



“India’s Pharma Industry is an asset not just for India but for the entire world. It has played a leading role in reducing the cost of medicines especially for developing countries”

**- Shri Narendra Modi,
Hon’ble Prime Minister of India**



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Ministry of Chemicals and Fertilizers
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India: Towards a Global Pharma Hub

Date: 27-07-2020



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Presentation Content

- Overview of Pharma sector : a vibrant sector
- Challenges
- Strategy to handle the challenges
- A constellation of Four Schemes





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Industry at a Glance (2019-20)



	Pharmaceuticals		Medical Devices		Total	
	Rs crore	USD Bn	Rs crore	USD Bn	Rs crore	USD Bn
Domestic Market	1,51,700	20.50	57,029	7.71	2,08,729	28.21
Import	40,139	5.42	41,412	5.60	81,551	11.02
Export	1,52,440	20.60	18,582	2.51	1,71,022	23.11
Industry Size	3,04,140	41.10	75,611	10.22	3,79,751	51.32

Growth Rate

- Drugs: 10-12%
- Medical Device : 12-15 %

Source: IPA/Globexim Report 2018-19/DGCIS

Continued...

FDI inflows:

■ Drugs:

- Rs. 3,650 crore in 2019-20
- Rs. 1,842 crore in 2018-19
- Increase of 98%

■ Medical Devices:

- Rs. 2,196 crore in 2019-20
- Rs. 1108 crore in 2018-19
- Increase of 98%

Challenges



**API/Bulk Drugs:
Import Dependence**





**Medical Devices:
Import Dependence**



**R&D and Skilling:
Need to focus on drug
discovery**



Import Dependence: Bulk Drugs

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- Bulk drugs/APIs are basic to growth of pharmaceutical industry
 - Future growth of pharma sector is contingent upon -
 - Our ability to ensure un-interrupted supply of quality bulk drugs and continued research and
 - Our capacity to upscale their manufacturing during emergency situations
 - Bulk drugs formed 63% (USD 3.41 Billion) of the total pharma imports in the country during FY 2019-20.
 - India imports bulk drugs largely for economic considerations.



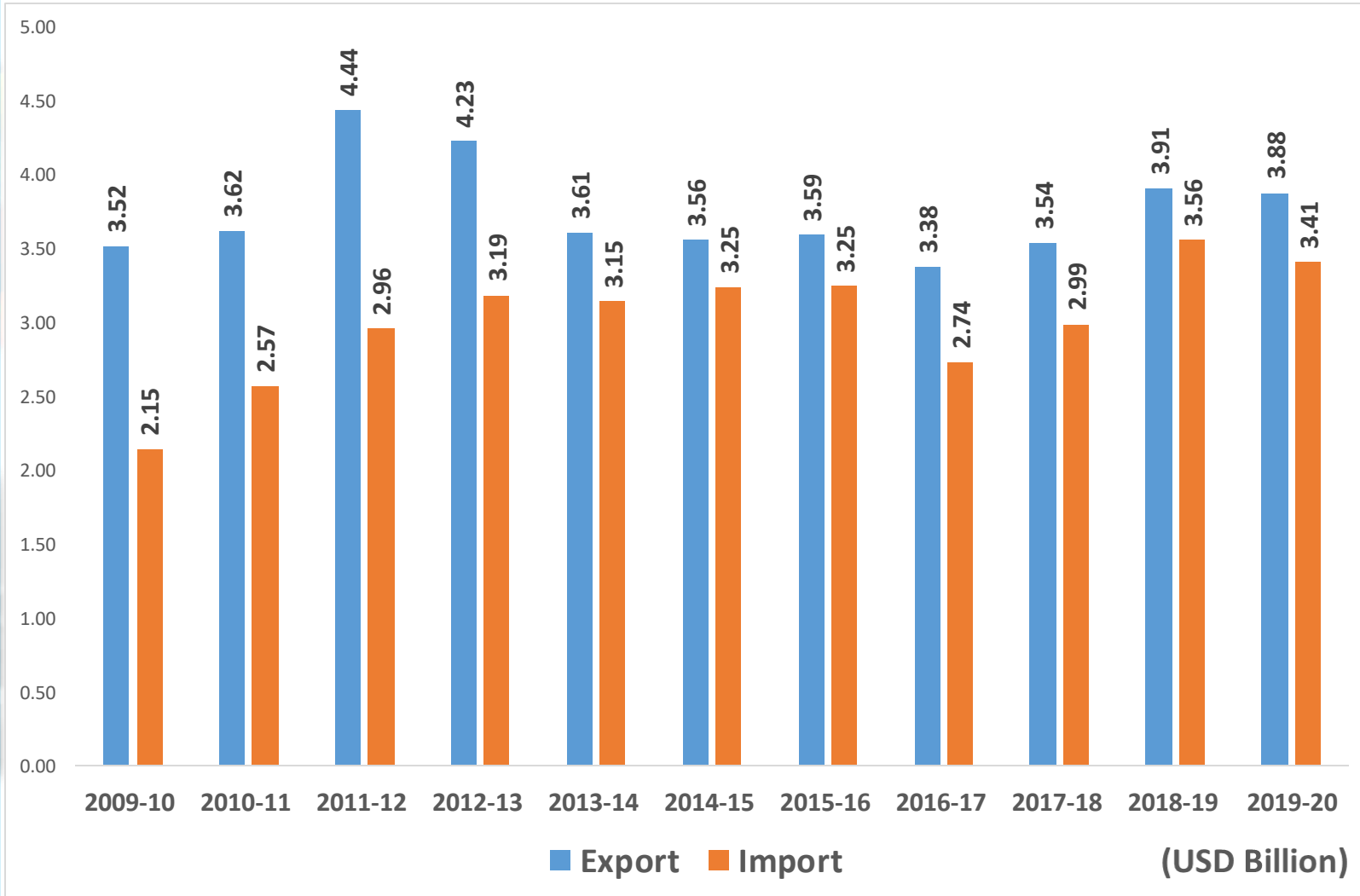
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Trade in Bulk Drugs



