

Department of  
Pharmaceuticals  
Ministry of Chemicals  
and Fertilizers,  
Government of India

# OPPORTUNITIES FOR INVESTMENT IN PHARMACEUTICAL AND MEDICAL DEVICE SECTOR IN INDIA.



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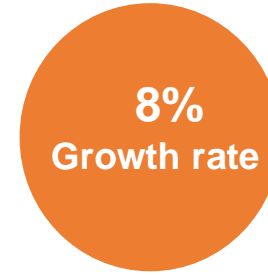


# SECTOR OVERVIEW - PHARMACEUTICALS

## India Ranks

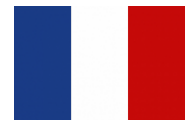
- 1<sup>st</sup>** Largest supplier of low cost Generics, Vaccines and Affordable HIV medicines
- 2<sup>nd</sup>** Highest FDA approved plants
- 3<sup>rd</sup>** Largest in terms of Volume
- 10<sup>th</sup>** Largest in terms of Value

- Source of 60,000 generic brands across 60 therapeutic categories, manufactures 500+ APIs
- Continuous supply of Hydroxy-Chloroquine to India and the world for COVID requirements even during countrywide shutdown



Export to 200+ countries and territories

## FDI Investment into India



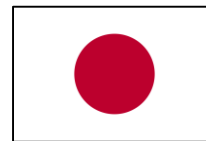
FRANCE



UK



GERMANY



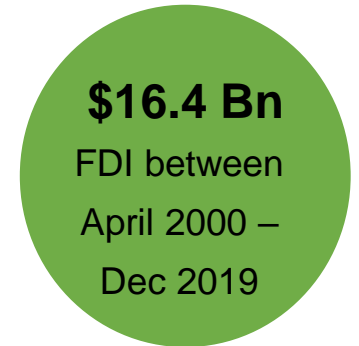
JAPAN



USA



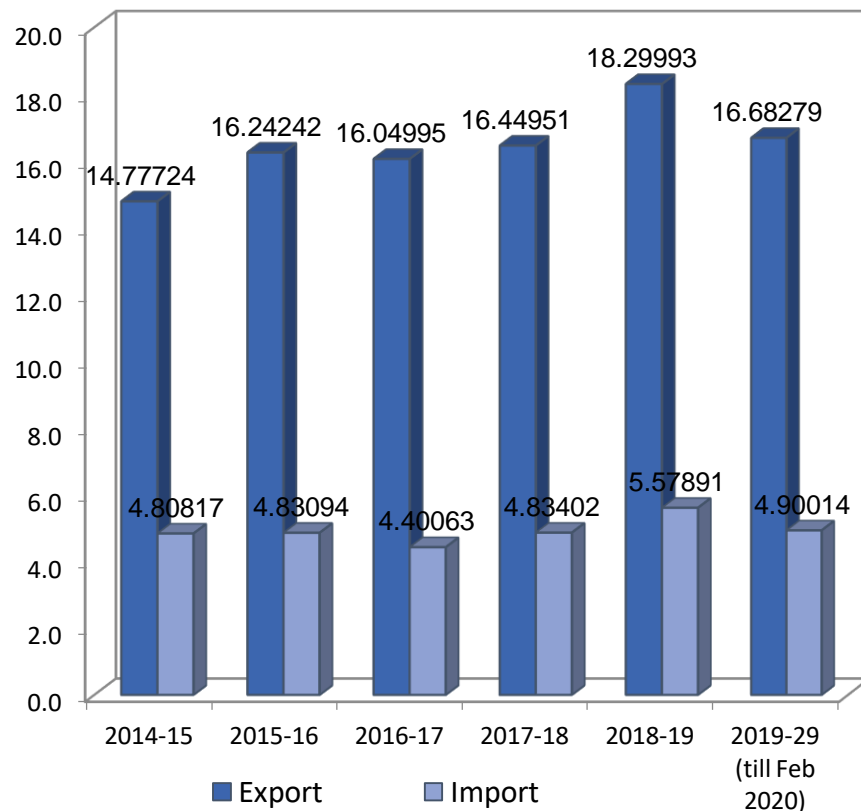
SPAIN





# TRADE

## PHARMA TRADE (\$ BN)



- Annual trade surplus
- Drug formulations & Biologicals contribute to 79% of the total pharmaceutical exports (the third largest among the principal commodities exported by India) (2018-19)
- Bulk drugs and intermediates contribute to 63% of the total pharmaceutical imports (2018-19)

# INITIATIVES FOR PROMOTING THE INDUSTRY



For handholding of the investors for sorting issues with Government departments : both Centre and States

17.16% CORPORATE INCOME TAX

A 4-Year window for new manufacturing units incorporated after 1 Oct 2019 and operational before 31 March 2023

LIBERAL FDI POLICY

**Greenfield** : 100% FDI under Automatic route  
**Brownfield** : 74% FDI under Automatic route; Beyond that under Government route

NEW SCHEMES FOR MANUFACTURING

Production Linked Incentive Scheme and Bulk Drug Parks



# PRODUCTION LINKED INCENTIVE SCHEME

## Incentive Mechanism

Incentive on incremental sales over the base year (FY 2019-20) for 7 years)

## Target Segments

53 KSMs/Drug Intermediates and APIs

## Outlay

USD 900 Million

### For fermentation based eligible products

Year	% on incremental sale of KSM/intermediate/API
2022-2023 to 2025-2026	20%
2026-27	15%
2027-2028	5%

### For chemically synthesized eligible products

Year	% on incremental sale of KSM/intermediate/API
2021-2022 to 2026-2027	10%

- ❖ Incentive linked with minimum investment
- ❖ Number of manufacturers limited per identified drug
- ❖ Greenfield/New plant of existing manufacturer



