of this anomaly, there exist a sufficient number of individuals available for employment, but their potential remains untapped. This phenomenon gives rise to a multitude of GMP concerns within industrial operations. Fortunately, there is a growing awareness among academic institutions on this matter, leading them to provide practical industrial exposure to young learners. The allocation of resources for the implementation of training and development initiatives is aimed at attracting and retaining high-caliber individuals, with a specific focus on scientific and research positions. The presence of a proficient labor force is of utmost importance in driving innovation and facilitating the creation of products.

India heavily depends on China (largest producer of Bulk drugs or APIs) for drugs that are critical for saving lives. India already imports 43 per cent of its overall drugs imports (refer to table 4). India's dependency on KSM from Beijing exceeds 50 per cent. This issue needs to be urgently addressed by the authorities to reduce sectoral, concentration and geo-political risks.

The previous year was characterized by significant disruptions in supply chain variables, worldwide corporate operations, geopolitical dynamics, and the epidemic's ongoing impact. The manufacturers are likely to be significantly concerned about the impact of an uncertain economy, as the rising prices of raw

materials is likely to lead to higher expenses for pharmaceutical businesses and consumers in the next year, therefore affecting supply chains. The latest data provided by Resilinc reveals that some pharmaceutical factories in Europe saw a ten-fold surge in electrical expenses as a result of escalating prices. Consequently, these companies have been compelled to reevaluate their supply chains in order to mitigate costs and guarantee uninterrupted operations.

Pharma Sector-An Inflection Point

The pharmaceutical sector in India has emerged as a prominent participant in the global healthcare business over an extended period of time. To maintain competitiveness in the global arena, it is essential for Indian pharmaceutical businesses to increasingly allocate resources towards research and development (R&D) endeavors. The expansion of market presence and income streams may be facilitated by the development of new pharmaceuticals, biosimilars, Radio Pharma, allergy immunotherapy, CDMO sterile injectables and generic copies of high-value medicines. It is recommended to allocate resources towards the enhancement of biotechnology capabilities and the advancement of biosimilars, since both sectors have substantial growth potential on a worldwide scale. Biosimilars have the potential to provide cost-effective alternatives to costly biologics, hence enhancing the accessibility of healthcare services. The company should pursue global expansion by further exploring and entering new markets, while simultaneously consolidating its position in existing countries. The establishment of strategic alliances and cooperation with multinational pharmaceutical corporations may help Indian enterprises in gaining entry into new markets and acquiring advanced technology.

The adherence to GMP and Good Clinical Practices (GCP) is of utmost importance in establishing credibility within the international market. The maintenance of high-quality standards and the assurance of conformity with international rules, such as, those set out by the FDA and WHO, are of utmost importance. It is advisable to closely monitor the expiry of patents in developed countries as a means of identifying potential avenues to produce generic pharmaceuticals. Adhering to international environmental standards has the potential to bolster the industry's image and attract customers that prioritize environmental sustainability.

The use of digital technologies, including artificial intelligence (AI) and data analytics, has the potential to enhance several aspects of the pharmaceutical industry, such as, drug research, clinical trials, supply chain management, and consumer interaction. The process of digitalization has the potential to enhance operational efficiency, decrease expenses, and expedite the speed at which decisions are made. The use of telemedicine and e-pharmacy services may be harnessed to enhance the distribution network and enhance the accessibility of medications for patients.

In sum, the pharmaceutical sector in India has displayed remarkable growth, innovation, structural transformation, resilience and adaptation throughout its history. At this defining moment of history, the industry can sustain its growth in 2023 by an accent on the well-established growth triggers, innovative strategies and making mid-course corrections, wherever necessary. Such well-conceived measures also help the Indian pharmaceutical industry to make a significant contribution towards enhancing global healthcare accessibility by inter-alia a robust and scalable response to public health emergencies, greater public private partnerships to support research and manufacturing hubs and development capacity and leveraging information and communication technologies (ICT). Simultaneously, the issue of retaining the competitive advantage in the pharmaceutical industry requires a sharper focus on improved data quality and incentivizing the development of new drugs. Evidently, it is important not to be behind the curve in terms of evolving trends and tendencies, regulatory stipulations and laws within the sector while ensuring the last mile availability in order to realize the humungous potential of this sector.

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