Import Dependence: Medical Devices

- The medical device industry is
 - highly capital intensive
 - has long gestation period
 - Requires continuous induction of new technologies
 - requires continuous training of health providers to adapt to new technologies
 - requires well-developed eco-system and innovation cycle which is yet to be fully developed in India
- The industry depends on imports up to an extent of 86%
- Domestic manufacturing is limited to surgical, cardiac stents and general medical devices and consumables



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Imports of Medical Devices

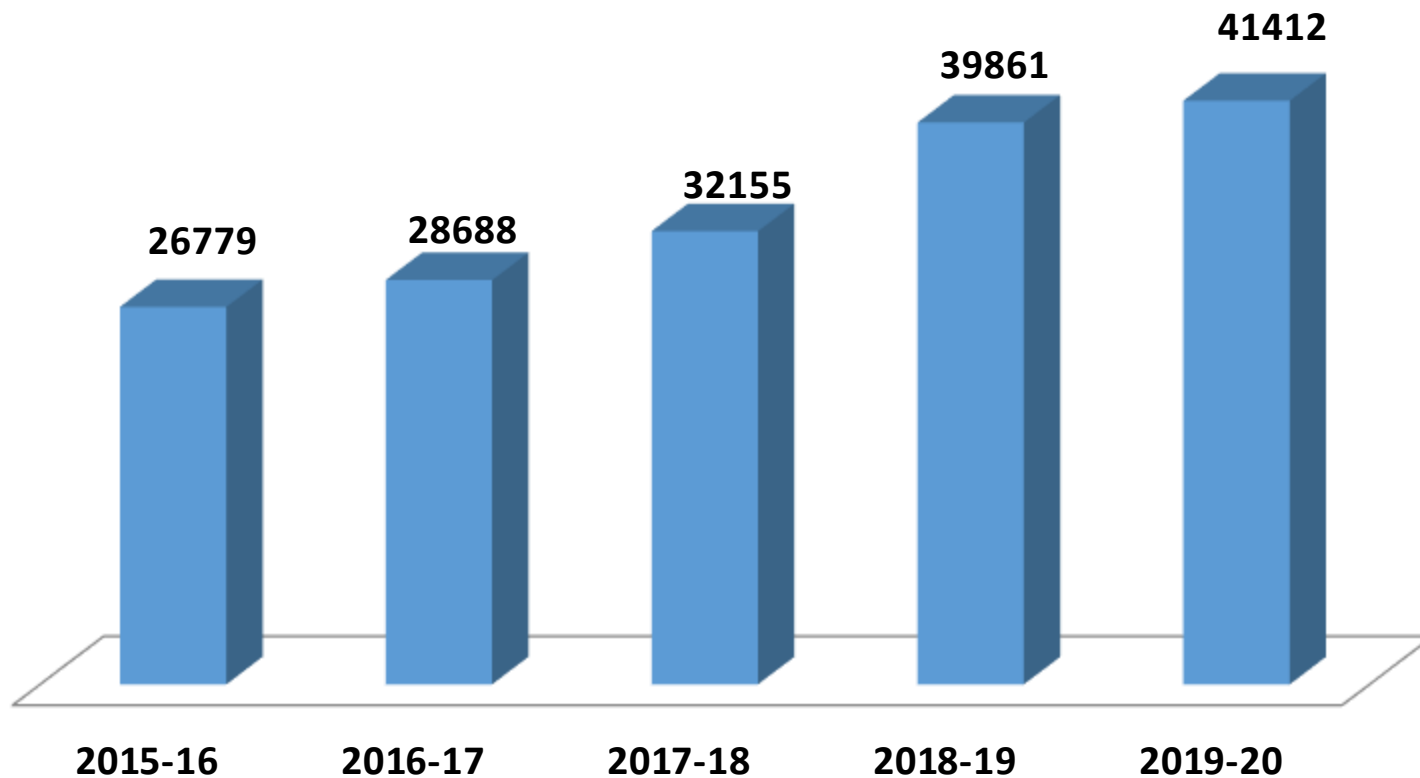


Fig in Rs crore

Source: DGCIS



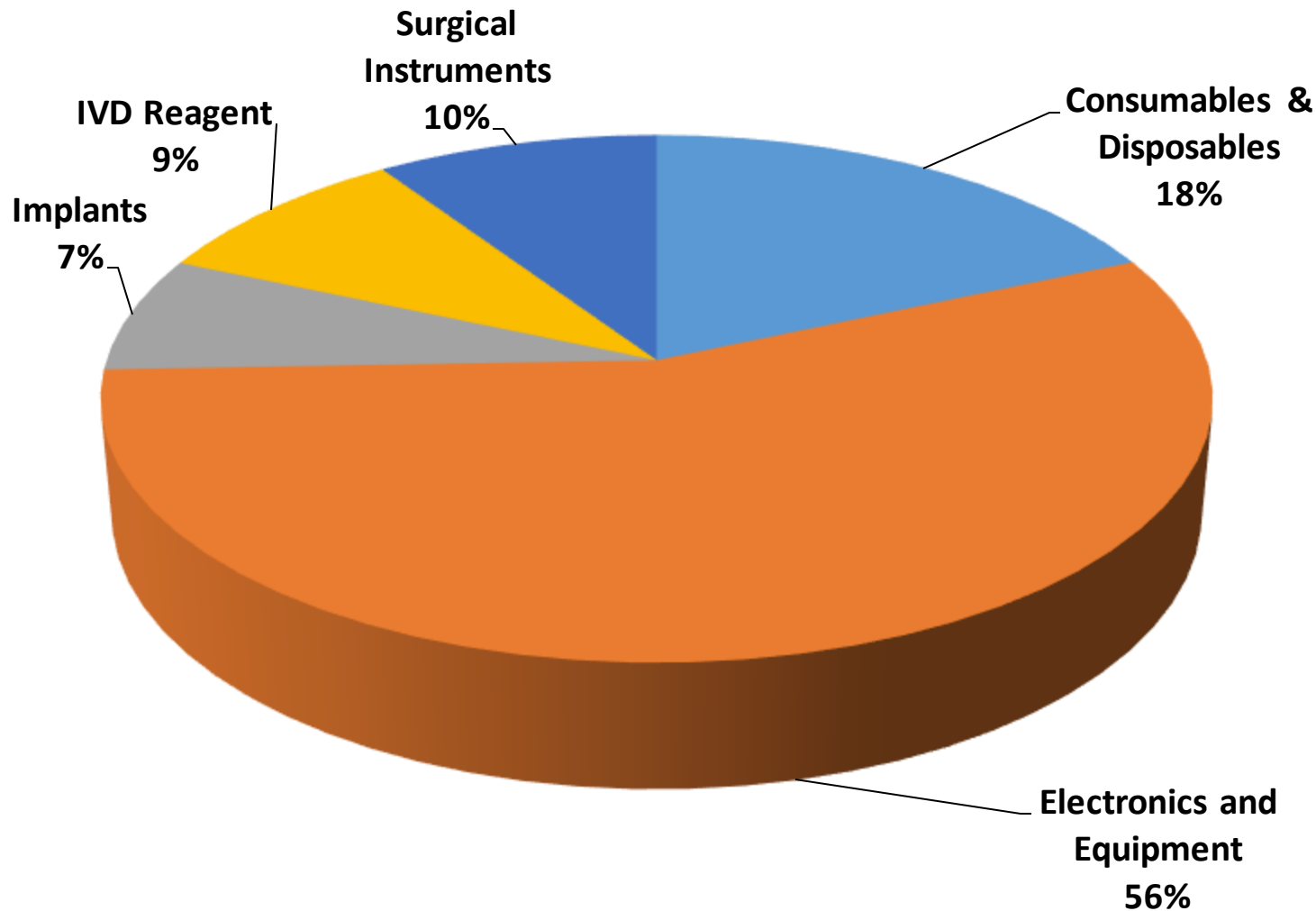
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Segment-wise Import of Devices (2019-20)



