

PHARMACEUTICALS

SUMMARY

The Pharmaceutical industry in India is the 3rd largest in the world in terms of volume and14th largest in terms of value. It contributes 3.5% of the total drugs and medicines exported globally. ¹

India, known as the Pharmacy of the World, is the largest provider of generic drugs and one of the biggest suppliers of low-cost vaccines globally.¹

India has contributed significantly to global healthcare by ensuring high quality, affordable and accessible medicines around the world. ¹

Pharmaceutical is one of the top ten attractive sectors for foreign investment in India.

The pharmaceutical exports from India reach more than 200 nations around the world, including highly regulated markets of the USA, West Europe, Japan, and Australia. 1

About 20% of the global exports in generic drugs are met by India.¹

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India supplied around 45 tons and 400 million tablets of hydroxychloroquine to around 114 countries globally.

REASONS TO INVEST

India's healthcare market may see a threefold jump in value terms to reach USD 372 bn by 2022 with rising income, greater health awareness, increased precedence of lifestyle diseases and improved access to insurance.²

Ayushman Bharat is National Health Protection Scheme, which will cover over 100 mn poor and vulnerable families (approximately 500 mn beneficiaries) providing coverage up to INR 5 lakh per family per year for secondary and tertiary care hospitalization.³

Under the 'Promotion of Bulk Drug Parks' Scheme, the Union government aims to develop 3 mega Bulk Drug parks in India in partnership with the States. The parks will have common facilities such as solvent recovery plant, distillation plant, power & steam units, and common effluent treatment plant. ⁷

The presence of a skilled workforce as well as high managerial and technical competence is a source of attraction for private players. Pharma companies have already increased spending in the country to tap rural markets and develop better infrastructure. ¹

Hon'ble Prime Minister, Shri Narendra Modi has given its approval to introduce the Production-Linked Incentive (PLI) Scheme in Pharmaceuticals Drugs through the Department of Pharmaceuticals with an financial outlay of INR 15000 cr over a five-year period for Enhancing India's Manufacturing Capabilities and Enhancing Exports – Atmanirbhar Bharat.

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RECENT ANNOUNCEMENTS

31st December 2020: Hon'ble PM, Shri Narendra Modi laid the foundation stone of AIIMS Rajkot.

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21st December 2020: Minister of State (I/C) for Labour and Employment Shri Santosh Kumar Gangwar laid the foundation stone of 100 bedded Employees State Insurance Corporation (ESIC) Hospital at Ompura, Budgam.

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17th December 2020: Union Minister for Chemicals and Fertilizers Shri D.V. Sadananda Gowda inaugurated the two-day Annual Summit of the Organisation of Pharmaceutical Producers of India (OPPI) to produce and export critical life-saving medicines to the rest of the world. Read More

9th December 2020: Cabinet approves Memorandum of Understanding between India and Suriname on Cooperation in the field of Health and Medicine. Read More

8th December 2020: A New Digital platform 'CO-WIN' is being used for COVID-19 Vaccination Delivery.

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STATISTICS

The annual turnover of the Pharmaceutical industry in India in the year 2018-19 is estimated at INR 2.5 lakh cr.¹

India recorded a growth of 10.72% in Pharmaceutical exports in 2018-19, which are valued at INR 1.33 lakh cr.¹

GROWTH DRIVERS

Ministry of Chemicals and Fertilizers issued guidelines for implementing the provisions of Public Procurement Order (PPO) related to the procurement of goods and services in Medical Devices.¹⁶

On 21st December 2020, MOU was signed between Tata Memorial Centre of India and Vietnam National Cancer Hospital to promote exchanges in the areas of training and scientific research, health care services, collaboration in diagnosis and treatment for cancer patients.¹⁷

FDI POLICY

Up to 100% FDI has been allowed through automatic route for Greenfield pharmaceuticals projects. For Brownfield pharmaceuticals projects, FDI allowed is up to 74% through automatic route and beyond that through government approval. ⁵

The cumulative FDI equity inflow in the Drugs and Pharmaceuticals industry is USD 16.867 mn during the period April 2000 to September 2020. This constitutes 3.37% of the total FDI inflow received across sectors. ⁴

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SECTOR POLICY

THE NATIONAL PHARMACEUTICAL PRICING POLICY, 2012 (NPPP-2012) NOTIFIED ON 07 DECEMBER 2012, WITH THE FOLLOWING SALIENT FEATURES: ¹

The regulation of prices of drugs on the basis of the essentiality of drugs as specified under the National List of Essential Medicines (NLEM) - 2011.

The regulation of prices of drugs on the basis of regulating the prices of formulations only.

The regulation of prices of drugs on the basis of fixing the ceiling price of formulations through Market-Based Pricing.

The provision of exemptions to drugs manufactured through indigenous R&D from price control for five years.

A Drug Price Control Order 2013 has been notified in May 2013 to implement the provisions of NPPP-2012.

<u>UMBRELLA SCHEME ¹</u>

The Department of Pharmaceuticals has prepared an Umbrella Scheme namely 'Scheme for Development of Pharma industry'.