# PROMOTION OF BULK DRUG PARKS

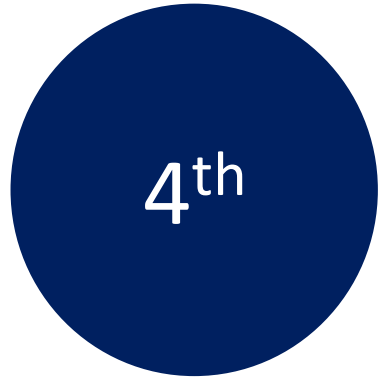
<b>Benefits</b>	Grant-in-Aid to 3 Bulk Drug Parks with a maximum limit of USD 135 Million per park or 70% of the project cost of Common Infrastructure Facilities (CIF), whichever is less
<b>Tenure</b>	Five years (2020-21 - 2024-25)
<b>Coverage</b>	<p>CIF such as:</p> <ul style="list-style-type: none"><li>• Solvent recovery and Distillation Plant</li><li>• Central Effluent Treatment Plants</li><li>• Captive Power Plants</li><li>• Steam and Cooling system</li><li>• Incubation facilities, Common Logistic facilities, Advance Common Testing Centre, Regulatory awareness facility Centre, Emergency Response Centre etc.</li></ul>

## Benefits to the manufacturer





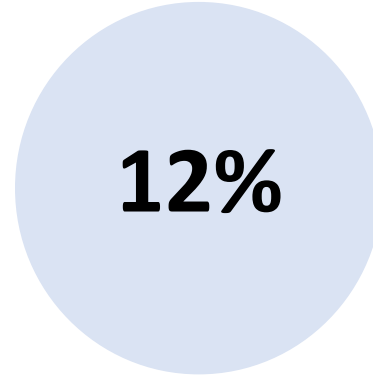
# SECTOR OVERVIEW – MEDICAL DEVICES



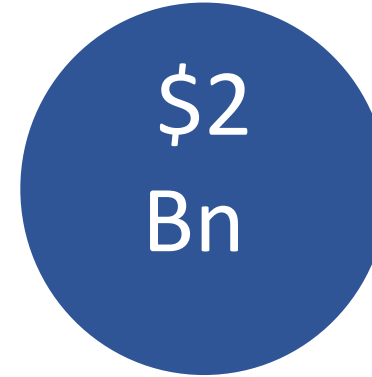
Largest Market in Asia



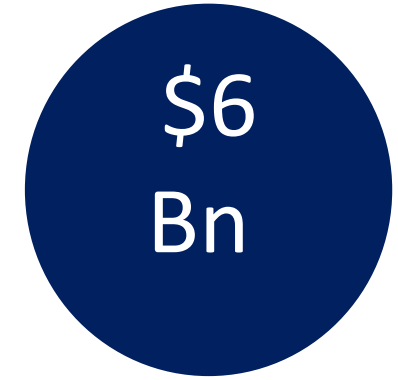
Current Market Size



CAGR Growth



Exports



Imports

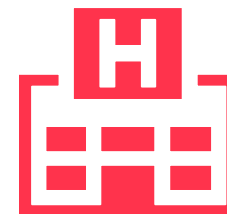
*After Japan, China & South Korea*



*Including implants, consumables, Medical Electronics*

*Over the period of 5 years*

*Poised to be the leader in Medical Devices*



*Import dependence is 85%*





# PRODUCTION LINKED INCENTIVE SCHEME

Scheme to provide financial incentive to individual manufacturers of target medical devices

- 5% financial incentive on the incremental production/sales of targeted medical device segments over the base year (FY 2019-20) for FY 2020-25
- Total outlay of \$ 456 Mn
- Target segments:
  - Cancer care/Radiotherapy medical devices
  - All Implants including implantable electronic devices
  - Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices
  - Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardiorespiratory Category & Renal Care Medical Devices

Segment	Incremental Investment	Incremental Sales of Manufactured Goods
<b>Targeted Medical Devices</b>	\$24 Mn over 3 Years  Cumulative Minimum:  Year 1: 8 Mn  Year 2: 16 Mn  Year 3: 24 Mn	Year 1: \$16 Mn  Year 2: \$32 Mn  Year 3: \$48 Mn  Year 4: \$61 Mn  Year 5: \$75 Mn



# PROMOTION OF MEDICAL DEVICE PARKS



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## Scheme for State Governments establishing Medical Device Parks in the Country

- Financial assistance for upcoming Medical Device Parks for creation of Common Infrastructure Facilities (CIFs), including:
  - Component Testing Centre,
  - Electromagnetic interference laboratory
  - Biomaterial / Biocompatibility testing centre
  - Medical grade low vacuum molding
  - Cabinet molding,
  - Injection molding centers,
  - 2D designing and printing for medical-grade products
  - Sterilization and Toxicity testing centre
  - Radiation testing centre
- CIFs significantly reduce manufacturing cost and create a robust ecosystem for medical device manufacturing
- The maximum limit for the grant in aid would be Rs. \$13.3 Mn per medical device park or 70% of the project cost of CIF (90% in the Hilly States or North Eastern Region) whichever is less
- Total Outlay of \$53.3 Mn for 4 Medical Device Parks during the period 2020-2025



## States having largest number of Pharma manufacturing units

Gujarat, Maharashtra, Himachal Pradesh, Telangana, Tamil Nadu, UP, Karnataka

## States having largest number of Medical Devices manufacturing units

Gujarat, Maharashtra, Karnataka, Tamil Nadu, Telangana, Andhra Pradesh

***Domo Arigato Gozaimasu!***