Source: DGCIS



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Strategy towards Atmanirbhar Bharat

- Challenges were discussed and flagged by various committees
- Reports & representations from various trade associations
- DoP prepared a blueprint/concept paper outlining two pronged strategy of-
 - Incentivizing production to offset high cost of production and
 - Creating infrastructure for common use, testing and lab facilities
- The need to prepare strategy to address issues of API and Medical devices was accepted by Government.
- In Budget 2020 speech, Hon'ble FM had declared an incentive scheme for medical device sector on the lines of the scheme of MeitY



Strategy towards Atmanirbhar Bharat

- 
- DOP formed two Technical Committees in February 2020 to assist department to frame appropriate schemes-
 - Technical Committee for bulk drugs identified 53 critical KSMs/DIs/APIs for an incentive scheme and also proposed establishment of bulk drug parks with higher assistance
 - Technical Committee for medical devices identified 4 segments of medical devices for incentive scheme and also suggested establishment of medical device parks with higher assistance
 - Extensive consultation with industry, various ministries/ Departments and NITI Aayog
 - CEO NITI Aayog is Chairman of two Empowered Committees for PLI schemes
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Four Schemes - Bulk Drugs & Medical Devices



Bulk Drugs

Medical Devices



Production Linked Incentive (PLI) Scheme
53 critical KSMs/Drug Intermediates and APIs

Production Linked Incentive (PLI) Scheme
medical devices in 4 target segments

3 Bulk Drug Parks
assistance for Common Infrastructure Facilities in parks

4 Medical Device Parks
assistance for Common Infrastructure Facilities in parks



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PLI Scheme for Domestic Manufacturing of Critical APIs/ KSMs/DIs





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PLI Scheme for APIs

Incentive

Incentive linked with

- Threshold investment &
- Incremental sales over base year

Eligible Products

53 KSMs/Drug
Intermediates and APIs

Total Outlay

Rs. 6,940 crore

- Company/Partnership firm/Proprietorship firm/LLP registered in India
- Eligibility: minimum **Net worth** should be 30% of proposed investment
- An applicant **can apply for multiple products/ units** with additional investment for every product
- Application window 120 days and approval thereafter within 90 days
- Application through online portal of Project Management Agency
- Applicants to be selected on the basis of objective evaluation on **two selection criteria**
 - capacity of the proposed plant (35%) &
 - sale price of API (65%)
- **Maximum number of selected applicants: 136**
- Waiting list

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Rate of Incentive

Fermentation based products

2023-24 to 2026-27: 20%

2027-28: 15%

2028-29: 5%

Chemically synthesized products

2022-23 to 2027-28: 10%





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Summary Of PLI Scheme for APIs