The said Umbrella Scheme comprises of the following sub-schemes:

Assistance to Bulk Drug Industry for Common Facilitation Centres

Assistance to Medical Device Industry for Common Facilitation Centres

Assistance to Pharmaceutical Industry (CDP-PS)

Pharmaceutical Promotion and Development Scheme (PPDS)

Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)

PHARMACEUTICALS PROMOTION DEVELOPMENT SCHEME (PPDS) 1

Under the PPDS, the Department of Pharmaceuticals aims to:

Conduct Training/knowledge improvement programs/activities on issues/subjects relevant to the growth of the pharmaceutical industry.

Organize Summits, Convention, Exhibitions, Pharmacy week, meetings etc. in India and abroad and produce promotional materials like films, displays etc.

Conduct research studies, sector reports etc.

Purchase books, quality standards, pharmacopoeias, magazines, directories, software for developing information data banks, developing e-learning modules etc. Give awards to achievers in pharmaceutical industry.

Under Production-Linked Incentive (PLI) Scheme in High-Efficiency Manufacturing of Medical Devices was proposed by the Department of Pharmaceuticals with a financial outlay of INR 15,000 cr.¹⁵

NATIONAL TELEMEDICINE SERVICES¹⁹

The National Telemedicine Service "eSanjeevani" is a digital health initiative of the Ministry to implement teleconsultation in all the 1.5 lakh Health and Wellness Centres in a 'Hub and Spoke' model, by December 2022.

eSanjeevani has completed 8 lakh consultations on 20 November 2020. Over 11,000 patients are seeking health services on a daily basis in 27 States/UTs.

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FINANCIAL SUPPORT

PROVISIONS OF BUDGET 2020-21

As per the Union Budget 2020-21, the allocation to the Department of Pharmaceuticals has been USD 44.47 mn.⁶

SCHEME FOR PROMOTION OF BULK DRUG PARKS

Under the scheme, the Government of India has approved a sum of INR 3,000 cr for setting up 3 mega Bulk Drug Parks in the country. Grants-in-Aid will be provided to States with a maximum limit of INR 1000 cr per Bulk Drug Park.⁷

PRODUCTION LINKED INCENTIVE (PLI) SCHEME

Under the scheme, the Government of India will provide up to 20% incentives on incremental sales of 41 products stipulated in the scheme guidelines. The total financial support approved by the government under this scheme is INR 6,940 cr. ⁸

INVESTMENT OPPORTUNITIES

The Indian Drugs & Pharmaceuticals Limited (IDPL), a public limited company, aims to encourage indigenous production of pharmaceuticals and to support various health programmes of the Central Government. It is currently manufacturing 86 products, under Public-Private Partnership, and 25 products, under non-Public Private Partnership mode. ¹

Japanese companies have been invited to invest in Indian Pharmaceutical and Medical Device Industry. Pharmaceutical Traders Association and Japan Federation of Medical Devices Associations have come to the mutual understanding that cooperation between the two countries can contribute to stabilize the global supply-chain especially of APIs and Medical Devices.⁹

A Bulk Drug Pharma Park has been proposed in Solan, Himachal Pradesh to give impetus to the Pharmaceutical industry. An amount of INR 200 cr has been sanctioned for the Bulk Drug Pharma Park and a Satellite extension centre of National Institute of Pharmaceutical Education and Research (NIPER).¹⁰

The Government of Assam has proposed a Pharmaceutical Park in Chaygaon, Kamrup Rural on a land area of 100 acres. The estimated project cost is INR 153.64 cr. 11

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FOREIGN INVESTORS

Teva Pharmaceuticals (Israel) Nipro Corporation (Japan) Procter & Gamble (USA) Pfizer (USA) Glaxo Smith Kline (UK) Johnson & Johnson (USA) Otsuka Pharmaceutical (Japan) AstraZeneca (Sweden-UK)

AGENCIES

1. Central Drugs Standard Control Organisation (CDSCO)

2. Department of Pharmaceuticals, Ministry of Chemicals & Pharmaceuticals

3. National Pharmaceutical Pricing Authority

KEY ACHIEVEMENTS

The Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana (PMBJP) achieved a sale of INR 258 cr (at MRP) in the FY 2019-20 (till 30th November 2019), which led to savings of approximately INR 1800 cr of the common citizens of the country. ¹

Under the 'Pradhan Mantri Bhartiya Janaushadhi Pariyojana' (PMBJP), 6068 PMBJP Kendras are functional across the country, and 696 out of 725 districts have been covered as on 20th December 2019. ¹

Under the 'Janaushadhi Suvidha', over 3.43 cr sanitary napkins have been sold at INR 1 per sanitary napkin since August 2019.¹

About 11600 educated unemployed youth of the country have got direct sustainable employment under the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP).¹

Total size of the drugs & medical device industry is around US\$43 billion .Currently, the growth rate is 7-8% in the drug sector and 15- 16% in the medical device sector.¹² The total export of drugs and medical devices is US\$20 billion of which drugs form around 90% of the total exports.¹²

During September 2020, 26 new medicines retail prices were fixed. This brings a cumulative figure to 1417 till September 2020.¹³

Under PLI Scheme for API/KSM/DI received total 215 application and PLI Scheme for Medical Devices received 28 application in November 2020.¹⁸

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