Parameter	Segment-1 04 Fermentation based KSMs/DIs	Segment-2 10 Fermentation based niche KSMs/DIs/APIs	Segment-3 04 Chemical Synthesis based KSMs/DIs	Segment-4 23 Chemical Synthesis based KSMs/Dis/APIs	Total
Max Incentive (Rs crore)	3,600	1,000	960	1,380	6,940
No of manufacturers	8	20	16	92	136
Minimum threshold investment (Rs crore)	400	50	50	20	
% incentive (6 Years)	20/15/5	20/15/5	10	10	



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Segment-1: Key Fermentation based KSMs/DIs

Number of selected applicants: 8

Number of selected applicants for each KSM: 2



S. No	KSM	Minimum production capacity(MT)	Maximum incentive for each selected applicant per annum (Rs. Crore)
1	Penicillin G	5000	Y1-Y4: 120; Y5:90; Y6:30
2	7-ACA	1000	Y1-Y4: 120; Y5:90; Y6:30
3	TIOC	800	Y1-Y4: 60; Y5:45; Y6:15
4	Clavulanic Acid	1.5 lakh Kg	Y1-Y4: 60; Y5:45; Y6:15

(Min investment Rs 400 crore)

Segment-2: Fermentation based KSMs/DIs/APIs

Number of selected applicants: 20

Number of selected applicants for each drug: 2



Sl. No	Name of the drug	Minimum production capacity (MT)	Maximum incentive for each selected applicant per annum (Rs. Crore)
1	Neomycin	175	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
2	Gentamycin	40	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
3	Betamethasone	2	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
4	Dexamethasone	2	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
5	Prednisolone	15	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
6	Rifampicin	100	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
7	Vitamin B1	200	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
8	Clindamycin Base	60	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
9	Streptomycin	50	Y1-Y4: 10; Y5: 7.5; Y6: 2.5
10	Tetracycline	450	Y1-Y4: 10; Y5: 7.5; Y6: 2.5

(Min investment Rs 50 crore)



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Segment-3: Key Chemical Synthesis based KSMs/DIs



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Number of selected applicants: 16

Number of selected applicants for each KSM: 4

S.No	KSM	Minimum production capacity (MT)	Maximum incentive for each selected applicant per annum (Rs. Crore)
1	2-MNI	800	10
2	CDA	1500	10
3	DCDA	8000	10
4	PAP	8000	10

(Min. investment Rs 50 crore)

Segment-4: Other Chemical Synthesis based KSMs/DIs/APIs

S.No	Name of the drug	Min Annual production capacity(MT)	Maximum incentive for each selected applicant per annum (Rs. Crore)
1	Meropenem	10	2.5
2	Atorvastatin	30	2.5
3	Olmesartan	25	2.5
4	Valsartan	25	2.5
5	Losartan	80	2.5
6	Levofloxacin	115	2.5
7	Sulfadiazine	20	2.5
8	Ciprofloxacin	300	2.5
9	Ofloxacin	100	2.5
10	Norfloxacin	15	2.5
11	Artesunate	35	2.5
12	Telmisartan	80	2.5
13	Aspirin	2800	2.5
14	Diclofenac Sodium	175	2.5
15	Levetiracetam	140	2.5
16	Carbidopa	2	2.5
17	Ritonavir	5	2.5
18	Lopinavir	7	2.5
19	Acyclovir	175	2.5
20	Carbamazepine	65	2.5
21	Oxcarbazepine	65	2.5
22	Vitamin B6	35	2.5
23	Levodopa	10	2.5

Minimum Investment Rs 20 crore

Number of selected applicants: 92

Number of selected applicants for each KSM: 4



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Scheme for Promotion of Bulk Drug Parks





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Promotion of Bulk Drug Parks

Objective

- Easy access to world class common and R&D infrastructure facilities at one place with assured land
- Easy access to testing facilities
- Economies of scale

Benefits

- Lowers the cost of production
- Single window for regulatory approvals
- Centre of excellence

- Scope: grant-in-aid of **Rs. 1000 crore each to 3 Bulk Drug parks**
- **Area minimum 1000 acres . For Hilly areas : 700 Acres**
- Minimum 50% of land area for bulk drug manufacturing units
- 3 States to be selected through challenge method
- Selection through ranking based on objective evaluation criteria
- States to apply within 60 days
- In-principle approval: within 30 days
- DPR submissions: within 180 days of in-principle approval
- Final approval after appraisal of DPR
- Land allotment: on long term lease basis





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Common Infrastructure Facility (CIF)



- i. Central Effluent Treatment Plant(s) (CETP)
- ii. Solid waste management
- iii. Storm water drains network
- iv. Common Solvent Storage System, Solvent recovery and distillation plant
- v. Common Warehouse
- vi. Dedicated power sub-station and distribution system with necessary transformers at factory gate
- vii. Raw, Potable and Demineralised Water
- viii. Steam generation and distribution system
- ix. Common cooling system and distribution network
- x. Internal road network, Compound Wall
- xi. Common logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges, etc.)
- xii. Advanced laboratory testing Centre, suitable for even complex testing/ research needs of APIs, including microbiology laboratory and stability chambers
- xiii. Emergency Response Centre
- xiv. Safety/ Hazardous operations audits centre

xv. Centre of Excellence:

- a) Regulatory awareness facilitation Centre
- b) Technology business incubator
- c) Intellectual Property Rights management services
- d) Process/ technology development laboratory/ Research Laboratory/ with pilot plants run by eminent scientists with track record of such competitive technology development for import substitution
- e) Industry Academia linkage Centre
- f) Training centre



Evaluation Criteria for Selection of States: Bulk Drug Parks

S. No.	Parameter	Maximum Marks
1	Utility charges (rates) as per proposal submitted by State Govt. Power (10), Effluent treatment (7),Water (3), Steam (3), Solid waste treatment (3), Warehouse charges (2), Park maintenance charges (2)	30
2	Total area of the proposed park 1. The hilly States ,2.5 marks for every additional 175 acres 2. Other States, 2.5 marks for every additional 250 acres of land	10
3	Land lease rate to be offered to individual units of bulk-drug units	10
4	Uninterrupted 24*7 availability of water and electricity	10
5	Suitability of location of the park from environmental angle. • Near the Coast (within 20 Km of coastline) or zero liquid discharge Effluent Treatment Plant (5) • Outside the municipal limits (5)	10
6	Policy incentives of State government applicable for Bulk Drug industry	10
7	Connectivity of the Park i. National Highway within 25 km from site (2) ii. Air Cargo / Airport within 50 km from site (2) iii. Sea Port / In-land waterway/ Dry port within 100 km from site (2)	6
8	Full exemption of Stamp Duty and Registration charges (Yes/No)	5
9	Ease of Doing Business Ranking (EODB) of the State	5
10	Availability of Technical Manpower in the State	2
11	Number of Pharma and chemical clusters in the State	2
	Total	100



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PLI Scheme for Domestic Manufacturing of Medical Devices





Target Segments

Target Segment No.	Description of Medical Devices covered under Target Segment#
Target Segment 1	Cancer care/Radiotherapy medical devices
Target Segment 2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices
Target Segment 3	Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices
Target Segment 4	All Implants including implantable electronic devices like cochlear implants and pacemaker

A key component which constitutes major part of the finished medical device will also be eligible



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Production Linked Incentive Scheme



Incentive

Incentive linked with threshold investment and incremental sales over base year

Rate of Incentive

5% on incremental sales from FY 2021-22 to 2025-26

Total Outlay

Rs. 3,420 crore

- **Company registered in India**
- **Minimum Rs. 180 crore investment by one unit.**
- **Eligibility: minimum Net worth should be Rs. 18 cr. (30% of threshold investment of first year)**
- **Applicant can apply**
 - **multiple products within one target segment**
 - **multiple target segments**
- **Application window 120 days and approval thereafter within 60 days**
- **Application through online portal of Project Management Agency**
- **Maximum number of applicants to be selected :28**
- **Applicants to be selected on the basis of objective evaluation criteria**



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Evaluation Criteria for selection

Weightage	Parameters /Score
50	Global Medical Device Manufacturing turnover of applicant and/or group company for FY 2018-19 \geq Rs.60 crore (5)
	For every additional Rs.60 crore (Global Medical Device) manufacturing turnover (5)
20	Existing Patent / Technology transfer with the applicant and/or group company in Target Segment (5)
	For every additional Patent / Technology transfer (5)
10	Existing ISO 13485 as on the date of application available with the applicant and / or group company (5)
10	Existing Product CDSCO / AERB approved / regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, European Union (CE) as on the date of application available with the applicant and / or group company (5)
	For additional regulatory approval out of above list (5)
10	Average R & D expenses of the applicant and/or group companies for the period of FY 2017-18 & FY 2018-19 as a percentage of sales revenue (which is capitalized in the books of account and/or in capital work in progress) from 5 to 10% (5)
	For more than 10% (5)





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Scheme for Promotion of Medical Device Parks





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Promotion of Medical Device Parks

Objective

- Easy access to world class common infrastructure facilities
- Easy access to testing facilities
- Economies of scale

Benefits

- Lowers the cost of production
- Single window for regulatory approvals
- Centre of excellence

- Scope: grant-in-aid of Rs. 100 cr each to 4 Medical Device parks
- 4 States to be selected through challenge method
- Selection through ranking based on objective evaluation criteria
 - Proposal to be submitted in 60 days
 - In-principle approval: within 30 days
 - DPR submissions: within 180 days of in-principle approval
 - Final approval after appraisal of DPR
- Minimum 50% of land area to be given to medical device manufacturing units
- Land allotment:
 - only on long term lease basis
 - may be cancelled if no production within two years of allotment



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Evaluation Criteria for selection of States



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Parameters	Weightage
Utility charges (rates) such as power, water, warehouse charges and park maintenance charges	25
Policy of incentives of State government applicable for Medical Device industry such as interest subvention scheme and GST reimbursement, subsidy, incentive etc.	12
Connectivity	12
Land lease rate	12
Total Area of proposed Park	12
Uninterrupted 24*7 availability of power and water supply	7
Exemption of Stamp duty and registration charges	5
Ease of Doing Business (EODB) Ranking of the State	5
Availability of technical manpower in the State	5
Institutes for technology transfer in the State	5
Industrial network	4



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Promotion of Medical Device Parks



Tenure

Five years (2020-21 - 2024-25)



Coverage

CIF such as:

- Component Testing Centre/ESDM/PCB/Sensors facility
- Electro-magnetic interference & Electro Magnetic Compatibility Centre
- Biomaterial / Biocompatibility /Accelerated Aging testing centres
- Medical grade moulding/milling/injection moulding/machining/tooling centres
- 3D designing and printing for medical grade products
- Sterilization/ETO/Gamma Centres
- Animal Lab and Toxicity testing centres
- Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo electrical crystals/power electronics facility
- Centre of Excellence/Technology Incubator/ ITI/Training Centres

Expected Outcomes

- **Import substitution and drug security**
- **Bulk Drug (PLI Scheme)- 53 bulk drugs**
 - **expected investment Rs. 8,500 crore approx.**
 - **direct employment generation - 25,500 approx.**
 - **ancillary industry and indirect employment generation**
- **Bulk Drug (Park Scheme)**
 - **lower cost of production**
 - **single window for regulatory approvals**
 - **centre of excellence**
 - **expected investment Rs. 24,000 crore approx.**
 - **direct employment generation - 72,000 approx.**
 - **ancillary industry and indirect employment generation**



Expected Outcomes

- **Import substitution**
 - **Medical Device (PLI Scheme)- 4 target segments**
 - **expected investment Rs. 5,400 crore approx.**
 - **direct employment generation– 18,000 approx.**
 - **Medical Device (Park Scheme)**
 - **world class testing facilities**
 - **lower cost of production**
 - **single window for regulatory approvals**
 - **centre of excellence**
 - **expected investment Rs. 40,000 crore approx.**
 - **direct employment generation– 1,40,000 approx.**
 - **ancillary industry and employment generation**
- **TOTAL INVESTMENT EXPECTED: Rs. 77,900 crore**
 - **TOTAL EMPLOYMENT GENERATION : 2,55,500**



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